Health Canada Santé Canada

Guidance Document

Interim Compliance Approach Regarding Donor Ova Processed Prior to February 4, 2020

Publication date 2020-12-18
Effective date 2020-12-18

Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre :
Ligne directrice : Règlement sur le remboursement relatif à la procréation assistée

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca

Publication date: December 18, 2020

Catalogue Number: H164-304/2020E-PDF
ISBN: 978-0-660-36756-9
Publication Number: 200309

Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable Guidance documents.

Table of contents

Introduction

Purpose/Overview

Health Canada is notifying establishments and health professionals who process, import, distribute and/or make use of donor ova for the purpose of assisted human reproduction (AHR) of its interim compliance approach with respect to the processing requirements for donor ova that were obtained prior to the *Safety of Sperm and Ova Regulations* (Safety Regulations) coming into force on February 4, 2020 ("pre-CIF donor ova").

The Safety Regulations establish a regulatory framework for donor sperm and ova, and are focused on reducing the risks to human health and safety, including the risk of the transmission of disease, arising from the use of donor sperm or ova intended for use in AHR in Canada. The regulatory framework includes technical requirements to conduct donor suitability assessment, as outlined in the *Health Canada Directive: Technical Requirements for Conducting the Suitability Assessment of Sperm and Ova Donors* (Directive), which is incorporated by reference in the Safety Regulations.

Before February 4, 2020, donor sperm was subject to the *Processing and Distribution of Semen for Assisted Conception Regulations* (Semen Regulations), made under the *Food and Drugs Act* in 1996, to mitigate the risk of infectious disease transmission from the use of donor semen in assisted conception. At the federal level, the safety of donor ova was unregulated in Canada until the coming into force of the Safety Regulations.

The Safety Regulations include transitional provisions which allow donor sperm that was processed before the coming into force of the Safety Regulations, but which was not processed in accordance with the Safety Regulations, to be distributed, imported, or used provided the donor sperm was processed in accordance with the Semen Regulations. However, as donor ova was not previously regulated at the federal level, the Safety Regulations have no such transitional provisions for donor ova and therefore must meet the requirements of the Safety Regulations, in order for it to be distributed, imported or used.

Since the coming into force of the Safety Regulations, the Department has learned from stakeholders that a significant number of pre-CIF donor ova do not meet all of the processing requirements outlined in the Safety Regulations, namely certain donor suitability assessment requirements. As such, where the requirements for directed donation or exceptional access cannot be met, the Safety Regulations are preventing the use of donor ova that was processed prior to the coming into force of the Safety Regulations for the purpose of building their families.

Therefore, on an interim basis, until the Safety Regulations may be amended to include transitional provisions to address pre-CIF donor ova, pre-CIF donor ova that do not meet all of the processing requirements outlined in the Safety Regulations will be considered of lower priority for enforcement provided certain processing requirements described below are met.

Policy objectives

Health Canada acknowledges the need to amend the Safety Regulations to better account for donor ova that was processed prior to February 4, 2020.

The objective of this interim compliance approach is to ensure that individuals continue to be able to make use of pre-CIF donor ova in order to build their families, while continuing to reduce the risks arising from the use of such ova.

Scope and application

This interim compliance approach applies to establishments and health professionals that process, import, distribute and/or use pre-CIF donor ova for the purpose of AHR.

Guidance for Implementation

In order for the distribution, importation and use of pre-CIF donor ova that were not processed in accordance with the Safety Regulations to be considered of lower priority for enforcement, the following conditions must be met.

All establishments and health professionals are still required to meet all other applicable regulatory requirements in respect of the pre-CIF donor ova they wish to distribute, import or use, including the applicable quality management, adverse reaction and error or accident requirements, and requirements for record keeping to ensure traceability.

