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September 1, 2017

Dear Minister Taylor:

Thank you for the opportunity to consult on the policy proposals to bring sections 10, 12, and 45 to 58 of the *Assisted Human Reproduction Act* (the Act) into force. Moving forward with these regulations is critical to the effective administration and enforcement of the Act. The federal government is to be commended for this development.

The comments provided below are informed by a combined 40+ years of academic work and advocacy on behalf of those who participate in assisted human reproduction (as donors, recipients, surrogates, and contracting parties), as well as those who are born of assisted human reproduction. Françoise Baylis, Professor and Canada Research Chair in Bioethics and Philosophy, was a consultant to the Royal Commission on New Reproductive Technologies (1991), author of the expert report for the Government of Canada in response to the legal challenge to the Act by the province of Québec (2006), and a member of the Board of Directors of Assisted Human Reproduction Canada (2006-2010). Alana Cattapan, Assistant Professor at the Johnson Shoyama Graduate School of Public Policy, is an expert on the governance of assisted human reproduction in Canada. Her research, funded by the Social Sciences and Humanities Research Council of Canada and the Canadian Institutes of Health Research focuses on the inclusion of citizen stakeholders in the regulation of reproductive biotechnologies.

The discussion document distributed by Health Canada—*Toward a Strengthened Assisted Human Reproduction Act: A Consultation with Canadians on Key Policy Proposals*—provides important information about the regulations to come. The document, however, also raises a number of important concerns. Our concerns are summarized below under the following headings: 1) feedback on the policy proposals in the discussion document; 2) concerns outside the scope of the current regulatory process; and 3) the consultation process.

1) Feedback on the Policy Proposals in the Discussion Document

The policy proposals in the discussion document address a wide range of topics and areas of expertise. We provide feedback on the following issues:

a) Importance of Eschewing Commercialization
b) Consideration of gamete donors and surrogates as patients in AHR

c) Clarity regarding the purpose, criteria, and administration of donor suitability assessments
d) Clarity regarding the roles of regulated parties and data collection in s.10
e) Clarity regarding "directed donation" versus "known donation"
f) The need to refine proposals on the reimbursement of expenditures

a) Importance of Eschewing Commercialization

The Act and the long policy process that preceded it demonstrate a strong commitment to the non-commercialization of human reproduction, supporting the prohibition on the use of reproductive capacity for trade, and for commercial ends. This is clearly reflected in the principles of the Act, namely s. 2(f). Some of the language in the discussion document, however, does not reflect this commitment.

Language like "product" safety (pages 8, 9, 10), "product traceability" (page 13), "supply chain" (page 14), and "consumer" (page 14), suggest the extent to which assisted human reproduction is understood not as a matter of health and reproduction, but rather as an industry. Ongoing commitments to ensuring that trade in human reproductive capacity and/or use for commercial ends are not occurring preclude the use of such language.

b) Consideration of gamete donors and surrogates as patients in AHR

The discussion document focuses primarily on the health and safety of Canadians who seek to build their families using AHR as well as the children they conceive, but rarely identifies concerns about the health and safety of gamete donors and surrogates. See, for example the sections of the discussion document numbered 4.1.2, 4.1.4 (Application and Conditional Exemptions), 4.1.7 (Donor Suitability Assessment and Genetic Disease Screening). This is particularly apparent in the discussion of the regulatory framework related to "product safety" wherein the principles and objectives focus explicitly on (1) those who use AHR to build families or (2) those who are born of AHR, with no mention of others involved in the process. This is particularly problematic for ova donors many of whom report not being treated as patients. Their experiences include a lack of informed consent, inadequate follow-up care, and ovarian hyper-stimulation.

Another concern about gamete donors as patients applies to both ova and sperm donors. The discussion document narrowly (and inappropriately) focuses on disclosure to intended recipients with no mention of prior disclosure to prospective donors. From an ethics perspective, the results of infectious and genetic disease testing must first be disclosed to prospective donors, at which time counselling should be provided. On this basis, prospective donors may elect not to become donors, in which case no information should be disclosed to intended recipients. An important element of informed consent is the right to withdraw. The regulations should include the important role of the treating physician in assessing risks and counselling gamete donors who, through the assessment process, may learn that they have an infectious or genetic disease.

Further, there may be reason to establish limits on the maximum number of times that an individual can be a gamete donor. Indeed, the risks associated with repetitive donation are substantial enough that other jurisdictions have recommended limits. For example, the American Society for Reproductive Medicine recommends no more than 25 pregnancies per sperm donor (to avoid inadvertent consanguinity, an issue of safety affecting potential offspring), and no more than six stimulated cycles for ova donors (to avoid health risks for the woman, including the risk

of infertility). The latter of these two recommendations is endorsed in the Canadian Fertility and Andrology Society's Guidelines for Third Party Reproduction (April 2016).

c) *Clarity regarding the purpose, criteria, and administration of donor suitability assessments*

References to "donor suitability" in the discussion document may be informed by the phrase "suitability of donor" in the *Health Canada Directive: Technical Requirements for Therapeutic Donor Insemination*. In both cases, reference to "suitability" is unclear. In the discussion document, it appears that suitability is to be assessed with reference to infectious disease screening, genetic disease screening and "social history of the donor." Two questions arise: 1) why the narrow focus on physiological health (i.e., focus on infectious and genetic disease with no mention of psychological health)? and 2) what is the point of social history screening?

Further, while it is clear that there will be guidance on infectious disease screening (provided by the CSA), it is not clear what guidance will be provided (and by whom) on genetic disease screening (for example, what genetic diseases will be deemed unsuitable?). It is also unclear what criteria and processes will be used for social history assessments. What elements of a prospective donor's social history could (and should) justify exclusion from the donation process on this basis? In addition to the above, it is also unclear what training and expertise Medical Directors (or their designates) are presumed to have on the basis of which to make decisions about the suitability of donors.

Relatedly, the proposed screening requirements properly emphasize the need for donor sperm and ova used in AHR to be safe for the recipient and for potential offspring. The discussion document, however, uses the language of both safety and "quality" (sometimes together, sometimes independently) as criteria for gamete selection and use. While safety is used to justify most screening requirements, it is unclear why "quality" is used in certain places. What is meant to be addressed with the additional reference to "quality" that "safety" alone does not capture? "Quality" is a highly subjective concept when it comes to gametes and to embryos. It is not part of the guiding principles of the legislation and should not be part of the regulations.

The concerns about donor suitability and "quality" discussed above point to another circumstance directly relevant to Q1 (p. 12): "Please explain any other circumstances that should be exempt, conditionally or unconditionally, from section 10 of the AHR Act". There may be circumstances in which recipients of donor gametes want to select for genetic traits that others may consider a genetic disease or disorder (e.g. deafness). In drafting the regulations, Health Canada will need to incorporate the potential request for exemptions in these (and similar) cases – when should the selection of specific genetic traits be permissible, restricted, or prohibited?

d) Clarity regarding the roles of regulated parties and data collection in s.10

There is some ambiguity regarding the various roles of regulated parties in s.10. The definition of "users" to include "a qualified medical professional who directly imports sperm or ova solely for use in AHR" may work, as per the discussion document, to exempt fertility clinics in Canada from the restrictions on importers, specifically that they would be required to notify Health Canada, and to import donor sperm and ova only from processors that are registered with Health Canada. As much of the sperm and ova used in Canada are imported for use in fertility clinics for a specific patient with the express purpose of being used in AHR (including eventual

clinical training and the improvement of reproductive techniques), a decision by Health Canada to treat medical professionals as "users" rather than "importers" will exempt most of the reproductive materials entering Canada from the proposed restrictions on importers.

The definition of "users" is somewhat unclear. Canadians who **use** donated sperm outside of a clinical setting (see page 14) are not "**users**". But what about Canadians who use AHR in a clinical setting—are they "users"? On page 14, the discussion document states that, "Under this proposed framework, users [i.e., medical professional who perform AHR and Canadians who use AHR in a clinic] would **not be required** to notify or register with Health Canada, but **will be required** to obtain donor sperm and ova from only registered processors." Does it follow that non-users [i.e., persons who use donor sperm outside a clinical setting] **are required** to notify or register with Health Canada, but **will not be required** to obtain donor sperm and ova from only registered processors?

Data collection in AHR remains an important issue in which Health Canada should intervene. Gametes and information about their donors and recipients must be tracked. It is imperative that Health Canada collect data about suspected cases of disease transmission and that when such cases are confirmed that both donors and recipients are informed (not just "Canadians who use AHR to help build their families"). As well, depending upon when the transmission of disease is reported, there may be offspring who have reached the age of consent. If so, it will be important that they be informed as well.

The proposed timelines regarding the registration of processors is also of concern. In particular, the proposal that "information about a change to the processor's business information, civic address, and contact details will have to be communicated to the minister as soon as possible after the change is made" (p. 15) will allow for gaps in the time in which Health Canada has accurate contact information for processors. Health Canada should be informed before (not after) about any change to the relevant business information, etc. Similarly, the notification requirements for importers and distributors should occur more than 30 days before the date on which the potential importer or distributor intends to begin their respective activities, as 30 days may be insufficient time for the Minister to review the relevant information and make a decision.

e) Clarity regarding "directed donation" versus "known donation"

The discussion document seems to assert that a "directed donation" occurs when a potential recipient chooses "someone they know as their donor." There are other circumstances, however, in which the term "directed donation" may apply. For example, gamete donors may "direct" that their gametes only be available to persons who share their religious faith or ethnic background. For example, a Jewish male might direct that his sperm only be donated to a Jewish female. Or, a black ova donor might direct that her ova only be used by a black woman or a black couple. Use of the word "someone" in the text suggests that Health Canada intends that "directed donation" should only apply in circumstances in which specific individual donors are providing their gametes to specific individuals or couples, but clarity on this point is advisable. Specifically, it should be clear whether scenarios such as those described above will be permitted, restricted, or prohibited.

The term "know," in the description of a prospective donor as "someone they know" is unclear. What does "know" mean in this context? Is a "known" prospective donor someone the recipient(s) has met virtually (e.g., on social media or in a chat room) in which case "known"

might simply mean "non-anonymous"? Or, is "known" intended to capture more than this? Is a "known" prospective donor an acquaintance, an old friend, an employee, a relative? Clarity on point is important insofar as different screening procedures and protocols apply when the recipient "knows" the donor. For example, on page 11 the discussion document states: "if a recipient has chosen someone they know as their donor, the recipient can choose to move ahead with the donation even in the event that their donor does not meet the screening and testing criteria." This strategy may not make sense when the donor is "known" to the recipient only in the sense of "non-anonymous". While proceeding in this way may "give Canadians more flexibility in choosing their donor and will make it easier to proceed with building their families" (p. 11) it may not sufficiently protect the health and safety of the recipients or the potential offspring. It is important that the regulations be written in a way that allows those using AHR to choose donors who are not their current or former sexual partners. Ease of use, however, is not a guiding principle of the legislation, and should not supersede health and safety. Clarity on what it means to "know" a donor is imperative.

