# New Organisms and Other Matters Bill

Government Bill

As reported from the Education and Science Committee

## Commentary

### Recommendation

The Education and Science Committee has examined the New Organisms and Other Matters Bill and recommends that it be passed with the amendments shown.

### Introduction

The New Organisms and Other Matters Bill is a Government bill that will amend the Hazardous Substances and New Organisms Act 1996 (the principal Act), the Medicines Act 1981, the Biosecurity Act 1993, and the Agricultural Compounds and Veterinary Medicines Act 1997.

The objective of the bill is to protect the environment and the health and safety of people and communities by preventing or managing the adverse effects of new organisms while:

- providing a precautionary approach to the use of genetic modification and new organisms, and preserving opportunities; and
- ensuring the Act is effective and efficient, and appropriately reflects the Treaty of Waitangi relationship.

The amendments made by this bill form part of the Government's response to the Report of the Royal Commission on Genetic Modification.

## New organisims

### Definition

We recommend that clause 6(2) be amended to clarify which parts of proposed section 2A(2) refer to genetically modified organisms and which to non-genetically modified organisms. Section 2A(2A) should also be amended to specify that organisms approved for conditional release, or qualifying organisms approved for release with controls, remain new organisms.

### Conditional release and qualifying organisms approved for release with controls

Section 28 of the Biosecurity Act 1993 prohibits the granting of biosecurity clearance for the release of any new organism. We recommend the inclusion of new clauses 61 and 62 to amend the Biosecurity Act so that biosecurity clearance can be granted to new organisms approved for conditional release, or qualifying organisms approved for release with controls, under the principal Act.

We recommend the inclusion of new section 38GA in clause 18 to require subsequent users of conditional release approvals to notify the Environmental Risk Management Authority so that enforcement officers are able to check compliance with, and enforce the conditions of, a conditional release approval.

### In containment

If an application for conditional release is declined, the organism should be able to be considered for use in containment. We recommend the inclusion in clause 19(2) of a reference to section 38C so that, if an organism does not meet the requirements for conditional release, the Authority may consider granting a containment approval for the organism.

In clause 5 of the bill fermentation is classified as a development process. In the principal Act large-scale fermentation is classified as a field test. We recommend the insertion of new clause 19A to remove the references to large-scale fermentation in section 40(2)(b) of the principal Act.

## Regenerative tissue

We consider that the inclusion of a definition of 'regenerative tissue' is unnecessary and will restrict traditional plant breeding technologies. We therefore recommend deleting the definition of 'regenerative tissue' from clause 5(1), amending the reference to this term in clauses 5(3) and 11(2), and deleting clause 5(7).

## Human cells

The genetic modification of human cells outside a human being is currently unregulated. We recommend transitional provisions be inserted in new clause 50A to deal with current work involving the genetic modification of human cells presently in registered containment facilities.

To enable the authority to delegate the power to impose controls upon activities covered by this transitional provision we recommend the insertion of new section 19(2)(bd) in clause 9(2).

## Qualifying organisms

Several amendments are required to ensure that the provisions of the principal Act which apply to conditionally released new organisms also apply to qualifying organisms approved for release with controls.

We recommend new section 38K in clause 18 be inserted, clauses 6, 12(1), 19(2), 34(1), 35(1), 49(2), and 56 be amended, and new clause 62 be inserted to cover qualifying organisms.

We recommend proposed section 63(3) in clause 35(2) be amended to make it clear that the exemption from compliance with the public notification requirement in section 53 of the principal Act applies only to qualifying organisms released with controls.

## Medicines Act

The amendments to the Medicines Act are confusing and do not fully clarify the requirements of sponsors of medicines with regard to both the principal Act and the Medicines Act.

We recommend the deletion of clauses 57 to 60 and the insertion of new clause 55A to clarify which approvals sponsors are required to seek before a medicine that is, or contains, a new organism can be released into the New Zealand market.

We recommend the inclusion of a reference to section 23 of the Medicines Act in section 24B(b) in clause 56 to cover provisional consent. We also recommend sections 24B and 24D be amended to include the words 'sell' and 'advertise' to bring the wording of these sections into line with the rest of the Medicines Act.

## Agricultural compounds and medicines in special emergencies

The controls attaching to the approval of an application to use agricultural compounds or medicines in a special emergency, and the consequences of expiry of an approval, should also include hazardous substances.

We recommend an amendment to proposed section 49D in clause 26 to include a reference to manufacturing, and to proposed section 49K to include approvals that relate to hazardous substances.

## Taxonomic classification

The comments in some submissions indicate that there is confusion about the term 'lower level taxon'. Submitters also suggest that it would be useful for the Authority to be able to exclude organism subgroups from an approval.

We recommend the term 'lower level taxon' be deleted from new section 27A(2) in clause 13. The wording of proposed section 27A(1) and (3) should be clarified to ensure that it is clear which organism and genetic modification the approval applies to, and a new subsection (4) should be included.

## Register of genetically modified organisms

The current requirement in the principal Act that the Authority maintain a register of low-risk genetically modified organisms does not adequately address the recording of project-based approvals. We recommend a new clause 9A be inserted to make provision for the register to record project approvals.

## Ngā Kaihautū Tikanga Taiao

Clause 10 establishes Ngā Kaihautū Tikanga Taiao as a statutory body. Several submissions suggest that the relationship between Ngā Kaihautū Tikanga Taiao and the Authority should be clarified.

We recommend proposed section 24B(1) be amended to ensure that Ngā Kaihautū Tikanga Taiao is able to provide advice and assistance to the Authority on applications made under the principal Act.

We expect a high level of consultation between the Authority and Ngā Kaihautū Tikanga Taiao. We also expect that when making an appointment to Ngā Kaihautū Tikanga Taiao the Authority will consult in accordance with administrative best practice.

