



NATIONAL ASSEMBLY

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Bill 29
(2013, chapter 11)

**An Act to amend the Act respecting
Héma-Québec and the haemovigilance
committee**

**Introduced 27 March 2013
Passed in principle 23 April 2013
Passed 28 May 2013
Assented to 5 June 2013**

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EXPLANATORY NOTES

This Act contains various amendments to the Act respecting Héma-Québec and the haemovigilance committee.

Héma-Québec's mission is broadened to include duties and functions in connection with human milk, stem cells and any human tissues, as well as any other human biological product determined by the Government. The Government is empowered to entrust Héma-Québec with any other mandate related to those duties and functions.

The governing board of Héma-Québec also undergoes certain modifications, particularly with respect to its composition and the length of its members' terms, and Héma-Québec is empowered to make an agreement with the Minister of Health and Social Services on the use of any surpluses generated by its activities. Furthermore, the health and social services institutions are to pay the price of the products and services provided by Héma-Québec, unless the Minister decides otherwise.

Héma-Québec may not construct, acquire, dispose of, convert or renovate an immovable without the Minister's authorization, except in the cases specified by the Government. The Government may determine the cases in which Héma-Québec must obtain the Minister's authorization to rent an immovable. Moreover, the Minister is granted powers as regards inspections and investigations.

The proposed amendments also allow Héma-Québec, in certain circumstances, to remove tissues after the donor's death is attested by a single physician who does not participate either in the removal or in the transplantation.

The Minister is empowered to broaden the mandate of the haemovigilance committee to take into account Héma-Québec's new duties and functions; consequently, the committee's composition and name are modified.

In addition, the compensation plan for victims of a Héma-Québec product is amended to take into account Héma-Québec's new duties and functions.

Lastly, various consequential and transitional amendments are introduced.

LEGISLATION AMENDED BY THIS ACT:

- Act respecting Héma-Québec and the haemovigilance committee (chapter H-1.1).

REGULATION AMENDED BY THIS ACT:

- Regulation respecting the conditions for compensation to victims of a Héma-Québec product (chapter H-1.1, r. 1).

Bill 29

AN ACT TO AMEND THE ACT RESPECTING HÉMA-QUÉBEC AND THE HAEMOVIGILANCE COMMITTEE

THE PARLIAMENT OF QUÉBEC ENACTS AS FOLLOWS:

1. Section 3 of the Act respecting Héma-Québec and the haemovigilance committee (chapter H-1.1) is amended

(1) by replacing “at the request of a body managing joint supplies to institutions that has been designated by the Minister of Health and Social Services” in subparagraph 8 of the second paragraph by “at the request of the Minister of Health and Social Services or a body managing joint supplies to institutions that has been designated by the Minister”;

(2) by replacing the last paragraph by the following paragraphs:

“Héma-Québec is also assigned, with the necessary modifications, such duties and functions in connection with human milk, stem cells and any human tissue, as well as any other human biological product determined by the Government.

Héma-Québec shall carry out any other mandate related to the duties or functions described in the preceding paragraphs that is entrusted to it by the Government.

In pursuing its mission, Héma-Québec must manage its human, material, information, technological and financial resources effectively and efficiently.”

2. Section 5 of the Act is amended by replacing “on blood or plasma donors with a view to reducing the risk of product contamination” by “on donors with a view to maintaining supply safety, in particular as regards the risk of product contamination”.

3. Section 7 of the Act is replaced by the following section:

“**7.** The affairs of Héma-Québec are administered by a governing board composed of 13 members.

Eleven of these members are identified with the following categories:

(1) the associations representing product recipients;

(2) the Association québécoise d'établissements de santé et de services sociaux;

(3) the product donors and volunteer donor clinic organizers;

(4) the Collège des médecins du Québec;

(5) the scientific research sector;

(6) the business sector; and

(7) the public health sector.

There must be at least one but not more than 3 members per category. All 11 members are appointed by the Government after consultation with the persons or sectors in that category.

The board must also include a person who is a member of the Ordre des comptables professionnels agréés du Québec, appointed by the Government after consultation with that professional order.

The president and chief executive officer, who may be designated by the title "président-directeur général" or "président et chef de la direction" in French, is also a member of the board, appointed to that position by the other members of the board."

4. Section 9 of the Act is replaced by the following section:

"9. The president and chief executive officer is appointed for a term of not more than five years and the other members of the governing board are appointed for a term of not more than four years. At the expiry of their terms, they remain in office until they are replaced or reappointed.

The members of the governing board, other than the president and chief executive officer, may be reappointed only twice, for a consecutive or non-consecutive term."

5. Section 10 of the Act is amended

(1) by adding the following sentence at the end of the first paragraph: "The offices of chair and president and chief executive officer may not be held concurrently.";

(2) by replacing "director general" in the second paragraph by "president and chief executive officer".

6. Section 13 of the Act is replaced by the following section:

“13. The Minister may designate a member of the biovigilance committee to attend the meetings of the governing board. That member is entitled to speak at the meetings.”

7. Section 25 of the Act is amended by adding the following paragraph at the end:

“Any surpluses are paid into the Consolidated Revenue Fund, unless a prior agreement between Héma-Québec and the Minister is entered into on the use of the surplus.”

8. Section 30 of the Act is replaced by the following section:

“30. Héma-Québec may not construct, acquire, dispose of, convert or renovate an immovable without the Minister’s authorization, except in the cases, on the conditions and to the extent determined by the Government.