Further, confusion is introduced in the discussion document as a result of the interchangeable use of two distinct phrases. The phrases: "someone they [the recipient] know" (p. 11) and "a specific third party recipient who knows the donor and is known by the donor" (p. 12) are not equivalent. In the latter instance, the "knowing" is bi-directional. The difference in phrasing requires correction or clarification. Is the change in wording intended to capture subtle differences in practice?

f) The need to refine proposals on the reimbursement of expenditures

The proposed framework for regulations on the reimbursement of expenditures are good, and require relatively limited revision. However, there are a number of important issues that Health Canada will want to consider in the actual drafting of the regulations.

First, one of the principles of s.12, as articulated in the discussion document, is that "there is no obligation to reimburse, meaning that only persons who wish to reimburse eligible expenditures will do so" (p. 23). While this is true—people should not be required to participate in a commercial transaction—as worded, this principle does not identify the importance of joint decision-making between those providing and those receiving reimbursement. A gamete donor or surrogate may be expecting the reimbursement of eligible receipted expenditures, but those providing the reimbursement may not want to reimburse all categories of eligible expenditures. This principle, and the regulations that reflect it, will need to ensure that donors and surrogates are not at risk of exploitation, and those using AHR to build a family are not at risk of extortion or coercion as a result of demands backed by the withholding of gametes or engagement in surrogacy.

Second, the discussion document stipulates that "the regulations will specify a verifiable process by which reimbursements may be made" (p. 23). This process—yet to be determined—is a good idea in principle. Health Canada may want to provide a template form for contact information as well as information about the nature of the AHR activities (i.e., gamete donation, surrogacy, etc.) to be filed with Health Canada at the time of first reimbursement so that compliance and enforcement activities can subsequently occur (including potential audits). As noted below, this could be coupled with a complaint mechanism and an ombudsperson to ensure that the reimbursement process is clearly and effectively implemented.

Third, in the discussion document legitimate expenditures are limited to those incurred "in the course of" donation and surrogacy. In our view, "the course of donation and surrogacy" extends beyond the retrieval of gametes and birth of a child and, as such, it is reasonable to anticipate (and allow) an extended reimbursement period of expenditures for follow-up care, counselling and legal services in the case of gamete donation, and post-birth care, counselling, and legal services in the case of surrogates.

Finally, as per s. 4.2.4 of the discussion document, clarity is needed regarding who can provide reimbursements. In cases of anonymous donation, these reimbursements are likely going to be provided by a third party (e.g. a lawyer) who will manage the transfer of funds. The use of this sort of intermediary may also be appropriate, however, in cases of directed donation when the parties are very familiar with one another in order to minimize risks of coercion and/or exploitation. Health Canada should consider who should qualify as a third party for managing reimbursement and whether (and how much) they can be paid for this service.

2) Concerns Outside of the Scope of the Current Regulatory Process

a) The need for regulations addressing the health and safety of Canadians vis-à-vis donor embryos

The version of s.10 of the Act introduced in 2012 (as per Bill C-38) does not include embryos, but instead focuses explicitly on the "risks to human health and safety arising from the use of sperm or ova for the purpose of assisted human reproduction, including the risk of the transmission of disease." This new language was introduced even though the original s.10 addressed risks to human health and safety that emerged from the use of sperm and ova for the purposes of creating embryos, in addition to the use of these embryos. This is a significant gap in the legislation introduced by C-38 (2012). Ideally, safety issues related to the use of embryos, including donor embryos should be addressed in the current regulatory process.

b) The need for a complaint process and/or enhanced system of oversight

In addition to the inspection system, Health Canada should establish a means for gamete donors, recipients of donor gametes, surrogates, contracting parties, children born of AHR technologies, and others to make complaints regarding the use of AHR. During the tenure of Assisted Human Reproduction Canada, several complaints were made about violations of the law. Except for the 2013 prosecution of Leia Picard (after Assisted Human Reproduction Canada had been shuttered), nothing meaningful is known to have been done in response to relevant complaints and clear violations of the law.

Clear information about how complaints can be made (and to whom) should be provided. Gamete and embryo donors and recipients, surrogates, and contracting parties, and the general public need to know how to register a complaint if they are aware of (or suspect) legal violations. While this ostensibly falls to the RCMP, it is not clear to stakeholders that this is how complaints can or should be registered. There may also be complaints that do not involve legal violations in which case there may be an important role for an ombudsperson. An ombudsperson and complaint system could be incorporated into the inspectorate currently being developed in relation to the proposed regulations.

c) Concerns about "revisiting" various aspects of the existing Act

The discussion document suggests that a number of issues "will be considered in the future when amendments to the Act may be contemplated" (p. 9) including addressing the prohibition of scientific advances including germline editing, the prohibition on payment for surrogacy and gamete donation, and the penalties associated with violating the prohibited activities in the Act.

In terms of germline editing and scientific developments that might be covered under s.5, the prohibitions are sound and consistent with international standards. For example, in relation to human germline gene editing, this is prohibited both by UNESCO and the Council of Europe (i.e. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, also known as the Oviedo Convention, ratified in 1997 by 29 countries). At present, the only country that explicitly permits heritable modifications is the UK. Unlike Canada, however, the UK has some measure of oversight through the Human Fertilisation and Embryology Authority. Canada has no equivalent governance mechanism since the AHRC was disbanded in 2012. As such, changes to the prohibitions in order to explicitly allow germline gene editing would stand in contrast to our international counterparts. Further, the 2015 International Summit on Human Gene Editing concluded that it would be irresponsible to proceed with germline gene editing without broad societal consensus. At the present time, there is no such consensus.

Regarding the prohibition of payment for surrogacy and gamete donation, it is unclear why the "policy underpinning sections 6 and 7 of the Act, which prohibit payment for surrogacy and the purchase of sperm and ova" would be revisited, given the Act's commitment to prohibiting trade in reproductive capabilities. The guiding principles of non-commercialization (s.2(f)) and non-exploitation should be vigorously defended. In support of the current legislation, Health Canada might consider what (if any) role it has to play in promoting altruistic donation.

Finally, as regards the potential reconsideration of "the penalties associated with medical and scientific activities," it is important to note that the law sets maximum penalties for violations; actual penalties are at the discretion of the courts. In the Picard prosecution—the only case where someone has been prosecuted under the Act to date—the court only imposed a $60,000 fine, despite a guilty plea to multiple counts of violating s.6 and s.7 of the Act.

3) The Consultation Process

To date, the consultation process has involved responses on the prepublication of the regulations, as well as the current call for feedback on the discussion document. These are important parts of the regulatory process, and we value the opportunity to provide feedback. At the same time, the legitimacy of public policy comes from substantive engagement with key stakeholders, that is, the stakeholders who stand to benefit from the legislation or regulations in question, in addition to those who might be harmed.

The consultations related to this regulatory process have, to date, included "health professionals, industry members, fertility lawyers…academics, researchers" (p. 4), and others with the organizational capacity, resources, and expertise to respond (under significant time constraints) to requests for written feedback on documents that include highly-technical language. Meanwhile, although the parameters of the current regulatory process are limited to sections 10,

12, and 45 to 58 of the Act, regulations under these sections of the Act have important implications well-beyond those who are ready and able to engage in these sorts of consultations.

Ensuring that the proposed regulations are legitimate and speak to the interests of all key stakeholders could occur through an amended consultation process that facilitates the substantive participation of gamete donors and surrogates as well as people with disabilities who might be invested in changes to the screening and donor suitability assessment processes. As well, the use of alternate strategies for providing feedback (i.e. discussion groups, roundtables) and the availability of resources might increase participation by these interested (and affected) parties.

In addition to the feedback provided here, we have attached two Appendices to aid with your work as you move forward with drafting the regulations. The first is a list of references for the concerns outlined in this letter (see Appendix A). The second is a version of the Health Canada discussion document with comments inserted where there are concerns (see Appendix B).

Thank you for the opportunity to provide feedback on the discussion document and the regulatory process. We would be pleased to discuss any aspect of this response with you, and to provide comments or input on future iterations of these regulations.

Sincerely,

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Appendix A: Relevant References

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Health Canada Santé Canada

Appendix B: Comments Inserted Where There Are Concerns

Toward a Strengthened *Assisted Human Reproduction Act*:

A Consultation with Canadians on Key Policy Proposals

Canada

Summary

In October 2016, recognizing the need to strengthen the regulatory framework governing assisted human reproduction in Canada, Health Canada announced its intention to bring into force the dormant sections of the *Assisted Human Reproduction Act* and to develop the necessary supporting regulations.

This consultation document provides an overview of the key policy proposals that will help inform the development of regulations to support bringing into force Section 10, Section 12 and Sections 45-58 of the Act. Specifically, the policy proposals describe the Department's position on the following:

Section 10: Safety of Donor Sperm and Ova

- Scope and application
- Regulated parties and their regulatory obligations
- Processing requirements, including donor suitability assessment
- Record-keeping and traceability

Section 12: Reimbursement

- Expenditures that may be reimbursed
- Process for reimbursement
- Creation and maintenance of records

Sections 45-58: Administration and Enforcement

- Scope of the administration and enforcement framework
- Role of inspectors designated under the Act

The purpose of the document is to provide Canadians with an opportunity to review the policy proposals and to provide feedback prior to the Department finalizing policy decisions and developing the regulations. In addition to requesting stakeholders' general feedback on the policy proposals, the Department is also seeking input on specific questions, which are included throughout the document.

Table of Contents

1. Introduction

Health Canada is committed to promoting transparency and stakeholder engagement during the regulatory development process. This includes providing Canadians with opportunities to provide meaningful feedback on important policy proposals.

In October 2016, recognizing the need to strengthen the regulatory framework governing assisted human reproduction (AHR) in Canada, the Minister of Health announced Health Canada's intention to bring into force the dormant sections of the *Assisted Human Reproduction Act* (AHR Act) and to develop the necessary supporting regulations.

This work includes drafting regulations aimed at reducing the risks to human health and safety arising from the use of assisted human reproductive technologies; drafting regulations regarding reimbursement of expenses incurred by donors and surrogates, and drafting the regulations necessary for the purpose of administering and enforcing the Act.

Comment [FB/AC1]: The AHR Act refers to "expenditures" not "expenses". This was a purposeful choice at the time the legislation was crafted, as evidenced by the Parliamentary debate. The policy proposals below largely use the language of "expenditures," and the regulations should also use "expenditures" to be consistent with the legislation.

This document provides an overview of Health Canada's key policy proposals that will help inform the development of regulations to support bringing into force Section 10, Section 12 and Section 45-58 of the Act. The purpose of this paper is to serve as a basis for early feedback and engagement with Canadians prior to the Department finalizing policy decisions and developing draft regulations. Canadians will have another opportunity to provide feedback when the draft regulations are published in *Canada Gazette*, Part I.

2. Feedback Information Request

Health Canada wants to hear directly from Canadians. This includes feedback from those who make use of and those who are born of AHR, those who are part of the AHR sector, including health professionals, industry members, fertility lawyers, as well as academics, researchers and all others who have an interest in these policy proposals.