## Role of local government

A number of submissions, including that from Local Government New Zealand, wanted the circumstances and interests of local communities to be incorporated into the Authority's decision-making process. We agree that any local authority with a potential interest in an application should have the maximum time available in which to consider the application and make a submission on the basis of the likely impact on the local authority's area.

We recommend the insertion of new clause 29(5) to extend the current discretionary provision from regional councils to all local authorities.

Several submissions expressed concern about the lack of clarity regarding the role of local government in the bill. Some of us believe that this situation is unclear and that the interrelationship between the principal Act, the Resource Management Act 1991, and the Local Government Act 2002 is still unsatisfactory.

Government members believe that this regime is clear. Local government does not have powers under the Resource Management Act 1991 or the Local Government Act 2002 to regulate genetically modified organisms. Such regulation is the role of the Authority under the principal Act. The Authority is a specialist body and responsibility should lie with it and not with local government.

## Compensation for loss resulting from enforcement action

The Biosecurity Act requires that compensation be paid for certain losses that arise as a result of using Biosecurity Act powers under that Act. However, neither the principal Act nor the amendments in the bill have equivalent compensation provisions.

We recommend new section 97A(3A) be inserted in clause 41 to incorporate access to these provisions of the Biosecurity Act for enforcement of the principal Act.

## Enforcement of the Act

We recommend an amendment to new section 97A(2) in clause 41 to clarify that enforcement officers appointed under the principal Act may exercise the powers of inspectors under the Biosecurity Act.

## Defences

We recommend proposed section 124B(3) in clause 48 be amended to clarify that in proceedings seeking pecuniary penalty for breaches of the principal Act the burden of proof lies with the defendant.

## Restricted period

A large number of submissions sought an extension of the restricted period for applications for the release of genetically modified organisms and the proposed conditional release of genetically modified organisms. The inclusion of any recommendations in this regard would be outside the scope of this bill (Standing Order 283(2)).

## National and ACT minority view

National and ACT have consistently supported the major recommendation of the Royal Commission on Genetic Modification which was: 'our major conclusion is that New Zealand should keep its options open, . . . but we should proceed carefully minimizing and managing risks, at the same time continuation of the development of conventional farming, organic and integrated pest management should be facilitated.'

National and ACT view an evidenced-based scientific approach to the bill as being fundamental, and we agree entirely with the Royal Commission that 'continuation of research is critical to New Zealand's future'.

National and ACT are also mindful of the New Zealand Biotechnology Taskforce Report and Strategy Report that stated 'transparency, predictability and best regulatory practices are essential'.

National and ACT support a rigorous approach to risk analysis, but are concerned that the bill may impose heavy financial burdens, time delays and compliance costs on applicants. This has the effect of

hindering rather than facilitating safe progress. It also acts against the Government's 'innovation and growth policy', which focuses on biotechnology as one of three key areas for New Zealand to promote.

National and ACT acknowledge that certain low risk applications will be streamlined under the bill but note that this should have happened much earlier and could have been included in the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002.

There are key areas in section 38 and section 42 where the bill has added unnecessary complexity and unpredictability.

National and ACT are also concerned that the Minister's powers to 'call in' applications have widened to include cultural, ethical and spiritual effects. The effect of these proposed changes will be to create further uncertainty for scientists and those that make commitments to biotechnology, with a resultant loss of confidence in the New Zealand regulatory environment for leading-edge research and development.

### Liabilities/penalties

National and ACT express concern about the level of fines proposed in this legislation and the nature of the liability proposed.

National and ACT note the advice from officials that there is nothing sufficiently different about genetic engineering (GE) from a liability perspective to justify a liability regime which is different in principle to those applied in other scenarios.

National and ACT are of the view that many and varied causes of action currently exist in common law and that the step of reversing the burden of proof, such as in new section 124B(3) with respect to liability, is a step that should be taken with great caution.

## New Zealand First minority view

New Zealand First holds serious concerns over the processing of commercial release, either conditional or full, of genetically modified organisms which will form part of the human food chain.

Given New Zealand's dependence on exports of food products, it is critical that the Authority has in place a robust methodology for economic assessment of both costs and benefits of any such application.

We do not believe evidence has been produced to demonstrate that the Authority has such capacity.

New Zealand First also expresses its concern at the extension of the Minister's call-in powers to spiritual grounds.

## Green Party minority view

The Green (non-voting) member of the committee does not support the bill because it will facilitate the release of genetically modified organisms into the environment. She agrees with the majority of the submissions that were opposed to this, and is persuaded by evidence given by a number of scientifically qualified submitters that genetically modified organisms can be unstable and unpredictable, and that no genetically modified foods have ever been tested on humans, or long-term on animals.

The Greens support sensible removal of red tape for contained laboratory work, and stricter penalties for breach of the principal Act, regulations and consent conditions. However, we are disappointed that there are no liability provisions in the case where a genetically modified organism causes harm when the law has not been breached.

The new category of conditional release will allow into the environment organisms which cannot meet the minimum standards of section 36, subject to conditions which may sometimes fail.

The Greens are concerned that a number of important recommendations of the Royal Commission have not yet been implemented: in their view there are no effective strategies in place to protect bees and bee products from contamination; to ensure co-existence of GE and GE free food production; or to prevent resistance to Bt developing in insects. Further, the economic analysis done so far is equivocal and the committee has received no evidence that the Authority has the expertise or the agreed methodology to assess the economic risks to New Zealand of losing markets in countries which are highly resistant to GE food.

District and regional councils, and Local Government New Zealand asked for clarity in the law with regard to their role, and for a voice in the decisions on GE that affect their communities. The Greens believe the bill should have addressed their request.

