

House of Representatives

Supplementary Order Paper

Thursday, 13 December 2001

Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Bill



Proposed amendments

Hon Marian Hobbs, in Committee, to move the following amendments:

Clause 1

To omit this clause from page 1, and substitute the following clause:

1 Title

This Act is the Genetically Modified Organisms and Restricted Biotechnical Procedures Act **2001**.

Clause 3

To add, as *subclause (2)*, after line 7 on page 2, the following subclause:

- (2) **Part 3** expires on the expiry of **Part 7A** of the Medicines Act 1981.

Clause 4

To add to *paragraph (d)* (in line 24 on page 2) the word “; and”, and to add, after line 24 on page 2, the following paragraph:

- (e) to provide for temporary measures, pending the development of a comprehensive legislative regime, to control the use of germ cell-line procedures and xenotransplantation procedures in respect of human beings to ensure that—
- (i) a procedure of that kind does not pose an unacceptable risk to the health or safety of the public and that any risks are appropriately managed; and
 - (ii) any ethical, cultural, or spiritual issues raised by a procedure of that kind are adequately addressed.

Heading to Part 2

To omit this heading from lines 26 and 27 on page 2, and substitute the following heading:

**Part
Amendments to Hazardous Substances and New
Organisms Act 1996**

To insert, before *clause 5* (before line 28 on page 2), the following clause:

- 4A Hazardous Substances and New Organisms Act 1996
called principal Act in this Part**
In this Part, the Hazardous Substances and New Organisms
Act 1996 is called “the principal Act”.

To add, after line 33 on page 7, the following Part:

**Part 3
Amendments to Medicines Act 1981**

- 10 Medicines Act 1981 called principal Act in this Part**
In this Part, the Medicines Act 1981 is called “the principal
Act”.
- 11 Part 7A inserted**
The principal Act is amended by inserting, after section 96,
the following Part:

**“Part 7A
“Restrictions on specified biotechnical procedures**

“96A Interpretation

In this Part, unless the context otherwise requires,—

“biological material means—

- “(a)** the whole or part of any organ, bone, tissue, or cell; or
“(b) blood or body fluids

“germ cell-line procedure means the artificial insertion or
injection of a modified gamete or a modified embryo into a
human being

“modified embryo means a zygote or an embryo that, as a
result of artificial processes, has a modified genetic structure

“modified gamete means an ovum or a sperm that, as a result
of artificial processes, has a modified genetic structure

“specified biotechnical procedure means—

- “(a)** any germ cell-line procedure; or
“(b) any xenotransplantation

“xenotransplantation—

- “(a)** means a medical procedure that involves the insertion
or injection into a human being of any matter that con-
sists of, or includes, living biological material of an

- animal, whether or not that biological material also includes biological material of a human being; and
- “(b) includes the transfusion into a human being of any human blood or any human body fluid if the blood or the fluid has, as part of a biotechnical procedure, been in contact with living biological material of an animal.

“96B Restrictions on specified biotechnical procedures

- “(1) No person may conduct a specified biotechnical procedure otherwise than in accordance with an authorisation under **section 96C or section 96D**.
- “(2) **Subsection (1)** applies to a person who continues, after the commencement of this section, to conduct a specified biotechnical procedure that was begun before that commencement.
- “(3) Every person commits an offence and is liable on summary conviction to imprisonment for a term not exceeding 6 months or to a fine not exceeding \$200,000 who contravenes **subsection (1)**.

“96C Authorisation of particular procedures

- “(1) The Minister may, by notice in writing, authorise a particular specified biotechnical procedure.
- “(2) The Minister may issue a notice under **subsection (1)** only if satisfied that the proposed authorisation is justified in view of the matters specified in **section 96E**.
- “(3) An authorisation granted by a notice under **subsection (1)** may be granted unconditionally or subject to any conditions that are specified in the notice.
- “(4) As soon as practicable after giving a notice under **subsection (1)**, the Minister must publish the notice in the *Gazette* and present a copy of the notice to the House of Representatives.
- “(5) The Minister may, at any time, by written notice, vary or revoke an authorisation given under **subsection (1)**; and the provisions of **subsection (4)** apply to any such notice.

“96D Authorisation of class of procedure

- “(1) The Governor-General may, by Order in Council made on the recommendation of the Minister, authorise 1 or more classes of specified biotechnical procedure.
- “(2) The Minister may make a recommendation under **subsection (1)** only if satisfied that the proposed authorisation is justified in view of the matters specified in **section 96E**.
- “(3) An authorisation granted by an Order in Council under this section may be granted unconditionally or subject to any conditions specified in the order.