All feedback provided on the policy proposals outlined in this consultation document will be considered prior to the development of regulations for Section 10, Section 12 and Sections 45 to 58 of the AHR Act.

For information on how to submit feedback, please refer to section 5.0 of this consultation document.

3. Background

3.1. History of the *Assisted Human Reproduction Act*

The AHR Act received royal assent on March 29, 2004. The Act was based on recommendations made by the 1993 Royal Commission on New Reproductive Technologies, which had the mandate to examine the ethical, legal, social and economic implications of reproductive technologies and their impact on Canadian society, and in particular on women, children and families.

The Act introduced a system of licensing, monitoring, inspection and enforcement designed to protect and promote the health, safety, dignity and rights of Canadians who use or are born of AHR technology. The Act was a comprehensive regulatory framework which identified prohibited activities and activities that were prohibited unless they were licensed, and it introduced new compliance and enforcement powers. It also created Assisted Human Reproduction Canada (AHRC), the federal Agency responsible for a wide range of activities related to AHR, including issuing and reviewing licences under the AHR Act, compliance and enforcement, and collecting, analyzing and managing health reporting information.

The legislation is written in such a way that many sections of the Act require the development and publication of regulations in order to come into force. Health Canada has been responsible for leading this regulatory work and in June 2007, the first of these sections was brought into force with the publication of the *Section 8 Consent Regulations*. These regulations set out requirements for how consent is provided or withdrawn with respect to the use of someone's reproductive material or *in vitro* embryos including the purposes for which consent to use can be provided.

In June 2008, before further regulatory work could be completed, the Quebec Court of Appeal ruled that significant portions of the AHR Act were unconstitutional in response to a 2004 filing by the provincial government. The Government of Canada filed an appeal to the Supreme Court of Canada (SCC) in August 2008 regarding the constitutionality of the challenged provisions. The SCC rendered its opinion in December 2010, finding almost all challenged sections unconstitutional, notably provisions relating to the Act's licensing framework in areas connected to the provinces' exclusive jurisdiction over hospitals and the practice of medicine, as well as those relating to the collection of health reporting information the regulation of AHR activities and related research.

In response to the SCC opinion, legislation was introduced in 2012 to repeal the sections of the AHR Act deemed unconstitutional for infringing on provincial jurisdiction as well as the sections establishing and providing the mandate of AHRC, which closed in September 2012. With the closure of the AHRC, Health Canada took over responsibility for all remaining federal functions related to the Act, such as compliance and enforcement, and outreach. As a result of the legal environment surrounding the AHR Act, the drafting of regulations for the remaining sections of the Act was put on hold.

3.2. AHR in Canada Today

Today, an increasing number of Canadians are turning to AHR technologies to grow or build their families. A 2012 Canadian study[1] found that infertility is on the rise in Canada, with roughly 16% of heterosexual couples experiencing infertility. In addition to rising infertility, the trend of delaying marriage and parenthood, scientific advances in cryopreserving ova, and the increasing use of AHR by LGBTQ2 couples and single parents to build a family are all contributing to an increase in the use of AHR technologies.

The growing use of reproductive technologies by Canadians to help build their families underscores the need to strengthen the AHR Act. While the approach to regulating AHR varies from country to country, Health Canada has considered international best practices and the need for regulatory alignment when developing the proposed policies set out in this document. (See *Appendix A: International Comparison of AHR Regulatory Oversight*)

3.2.1. Federal Regulatory Oversight

Although the scope of the AHR Act was significantly reduced in 2012 and some of the remaining sections have not yet been brought into force, there are many important sections of the Act that are currently administered and enforced by Health Canada, as summarized generally below:

Sections 1-4: Principles and Application

Sections 1-4 establish the application of the Act and define some of the terms contained within the legislation. Of particular importance is Section 2, which sets out key principles that underpin the remainder of the Act.

Section 5: Prohibited Scientific and Research Procedures

Section 5 prohibits certain types of scientific research and clinical procedures that are deemed unacceptable, including: human cloning, the creation of an embryo for non- reproductive purposes, maintaining an embryo outside the human body beyond the fourteenth day, sex selection for non-medical reasons, altering the genome in a way that could be transmitted to descendants, and creating a chimera or a hybrid.

Sections 6 & 7: Non-Commercialization Prohibitions

One of the principles set out in Section 2 of the Act recognizes that trade in the reproductive capabilities of women and men, and the exploitation of children, women and men for commercial ends raise health and ethical concerns that justify their prohibition. As a result, Sections 6 and 7 prohibit payment for surrogacy and the purchase of sperm and ova from a donor or a person acting on behalf of a donor, respectively.

[1] Estimating the prevalence of infertility in Canada: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3279129/

Section 8: Consent

Section 8 prohibits the use of reproductive material unless consent is obtained from the donor, in accordance with the *Consent to Use Regulations*.

Section 9: Minimum Age for Gamete Donors

Section 9 prohibits any person from obtaining sperm or ova from a donor under 18 years of age, or using any sperm or ova so obtained, except for the purpose of preserving it for the minor's own future reproductive use (e.g. in the case of a minor undergoing treatment that may affect his or her reproductive capabilities, such as cancer therapy).

Remaining Provisions not yet in Force

The majority of the remaining sections of the AHR Act as introduced in 2004 were repealed as a result of the SCC decision in 2012. This proposal seeks to lay the policy ground for bringing Sections 10, 12 and 45-58 into force as part of the current regulatory work to strengthen the Act.

Regulation of Sperm

Regulations for sperm were first introduced in Canada in 1996 under the *Food and Drugs Act*, in response to an urgent health and safety risk, namely the transmission of HIV via semen. In 2000, the *Health Canada Directive: Technical Requirements for Therapeutic Donor Insemination* was published, which updated the requirements for donor suitability assessment, including donor screening and testing, to reflect scientific advances and clarify some questions of regulatory oversight.

Did you Know?

The safety of donor sperm is currently regulated by the *Processing and Distribution of Semen for Assisted Conception Regulations* (Semen Regulations) made under the *Food and Drugs Act*. They will be repealed once section 10 of the AHR Act is brought into force.

3.2.2. Regulatory Gaps

Scientific advances since the AHR Act was first introduced have left health and safety gaps with respect to donor sperm and ova used for the purpose of AHR that must be addressed. For instance, there is a need to modernize the regulatory requirements for the safety of donor sperm, and move them from the *Food and Drugs Act* to the AHR Act. Furthermore, to date, no regulatory requirements for the safety of donor ova have been introduced in Canada.

Comment [FB/AC2]: Because there are currently no regulations for the safety of donor ova, no embryos currently in storage could be compliant with the proposed section 10 regulations. The safety of donor embryos is thus another regulatory gap that requires attention.

Similarly, the knowledge gained through scientific advances in human genetics, combined with new possibilities for mitigating the risk of transmitting genetic diseases to donor- conceived offspring, allows for regulatory improvements to the safety of donor sperm and ova previously never envisioned. Furthermore, other scientific advances have led to previously unforeseen regulatory challenges, such as the application of CRISPR/Cas-9 technology to germline editing research and mitochondrial replacement therapy.

Although the scope of this project does not include revisiting the prohibitions currently in force, including those that prohibit the purchase of sperm and ova from a donor or persons acting on behalf of a donor, or payment for surrogacy arrangements, there is a clear need for providing Canadians with more clarity on the types of expenses that can be reimbursed and outlining a process for doing so.

3.2.3. The Canadian Standards Association

In 2000, before the AHR Act came into force, Health Canada contracted the Canadian Standards Association (CSA) to develop a national standard on tissues for assisted reproduction.

The CSA is an independent, not-for profit member based association, accredited by the Standards Council of Canada (an organization that co-ordinates Canada's National Standards System). The CSA maintains its accreditation by developing consensus standards, where all members have an equal voice. The CSA Reproductive Tissues Standard sets out minimum standards and best practices for organizations and individuals involved in all aspects of assisted reproduction. Although the standard does not have the force of law and some of its scope extends beyond federal jurisdiction, its key objective is to enhance the safety and effectiveness of AHR technologies in order to protect individuals who use or who are conceived through assisted reproduction and to guide health care personnel.

Did you Know?

The CSA, a non-governmental organization, has responsibility for maintaining their Reproductive Tissues Standard. The CSA Technical Subcommittee is in the process of developing updated evidence-based infectious disease screening criteria for sperm and ova donors.

Although Health Canada has membership on the CSA Technical Subcommittee responsible for maintaining and updating the standard, a consensus-based process is implemented by the subcommittee to determine its content. The Department has leveraged some of the work done by the Technical Subcommittee in developing the policy proposals contained within this document.

Comment [FB/AC3]: The development of evidence-based infectious disease screening standards is clearly within the CSA's area of expertise. Can this work be expanded to include evidence-based infectious disease screening standards for embryos?

3.3. Intention to Strengthen the AHR Act

On October 1, 2016 Health Canada announced its intention to update and strengthen the AHR Act.

A Notice of Intent (NOI) published in the Canada Gazette outlined the Department's plans to draft regulations in order to bring into force key sections of the Act. Specifically, Health Canada announced plans to:

- Draft regulations aimed at reducing the risks to human health and safety arising from the use of donor sperm and ova for the purpose of AHR, including the risk of the transmission of disease, and bring section 10 of the AHR Act into force;
- Draft regulations regarding reimbursement of expenses incurred by donors and surrogates and bring section 12 of the AHR Act into force; and,

- Draft supporting regulations, as required, to bring into force sections 45 to 58 and designate inspectors for the purpose of administering and enforcing the Act and its regulations.

The Department invited the public to submit their feedback on the proposed initiative. A 60 day consultation period took place with various stakeholders participating, including individuals who use AHR procedures, fertility clinics, researchers, academics, gamete banks, fertility lawyers, and various association groups (e.g. medical associations, LGBTQ2 groups, fertility awareness groups).

The feedback received from stakeholders has helped to inform the important policy work undertaken by Health Canada that will underpin the regulatory development process.

3.4. Stakeholder Feedback

In general, Canadians who commented on the NOI are supportive of the Department's intention to strengthen the AHR Act, some citing the continued importance of the legislation and the fact that action is overdue. Some stakeholders have also expressed the need to address specific areas currently lacking regulatory oversight, including:

Product Safety The need for: ○ Evidence based screening and testing requirements for sperm and ova donors ○ Regulatory requirements for processing, handling and quarantining of donated ova	**These issues will be discussed in section 10 policy proposals (See section 4.1 of this document)**
Reimbursement The need for: ○ Clarity on type and nature of expenses incurred by donors and surrogates that may be reimbursed ○ A reimbursement process that is not overly burdensome	**These issues will be discussed in section 12 policy proposals (See section 4.2 of this document)**
Administration and Enforcement The need for: ○ A comprehensive compliance system that has oversight over importers, processors and distributors ○ Transparent auditing and inspection systems and effective complaint handling	**These issues will be discussed in sections 10 and 45-58 policy proposals (See sections 4.1 and 4.3 of this document)**

Out of Scope of Current Regulatory Project

Many other comments beyond the narrow scope of the current regulatory project were received, including the need to:

- Review the procedures prohibited by section 5 of the AHR Act (e.g. germline editing) in light of scientific advances
- Revisit the policy underpinning sections 6 and 7 of the Act, which prohibit payment for surrogacy and the purchase of sperm and ova
- Reconsider the penalties associated with medical and scientific activities

While these issues will not be addressed during the current regulatory project, they will be considered in the future when amendments to the AHR Act may be contemplated.