# Appendix

## Committee process

The New Organisms and Other Matters Bill was referred to the committee on 6 May 2003. The closing date for submissions was 13 June 2003. We received and considered 137 submissions from interested parties. We heard 74 submissions, and the hearing of evidence on the bill took 20 hours and 45 minutes.

We spent 12 hours and 40 minutes considering the bill.

We received advice from the Ministry for the Environment, the Ministry of Justice, the Ministry of Agriculture and Forestry, the Ministry of Health, the Ministry of Research, Science and Technology, the New Zealand Food Safety Authority, the Ministry of Economic Development, the Treasury, Te Puni Kokiri, and the Department of Conservation.

## Committee membership

Hon Brian Donnelly (Chairperson)

Jill Pettis (Deputy Chairperson)

Donna Awatere Huata

Dr Ashraf Choudhary

Helen Duncan

Dr Paul Hutchison

Bernie Ogilvy

Mark Peck

Simon Power

Metiria Turei (Non-voting member)

Jeanette Fitzsimons replaced Metiria Turei as a member of the committee for the purposes of its consideration of the bill, but without the right to vote on any questions before the committee.

# Key to symbols used in reprinted bill

## As reported from a select committee

| | |
|---|---|
| **Struck out (unanimous)**<br>Subject to this Act, | Text struck out unanimously |
| **New (unanimous)**<br>Subject to this Act, | Text inserted unanimously |
| (*Subject to this Act,*) | Words struck out unanimously |
| Subject to this Act, | Words inserted unanimously |

*Hon Marian Hobbs*

# New Organisms and Other Matters Bill

Government Bill

## Contents

## The Parliament of New Zealand enacts as follows:

### 1 Title

This Act is the New Organisms and Other Matters Act **2003**.

# Part 1
# Preliminary provisions

### 2 Commencement

This Act comes into force on (*the day after the date on which it receives the Royal assent*) 30 October 2003.

**Struck out (unanimous)**

**3 Purpose**

The purpose of this Act is—

(a) to make certain changes to the Hazardous Substances and New Organisms Act 1996, including—

(i) streamlining the approval of the genetic modification of new organisms in laboratories; and

(ii) providing for the approval of the conditional release of new organisms; and

(iii) clarifying enforcement responsibilities; and

(b) to improve the operation of the Hazardous Substances and New Organisms Act 1996, and related enactments, for new organisms.

## Part 2
## Hazardous Substances and New Organisms Act 1996

**4 Hazardous Substances and New Organisms Act 1996 called principal Act in this Part**

In this Part, the Hazardous Substances and New Organisms Act 1996[1] is called the principal Act.

[1] 1996 No 30

**New (unanimous)**

**4A Purpose of this Part**

The purpose of this Part is—

(a) to make certain changes to the Hazardous Substances and New Organisms Act 1996, including—

(i) streamlining the approval of the genetic modification of new organisms in laboratories; and

(ii) providing for the approval of the conditional release of new organisms; and

(iii) clarifying enforcement responsibilities; and

(b) to improve the operation of the Hazardous Substances and New Organisms Act 1996 for new organisms.

**5 Interpretation**

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

"**conditional release approval** means an approval under **section 38C**

"**conditionally released new organism** means a new organism that is subject to a conditional release approval

"**host organism** means an organism that is the subject of a genetic modification procedure

"**human cells**—

"(a) means human cells, human cell lines, or human tissues that are being grown or maintained outside the human body; and

"(b) includes human reproductive cells or human embryonic cells that are being grown or maintained outside the human body; but

"(c) does not include a development stage of a human being

"**prescribed** means prescribed by regulations made under this Act

"**qualifying medicine** means a medicine or new medicine (as defined in section 3 of the Medicines Act 1981) that—

"(a) is or contains a new organism; and

"(b) meets the criteria set out in **section 38H(3)**

"**qualifying organism** means a new organism that is or is contained in a qualifying medicine or qualifying veterinary medicine

"**qualifying veterinary medicine** means a veterinary medicine (as defined in section 2(1) of the Agricultural Compounds and Veterinary Medicines Act 1997) that—

"(a) is or contains a new organism; and

"(b) meets the criteria set out in **section 38H(3)**

**Struck out (unanimous)**

"**regenerative tissue** means biological material from a new organism that cannot, without human intervention, be used to reproduce the organism

"**responsible chief executive** means the chief executive of the Authority and the chief executive of the department for the time being responsible for the administration of the Medicines Act 1981 or the Agricultural Compounds and Veterinary Medicines Act 1997, as the case may be

"**taxonomic classification**, in relation to an organism, means the genus, species, subspecies, infrasubspecies, variety, strain, cultivar, or other appropriate (*taxonomic*) classification that the organism belongs to".

(2) Section 2(1) of the principal Act is amended by omitting from paragraph (b) of the definition of **containment facility** the words "section 42 or 45 of this Act", and substituting the words "any of sections 42, **42A, 42B**, or 45".

(3) Section 2(1) of the principal Act is amended by repealing the definition of **develop**, and substituting the following definition:

"**develop**, in relation to organisms,—

"(a) means—

"(i) genetic modification of an organism:

"(ii) regeneration of a new organism from (*regenerative tissue*) biological material of the organism that cannot, without human intervention, be used to reproduce the organism:

"(iii) fermentation of a micro-organism that is a new organism; but

"(b) does not include field testing".

(4) Section 2(1) of the principal Act is amended by omitting from the definition of **field test** the words "; and includes large-scale fermentation of microorganisms".

(5) Section 2(1) of the principal Act is amended by repealing paragraph (a) of the definition of **organism**, and substituting the following paragraphs:

"(a) does not include a human being:

"(ab) includes a human cell:".

(6) Section 2(1) of the principal Act is amended by omitting from paragraph (c) of the definition of **organism** the words "other than a genetic structure derived from a human being", and substituting the words "other than a human cell".