Donor screening and physical examination

- In the absence of donor screening or physical examination results, there is an obligation on the primary establishment to review any existing results, complete the donor suitability assessment if possible, and document any parts of the assessment that have not been conducted (i.e., as is the case under Exceptional Access and certain Directed Donations).

Donor testing

- The donor must have been tested and the tests been non-reactive for the following infectious disease agents:
  - Human Immunodeficiency Virus 1 (HIV-1) and 2;
  - Hepatitis C Virus;
  - Hepatitis B Virus;
  - Treponema pallidum (syphilis) using:
    - non-treponemal test; or
    - treponemal-specific test;
  - Chlamydia trachomatis; and
  - Neisseria gonorrhoeae.
- Testing for these specific infectious disease agents must be performed:

- using appropriate and effective tests[1];
- by a laboratory that meets the accreditation requirements of the province in which the laboratory is located or, if the testing is performed outside Canada, by a laboratory that meets a recognized equivalent accreditation requirement;
- using in vitro diagnostic devices that are licensed in Canada, the United States or the jurisdiction where donor testing was conducted;
- in accordance with the manufacturer's requirements for specimens, and the manufacturer's instructions for the performance of the test and interpretation of test results; and,
- using specimens collected within a scientifically justified timeframe that ensures the test results accurately reflect the infection status of the donor at time of obtaining ova. (Note: such a timeframe may differ between infectious diseases and is dependent upon the type of test being used. As such, it is the responsibility of the primary establishment to justify the chosen timeframe for specimen collection. Such a timeframe must ultimately support the health professional's obligation to determine and document that the use of the ova would not pose a serious risk to human health and safety.)

Action by the primary establishment

The primary establishment has a critical role in ensuring the safety of sperm or ova for the purpose of AHR. In order to consider the distribution, importation and use of pre-CIF donor ova not processed in accordance with the Safety Regulations to be of lower enforcement priority, the primary establishment must meet the following requirements:

- review all available medical information about the donor
- review all available results of any donor screening, physical examination, or donor testing that was previously conducted
- complete the donor suitability assessment unless it is not medically possible to do so (e.g., the donor is not unreachable or is deceased)

Summary document

- Before distributing or making use of the pre-CIF ova, the primary establishment or a health professional must create and sign a summary document that contains the following information:

[1] A test is considered appropriate and effective if it is:

- licensed for the detection of the infectious disease agent or marker;
- used in accordance with the test kit manufacturer's instructions; and
- used for the detection of an infectious disease marker that is relevant at the time testing is performed.

- The dates and results of any donor screening, physical examination and donor testing;
- A list of any parts of the donor suitability assessment that have not been conducted or that were conducted outside of the timeframe specified in the Directive.

Storage

- An establishment and a health professional must ensure that pre-CIF donor ova not processed in accordance with the Safety Regulations in their possession or control are segregated either physically or electronically from donor ova that are compliant with the Safety Regulations.

Labelling

- In addition to the labelling requirements set out in the Safety Regulations, prior to distributing or making use of the pre-CIF donor ova, an establishment or a health professional must ensure that the documentation that accompanies the immediate container of ova contains a statement indicating that the donation was obtained before the coming into force of the Safety Regulations and has not been processed in accordance with the Safety Regulations.

Communication of risk

- A health professional must meet the following requirements before making use of the ova obtained pre-CIF that were not processed in accordance with the Safety Regulations:
  - Create a document that states that, based on the summary document and any risk mitigation measures taken[2], in their medical opinion, the use of the ova would not pose a serious risk to human health and safety; and
  - Create a document that states that the health professional has informed the recipient of the risks that the use of the ova could pose to human health and safety and that the health professional has obtained written consent from the recipient.

[2] Risk mitigation measures could include prophylactic measures, such as any medication to prevent HIV infection, or retroactive donor testing.

Contact Information

Inquiries and information requests regarding this interim compliance approach should be submitted directly to the Biological Product Compliance Program by email: hc.bpcp-pcpb.sc@canada.ca.