4. Policy Proposals for Consideration

In order to develop the regulations required to bring into force sections 10, 12 and 45 to 58 of the AHR Act, key policy issues related to those sections had to be explored. The purpose of this part of the consultation paper is to outline the proposed policy foundation on which Health Canada proposes to build the regulations. Questions have been identified throughout the following sections to help guide the consultation process.

4.1. Section 10 - Product Safety

4.1.1. Context

Section 10 of the AHR Act was introduced in 2012, when the Act was amended to repeal the sections that had been deemed unconstitutional by the SCC. The purpose of section 10 is to reduce the risks to human health and safety arising from the use of sperm or ova for the purpose of AHR, including the risk of the transmission of disease. Section 10 achieves this purpose by prohibiting the distribution, use or importation of donor sperm or ova unless it complies with the section 10 regulations.

4.1.2. Principles and Objectives

The objective of the product safety regulatory framework under the AHR Act is to protect the health and safety of Canadians who use AHR to help build their families, as well as to protect those who are born of these technologies.

Comment [FB/AC4]: Use of the word "product" is problematic because it invites market language (such as "consumer" and "supply chain"). Use of this term is inconsistent with the Act's guiding principle of non-commercialization (Sec.2.f). Furthermore, use of this term is not necessary. For example, this section could be titled "safety of human gametes" or "safety of sperm and ova". Terms such as "product", "consumer", "supply chain" are to be avoided and should not appear in the regulations.

Comment [FB/AC5]: As per the comment above delete the word "product"

Comment [FB/AC6]: There is no mention here of the health and safety of Canadians who are gamete donors or surrogates. The principles and objectives of the safety regulatory framework should not focus narrowly on (1) those who use AHR to build families or (2) those who are born of AHR. They should also address the health and safety needs of (3) those who participate in the activities intended to help others build families using AHR (gamete donors and surrogates).

Policy work to develop the section 10 regulations has been guided by the following principles:

- The role of Health Canada is to reduce the risks to human health associated with the use of donor sperm and ova for third party use;
- Individuals have the right to make an informed decision to accept certain risks in using AHR technology to build their families;
- The role of the treating physician in assessing these risks and counselling their patients is a critical one in the safe application of AHR technology; and,
- The unique and personal nature of third party reproduction gives rise to circumstances that should be taken into consideration.

4.1.3. Scope

There is a risk of disease transmission associated with the use of third party sperm or ova for the purpose of AHR, including the use of third party sperm in *in vitro* fertilization (IVF). This includes the risk of infectious disease transmission from the donor to the recipient, as well as to the child born of AHR technologies, as well as the risk of genetic disease transmission from the donor to the child.

As such, Health Canada proposes that section 10 regulations include measures to reduce the risks associated with transmission of both infectious and genetic disease, from the sperm or ovum donor to the recipient, and/or to the children born through AHR.

4.1.4. Application

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 those risks and counselling their patients. In keeping with these principles and in response to years of stakeholder feedback on this issue, the Department is proposing to introduce a more flexible regulatory framework that is responsive to the needs of individuals who use AHR, while still protecting their health and safety. In particular, Health Canada is proposing to introduce changes to make it easier for Canadians who know their donor to proceed with building their families. This section describes the proposed regulatory framework.

APPLICATION AND AUTHORITIES

The proposed section 10 regulations will apply to donor sperm and ova intended for use in AHR by a recipient who is not the spouse, common-law partner or sexual partner of the donor, as well as to ova intended for the donor's use as a surrogate. This includes the use of donor sperm in IVF.

The AHR Act provides the authority to make regulations that exempt persons from section 10, conditionally or unconditionally, in the circumstances provided for in regulations. In keeping with the principles described in the previous section, Health Canada proposes the following exemptions:

Comment [FB/AC7]: Equivalent wording for informed decision making by gamete donors and surrogates who may experience "risks to human health" should be included here

Comment [FB/AC8]: Again, it is important to state that gamete donors and gamete recipients are both patients. This is not properly reflected in this document, but must be properly reflected in the regulations.

Comment [FB/AC9]: Above, under 3.2.3, we learn that the CSA Technical Subcommittee is in the process of developing updated evidence-based infectious disease screening criteria. What organization will be responsible for developing evidence-based genetic disease screening criteria? This is a potential ethical challenge especially given important substantive disagreement on (1) what constitutes a genetic disease (e.g., deafness); as well as (2) what constitutes a "serious" genetic disease.

Comment [AC10]: Here disease transmission is defined with respect to both infectious disease and genetic disease. Below, however, there are multiple references to genetic disorders (instead of genetic diseases). This inconsistency should be avoided (or explained).

Comment [FB/AC11]: HC must recognize that the recipients of donor gametes are not the only patients. Consider, for example, the important role of the treating physician in assessing risks and counselling gamete donors who, through the assessment process, may learn that they have an infectious or genetic disease? In this discussion document, HC does not address interests of those who participate in AHR to assist others in building a family. This is a serious issue that must be corrected in the regulations.

Comment [AC12]: HC should avoid, wherever possible, the language of "need". The desire for a genetically related child is strongly felt, but it is a "want" rather than a need.

Comment [FB/AC13]: Nowhere is there any mention of a maximum number of times an individual can be a gamete donor. Arguably this is a relevant health and safety concern for donors and recipients. Perhaps this maximum could be expressed, as in other jurisdictions, in terms of a maximum number of donations and a maximum number of offspring.

Comment [FB/AC14]: Phrasing is unclear here – if HC is referring to surrogates who provide eggs themselves, then it is unclear why her ova would be subject to s.10 regulations (especially as she is likely going through "traditional" surrogacy in these cases).

UNCONDITIONAL EXEMPTIONS

Unknown future use: Sperm and ova will be exempt from section 10 where the future use of the sperm and ova is unknown at the time of cryopreservation. This exemption is meant to include cases such as sperm or ova cryopreserved prior to a patient undergoing a medical treatment or procedure that may affect his/her fertility (e.g. cancer treatment) and where the use of the cryopreserved gamete has not yet been determined (e.g. patient does not have a spouse, common-law partner or sexual partner, or it is unclear if the services of a surrogate would be required, at the time of sperm or ova cryopreservation).

Note: Where sperm or ova that was originally cryopreserved for unknown future use is subsequently intended for third party use, and where the sperm or ova was not processed in accordance with the section 10 regulations, the use may be permitted under Exceptional Distribution, as described below.

Ova processed prior to section 10 coming into force: Ova processed before section 10 comes into force will not be subject to the requirements of section 10 regulations.

CONDITIONAL EXEMPTIONS

Sperm processed prior to section 10 coming into force: Sperm processed before section 10 comes into force will not be subject to the requirements of the section 10 regulations, provided that the sperm has been processed in accordance with the current *Semen Regulations*.

Directed Donation: All donors must be screened and tested in accordance with section 10; however, if a recipient has chosen someone they know as their donor, the recipient can choose to move ahead with the donation even in the event that their donor does not meet the screening and testing criteria. This will give Canadians more flexibility in choosing their donor and will make it easier to proceed with building their families.

For those who have chosen someone who they know as their donor, the donated sperm or ova will be exempt from the section 10 regulations provided certain conditions are met, including:

- The sperm or ova have been processed in accordance with section 10 regulations; and,
- The donor's suitability has been conducted in accordance with the section 10 regulations.

Introducing these conditions will help the treating physician to assess the risks associated with using the directed donation, and to inform the recipient of those risks. The physician's assessment, combined with their authorization, will allow the recipient to make an informed decision with respect to the use of the sperm or ova in directed donation.

Comment [AC15]: If the principles and objectives are "to protect the health and safety of Canadians who use AHR" what is the rationale for this exemption? For example, would a prospective recipient not prefer to have ova that have been screened for disease?

Comment [FB/AC16]: HC appears to use "directed donation" and "known donation" interchangeably, which introduces some confusion. For example, does a directed donation have to be to a "known" individual or could it be to a "known" religious, ethnic, racial or other group?

Comment [FB/AC17]: What does it mean to "know someone"? Is this "know" as in a Facebook friend, a colleague, an employee, a relative? Does "known" mean "not anonymous" or is there something else involved in "knowing"? Clarity on this point is imperative. Also, below the reference to "knowing" is bi-directional – "recipient who knows the donor and is known by the donor". The reason for the difference is unclear and merits revision or explanation.

Comment [FB/AC18]: Does this means that the donor will be screened and tested, but the recipient and donor can proceed despite the fact that the donor has failed to meet screening and testing criteria? If so, then presumably the point is to promote informed choice. If this supposition is correct, then this should be made clear.

Comment [FB/AC19]: It is important to note that "ease" is not one of the guiding principles or objectives of the legislation. In the regulations this should be reworded to make reference to "reducing access challenges".

Comment [FB/AC20]: Information about infectious or genetic disease risks is not just for the intended gamete recipients, but also for the prospective gamete donors. Donors are patients as well and should be informed of health risks.

Comment [FB/AC21]: Information about infectious or genetic disease risks is not just for the intended gamete recipients, but also for the prospective gamete donors. Again, donors are patients and should be informed of health risks.

Comment [AC22]: What is the physician "authorizing"? Elsewhere in the document the emphasis is on joint decision-making. This is the only time the term "authorize" is used with reference to the physician's responsibilities.

Exceptional Distribution: The use of cryopreserved donor sperm and ova that have not been processed in accordance with the AHR Act will be permitted under some exceptional circumstances, including:

- Sperm that is not compliant with section 10 regulations may be permitted under exceptional distribution where the recipient has already been exposed to the donor sperm (e.g. women or couples who have already had a child through AHR and wish to have another child using non-compliant semen from the same donor to ensure their children will be genetic siblings).
- Sperm processed before section 10 regulations come into force, and not deemed compliant with the *Semen Regulations,* may be permitted under exceptional distribution where the recipient has already been exposed to the donor sperm (e.g. to create genetic siblings), or for the use of a specific third party recipient who knows the donor and is known by the donor.
- Sperm or ova exempt from the regulatory requirements of section 10 (i.e., originally intended for the use by the spouse, common-law partner or sexual partner of the donor and no longer needed for family building purposes, or cryopreserved for unknown future use) may be permitted for use of a specific third party recipient who knows the donor and is known by the donor.

QUESTION FOR STAKEHOLDERS
Q1: Please explain any other circumstances that should be exempt, conditionally or unconditionally, from section 10 of the AHR Act.