**Struck out (unanimous)**

(7) Section 2(1) of the principal Act is amended by inserting, after paragraph (c) of the definition of **organism**, the following paragraph:

"(ca) includes regenerative tissue:".

## 6 Meaning of new organism

(1) Section 2A(1) of the principal Act is amended by inserting, after paragraph (c), the following paragraphs:

"(ca) an organism for which a conditional release approval has been given:

**New (unanimous)**

"(cb) a qualifying organism approved for release with controls:".

(2) Section 2A of the principal Act is amended by repealing subsection (2), and substituting the following subsections:

**Struck out (unanimous)**

"(2) An organism is not a new organism if—

"(a) an approval is granted under section 38 to release an organism of the same taxonomic classification; or

"(b) in the case of a genetically modified organism an approval is granted under section 38 to release an organism of the same taxonomic classification with the same genetic modification; or

"(c) an organism of the same taxonomic classification has been prescribed as not a new organism; or

"(d) the new organism was deemed to be a new organism under section 255 and other organisms of the same taxonomic classification were lawfully present in New Zealand before the commencement of that section and in a place that was not registered as a circus or zoo under the Zoological Gardens Regulations 1977.

**New (unanimous)**

"(2) An organism is not a new organism if—

"(a) the organism is not a genetically modified organism and—

"(i) an approval is granted under section 38 to release an organism of the same taxonomic classification; or

"(ii) the organism is a qualifying organism and an approval has been granted under **section 38H** to release an organism of the same taxonomic classification without controls; or

"(iii) an organism of the same taxonomic classification has been prescribed as not a new organism; or

"(b) the organism is a genetically modified organism and—

"(i) an approval is granted under section 38 to release an organism of the same taxonomic classification with the same genetic modification; or

"(ii) the organism is a qualifying organism and an approval has been granted under **section 38H** to release an organism of the same taxonomic classification with the same genetic modification without controls; or

"(iii) an organism of the same taxonomic classification with the same genetic modification has been prescribed as not a new organism; or

"(c) the new organism was deemed to be a new organism under section 255 and other organisms of the same taxonomic classification were lawfully present in New Zealand before the commencement of that section and in a place that was not registered as a circus or zoo under the Zoological Gardens Regulations 1977.

**Struck out (unanimous)**

"(2A) A new organism does not cease to be a new organism because it is subject to a conditional release approval."

**New (unanimous)**

"(2A) A new organism does not cease to be a new organism because—

"(a) it is subject to a conditional release approval; or

"(b) it is a qualifying organism approved for release with controls."

**7 Powers, functions, and duties of Authority**

(1) Section 11 of the principal Act is amended by inserting, after paragraph (fa), the following paragraph:

"(fb) approve standards for containment facilities:".

(2) Section 11 of the principal Act is amended by adding, as subsection (2), the following subsection:

"(2) The Authority must, before exercising the function specified in **subsection (1)(fb)**, consult the persons whom the Authority considers are representative of the classes of person who are likely to have an interest in the standards."

**8 Eligibility for appointment as member of Authority**

Section 16 of the principal Act is amended by adding, as subsection (2), the following subsection:

"(2) In subsection (1), **matters** includes matters relating to the Treaty of Waitangi and tikanga Māori."

**9 Delegation by Authority**

(1) Section 19(2)(a) of the principal Act is amended by omitting the words "section 35 or section 42 of this Act", and substituting the words "any of sections 35, 42, **42A**, or **42B**".

(2) Section 19(2) of the principal Act is amended by inserting, after paragraph (b), the following paragraphs:

"(ba) the power to assess and approve an application under **section 38H(1)** for the release of a qualifying organism to the responsible chief executive:

"(bb) the power to determine whether a medicine or veterinary medicine is a qualifying medicine or qualifying veterinary medicine to the responsible chief executive:

"(bc) the power to review and amend controls under **section 38G** in relation to qualifying medicines and qualifying veterinary medicines to the responsible chief executive:

**New (unanimous)**

"(bd) the power to impose controls under section 45(2) in relation to a genetically modified human cell to which **section 50A** of the **New Organisms and Other Matters Act 2003** applies:".

**9A Obligation to prepare and maintain register**

Section 20(2) of the principal Act is amended by inserting, after paragraph (c), the following paragraph:

"(ca) if applicable, the project concerned:".

**10 New Part 4A inserted**

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

## "Part 4A
## "Nga Kaihautu Tikanga Taiao

"24A **Establishment of Nga Kaihautu Tikanga Taiao**

This section establishes a committee to be called Nga Kaihautu Tikanga Taiao.

"24B **Function of Nga Kaihautu Tikanga Taiao**

"(1) The function of Nga Kaihautu Tikanga Taiao is to provide advice and assistance to the Authority as sought by the Authority on matters (*of policy and process*) relating to policy, process, and applications.

"(2) The advice and assistance must be given from the Māori perspective and come within terms of reference set by the Authority for Nga (*Kaihauta*) Kaihautu Tikanga Taiao.

"24C **Appointment and remuneration of members and chair**

"(1) The Authority must appoint not fewer than 4 and not more than 8 members of Nga Kaihautu Tikanga Taiao.

"(2) The Authority must appoint 1 of the members to be the chairperson of Nga Kaihautu Tikanga Taiao.

"(3) The members of Nga Kaihautu Tikanga Taiao are entitled to be paid remuneration at a rate set by the Authority.

"24D **Review of terms of reference**

The Authority must, at intervals of not more than 3 years, review the terms of reference set by it for Nga Kaihautu Tikanga Taiao."

**11 Prohibition of import, manufacture, development, field testing, or release**

(1) Section 25(2) of the principal Act is amended by omitting the words "the Second Schedule to this Act", and substituting the expression "**Schedule 2**".