Héma-Québec may, however, rent an immovable without the Minister’s authorization, except in the cases, on the conditions and to the extent determined by the Government.

The Minister’s authorization is also necessary for any purchase or rental of equipment for an amount exceeding the thresholds determined by the Government, unless the equipment is required to ensure the safety of Héma-Québec products. In the latter case, Héma-Québec must, within 90 days after the purchase or rental, provide the Minister with proof that the purchase or rental was justified.”

9. The Act is amended by inserting the following sections before section 32:

“31.1. The Minister or a person authorized in writing by the Minister may conduct an inspection and, at any reasonable time, enter any premises under the responsibility of Héma-Québec to verify compliance with this Act or the regulations.

The inspector may

(1) examine and make a copy of any document relating to Héma-Québec activities; and

(2) demand any information relating to the application of this Act or a regulation and the production of any document connected with it.

A person having custody, possession or control of such documents must, on request, make them available to the inspector.

The inspector must, on request, produce a certificate of authorization signed by the Minister.

No proceedings may be brought against the inspector for acts in good faith in the performance of inspection duties.

“31.2. The Minister may investigate or direct a person the Minister designates to investigate any matter relating to the application of this Act or the regulations.

For the purposes of such an investigation, the person who conducts an investigation has the powers and immunity conferred on commissioners appointed under the Act respecting public inquiry commissions (chapter C-37), except the power to order imprisonment.

“31.3. No person may hinder a person in the performance of inspection or investigation duties, mislead or attempt to mislead that person by misrepresentation or deceptive statements, refuse to produce documents required by that person or omit or refuse, without good cause, to answer any question that may lawfully be asked.

“31.4. Once the inspection or investigation is completed, the Minister may require Héma-Québec to submit an action plan to remedy the situation, if applicable.”

10. The heading of Division VI of the Act is amended by adding “AND SERVICES” at the end.

11. The Act is amended by inserting the following section before section 38:

“37.1. The price of the products and services provided by Héma-Québec to health and social services institutions is to be paid in full by the institutions. However, if the Minister considers it expedient, the Minister may pay all or part of the cost directly, in the manner agreed by the Minister and Héma-Québec.”

12. Section 45 of the Act is amended

(1) by replacing “haemovigilance” wherever it appears by “biovigilance”;

(2) by replacing “bone marrow or any other human tissue” in the third paragraph by “human milk, stem cells, human tissues or organs and any other human biological product”.

13. Section 46 of the Act is amended

(1) by replacing “haemovigilance” in the introductory clause of the first paragraph by “biovigilance”;

(2) by replacing “two persons” in subparagraph 2 of the first paragraph by “one person”;

(3) by replacing “four” in subparagraph 5 of the first paragraph by “three”;

(4) by adding the following subparagraph after subparagraph 6 of the first paragraph:

“(7) one expert in the field of perinatal care.”;

(5) by replacing the last paragraph by the following paragraph:

“The Minister may also appoint up to three other members to the committee if the Minister considers that their expertise would advance the work of the committee.”

14. Section 54.1 of the Act is amended

(1) by replacing the definition of “Héma-Québec product” by the following definition:

““Héma-Québec product” means any product distributed by Héma-Québec, except

(1) when such a product is used for research or clinical trials, unless the Minister decides otherwise; or

(2) when such a product is made from a human biological product determined by the Government and the Government has decided to exclude it from the compensation plan for victims;”;

(2) by striking out “through a transfusion or graft” in the definition of “victim”.

15. The Act is amended by inserting the following section before section 55:

“54.13. Despite article 45 of the Civil Code, if cardiac and breathing functions have ceased simultaneously and irreversibly and are not maintained artificially, in compliance with the conditions determined by government regulation, tissues may be removed by Héma-Québec after the death of the donor is attested by a physician who does not participate either in the removal or in the transplantation.”

16. The Act is amended by replacing “haemovigilance committee” by “biovigilance committee” in the title of the Act, in the heading of Chapter II and in sections 37 and 44 and by replacing “Comité d’hémovigilance” in section 44 by “Comité de biovigilance”.

17. The Act is amended by replacing “director general” wherever it appears in sections 14 to 17 by “president and chief executive officer”.

18. Sections 57 to 74 of the Act are repealed.

REGULATION RESPECTING THE CONDITIONS FOR
COMPENSATION TO VICTIMS OF A HÉMA-QUÉBEC PRODUCT

19. The Regulation respecting the conditions for compensation to victims of a Héma-Québec product (chapter H-1.1, r. 1) is amended by inserting the following section after section 1:

“**1.1.** For the purposes of section 54.1 of the Act, the following reactions, associated with the normal constituents of human milk, in relation to the standards in force when a Héma-Québec product is administered, are adverse effects not constituting a bodily injury:

- lactose intolerance;
- necrotizing enterocolitis; and
- allergic reaction.”

TRANSITIONAL AND FINAL PROVISIONS

20. The members of the governing board of Héma-Québec in office on 4 June 2013 continue in office on the same terms, for the unexpired portion of their term, until they are replaced or reappointed.

The director general of Héma-Québec continues in office as president and chief executive officer on the same terms, for the unexpired portion of the term.

21. The members of the haemovigilance committee in office on 4 June 2013 continue in office as members of the biovigilance committee on the same terms, for the unexpired portion of their term, until they are replaced or reappointed.

22. This Act comes into force on 5 June 2013, except

(1) section 8, which comes into force on the date to be set by the Government; and

(2) section 15, which comes into force on the date of coming into force of the first regulation made under this Act.