Exceptional distribution of donor sperm and ova will only be permitted provided:

- The donor sperm or ova has already been obtained and obtaining another sample of sperm or ova that is processed in accordance with section 10 of the AHR Act is not possible or would pose a risk to the health of the donor;
- Reproductive needs of the recipient cannot be met using a sperm/ovum that is processed in accordance with section 10 of the AHR Act (e.g. women or couples who have already had a child through AHR and wish to have another child using non-compliant semen from the same donor to ensure their children will be genetic siblings); and,
- The use of Exceptional Distribution is not intended to circumvent the regulations.

Other conditions for exceptional distribution will also need to be met, such as a completed donor suitability assessment, the purpose of which will be to help the treating physician and the patient make informed decisions regarding the risks involved in using the gamete.

Health Canada proposes that additional labelling requirements also be introduced to mitigate risks associated with sperm and ova not processed in accordance with the regulations and where the donor suitability requirements have not been met.

Comment [FB/AC23]: Is this wording (e.g. to create genetic siblings) meant as equivalent to the text in the preceding bullet point (e.g. women or couples who have already had a child through AHR and wish to have another child using non-compliant semen from the same donor to ensure their children will be genetic siblings)? If so, repetition of the text would help with clarity. Otherwise, the reader is left to wonder if there is a difference.

Comment [FB/AC24]: See previous comment about the meaning of "known". Here (unlike above) the "knowing" is bi-directional – the recipient knows the donor and is known by the donor. This begs the question "Why the difference" in wording? Is this meant to capture some subtle difference in practice?

Comment [FB/AC25]: Regarding Question 1, What about persons who want to select for genetic traits that some might consider a genetic disease (e.g., deafness). Could a donor who fails the genetic screening be given an unconditional exemption? What is the genetic screening reveals a genetic trait for a late onset genetic "disease"?

It is not clear how the genetic screening criteria are going to be developed and used. Will this just be about providing information or will physicians be "authorizing"?

Comment [FB/AC26]: As noted above, HC should not describe a "desire" for a genetically-related child as a "need".

Comment [AC27]: Best to use consistent wording – i.e., "sperm or ova".

Comment [FB/AC28]: This seems to describe joint decision-making, but above there is reference to physician "authorization".

Comment [FB/AC29]: Neither this document, nor the existing sperm regulations are clear about suitability requirements. Is this meant as a reference to "disease free" where disease refers to both infectious and genetic disease? The reason for asking this question is that below (on p. 18) the following appears:

"Sperm and ova donors must be screened (based on their medical, social and genetic history) as per the proposed screening criteria outlined below."

Are social and genetic history to be part of "donor suitability requirements"?

Note: Exceptional Distribution is intended to replace the Donor Semen Special Access Programme (DSSAP), which will no longer exist once section 10 of the AHR Act is brought into force.

4.1.5. Requirements for persons who process, import, distribute, or make use

Health Canada is proposing to oversee supply chain compliance and integrity for donor sperm and ova through a registration and notification scheme to:

- Support high standards of quality and safety for gametes intended for AHR; and,
- Support protection of human health via product traceability.

The proposed regulations would complement and be supported by existing provincial and territorial laws, particularly as they pertain to the practice of medicine in Canada.

REGULATED PARTIES AND ACTIVITIES

Processors: Health Canada is proposing to define processors as persons responsible for the processing activities with respect to donor sperm and ova for use in AHR. A processor would also be responsible for determining whether the sperm and ova are safe and would be required to apply for a registration number with Health Canada as per the registration requirements detailed below. Toward this end, Health Canada is proposing that only the processor who is ultimately responsible for the safety and quality of the donor sperm and ova will be required to register and they will be responsible for ensuring both their compliance with the AHR Act and its regulations, as well as the compliance of any third-party contractors that they use for any aspect of processing donor sperm or ova for AHR.

Processing activities include obtaining, preparing, preserving, quarantining, identifying, labelling and storing, and assessing the quality of donor sperm and ova for use in AHR. It also includes the testing and screening of donors to assess their suitability.

This proposed definition encompasses both foreign and domestic processors and includes persons processing both directed and anonymous donations.

Importers: Heath Canada is proposing to define importers as persons in Canada who import donor sperm and ova from a foreign country for the purpose of distribution for use in AHR, including storing donor sperm and ova for the purpose of distribution. Importers would be required to notify Health Canada, as per the notification requirements outlined below, and would be required to only import donor sperm and ova from processors that are registered with Health Canada. Unlike the current approach under the Semen Regulations, a qualified medical professional who directly imports sperm or ova solely for use in AHR would be a user, not an importer.

Distributors: Health Canada is proposing to define distributors as persons in Canada who distribute donor sperm and ova for use in AHR, including storing donor sperm and ova for the purpose of distribution. Distributors would be required to notify Health Canada as per the notification requirements, outlined below, and would be required to obtain donor sperm and ova from processors that are registered with Health Canada. Unlike the current approach

Comment [FB/AC30]: What is meant to be captured with the additional reference to "quality," rather than simply safety as appears elsewhere?

Comment [FB/AC31]: Again, there are concerns about the language of "product" to refer to gametes. For example, this could be reworded: "Support protection of human heath via the traceability of gametes". All other uses of "traceability" in this document do not make reference to "product".

Comment [FB/AC32]: Again, above the reference is to "quality and safety" but here the reference is only to "safety". What is the precise and discrete meaning of these terms in this context?

Comment [FB/AC33]: Again, above the reference is to "quality and safety" then "safety" alone then "safety and quality" (i.e., the ordering of the two terms has changed). What is the precise and discrete meaning of these terms in this context?

Comment [FB/AC34]: See above, re: "quality"

Comment [FB/AC35]: As per above, what does suitability mean, exactly? Does this just mean "passed infectious and genetic disease screening"? Or, is this a reference to social and genetic history as per p. 18? Or, could this be about other social criteria such as ethnic or cultural matching? For example, would it be "suitable" for a black couple to explicitly request Asian gametes? Or, could this be about a psychological assessment to ascertain if, for example, a prospective donor is likely to regret the decision to donate gametes?

Comment [FB/AC36]: Does this mean that qualified medical professionals as "users" don't have to notify HC? What are the implications of this from a "business" perspective? Is this about eliminating companies that import gametes?

under the Semen Regulations, a qualified medical professional who solely makes use of donor sperm or ova in the performance of AHR would be a user, not a distributer.

Users: Health Canada is proposing to define users as persons who make use of donor sperm or ova in the performance of AHR in a clinical setting, including storing donor sperm and ova for the purpose of making use. For example, this definition would include persons who:

- Import cryopreserved donor sperm and ova that is being stored for use in a fertility clinic in a foreign country to a fertility clinic in Canada;
- Make use of donor sperm and ova, such as qualified medical professionals who perform assisted human reproduction procedures;
- Directly import donor sperm and ova for use in AHR, such as a qualified medical professional who imports sperm or ova solely for use in AHR on a single patient; and,
- Store donor sperm and ova solely for the purpose of making use.

Note: Health Canada is proposing to not consider persons who use donor sperm or ova outside of a clinical setting (e.g. at-home insemination) as users.

Under this proposed framework, users would not be required to notify or register with Health Canada, but will be required to obtain donor sperm and ova from only registered processors.

Furthermore, Health Canada proposes that all users of donor sperm or ova will be required to maintain records that identify the patient on whom the assisted reproduction was performed.

Finally, for greater clarity, if a user of donor sperm or ova engages in a regulated activity for which notification or registration is required, Health Canada is proposing that they will not be exempt from the regulatory requirements of that activity.

REGULATORY TRANSPARENCY

Health Canada is proposing that the names of all registered processors and Canadian importers and distributors that have notified Health Canada will be posted on the Health Canada web site and used as a reference tool for users of donor sperm and ova and interested stakeholders.

Health Canada is also proposing to make information about non-compliant processors, importers, and distributors public. This will support a more informed consumer so that Canadians make more informed choices about their health. Regulatory transparency will also strengthen the safety, security, and integrity of the supply chain by:

- Supporting a culture of safety and quality within the reproductive health sector;
- Fostering public participation and stakeholder engagement with respect to scrutiny and accountability of regulated parties; and,
- Enhancing public confidence in the oversight of donor sperm and ova for assisted human reproduction.

Comment [AC37]: Above the spelling is "distributor."

Comment [FB/AC38]: Are persons who use donor sperm or ova to build a family (but are not themselves qualified medical practitioners involved in the performance of AHR) "users"? Intuitively, recipients of donor gametes are "users" as they are using donor gametes to build a family, but their status is not clear as they are not among the examples given. There appears to be a difference in status depending upon whether "use" is or is not in a clinical setting.

Comment [FB/AC39]: Currently, ova are not used outside of a clinical setting. This seems like an error.

Comment [FB/AC40]: This makes stark the problem alluded to above regarding ambiguity with the term "users". Are those "who use donor gametes" only qualified medical practitioners involved "in the performance of AHR" or does this category capture some gamete recipients? If gamete recipients "makes use" outside a clinic then they are not "users" but if gamete recipients "make use" in a clinic they are "users"?

Comment [FB/AC41]: The term "consumer" should not be included in the regulations (or elsewhere). At the very least, use of this term is inconsistent with the principle of non-commercialization.

Comment [FB/AC42]: If the non-compliance is with genetic-disease screening, it is not clear how informed decision-making by gamete recipients is relevant to the health of gamete recipients? It is certainly relevant to the health of offspring, but they are not the ones making informed decisions. What is the issue HC wants to address: health? safety? informed decision-making?

Comment [FB/AC43]: This sentence makes no reference to "quality" and yet this appears in the first bullet below. As previously noted, there is reason to question use of the term "quality."

Comment [FB/AC44]: HC will want to avoid this kind of language; problem of commodification.

Comment [FB/AC45]: Again, there is the concern about "safety" or "safety and quality". What is captured by the term "quality"?

REGISTRATION REQUIREMENTS

Processors perform high risk activities and are responsible for ensuring the quality and safety of donor sperm and ova to which Canadians have access. As such, Health Canada is proposing that all processors will be required to apply for a registration number with Health Canada through an application form. It is being proposed that applicants for a registration number will be required to submit the following information:

- Details about the processor's business information, civic address and contact details;
- Information about the type of reproductive materials processed;
- The types of processing activities carried out by the processor or for which the processor is responsible, such as activities that are contracted out to a third party; and,
- Information demonstrating that the processor is in compliance with the AHR Act and its regulations.

In addition, it is being proposed that Health Canada may request additional information from the applicant to complete the review process. If it is deemed that the information provided is sufficient, satisfactory, and complete, the Minister will issue a registration number to the processor.

Any change in the information provided on the registration application must be communicated according to the following proposed timelines:

- Information about a change to the processor's business information, civic address and contact details will have to be communicated to the Minister as soon as possible after the change is made;
- Information about a change in the type of reproductive materials processed and the types of processing activities conducted will have to be communicated to the Minister, who will issue an amended registration, in advance of making the change; and,
- Any cessation of regulated activities by the processor will have to be communicated to the Minister within 30 days.

Health Canada further proposes that, on an annual basis, processors who are registered with Health Canada will be required to complete and submit to the Minister a declaration attesting to their continued compliance with the AHR Act and its regulations. The declaration will confirm that the processor systematically monitors its compliance and implements preventive and corrective actions where considered necessary.