(2) Section 25 of the principal Act is amended by repealing subsection (3), and substituting the following subsections:

"(3) If an organism has a conditional release approval, no further approvals are required for the conditional release of the organism on the same conditions.

"(4) If an organism has an approval for importation into containment, no further approvals are required for the importation into containment of the organism.

"(5) The prohibition on the importation of a new organism does not apply to ~~(*regenerative tissue*)~~ biological material of the organism that cannot, without human intervention, be used to reproduce the organism.

"(6) No person may do any of the things specified in subsection (1)(a) or (b) in relation to any hazardous substance or new organism that is the subject of an innovative agricultural compound application or an innovative medicine application unless the person has applied for and been granted an approval to do that thing.

"(7) **Subsection (6)** ceases to apply in respect of a hazardous substance or new organism on the date that section 55(3) to ~~(*(6)*)~~ (4B) ceases to apply either to the Authority or to any information held by the Authority in relation to the hazardous substance or new organism concerned.

"(8) In this section,—

"**innovative agricultural compound application** has the same meaning as in section 72 of the Agricultural Compounds and Veterinary Medicines Act 1997

"**innovative medicine application** has the same meaning as in section 23A of the Medicines Act 1981."

**New (unanimous)**

**11A Section 25AA repealed**

(1) Section 25AA of the principal Act is repealed.

(2) Section 6 of the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002 is consequentially repealed.

**12 Types of approval**

(1) Section 27 of the principal Act is amended by inserting, after paragraph (b), the following paragraphs:

"(ba) a conditional release approval to import for release or release from containment a new organism:

**New (unanimous)**

"(bb) an approval to import for release or to release from containment a qualifying organism:".

(2) Section 27 of the principal Act is amended by adding the following paragraph:

"(f) an approval to import an agricultural compound or medicine for release in a special emergency, release an agricultural compound or medicine from containment in a special emergency, or use an agricultural compound or a medicine in a special emergency."

**13 New section 27A inserted**

The principal Act is amended by inserting, after section 27, the following section:

"27A **Approvals at any taxonomic classification**

"(1) An approval referred to in section 27(b), (*section 27*)**(ba)**, **(bb)**, or (*section 27*)(c) may be granted for a new organism at any taxonomic classification that the Authority thinks fit.

"(2) An approval that is granted for a new organism (that is not a genetically modified organism) in a taxonomic classification—

"(a) applies to all the organisms in the taxonomic classification(*; and*).

**Struck out (unanimous)**

"(b) includes all organisms in any lower level taxon.

"(3) An approval that is granted for a genetically modified organism in a taxonomic classification applies only to organisms (*of*) in the (*same*) taxonomic classification with the same genetic modification as specified in the approval.

**New (unanimous)**

"(4) Despite **subsections (2) and (3)**, an approval may exclude any organism or groups of organisms from its scope."

**14 (*Approvals for innovative agricultural compounds and medicines*) Section 29A repealed**

(1) Section 29A of the principal Act is repealed.

**New (unanimous)**

(2) Section 10 of the Hazardous Substances and New Organisms Amendment Act 2000 is consequentially repealed.

**15 Application for approval to import or release**

(1) Section 34(1) of the principal Act is amended by inserting, after the word "apply", the words ", under this section or under **section 38A**,".

(2) Section 34(2) of the principal Act is amended by inserting, after the word "application", the words "under this section".

**16 New section 34A inserted**

The principal Act is amended by inserting, after section 34, the following section:

"34A **Applications for conditional release and for release in respect of same new organism**

"(1) The user of a conditional release approval may, at or after the time of applying for the approval, apply to the Authority for

approval to release the new organism at the expiry of the conditional release approval.

"(2) The application must be treated as if it were an application under section 34 to release the new organism from containment.

"(3) If the application is granted, the approval takes effect immediately after the expiry of the conditional release approval."

**17 Determination of applications to import or release**

(1) Section 38(1) of the principal Act is amended by omitting the words "of this Act" in the second place where they occur, and substituting the words "or any other section".

(2) Section 38 of the principal Act is amended by repealing subsection (2), and substituting the following subsection:

"(2) An approval under subsection (1) must be granted without controls."

(3) Section 38 of the principal Act is amended by inserting, after subsection (3), the following subsection:

"(3A) However, subsection (3) does not apply to an approval under this section that takes effect on the expiry of a conditional release approval."

**18 New headings and sections 38A to 38J inserted**

The principal Act is amended by inserting, after section 38, the following headings and sections:

"*Conditional release of new organisms*

"38A **Application for approval to import or release new organism with controls**

"(1) A person may apply to the Authority for a conditional release approval to import for release or to release from containment a new organism with controls.

"(2) An application for a conditional release approval must be in the approved form and must include—

"(a) all prescribed information (if any); and

"(b) information on all occasions where the organism has been considered by the government of any prescribed state or country or by any prescribed organisation and the results of the consideration; and

"(c) the identification of the organism; and

"(d) any likely inseparable organisms; and
"(e) all the possible adverse effects of the organism on the environment; and
"(f) the affinities of the organism with other organisms in New Zealand; and
"(g) the proposed use for the organism; and
"(h) the controls that the applicant proposes the organism would be subject to on its release.

"(3) The Authority may, by written notice given to the applicant, require the applicant to verify an application by statutory declaration.

"(4) Any applicant may, by written notice to the Authority, withdraw the application at any time.

"38B **Application under section 34 may be treated as application under section 38A**

The Authority may, with the agreement of the applicant, treat an application made under section 34 as if it were an application made under **section 38A**.

"38C **Determination of applications to import or release new organisms with controls**

"(1) The Authority may approve an application made under **section 38A** and grant a conditional release approval with controls, but only if the Authority determines that,—
"(a) after taking into account the matters in **subsection (3)**, the new organism is likely to meet the minimum standards set out in section 36; and
"(b) there is sufficient information available to assess the adverse effects of the organism; and
"(c) after taking into account the matters in **subsection (2)**, the positive effects of the organism outweigh the adverse effects of the organism and any inseparable organism.

