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

Government Bill

As reported from the committee of the whole House

This bill was formerly part of the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Bill as reported from the Finance and Expenditure Committee. On the recommendation of the Committee, the bill was retitled the Genetically Modified Organisms and Restricted Biotechnical Procedures Bill. The committee of the whole House has further amended the bill and has divided it into the following bills:

- This bill, comprising clause 1 and Parts 1 and 2
- The Medicines (Restricted Biotechnical Procedures) Amendment Bill, comprising Part 3

Key to symbols used in reprinted bill

As reported from a select committee

Struck out (majority)

Subject to this Act, — Text struck out by a majority

New (majority)

Subject to this Act, — Text inserted by a majority

〈*Subject to this Act,*〉 — Words struck out by a majority

〈Subject to this Act,〉 — Words inserted by a majority

As reported from the committee of the whole House

Struck out

Subject to this Act, — Text struck out

New

Subject to this Act, — Text inserted

Hon Marian Hobbs

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

Government Bill

Contents

The Parliament of New Zealand enacts as follows:

1 Title

(1) This Act is the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act **2002**.

(2) In this Act, the Hazardous Substances and New Organisms Act 1996[1] is called "the principal Act".

[1] 1996 No 30

Part 1
Preliminary provisions

2 Commencement

This Act comes into force on the day after the date on which it receives the Royal assent.

3 Expiry

Sections 5 and 8 expire on the close of 29 October 2003.

Struck out

New (majority)

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

4 Purpose

The purpose of this Act is—

(a) to require the Environmental Risk Management Authority (the **Authority**) to consider additional matters when considering 〈certain〉 applications in relation to 〈*certain*〉 genetically modified organisms and, if it approves the applications, to include 〈particular〉 controls for 〈*secure containment and other matters*〉 〈field tests and certain developments〉; and

(b) to impose a restriction, from 29 October 2001 to the close of 29 October 2003, on the Authority considering or approving applications to import new organisms for release or to release new organisms from containment if the new organisms are genetically modified organisms; and

(c) to provide exceptions to the restriction; and

(d) to provide transitional provisions for approved applications relating to certain genetically modified organisms; and

Struck out

New (majority)

(e) to provide for temporary measures, pending the development of a comprehensive legislative regime, to control the use of germ-cell genetic 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.

Part 2
⟨*Release and field testing of genetically modified organisms*⟩ ⟨Amendments to Hazardous Substances and New Organisms Act 1996⟩

New

Part 2
Amendments to Principal Act

New (majority)

Struck out

5AA Hazardous Substances and New Organisms Act 1996 called principal Act in this Part

In this Part, the Hazardous Substances and New Organisms Act 1996[2] is called "the principal Act".

[2] 1996 No 30

New (majority)

5AB Interpretation

Section 2(1) of the principal Act is amended by inserting, in their appropriate alphabetical order, the following definitions:

"**containment structure** means a containment facility that is a vehicle, room, building, or other structure, set aside and equipped for the development of genetically modified organisms

"**genetic element**, in relation to a new organism, means—

"(a) heritable material; and

"(b) any genes, nucleic acids, or other molecules from the organism that can, without human intervention, replicate in a biological system and transfer a character or trait to another organism or to subsequent generations of the organism

"**heritable material**, in relation to a new organism, means viable biological material, including gametes and spores, arising from the organism that can, without human intervention, regenerate the organism or reproduce a new generation of the same species of the organism".

5 New section 25AA inserted

The principal Act is amended by inserting, before section 25, the following section:

"25AA **This Part subject to Part 5A**

This Part applies subject to **Part 5A**."

6 New section 44A inserted

(1) The principal Act is amended by inserting, after section 44, the following section:

Struck out (majority)

"44A **Additional matters to be considered for certain field tests**

"(1) This section applies to an application to field test a new organism in containment if the new organism is—

"(a) a genetically modified plant; or

"(b) a genetically modified animal.

"(2) In deciding whether to approve or decline an application, the Authority must take into account—

"(a) the safety and any ecological effects of the field test; and

"(b) any alternative method of achieving the research objectives that is as effective as, or more effective than, the field test.

"(3) The matters referred to in **subsection (2)** are in addition to the matters referred to in section 45."

New (majority)

"44A **Additional matters to be considered for certain developments and field tests**

"(1) This section applies to an application—

"(a) to develop a new organism in containment that is a genetically modified organism, to the extent that the development does not take place in a containment structure:

"(b) to field test a new organism in containment if the new organism is a genetically modified organism.