“96E Criteria for authorisations

- “(1) Before the Minister grants any authorisation under **section 96C** for a particular specified biotechnical procedure, or recommends that an authorisation be granted under **section 96D** for a class of specified biotechnical procedure, the Minister must be satisfied that—
- “(a) the procedure or class of procedure proposed to be authorised does not pose an unacceptable risk to the health or safety of the public and that any risks will be appropriately managed; and
 - “(b) any ethical, cultural, or spiritual issues raised by the procedure or the class of procedure or by any technology involved have been adequately addressed.
- “(2) For the purposes of **subsection (1)**, the Minister may seek advice from 1 or more persons who, in the Minister’s opinion, are appropriately qualified, or have the appropriate expertise, to provide that advice.

“96F Applications

- “(1) A person may, by application to the Minister, request the Minister to grant an authorisation under **section 96C** or to recommend an authorisation under **section 96D(1)**.
- “(2) An application under **subsection (1)** must be in a form approved by the Director-General and must be accompanied by the prescribed fee.
- “(3) The Minister may—
- “(a) request a person who applies under **subsection (1)** to obtain the advice of 1 or more nominated persons who, in the Minister’s opinion, are appropriately qualified or have the appropriate expertise to provide relevant advice; and
 - “(b) defer consideration of the application until the person has obtained that advice.

“96G No compensation

No compensation is payable by the Crown to any person for any loss or damage arising from the restriction set out in **section 96B**.

“96H Enforcement powers

Sections 63(1), 63(2)(a) to (d), (h), (k), and (3), 66, 68, 74(1), and 85 apply to any investigation or, as the case requires, any prosecution, of an offence against **section 96B** as if—

- “(a) the term **medical device** included any substance or thing used as part of, or in connection with, a specified biotechnical procedure:

- “(b) there were inserted in section 63(2)(a), after the word ‘manufactured’, the word ‘used,’:
 - “(c) there were inserted in section 63(2)(b), after the word ‘manufacture’, the word ‘use,’:
 - “(d) there were inserted in section 66(1)(a), after the word ‘sale’, the words ‘or for use in a specified biotechnical procedure (within the meaning of **Part 7A**)’:
 - “(e) there were inserted in section 66(1), after the words ‘dealing with the importation’, the word ‘use,’.
- “(2) To avoid any doubt, **subsection (1)** does not limit the application of any of sections 75, 76, 79, and 84 to any matter concerning, or arising out of, the commission, investigation, or prosecution of an offence against **section 96B**.

“96I **Expiry of Part**

- “(1) This Part expires on the close of **30 June 2003**.
- “(2) The Governor-General may, by Order in Council, before the date specified in **subsection (1)**, on the recommendation of the Minister, specify a later date in substitution for that date, but that substituted date may not be later than **30 June 2005**.
- “(3) An Order in Council under this section is a regulation for the purposes of the Regulations (Disallowance) Act 1989.”

Explanatory note

This Supplementary Order Paper extends the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Bill by imposing restrictions on certain biotechnical procedures. Two procedures are involved, and are referred to as “specified biotechnical procedures”. They are, first, clinical xenotransplantation (transplanting animal cells, tissues, or organisms to humans or mixing body materials between animals and humans). Second, modifications to human germ cell-lines that attempt to modify the genome of an embryo. These procedures may pose threats to individuals and to the public, and may raise ethical, cultural, and spiritual concerns.

The Supplementary Order Paper provides for interim controls of those biotechnical procedures. It inserts a *new Part 7A* into the Medicines Act 1981. The new Part expires on 30 June 2003. Provision is, however, made for the duration of the Part to be extended, by Order in Council, until a later date that may not be later than 30 June 2005 (see *new section 96I*).

New section 96B prohibits persons from conducting specified biotechnical procedures otherwise than in accordance with an authorisation granted under the legislation. The prohibition covers the continuation of procedures that were started before the commencement of *new Part 7A*. The maximum penalty for the offence is a fine of \$200,000 or 6 months imprisonment.

A particular specified biotechnical procedure, or a class of specified biotechnical procedure, may be authorised if the Minister of Health is satisfied that the procedure does not pose unacceptable risks to the health or safety of the public and that any risks will be appropriately managed. Furthermore, the Minister must be satisfied that any ethical, cultural, or spiritual issues raised by the procedure have been adequately addressed. Authorisations for particular procedures are granted by the Minister. Authorisations for a class of procedure are granted by Order in Council.

New section 96F makes provision for applications for authorisations. An application must be accompanied by a fee prescribed by regulations. The Minister may, as a condition for considering an application, require an applicant to seek the advice of 1 or more specified persons.

New section 96G provides that no compensation is payable by the Crown for any loss arising out of the restrictions placed on specified biotechnical procedures.

New section 96H ensures that relevant enforcement provisions in the Medicines Act 1981 are available for investigations and prosecutions of offences under *new section 96B*.