"(2) The matters to be taken into account under **subsection (1)(c)** are—
"(a) all the effects of the organism and any inseparable organism; and
"(b) the ability of the organism to establish a self-sustaining population; and

"(c) the ease with which the organism could be recovered or eradicated if it established an undesirable self-sustaining population; and

"(d) all the controls that will be imposed on the organism.

"(3) The matters to be taken into account in **subsection (1)(a)** are—

"(a) the controls that will be imposed on the approval; and

"(b) whether the controls are likely to be effective in meeting the objective of the controls; and

"(c) the ease with which the organism could be recovered or eradicated if it formed a self-sustaining population.

"38D **Controls**

"(1) The controls that the Authority may impose on a conditional release approval include—

"(a) controlling the extent and purposes for which organisms could be used:

"(b) requiring any monitoring, auditing, reporting, and record-keeping:

"(c) imposing any obligation to comply with relevant codes of practice or standards (for example, to meet particular co-existence requirements):

"(d) requiring contingency plans to be developed to manage potential incidents:

"(e) limiting the dissemination or persistence of the organism or its genetic material in the environment:

"(f) requiring the disposal of any organisms or genetic material:

"(g) limiting the proximity of the organism to other organisms, including those that could be at risk from the conditionally released organism:

"(h) setting requirements that must be met for any material derived from the organism:

"(i) imposing obligations on the user of an approval, including levels of training or knowledge, limits on the numbers of users who may hold an approval, and the persons that they could deal with in respect of the organism:

"(j) specifying the duration of the approval or of a control before requiring review by the Authority, and the nature of that review.

"(2) **Subsection (1)** does not limit the type of controls the Authority may impose on a conditional release approval.

"38E **Duration of conditional release approval**

"(1) A conditional release approval that expressly states that it does not expire expires on the close of the date on which the last control to which the approval relates expires.

"(2) In any other case, a conditional release approval expires on the earlier of the following:

"(a) the date of expiry (if any) specified in the approval; or

"(b) if no date of expiry is specified, 5 years after the date on which the approval is granted; or

"(c) the close of the date on which the last control to which the approval relates expires.

"38F **Consequences of expiry of conditional release approval**

On the expiry of a conditional release approval, the new organism concerned must be disposed of unless, before the expiry of the approval, another approval has been granted under this Act.

"38G **Review of controls on conditional release approval**

"(1) The Authority may, on its own initiative or on the application of any user of a conditional release approval or of any person specified in section 97 or **section 97A**, review the controls that it has imposed on the conditional release approval, but only if—

"(a) the review is to amend a control so that it better meets the objective of the control; or

"(b) the control included a review requirement specifying—

"(i) the circumstances in which the control would be reviewed; and

"(ii) the potential consequences of the review.

"(2) The Authority—

"(a) may carry out the review without publicly notifying the review in accordance with section 53; but

"(b) if it does so, must—

"(i) consult, and consider the views of, the Department of Conservation and any other (*interested*) government agency (as defined in **section 49A**) that the Authority considers is likely to have an interest in the review; and

"(ii) publicly notify the results of the review.

"(3) This section does not limit section 67A.

**New (unanimous)**

"38GA **Restriction on release of new organism subject to conditional release approval**

A person who did not obtain a conditional release approval for a new organism that is subject to a conditional release approval must not release the new organism in accordance with the approval unless, before the release, the person has given notice in writing to the Authority of the proposed release.

"*Release of qualifying organisms*

"38H **Assessment of applications for release of qualifying organisms**

"(1) If the Authority receives an application under section 34 that relates to a qualifying organism, the Authority may—

"(a) make a rapid assessment of the adverse effects of importing for release or releasing from containment the qualifying organism; and

"(b) approve the importation for release or the release from containment of the qualifying organism with or without controls.

"(2) If the Authority does not approve an application under this section, the Authority must assess and determine the application under section 38.

"(3) The Authority or the responsible chief executive, as the case may be, may determine that a qualifying organism is or is contained in a qualifying medicine or a qualifying veterinary medicine only if satisfied that, taking into account all the controls that will be imposed (if any), it is highly improbable that—

"(a) the dose and routes of administration of the medicine or veterinary medicine would have significant adverse effects on—

"(i) the health of the public; or

"(ii) any valued species; and

"(b) the qualifying organism could form an undesirable self-sustaining population and would have significant adverse effects on—

"(i) the health and safety of the public; or

"(ii) any valued species; or

"(iii) natural habitats; or

"(iv) the environment.

"(4) In determining under **subsection (3)** whether a qualifying organism is or is contained in a qualifying medicine or a qualifying veterinary medicine, the following effects (if any) are not to be taken into account:

"(a) any effect of the medicine or qualifying organism on the person who is being treated with the medicine:

"(b) any effect of the veterinary medicine or qualifying organism on the animal that is being treated with the veterinary medicine.

"(5) An approval granted under this section is not an approval—

"(a) to use a qualifying medicine until the medicine has been lawfully supplied for use under the Medicines Act 1981; or

"(b) to use a qualifying veterinary medicine until the veterinary medicine has been approved for use under the Agricultural Compounds and Veterinary Medicines Act 1997.

"38I **Procedure for assessing and approving application by responsible chief executive**

If the Authority has delegated to the responsible chief executive its power to assess and approve an application under section 38 for the release of a qualifying organism, the responsible chief executive must—

"(a) be paid the fee set by the Authority for the assessment and approval of the application; and

"(b) determine whether the medicine is a qualifying medicine or the veterinary medicine is a qualifying veterinary medicine, as the case may be; and

"(c) if the responsible chief executive is satisfied that the medicine is a qualifying medicine or the veterinary medicine is a qualifying veterinary medicine, the responsible chief executive may, with or without controls, approve the release of the qualifying organism.