"(2) In deciding whether to approve or decline an application, the Authority must take into account—

"(a) any adverse effects of developing or field testing the organism on—

"(i) human health and safety; and

"(ii) the environment, in particular ecosystems and their constituent parts; and

"(b) any alternative method of achieving the research objective that has fewer adverse effects on the matters

New (majority)

referred to in **paragraph (a)** than the development or field test; and

"(c) any effects resulting from the transfer of any genetic elements to other organisms in or around the site of the development or field test.

"(3) The matters referred to in **subsection (2)** are in addition to the matters referred to in sections 44 and 45.

"(4) In this section, **field test** does not include large-scale fermentation of micro-organisms inside a containment structure."

(2) This section does not apply in relation to applications for approvals to develop new organisms in containment made before 1 April 2002.

7 New section 45A inserted

(1) The principal Act is amended by inserting, after section 45, the following section:

Struck out (majority)

"45A **Containment and other controls required for certain field tests**

"(1) An approval under section 45 to field test a new organism that is a genetically modified plant must include controls to ensure that,—

"(a) if any reproductive structure on or above the ground contains pollen, seeds, or other heritable material, the material is securely contained, or removed and destroyed, before the material is capable of being released:

"(b) when the field test is complete, any tubers, bulbs, rhizomes, or other heritable material from the organism beneath the ground is—

"(i) removed and either securely contained or destroyed; or

"(ii) destroyed without being removed:

Struck out (majority)

"(c) any reproductive structure or heritable material from the organism required for research purposes is securely contained:

"(d) any reproductive structure or heritable material from the organism that is transported is transported in secure containment:

"(e) all material associated with the test is capable of being—

"(i) removed; or

"(ii) destroyed without being removed.

"(2) An approval under section 45 to field test a new organism that is a genetically modified animal must include controls to ensure that the animals and their offspring—

"(a) are securely contained; and

"(b) can be identified.

New (majority)

"45A **Controls required for certain developments and for all field tests**

"(1) This section applies to an approval under section 45—

"(a) to develop a new organism in containment that is a genetically modified organism, to the extent that the development does not take place in a containment structure; or

"(b) to field test a new organism in containment if the new organism is a genetically modified organism.

"(2) An approval—

"(a) must include controls to ensure that, after the end of the development or field test, the organism and any heritable material from the organism is removed or destroyed; and

"(b) may include controls to ensure that, after the end of the development or field test and after heritable material is removed or destroyed, some or all of the genetic elements remaining from the organism are removed or destroyed.

New (majority)

"(3) In **subsection (2)**, **destroyed** includes leaving genetic elements to break down or become inactive at the site of the development or field test."

(2) This section does not apply in relation to applications for approvals to develop new organisms in containment made before 1 April 2002.

8 New Part 5A inserted

The principal Act is amended by inserting, after Part V, the following Part:

"Part 5A
"Restrictions on approving certain applications

"73A **Interpretation**

In this Part, unless the context otherwise requires,—

"**medicine** and **new medicine** have the same meaning as in section 3 of the Medicines Act 1981

"**restricted period** means the period beginning on 29 October 2001 and ending on the close of 29 October 2003

"**veterinary medicine** has the same meaning as in section 2(1) of the Agricultural Compounds and Veterinary Medicines Act 1997.

"73B **Application**

This Part applies to new organisms that are genetically modified organisms.

"73C **Authority must not consider or approve certain applications during restricted period**

"(1) If an application that **subsection (2)** applies to is made to the Authority during the restricted period (whether before or after the commencement of the **Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2001**), the Authority—

"(a) must not consider the application; and

"(b) must not approve the application; and

"(c) must return the application, and any fee accompanying it, to the applicant as soon as practicable.

"(2) This subsection applies to the following applications:

"(a) an application to import a new organism for release:

"(b) an application to release a new organism from containment.

"(3) However, **subsection (2)** does not apply to the following applications:

"(a) an application to import a new organism for release or to release a new organism from containment if the organism is—

"(i) a medicine or new medicine—

"(A) to which the Minister of Health has given his or her consent or provisional consent under section 20 or section 23 of the Medicines Act 1981; or

"(B) that is the subject of a clinical trial approved by the Director-General of Health under section 30 of that Act; or

"(ii) the subject of an application to register ⟨*the organism*⟩ ⟨a trade name product⟩ under section 9 or section 26 of the Agricultural Compounds and Veterinary Medicines Act 1997 and the organism will be a veterinary medicine used for therapeutic or prophylactic purposes:

"(b) an application under section 47 of this Act.