Under this proposed registration framework, the Minister will have the power to refuse to issue a registration number if there is reason to believe that any information provided on the form is false, misleading, inaccurate, or incomplete, or if the Minister has reasonable grounds to believe that issuance of the registration could compromise human safety or the safety of gametes intended for AHR. In addition, the Minister will also have the ability to require

Comment [FB/AC46]: This section sometimes makes reference to sperm and ova and sometimes to reproductive materials. It is unclear what is motivating the choice of terms in the different instances.

Comment [FB/AC47]: If this phrasing is to be used in the regulations, then this should read "communicated to the Minister" to be consistent with the text in the three bullet points below.

Comment [FB/AC48]: This should be communicated "before" not "after". If the communication is "after" there could be a time when HC has no accurate contact information. Also, there should be a specified date – e.g., no less than 30 days prior to change. ASAP is too vague – last bullet point has exact days and same should be true here as well.

Comment [FB/AC49]: A declaration of compliance is insufficient. There must be regularly scheduled inspections. There is mention of inspections in 4.3.3.

Comment [FB/AC50]: Again, here there is reference to "safety" alone, not "safety and quality."

processors to submit any additional relevant information to demonstrate that the activities it conducts are in compliance with the AHR Act and its regulations at any point.

Finally, Health Canada is proposing that registrations may be cancelled by the Minister when a processor has informed the Minister that they have ceased regulated activities or if there are reasonable grounds to believe that the processor is not in compliance with the AHR Act and its regulations.

QUESTION FOR STAKEHOLDERS
Q2: Please explain, and support with scientific rationale, what level of regulatory oversight would be considered appropriate for fertility clinics that solely process directed donations. Should it differ from the processor registration framework proposed above?

NOTIFICATION REQUIREMENTS

Due the lower risk activities involved with importation and distribution, Health Canada is proposing that all importers and distributors, as defined above be required to notify the Minister, in writing, 30 days before the date on which they intend to begin importing or distributing, including storing for the purpose of distributing, donor sperm and ova. It is being proposed that notifications be required to include:

- Details about the importer's or distributor's business information, civic address and contact details;
- Information about the processor(s) to be used by the importer or distributor;
- The types of reproductive materials being imported or distributed; and,
- The date on which the person will begin to import or distribute donor sperm and ova.

Any change in the information provided on the notification must be communicated according to the following proposed timelines:

- Information about a change to the importer's or distributor's business information, civic address and contact details will have to be communicated to the Minister as soon as possible after the change is made; and,
- Information about a change in the processor(s) being used by the importer or distributor and the types of reproductive materials being imported or distributed will have to be communicated to the Minister in advance of making the change.

As long as the importer or distributor has notified the Minister and continues to conduct that activity, Health Canada is proposing that no new notification is required. However, if the person ceases importing or distributing donor sperm and ova, including storing donor sperm and ova for the purpose of distribution, it is being proposed that they be required to notify the Minister within 30 days after they have stopped conducting regulated activities.

Comment [FB/AC51]: Thirty days may not be sufficient time for the Minister to review and make a decision. HC may want to consider a longer time span.

Comment [FB/AC52]: This should be "before" instead of "after". Also, there should be a specified time frame – e.g., no less than 30 days prior to move. If "after", then there could be a time when HC has no accurate contact information.

Comment [FB/AC53]: Presumably information about a change in the processor must first be approved and only if approved communicated… (i.e., same standard as the original consideration).

Finally, under this notification framework, persons in Canada who have notified Health Canada may import and distribute donor sperm and ova, including storing that donor sperm and ova for the purpose of distribution, originating from any processor (foreign or domestic) registered with Health Canada.

4.1.6. Establishment Requirements

To help ensure that gametes intended for AHR in Canada are safe, Health Canada is proposing the following establishment requirements for all processors, importers, and distributors of donor sperm and ova:

PERSONNEL

Establishments will be required to have sufficient personnel with the qualifications necessary to perform their assigned duties. Personnel may be qualified by education, training or experience (or a combination thereof). Establishments must have a system in place to provide personnel with initial and ongoing training and to evaluate their competency.

FACILITIES

Establishments will be required to have facilities that are designed, constructed, and maintained so as to allow for the performance of all its activities, the efficient cleaning and disinfection to prevent contamination or cross-contamination, environmental and microbiological monitoring and control in all designated areas, and controlled access to all areas where its activities are carried out.

EQUIPMENT AND SUPPLIES

All establishments will be required to use equipment that is cleaned and maintained, qualified, calibrated, disinfected or sterilized appropriate to its use and impact to the quality of the sperm or ova. Equipment used to store gametes must maintain the validated storage temperature.

QUALITY ASSURANCE

All establishments will be required to have a quality assurance system in place that complies with the requirements of the regulations and enables them to carry out all their activities. An important component of a quality assurance system is the standard operating procedures (SOP), which must be kept current, be approved by a qualified person, such as a Medical Director or Scientific Director (approval also required before the implementation on any subsequent changes as well), and available where relevant activities are carried out.

Comment [FB/AC54]: What about standards for record keeping? What about standards for insurance? What about standards of practice in the event that information about a health risk is obtained after use?

Comment [FB/AC55]: Note reference to "safety" without mention of "quality"

Comment [FB/AC56]: What constitutes sufficient personnel and who decides?

Establishments will be required to review their SOPs every two years. An establishment will also be required to conduct an audit every two years of the activities that it carries out, by a qualified person who does not have direct responsibility for the activities being audited, to verify that those activities comply with the relevant regulations and with its SOPs.

QUESTION FOR STAKEHOLDERS:
Q3: Please explain if any of the establishment requirements listed above should not be applied equally for all persons engaged in regulated activities (processing, importing, and distributing) and why.

4.1.7. Processing Requirements

SPERM AND OVA PROCESSING REQUIREMENTS

Health Canada proposes to introduce regulations for processing of sperm and ova intended for the use in AHR to ensure that sperm and ova are obtained, prepared, preserved, quarantined, identified, labelled and stored properly, and that their quality is assessed. In addition, Health Canada proposes that each processing establishment be required to develop and follow SOPs to ensure that they are processing donor gametes in accordance with the regulations. The disposal of donor gametes will also be done in accordance with the establishment's SOPs.

DONOR SUITABILITY ASSESSMENT

Health Canada also proposes to develop regulations for assessing the suitability of potential donors of sperm and ova intended for the use in AHR. The proposed regulations will require that all sperm and ova donors be informed of the possible health risks associated with sperm and ova donation, prior to donation. In addition, all sperm and ova donors will be required to consent to having their donor suitability assessed, and their results disclosed, as deemed appropriate by the medical director or treating physician, to inform the recipient of any risks.

It is proposed that anonymous and directed sperm and ova donors be required to undergo a donor suitability assessment that includes the following requirements:

- Sperm and ova donors must be screened (based on their medical, social and genetic history) as per the proposed screening criteria outlined below.
- Sperm and ova donors must be tested for infectious disease agents, and for blood compatibility, as per the proposed testing criteria outlined below.
- A review of the donor's overall suitability assessment must be conducted by a Medical Director or a physician designated by a Medical Director, and must include review of outcomes of the following: donor screening, donor testing and a physical examination (if required).

Comment [FB/AC57]: Note: reference to "quality" without reference to "safety"

Comment [FB/AC58]: This is vague and could allow for considerable diversity across the country as standards of practice vary considerably between fertility clinics. Are there relevant ISO standards?

Comment [FB/AC59]: Presumably this should also be in accordance with the consent regulations…this highlights the problem of lack of information in the consent regulations regarding consent to "discard" unused embryos.

Comment [FB/AC60]: Results must be disclosed to persons other than intended recipients. Results should first be disclosed to prospective donors, who may then elect not to become donors (in which case no information should be disclosed to recipients). HC should take considerable care in the drafting of the regulations to ensure that gamete donors are also seen as patients.

Further, an important element of informed consent is the right to withdraw. The prospective donor should receive the results of the suitability assessment and at that time be invited to make a decision about whether to go forward with the donation and consent to the disclosure of information.

Comment [FB/AC61]: This seems like treacherous territory. What is meant by "social history" and what social history will be assessed by the Medical Director? Will there be set criteria or will there be idiosyncratic decision-making? Is this about more than a criminal check?

Note: this sentence makes reference to screening, not merely collecting information.

Comment [FB/AC62]: The Medical Director or his/her designate may not have the relevant expertise to make the overall suitability assessment (especially as this includes social history).

Comment [FB/AC63]: It is unclear why a physical examination might be necessary. HC should be clearer about what would necessitate such an examination.

- Donor suitability assessment must be completed prior to the release of donation. Where donor suitability has not been completed, donations must be quarantined, clearly identified and easily distinguished from those for which donor suitability assessment has been completed.

NOTE:
Retesting of anonymous sperm donors for infectious disease agents 6 months after the date of donation is considered a part of donor suitability assessment. This retesting requirement will not apply to directed sperm donors and anonymous or directed ova donors.

Comment [FB/AC64]: HC may want to consider (and work together with the provinces) to establish a sound tracking system for all gametes from the time of collection.

Comment [FB/AC65]: Regarding the note on the retesting of donors, it is not clear why this would not be applied to anonymous ova donors? Is this a scientific limitation?

QUESTION FOR STAKEHOLDERS
Q4: As part of the donor suitability assessment, should anonymous sperm and ova donors be excluded based on their upper age? If so, what is a reasonable upper age limit beyond which sperm and ova donations should no longer be accepted?

(Note: Section 9 of the AHR Act already prohibits obtaining sperm or ovum from a donor under 18 years of age, except in narrowly prescribed circumstances.)

SCREENING CRITERIA

Comment [FB/AC66]: This section discusses infectious disease screening and genetic screening, but makes no mention of social history screening and yet this is identified as part of overall suitability.

As HC is working with CSA to develop evidence-based infectious disease criteria it behooves us to ask who is HC working with to develop evidence-based social history screening criteria?

Infectious Disease Screening

Health Canada is proposing that all sperm and ova donors be screened for infectious disease risk factors and that screening be repeated every 6 months while the donor is actively donating. While anonymous sperm and ova donors will be excluded from donation if they meet any of the exclusion criteria, directed donors will be permitted to donate under specific conditions outlined in section 4.1.4.

Health Canada is currently working with subject matter experts, including the CSA Technical Subcommittee responsible for maintaining and updating the Reproductive Tissues Standard, to develop evidence-based infectious disease screening criteria for sperm and ova donors.

Comment [FB/AC67]: In a number of other jurisdictions and per the guidelines of the American Society of Reproductive Medicine, commitments to the safety of donors and donor conceived people necessitates a limit on the number of times a donor can provide gametes. There should be a limit on the number of donations/offspring per donor.

Genetic Disease Screening

Comment [FB/AC68]: For infectious disease screening, there is a reference to the CSA as subject matter experts. Were subject matter experts consulted for genetic disease screening?

Health Canada proposes to introduce regulations that will require that appropriate and effective measures are taken to screen donors for the risk of genetic disease transmission. The intent of genetic disease screening is to assess the donor's overall risk of genetic disease transmission, and make this information available to the treating physician and to the recipient.