"38J **Controls**

"(1) The type of controls that may be imposed on the importation for release or release from containment of a qualifying organism include—

"(a) controls for the distribution of the qualifying medicine or qualifying veterinary medicine:

"(b) controls providing for the methods of administering the qualifying medicine or qualifying veterinary medicine:

"(c) controls concerning the persons who may administer the qualifying medicine or qualifying veterinary medicine:

"(d) controls concerning the persons to whom the qualifying medicine may be administered:

"(e) controls concerning the animals to which the qualifying veterinary medicine may be administered.

"(2) **Subsection (1)** does not limit the type of controls that may be imposed on the importation for release or release from containment of a qualifying organism.

**New (unanimous)**

"38K **Review of controls for qualifying organisms**

"(1) The Authority may, on its own initiative or on the application of the holder of an approval under **section 38H** or of any person specified in section 97 or **section 97A**, review any controls that it has imposed on the approval, but only if—

"(a) the review is to amend a control so that it better meets the objective of the control; or

"(b) the control included a review requirement specifying—

"(i) the circumstances in which the control would be reviewed; and

"(ii) the potential consequences of the review.

"(2) The Authority—

"(a) may carry out the review without publicly notifying the review in accordance with section 53; but

"(b) if it does so, must—

"(i) consult, and consider the views of, any government agency (as defined in **section 49A**) that the Authority considers is likely to have an interest in the review; and

**New (unanimous)**

"(ii) publicly notify the results of the review.

"(3) This section does not limit section 67A."

## 19 Importation or development of new organisms in containment

(1) Section 39(1)(a) of the principal Act is amended by omitting the words "genetically modified", and substituting the word "new".

(2) Section 39 of the principal Act is amended by repealing subsection (2), and substituting the following subsections:

"(2) A decision by the Authority under section 38 **or section 38C or section 38H** to decline an application does not prevent the Authority from granting an approval to import a new organism into containment, develop a new organism in containment, or field test a new organism in containment for 1 or more of the purposes specified in subsection (1).

"(3) If an application has been made to the Authority for a conditional release approval, (*a user of the conditional release approval*) any person may apply to the Authority for approval to put the organism into containment and the application—

"(a) must be treated in all respects as an application to import a new organism into containment; and

"(b) may be granted only for 1 or more of the purposes specified in subsection (1).

**New (unanimous)**

"(4) If an application has been made to the Authority for an approval under **section 38H**, any person may apply to the Authority for approval to put the qualifying organism into containment, and the application—

"(a) must be treated in all respects as an application to import a new organism into containment; and

"(b) may be granted only for 1 or more of the purposes specified in subsection (1)."

**New (unanimous)**

**19A Application for containment approval for new organisms**
Section 40(2)(b) of the principal Act is amended by omitting the words "and large scale fermentation" in both places where they occur.

**20 New sections 42A and 42B inserted**
The principal Act is amended by inserting, after section 42, the following sections:

"42A **Rapid assessment of projects for low-risk genetic modification**

"(1) An application made under section 40 to develop a new organism in containment may, instead of specifying the information required by or under section 40(2), describe—

"(a) a project for the development of genetically modified organisms; and

"(b) the identity of the host organisms; and

"(c) the nature and range of the proposed genetic modifications.

"(2) After the Authority receives an application under section 40 that complies with **subsection (1)**, the Authority may make a rapid assessment of the adverse effects of carrying out the project if it is satisfied that—

"(a) any host organism specified for the project meets the criteria for host organisms prescribed in regulations made under section 41; and

"(b) any genetic modification specified for the project meets the criteria for genetic modification procedures prescribed in regulations made under section 41.

"(3) If the Authority has completed a rapid assessment under **subsection (2)**, the Authority may—

"(a) approve the application; and

"(b) impose controls providing for each of the matters specified in the Third Schedule as the Authority thinks fit; and

"(c) direct the applicant to provide progress reports on the development at the times specified or required by the Authority.

"42B **Rapid assessment of adverse effects for importation of genetically modified organisms into containment**

"(1) After the Authority receives an application under section 40 to import a genetically modified organism into containment, the Authority may make a rapid assessment of the adverse effects of importing the organism.

"(2) If the Authority is satisfied that the importation meets the criteria for a low-risk genetic modification specified in regulations made under section 41, the Authority may approve the application and impose controls providing for each of the matters specified in the Third Schedule as the Authority thinks fit.

"(3) Section 25**(4)** does not apply if an application is approved under this section by a person acting under delegated authority from the Authority under section 19(2)(a)."

**21 New section 43 substituted**

The principal Act is amended by repealing section 43, and substituting the following section:

"43 **Additional matters to be considered when application made for developing new organisms in containment**

The Authority, when making a decision under section 45, must have regard to,—

"(a) in the case of an application made under section 40(1)(b) to genetically modify an organism, the matters specified in regulations made under section 41; and

"(b) in the case of all applications made under section 40(1)(b), the matters specified in section 37."

**22 Additional matters to be considered for certain developments and field tests**

Section 44A(4) of the principal Act is repealed.

**23 Determination of application**

(1) Section 45(1) of the principal Act is amended by omitting the words "section 42 of this Act", and substituting the words "section 42 or **section 42A or section 42B**".

(2) Section 45(1)(a)(ii) of the principal Act is amended by omitting the words "should the organism escape".

(3) Section 45 of the principal Act is amended by adding the following subsection:

"(4) In taking into account the adverse effects of the organism under subsection (1)(a)(ii), the Authority must take into account—

"(a) the adverse effects (if any) of having the organism and any inseparable organism in containment; and

"(b) the probability that the organism may escape after considering all the controls to which the organism would be subject if the application were approved; and

"(c) the effects of the organism, if the organism were to escape."

