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

Member's Bill

Explanatory note

This bill reinstates the provisions of sections 6 and 9 of the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002. Those provisions expired on 29 October 2003.

The Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002 inserted a new Part 5A into the Hazardous Substances and New Organisms Act 1996. Part 5A placed a restriction on the consideration of applications to import new organisms for release or to release new organisms from containment if those organisms were genetically modified organisms.

The bill also provides for the reconsideration of applications received between the expiry of the Part 5A inserted by the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002, and its reinstatement on the commencement of this bill.

Clause 1 relates to the Title of the bill.

Clause 2 provides for the bill to come into force on the day after the date on which it receives the Royal assent.

Clause 3 provides for the bill's provisions to expire on 31 October 2008.

Clause 4 sets out the purpose of the bill.

Clause 5 reinstates section 25AA, making the provisions of Part 5 of the Hazardous Substances and New Organisms Act 1996 relating to the assessment of hazardous substances and new organisms subject to new Part 5A.

Clause 6 reinstates Part 5A, placing a restriction on the consideration of applications to import new organisms for release or to release new organisms from containment if those organisms were genetically modified organisms, and providing for exceptions to the restriction.

Clause 7 contains a transitional provision, requiring reconsideration of applications received between the expiry of Part 5A and its reinstatement on the commencement of this bill.

Ian Ewen-Street

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Contents

The Parliament of New Zealand enacts as follows:

1 Title

(1) This Act is the Hazardous Substances and New Organisms (Genetically Modified Organisms Moratorium Reinstatement) Amendment Act **2004**.

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

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

This Act expires on the close of 31 October 2008.

4 Purpose

The purpose of this Act is—

(a) to reinstate, to the close of 31 October 2008, the restriction that expired on 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

(b) to provide exceptions to the restriction; and

(c) to provide transitional provisions for approved applications relating to certain genetically modified organisms received between the expiry of the restriction and the commencement of this Act.

Part 2
Amendments to principal Act

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 Part 5A inserted

The principal Act is amended by inserting, after Part 5, 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 2003 and ending on the close of 31 October 2008

"**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 Moratorium Reinstatement) Amendment Act 2004**), 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 a 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 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.

"(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.

"(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.

"(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 31 October 2008."

7 Transitional provision

(1) This section applies to an approval issued by the Authority if the approval was issued in the period beginning on 29 October 2003 and ending on the close of the day before the date on which this Act receives the Royal assent.

(2) The Authority must, having regard to sections 44A and 45A of the principal Act, review the approval within 5 working days after the commencement of this Act.

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

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