Comment [FB/AC69]: It is not clear why examples are given about genetic "disorders" (below) but not "diseases." This appears to be a matter of consistency of language, which HC may want to be attentive to in the regulations. If there is a substantive difference between disorder and disease then more clarity is needed.

Comment [FB/AC70]: See earlier comments about prior obligation to share the information about screening with the prospective donor (who is also a patient). The prospective donor may use this information to self-select out of the role of donor.

Health Canada is proposing that sperm and ova donors be screened for the following:

a) Presence of any major Mendelian[2] disorder in the donor;
b) Presence of any autosomal recessive disorder in the donor, known to be prevalent in the donor's ethnic background, according to accredited/recognized national or international professional medical guidelines; and,
c) Three generations of family genetic history for any autosomal recessive disorders known to be prevalent in the donor's ethnic background, if known.

Anonymous sperm or ova donors who are known to have any major Mendelian disorders (autosomal dominant, X linked disorders, or autosomal recessive inheritance (homozygous)) or serious chromosomal abnormalities will be excluded, however, directed donors will be permitted to donate under specific conditions outlined in section 4.1.4.

Sperm and ova donors who are determined to be heterozygous (a carrier) for autosomal recessive disorders, will not be excluded. Depending on the pattern of inheritance of a particular genetic disease, in combination with other environmental factors, the medical practitioner will be able to assess the overall genetic risk based on the results of donor screening, and advise the recipient accordingly.

Health Canada would consider the use of genetic tests to reveal information that would otherwise be obtained as the result of donor screening to be an appropriate and effective measure to assess the risk of genetic disease transmission.

QUESTION FOR STAKEHOLDERS
Q5: Please explain whether or not Health Canada should provide additional criteria on genetic disease screening, including a list of serious genetic diseases that a donor of sperm or ova should be screening for and why.

TESTING CRITERIA

Health Canada is proposing that all sperm and ova donors be tested to determine their blood compatibility (ABO and Rh status).

Infectious Disease Testing

Health Canada is proposing that regulations require all donors of sperm and ova be tested for infectious disease agents using appropriate test kits licensed in Canada. The use of test kits licensed in Canada or the United States will be permitted for testing done outside of Canada.

Anonymous donors of sperm or ova who test positive for any of the infectious disease agents listed below, with the exception of Cytomegalovirus, will be excluded from donating. Directed donors who test positive for any infectious disease agents may be permitted to donate under specific conditions (see section 4.1.4).

[2] Mendelian Disorder: a disease caused by mutation(s) in a single gene that is inherited according to Mendel's law of Genetics

Comment [FB/AC71]: Who decides what is to be considered a major disorder? This notion has shifted over time and very likely will continue to shift.

Comment [FB/AC72]: Again, the proposed screening is for specific disorders, rather than diseases. Is HC using disease and disorder interchangeably?

Comment [FB/AC73]: National and professional guidelines have not been harmonized. It follows that existing guidelines may conflict. There should be a reference to specific guideline (preferably a Canadian guideline).

Comment [FB/AC74]: Who is responsible for counselling and advising the donor who may just have received devastating news relevant to their own reproductive decision-making? This may be particularly important for donors and surrogates who may not yet have children of their own.

Comment [FB/AC75]: Again, note the use of disease rather than disorder.

Comment [FB/AC76]: Regarding Question 5: If social history is part of overall suitability, this needs to be carefully defined so as to avoid discrimination, stigmatization, and bias.

Comment [FB/AC77]: Does this sentence only apply to testing done in Canada? This question is prompted by the second sentence in this paragraph.

It is being proposed that testing be repeated every 3 months for directed sperm donors and anonymous or directed ova donors, while actively donating.

Comment [FB/AC78]: As noted above, there should be a limit on the number of donations/offspring per donor.

It is being proposed that sperm and ova donors be tested for the following infectious disease agents:

a) Human immunodeficiency virus type 1
b) Human immunodeficiency virus type 2
c) Hepatitis B virus
d) Hepatitis C virus
e) West Nile virus
f) Treponema pallidum (syphilis)
g) Chlamydia trachomatis
h) Neisseria gonorrhoeae

In addition, it is being proposed that sperm donors be tested for following infectious disease agents:

a) Human T-lymphotropic virus type 1
b) Human T-lymphotropic virus type 2
c) Cytomegalovirus

QUESTION FOR STAKEHOLDERS
Q6: Please list any additional infectious disease agents that should be tested for and explain the scientific interpretation for why they should be included.

Infectious Disease Retesting

It is being proposed that the regulations will require that sperm from anonymous donors be quarantined and the donor retested for infectious disease agents at least 6 months after the date of donation prior to the release and distribution of their donation. All other donors, including anonymous ova donors, will not require retesting as part of their donor suitability assessment.

4.1.8. Records

Health Canada proposes that the regulations will require all processors of donor sperm or ova for distribution to maintain records of each donor. These records will include information that identifies the donor and the date of each donation, as well as the results of the tests, screening and donor suitability assessment.

It is being proposed that all importers and distributors of donor sperm or ova be required to maintain records that identify the entity from which the donation was received (i.e. a processor, an importer or another distributor). Importers and distributors will also be required to maintain records that demonstrate evidence that the sperm or ova were processed in accordance with the section 10 regulations as well as copies of any additional labelling required by the section 10 regulations in the case of directed donation and exceptional distribution.

Health Canada proposes that all users of the donor sperm or ova be required to maintain records that identify the patient on whom the assisted reproduction was performed. Additionally, in the case of directed donation or exceptional distribution, the regulations will require the person who makes use of the donor sperm or ova to maintain the patient's written consent to use the sperm or ova.

Record retention requirements will also be established in the regulations.

Comment [FB/AC79]: This is good news and HC should proceed with the establishment of record retention requirements. However, there are a number of issues that will have to be considered, including what records need to be retained, and for how long, as well as privacy concerns related to the storage and transfer of relevant material.

Some of these issues will be exacerbated when reproductive materials are donated, but stored (i.e. cryopreserved), as there is no storage limit on reproductive material in Canada. HC may want to consider introducing a storage limit, or working together with the provinces and the relevant professional medical bodies to do so.

4.1.9. Traceability

Health Canada proposes that regulations with respect to tracing donor sperm and ova be introduced to identify persons who have imported, distributed, or made use of the donor sperm and ova, or who are storing the donor sperm and ova for the purpose of distribution or use in AHR, so that necessary steps can be taken in the event of:

- errors or accidents from processing and handling of donor sperm or ova that could affect their quality and safety; and,
- adverse outcomes to the recipient, potentially attributable to the use of donor sperm or ova.

Comment [FB/AC80]: HC may want to add here concerns about the adverse outcomes that may be experienced by those conceived using donor gametes.

In order to reduce the risk of potentially preventable adverse outcomes, as well as to mitigate the risks resulting from errors or accidents, Health Canada is proposing that the regulations require the communication of information to Health Canada and all other relevant parties along the distribution chain, which may include donors of the sperm and ova and the persons who have undergone AHR procedures in which the sperm or ova were used.

Health Canada proposes that the regulations also require an investigation of any suspected errors or accidents and adverse outcomes by the responsible party (to determine the nature, cause and extent of the risks to human health and safety) and, appropriate measures be taken in respect of the sperm and ova to reduce those risks.

Did you Know?

While it is proposed that the new regulations will require that information pertaining to donor sperm and ova accompany the donations throughout the distribution chain from processor to the eventual recipient, the personal information of donors is not part of that information. Rather, the regulations will require the use of a donor identification code, which is an alphanumeric code that identifies the donor and the date of donation. The donor identification code serves as a means to identify the donor without disclosing their identity and relates the sperm or ova to the donor and to all other records related to the sperm or ova.

Clear timelines will be established for the responsible party in reporting adverse outcomes and/or errors and accidents to Health Canada.

QUESTION FOR STAKEHOLDERS
Q7: Please explain whether or not cases of suspected transmission of a genetic disease from donor sperm or ova should be reported to Health Canada and why. What would be the expectation for Health Canada's role in assessing and taking action for such cases?

Comment [FB/AC81]: Regarding Question 7, it is imperative that HC collect data about suspected cases of disease transmission and that when such cases are confirmed, both the donors and the recipients are informed.

As well, depending upon when the transmission of genetic disease is reported, there may be offspring who have reached the age of consent. If so, it will be important that they be informed as well.

4.2. Section 12 Reimbursement

4.2.1. Context

Sections 6 and 7 of the AHR Act prohibit the payment for surrogacy and the purchase of sperm and ova from a donor or a person acting on behalf of a donor, respectively. Despite these prohibitions, Parliament recognized that in order to promote an altruistic system, donors and surrogates should be permitted to be reimbursed for out-of-pocket expenditures incurred as a result of their donation or surrogacy. As such, section 12 of the AHR Act deals with the reimbursement of expenditures and loss of work-related income. Specifically, section 12 prohibits reimbursement except in accordance with regulations.

4.2.2. Principles and Objectives

The principles of reimbursements made under the AHR Act are as follows:

- Only expenditures incurred in the course of sperm or ova donation, in the maintenance or transportation of an *in vitro* embryo, or, for surrogates, in the relation to the surrogacy, including the loss of work-related income for surrogates, may be reimbursed.
- There is no obligation to reimburse, meaning that only persons who wish to reimburse eligible expenditures will do so.
- Reimbursement must not involve monetary gain by involved parties, nor should it be a disguised form of payment or purchase. AHR-related expenditures that are not specifically set out in the regulations are not eligible for reimbursement.
- A receipt for the expenditure must be provided to the reimburser as a condition of the reimbursement.

The objective of the reimbursement regulatory framework under the AHR Act is to provide parameters around the reimbursement of expenditures. For the most part Health Canada is proposing that this be accomplished in two ways:

- First, the regulations will set out categories of expenditures that could reasonably be incurred by a donor or surrogate as a consequence of their donation or surrogacy. This will have the effect of limiting reimbursements, as they will only be permitted for the categories of expenditures listed in regulations.
- Second, the regulations will specify a verifiable process by which reimbursements may be made. Specifically, they will require evidence that a reimbursement has been made in accordance with the Act and regulations, which is to be documented by the parties involved. This is to enable compliance enforcement activities, as well as to provide clarity and structure to the reimbursement process for stakeholders.

Comment [FB/AC82]: People should not be required to participate in a commercial transaction and so it is certainly correct that people shouldn't have to reimburse expenses if they do not want to. As worded, however, this does not communicate that non-reimbursement is a joint (agreed-upon) decision. It follows that the gamete donor or the surrogate may be expecting reimbursement of eligible receipted expenditures and the recipient does not wish to reimburse (any or all) eligible expenditures claimed. This point will need to be carefully worded to avoid the risks of exploitation and coercion for donors, surrogates and recipients.

Comment [FB/AC83]: In principle this is a good idea, but this is a very significant part of the proposed regulations that will require further consultation to ensure legitimacy. HC may want to consider additional engagement with all relevant stakeholders, including egg donors and surrogates who have previously received reimbursements.

