NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Canada  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:** Department of Health  **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**  Canada’s Notification Authority and Enquiry Point  Global Affairs Canada  Technical Barriers and Regulations Division  111 Sussex Drive, Ottawa, ON K1A 0G2  Canada  Telephone: (343)203-4273  Fax: (613)943-0346  E-mail: [enquirypoint@international.gc.ca](mailto:enquirypoint@international.gc.ca) |
| **3.** | **Notified under Article 2.9.2 [X], 2.10.1 [****], 5.6.2 [X], 5.7.1 [****], other:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Sperm and ova for assisted human reproduction |
| **5.** | **Title, number of pages and language(s) of the notified document:** (1) Proposed regulations entitled Safety of Sperm and Ova Regulations (47 pages, available in English and French) (2) Proposed Technical Directive entitled Technical Requirements for Conducting the Suitability Assessment of Sperm and Ova Donors (14 pages, available in English and French) Note: The proposed Technical Directive is incorporated by reference into the proposed Safety of Sperm and Ova Regulations. |
| **6.** | **Description of content:** The proposed *Safety of Sperm and Ova Regulations* would establish a human health and safety framework for donor sperm and ova for assisted human reproduction. Specifically, the  proposed regulations would:   * Establish minimum requirements for screening and testing sperm and ova donors; * Establish a risk-based registration and notification oversight scheme for establishments who process, import and distribute donor sperm and ova; * Establish a traceability system whereby donor sperm and ova are identified, labelled and stored so that appropriate steps may be taken in the event of an error, accident or adverse reaction; and   Establish a quality management system to ensure that establishments who conduct their activities do so in a manner that prevents contamination or cross-contamination, prevents the transmission of an infectious disease and maintains the quality of the sperm and ova. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** There is a need to strengthen the federal regulatory framework governing the safety of donor sperm and ova used for the purposes of assisted human reproduction in Canada. The proposed regulations would address regulatory gaps by: (a) modernizing the outdated regulations for donor semen which were made under the *Food and Drugs Act* in 1996; and (b) introducing new regulations for donor ova, which are currently unregulated in Canada. |
| **8.** | **Relevant documents:**  (1) *Canada Gazette*, Part I, 27 October 2018, pages 3696-3734 (in English and French)  (2) *Technical Requirements for Conducting the Suitability Assessment of Sperm and Ova Donors* (in English and French)  Additional information on the proposal is available from the following web sites, in English and French:  Backgrounder:  <https://www.canada.ca/en/health-canada/news/2018/10/backgrounder-directed-donation-process-for-sperm-and-ova-donors.html>  <https://www.canada.ca/fr/sante-canada/nouvelles/2018/10/document-dinformation-processus-de-don-dirige-pour-les-donneurs-de-sperme-et-dovules.html>  Guidance Document:  <https://www.canada.ca/en/health-canada/programs/consultation-assisted-human-reproduction-regulations/document.html>  <https://www.canada.ca/fr/sante-canada/programmes/consultation-reglement-procreation-assistee/document.html> |
| **9.** | **Proposed date of adoption:**  On the date the regulations are registered, Notification of registration would occur through publication in Canada Gazette, Part II, which is anticipated to be in Spring 2019.  **Proposed date of entry into force:**  The proposed Safety of Sperm and Ova Regulations would come into force six months after the publication of the regulations in the Canada Gazette, Part II, with a few exceptions for certain provisions. This period is proposed to provide industry with time needed to update their practices to come into compliance with the regulations. At the same time, an Order in Council would bring into force the related prohibitions under section 10 of the Assisted Human Reproduction Act. It is proposed that the remaining provisions of the regulations come into force twelve months after publication, to provide time for primary establishments to be provided with and communicate their registration numbers.  The requirements set out in the proposed Technical Directive would take effect six months following the publication of the regulations in Canada Gazette, Part II. |
| **10.** | **Final date for comments:** 10 January 2019 |
| **11.** | **Texts available from: National enquiry point [****X] or address, telephone and fax numbers and email and website addresses, if available, of other body:**  The electronic version of the regulatory text and the Draft Technical Directive can be downloaded at:  <http://gazette.gc.ca/rp-pr/p1/2018/2018-10-27/html/reg2-eng.html>  <http://gazette.gc.ca/rp-pr/p1/2018/2018-10-27/html/reg2-fra.html>  <https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-assisted-human-reproduction-regulations/technical-directive-eng.pdf>  <https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-assisted-human-reproduction-regulations/technical-directive-fra.pdf> |