"73D **Additional information required for certain applications**

"(1) This section applies to an application—

"(a) referred to in **section 73C(3)(a)**; and

"(b) made during the restricted period.

"(2) An application must include information demonstrating that the new organism, and any inseparable organism, that the application relates to cannot persist viably in the physical environment beyond the human being or animal that is subject to treatment.

"(3) The information referred to in **subsection (2)** is in addition to other information required by or under this Act.

New (majority)

"(4) For the purposes of **subsection (2)**, an organism cannot persist viably unless the organism can, without human intervention and other than on a temporary basis, regenerate or reproduce further generations of the same species of the organism.

"73E **Additional matters Authority must consider for certain applications**

"(1) This section applies to an application—

"(a) referred to in **section 73C(3)(a)**; and

"(b) made during the restricted period.

Struck out (majority)

"(2) In considering whether to approve or decline an application, the Authority must take into account—

"(a) the safety and ecological effects of the new organism; and

"(b) the efficacy of the new organism as a medicine, new medicine, or veterinary medicine compared to medicines, new medicines, or veterinary medicines that are used to treat the same condition.

New (majority)

"(2) In considering whether to approve or decline an application, the Authority must take into account—

"(a) any adverse effects of the new organism on—

"(i) human health and safety; and

"(ii) the environment, in particular ecosystems and their constituent parts; and

"(b) the information provided under **section 73D(2)**; and

"(c) the efficacy of the new organism as a medicine, new medicine, or veterinary medicine compared to a medicine, new medicine, or veterinary medicine that does not contain a genetically modified organism.

"(3) The matters referred to in **subsection (2)** are in addition to the matters that the Authority is required to take into account by or under this Act.

New (majority)

"(4) In **subsection (2)**, **efficacy** means the ability of a medicine, new medicine, or veterinary medicine to produce the intended therapeutic effect, but does not include the potency of the medicine.

"73F **No compensation**

No compensation is payable by the Crown to any person for any loss or damage arising from the restriction imposed by **section 73C**.

"73G **Expiry**

This Part expires on the close of 29 October 2003."

9 Transitional provision

(1) This section applies to an approval issued by the Authority if—

(a) the approval was issued in the period beginning on 29 October 2001 and ending on the close of the day before the date on which this Act receives the Royal assent; and

(b) had this Act been in force when the approval was issued, **sections 44A and 45A** of the principal Act would have applied to the approval.

(2) The Authority must review the approval within 5 working days after the commencement of this Act.

(3) The Authority must cancel the approval if, after reviewing the approval, it decides that, had **section 44A** of the principal Act been in force when it considered whether to approve or decline the application, it would have declined the application.

(4) If the Authority cancels an approval under **subsection (3)**, the owner of the organism must, within the time specified by the Authority,—

(a) stop the field test of the organism; and

(b) dispose of the organism in accordance with the controls as to disposal in the approval.

(5) The Authority must include additional controls, or substitute controls, or both, if, after reviewing the approval, it decides that,—

(a) had **section 45A** of the principal Act been in force when it approved the application, it would have included in the approval controls relating to the matters referred to in that section:

(b) had **section 44A** of the principal Act been in force when it approved the application, it would have included in the approval different controls.

(6) Controls added or substituted under **subsection (5)** apply immediately.

(7) No compensation is payable by the Crown to any person for any loss or damage arising from the enactment or operation of this section.

New (majority)

9A Third Schedule amended

(1) Part I of the Third Schedule of the principal Act is amended by omitting from clause 6 the words "or field testing".

(2) Part I of the Third Schedule of the principal Act is amended by inserting, after clause 6, the following clauses:

"6A Controls imposed on an approval to field test a genetically modified organism—

"(a) must specify—

"(i) inspection and monitoring of containment facilities during the field test; and

"(ii) inspection and monitoring of the site, after the field test, to ensure that all heritable material is removed or destroyed; and

"(b) may specify inspection of the site before field testing commences.

New (majority)

"6B **Clause 6A** applies, with all necessary modifications, to controls imposed on an approval to develop a new organism that is a genetically modified organism, to the extent that the development does not take place in a containment structure."

. . . . .

Legislative history

21 May 2002 Divided from Genetically Modified Organisms and Restricted Biotechnical Procedures Bill (Bill 175–2) as Bill 175–3A

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