4.2.3. Scope and Application

The regulations will apply to all payments made to donors of sperm and ova for third party use for the purpose of reimbursing eligible expenses incurred in the course of the donation, to surrogates for the purpose of reimbursing expenses incurred in the course of surrogacy, and to persons for the purpose of reimbursing expenses incurred in the maintenance and transport of *in vitro* embryos.

EXPENDITURES THAT MAY BE REIMBURSED

It is proposed that the regulations will specify that the following expenditures are eligible for reimbursement:

For sperm and ova donors and surrogates

- Travel expenditures, including expenditures for transportation, parking, meals and accommodation
- Expenditures for the care of dependents
- Expenditures for counselling services
- Expenditures for legal services and disbursements
- Expenditures related to shipping (for sperm and ova only)
- Expenditures for other items or services that are provided by or recommended in writing by a qualified medical practitioner

For ova donors and surrogates

- Expenditures for medication

For surrogates

- Expenditures for maternity clothes
- Expenditures related to the delivery

For maintenance and transport of *in vitro* embryos

- Expenditures for storage of the *in vitro* embryos
- Expenditures for preparing the *in vitro* embryos for transport
- Expenditures for the shipping container and for preparing the container for transport
- Expenditures for transporting the *in vitro* embryos

QUESTION FOR STAKEHOLDERS
Q8: Please identify any other categories of expenditure that should be considered for reimbursement and explain why.

Comment [FB/AC84]: Again, in the regulations, HC should be consistent in using the language of "expenditures" as per the legislation.

Comment [FB/AC85]: Although the expenditures, as listed below are to occur "in the course of" donation or surrogacy, it is reasonable to anticipate, that at least two categories of expenditures may be incurred after donation or surrogacy – counselling services and legal services. For example, gamete donors may require counselling if they become infertile as a result of their donation and are unable to have their own children. Similarly, it is easy to imagine surrogates needing counselling services before, during and after surrogacy.

Comment [FB/AC86]: It is advisable to use narrower language, not merely "recommended in writing", but rather "deemed necessary" by a qualified medical practitioner. Clear guidance should be provided for "other items or services". It will be especially important to provide ova donors, sperm donors and surrogates with specific information. A modified version of the list provided by the CSA might be useful starting point.

4.2.4. Process for Reimbursement

For the purpose of enabling compliance enforcement activities and to provide clarity and structure to the reimbursement process for stakeholders, Health Canada is proposing to establish a verifiable process by which reimbursements may be made.

Under the proposed process, a person will only be allowed to reimburse another person for an expenditure incurred as a result of their donation or surrogacy if the following documents are obtained:

- A declaration dated and signed by the person who requests reimbursement (i.e. the donor, the surrogate, or the person who maintained or transported an *in vitro* embryo);
- The receipt for each expenditure for which reimbursement is sought; and,
- If applicable, the written recommendation from a qualified medical practitioner.

Comment [FB/AC87]: Clarity re "person" reimbursing is important. In the case of directed donation there are the risks of coercion and exploitation unless there in a third-party (e.g., lawyer) managing the transfer of funds.

Are there differences between directed and anonymous reimbursement? At the very least with anonymous donation a third-party (e.g., lawyer) will need to be involved in reimbursement.

It will be important to clarify whether the third-party can charge the recipient for services rendered.

Comment [FB/AC88]: Again, it is advisable to use narrower language, not merely recommended, but rather "deemed necessary" by a qualified medical practitioner.

4.2.5. Reimbursing a surrogate for the loss of work-related income

The AHR Act allows a surrogate to be reimbursed for the loss of work-related income incurred during their 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.

Health Canada is proposing that such reimbursements be permitted provided the loss has not otherwise been covered by another person, including the surrogate's employer, and the loss is not greater than the amount the surrogate would have received during the period for which the reimbursement is claimed from their employer or self-employment.

A person will only be allowed to reimburse a surrogate for the loss of work-related income if the following documents are obtained:

- A declaration dated and signed by the surrogate who requests reimbursement;
- Proof of income to validate the claimed amount; and,
- A copy of the medical practitioner's written certification.

4.2.6. Creation and maintenance of records

Health Canada proposes that persons who issue a reimbursement under section 12 of the AHR Act will be required to keep all forms, documents and receipts for a period of 6 years after the reimbursement is issued.

Comment [FB/AC89]: As the specifics of these regulations are being developed, HC will want to consider questions such as:

- Will there be periodic oversight/verification, such as a random 5-10% verified per annum?
- Or, is it simply that problems with documentation will come to light in the event that there is a legal problem at which time the documents may or may not be available?
- Will there be a penalty for failure to keep proper documentation. This approach presumably would be inconsistent with a "risk-based approach to compliance and enforcement".

4.3. Section 45 to 58 – Administration and Enforcement

4.3.1. Context

Sections 45 to 58 of the AHR Act were amended in 2012 to narrow their application to certain prohibitions (sections 8, 10, and 12 of the Act) and remove references to the AHRC, which was closed in 2012. The purpose of sections 45 to 58 is to establish a regulatory framework for compliance verification by designated inspectors, as well as and enforcement activities in relation to the Act.

Similar authority currently exists over donor sperm under the *Food and Drugs Act*. The safety of donor ova is currently unregulated at the federal level. Once sections 45-58 are brought into force, Health Canada will align its administration and enforcement oversight of AHR into a single regime.

4.3.2. Principles and Objectives

The administration and enforcement framework of the AHR Act is guided by the principles of regulatory transparency and a risk-based approach to compliance and enforcement.

The objective of the administration and enforcement framework under the AHR Act is to establish a comprehensive compliance verification regime that provides effective oversight over processors, importers, and distributors.

Comment [FB/AC90]: What about users?

4.3.3. Scope and Application

Sections 45 to 58 of the AHR Act authorize designated inspectors to verify compliance with any of the requirements of sections 8, 10, and 12 of the AHR Act. Health Canada proposes that the administration and enforcement framework be designed to verify that consent is received from donors for reproductive material, that evidence based screening and testing standards are used for donor ova and sperm, that traceability is ensured for donor ova and sperm, and that the reimbursement of expenditures related to donation or surrogacy comply with regulatory requirements.

The administration and enforcement framework consists of four main components:

- Sections 46 to 53 authorize the Minister to designate inspectors to administer and enforce the AHR Act and outlines the powers of inspectors to verify compliance and address non-compliance, including the ability to enter a place or conveyance where they have reasonable grounds to believe an activity under the Act is being conducted, to examine any material or information regulated by the Act, and to seize any non-compliant material or information related to a contravention of the AHR Act;
- Section 54 sets out a requirement for Health Canada to take all reasonable measures to preserve any viable sperm, ovum or *in vitro* embryo that is seized under this Act or the Criminal Code;

- Sections 55 to 57 authorizes the Minister to designate analysts to administer and enforce the AHR Act and outlines the powers and responsibilities of analysts; and,
- Section 58 enables the Minister to establish agreements with other federal, provincial, or law enforcement departments and agencies for enforcement of the AHR Act.

Most of sections 45-58 will be brought into force with sections 10 and 12 without additional regulations, but there are three areas (sections 51, 52(3), and 54) that require additional regulations to be put into place.

4.3.4. Process for restoring seized information or human reproductive material

Under section 50, once entered into a place, inspectors will have the authority to seize, among other things, embryos and any other human reproductive material outside the body, as well as any information, if they have reasonable grounds to believe that the Act has been contravened or if it relates to a contravention of the Act.

Section 51 establishes notification requirements for a person applying to a provincial court for the restoration of material or information that was seized from them. In order for that material or information to be returned under section 51, persons are required to notify the Minister of their intention to apply for an order of restoration to a provincial court judge.

It is proposed that the notice will be required to be sent to the Minister 15 days before the application for an order of restoration is to be made to a provincial court judge and that the notice includes:

- Information on the time and location of the hearing;
- Information regarding the material or information seized; and,
- Evidence that will be used to establish the applicant is entitled to the material or information.

4.3.5. Defining designated officer under ss. 52(3) and 54

The concept of “designated officer” was introduced into the AHR Act in 2012 to replace former references to the “Agency” when the AHRC was closed. It is proposed that “designated officer” will be defined by the Minister.

4.3.6. Measures to maintain viable material when consent cannot be obtained

Section 54 requires the designated officer to make reasonable efforts, and in a manner that is consistent with the consent of the donor, to preserve any viable sperm, ovum, or *in vitro* embryo that has been seized under the Act or the Criminal Code. Although it is expected that further measures, which could include disposal, would be taken only exceptionally, such measures would be taken in a manner consistent with the consent of the donor. However, in those circumstances in which consent of the donor cannot be obtained, it is proposed that regulations will set out the parameters for such measures.

5. How to Submit Feedback

Comments regarding the policy proposals set out in this document may, within 60 days of the date of its publication, be submitted by:

Mail:

Office of Policy and International Collaboration
Biologics and Genetic Therapies Directorate
Address Locator 0601B, Tunney's Pasture
100 Eglantine Driveway, Ottawa, Ontario
K1A 0K9

Tel: 613-957-2991
Fax: 613-952-5364

Email:

bgtd_ahr-dpbtg_pa@hc-sc.gc.ca

Online:

https://www.canada.ca/en/health-canada/programs/consultation-assisted-human-reproduction.html

All feedback received on or before September 9 will be considered during the regulatory development phase of the project. Interested stakeholders will be given an opportunity to provide feedback on regulatory proposals following their prepublication in the *Canada Gazette*, Part I.

6. Appendix

6.1. Appendix A: International Comparison of AHR Regulatory Oversight

Comment [FB/AC91]: Given the diversity of approaches to the regulation of AHR in other jurisdictions, in the future (if doing additional comparisons), HC may want to consider expanding this work to include jurisdictions beyond the United States and the UK -- especially jurisdictions with a similar health care system.

	Canada	United States	United Kingdom
Governing Legislation	*Assisted Human Reproduction Act* (AHRA)	*Title 21 Code of Federal Regulations (CFR) Part 1271* sets out regulations for the safety of use of donor sperm and ova at the federal level Other regulations of AHR technologies vary at the state level	*Human Embryology & Fertilisation Act* (HEFA) In addition to HEFA, the *Surrogacy Arrangement Act*, prohibits commercial surrogacy
Scientific procedures	AHRA prohibits certain procedures (e.g. germline modifications)	Prohibitions vary at the state level	HEFA prohibits certain procedures
Surrogacy	Commercial surrogacy is prohibited but altruistic surrogacy is permitted	Commercial surrogacy is not prohibited at the federal level	Commercial surrogacy is prohibited but altruistic surrogacy is permitted
Commercial trade of human ova, sperm and embryos donations	Prohibited to purchase sperm or ova from a donor or a person acting on behalf of a donor	Commercial trade is not prohibited at the federal level	Commercial trade is prohibited
Reimbursement of expenses incurred by surrogates and donors	Reimbursement of eligible expenses is legally permissible	Reimbursement of expenses is not applicable due to commercial trade	Reimbursement of expenses is legally permissible