**24 New section 45B inserted**

The principal Act is amended by inserting, after section 45A, the following section:

"45B **Animals in circus or zoological garden deemed approved under section 255**

The Authority may, for a deemed approval under section 255,—

"(a) include controls that provide for each of the applicable matters specified in the Third Schedule; and

"(b) include controls that provide for any other matters in order to give effect to the purpose of this Act; and

"(c) remove or vary the conditions imposed under section 255 that the organism remains at a particular place."

**25 Exemptions from provisions of Act in emergencies**

Section 49 of the principal Act is amended by omitting the words "section 50 of this Act", and substituting the words "**sections 49A** to 50".

**26 New heading and sections 49A to 49K inserted**

The principal Act is amended by inserting, after section 49, the following heading and sections:

*"Rapid assessment and approval of agricultural compounds and medicines in special emergencies*

"49A **Interpretation**

In **sections 49B to 49K**,—

"**adverse event** includes, but is not limited to, any of the events or emergencies specified in section 46(1)

"**agricultural compound** means an agricultural compound (as defined in section 2(1) of the Agricultural Compounds and Veterinary Medicines Act 1997) that is or contains a hazardous substance or a new organism

"**government agency** means—

"(a) a department specified in the First Schedule of the State Sector Act 1988:

"(b) a Crown entity specified in the Fourth Schedule of the Public Finance Act 1989

"**interested government agency** means a government agency that, in the opinion of the Authority, is likely to have an interest in the approval of an agricultural compound or medicine in a special emergency

"**medicine** means a medicine (as defined in section 3 of the Medicines Act 1981) that is or contains a hazardous substance or new organism

"**responsible Minister** means the Minister who, under the authority of any warrant or with the authority of the Prime Minister, is for the time being responsible for the administration of—

"(a) this Act; or

"(b) the Agricultural Compounds and Veterinary Medicines Act 1997; or

"(c) the Biosecurity Act 1993; or

"(d) the Conservation Act 1987; or

"(e) the Fisheries Act 1996; or

"(f) the Health Act 1956; or

"(g) the Medicines Act 1981

"**special emergency** means a special emergency declared under **section 49B**.

"49B **Declaration of special emergency**

"(1) A responsible Minister may declare an adverse event to be a special emergency if the adverse event is a matter that comes within the Minister's portfolio.

"(2) A declaration of a special emergency—

"(a) must be notified or published in the *Gazette* as soon as practicable after the special emergency is declared; and

"(b) is not a regulation for the purposes of the Acts and Regulations Publication Act 1989.

"(3) A special emergency expires—

"(a) on the close of the date (if any) specified in the declaration as the expiry date; or

"(b) if **paragraph (a)** does not apply, then on the close of a date specified by notice in the *Gazette* as the date of expiry of the emergency.

"49C **Application of sections 49D to 49K**

**Sections 49D to 49K** apply to a special emergency whether or not—

"(a) the special emergency is foreseeable; and

"(b) the importation, release, or use of an agricultural compound or medicine in the special emergency is foreseeable.

"49D (*Prohibition on using*) **Application for approval to use agricultural compound or medicine in special emergency**

"(1) A person who does not have approval under this Act to do a thing specified in **subsection (2)** may apply to the Authority to do the thing in a special emergency.

"(2) The things are—

"(a) import any agricultural compound or medicine for release; or

**New (unanimous)**

"(aa) manufacture an agricultural compound or medicine that is a hazardous substance otherwise in containment; or

"(b) release any agricultural compound or medicine from containment; or

"(c) use any agricultural compound or medicine in a manner that would contravene this Act or any regulations.

"(3) For the purposes of **subsection (1)**,—

"(a) it does not matter whether the application is made or approved before or after the special emergency has been declared:

"(b) the applicant may import, release, or use the agricultural compound or medicine before the declaration of the special emergency has been notified or published in the *Gazette*.

"49E **Contents of application**

"(1) An application under **section 49D** must be in the approved form and must include information required by the Authority that, having regard to the particular circumstances of the special emergency, the applicant can provide to the Authority in the time available.

"(2) Without limiting **subsection (1)**, the Authority may require the following information:

"(a) information to identify the agricultural compound or medicine and the hazardous substance or new organism that is or is contained in the agricultural compound or medicine; and

"(b) information showing that the agricultural compound or medicine is necessary to deal with the special emergency; and

"(c) a proposed plan for dealing with the use of the agricultural compound or medicine in the special emergency; and

"(d) any reports by experts available from—

"(i) the applicant:

"(ii) any overseas regulatory agencies; and

"(e) written confirmation by the applicant that the agricultural compound or medicine satisfies all relevant manufacturing practices and standards; and

"(f) information on whether the agricultural compound or medicine has been approved for use in an overseas country; and

"(g) information on whether approval for use of the agricultural compound or medicine has been declined in an overseas country; and

"(h) information on the nature of the special emergency; and
"(i) information on the nature of the agricultural compound or medicine; and
"(j) information on the labelling of the agriculture compound or medicine; and
"(k) all other prescribed information (if any).

"(3) The Authority may, by written notice given to the applicant, require the applicant to verify the application by statutory declaration.

"(4) An applicant may, by written notice to the Authority, withdraw the application at any time.

"49F **Determination of applications**

"(1) As soon as practicable after receiving an application under **section 49D**, the Authority must complete a rapid assessment of the application and decide whether to approve or decline the application.

"(2) In determining whether to approve or decline the application, the Authority must—
"(a) consult, and have particular regard to the views of, the Department of Conservation; and
"(b) consult and consider the views of any other interested government agency; and
"(c) consider all the information on the matters specified in **section 49E** that, having regard to the particular circumstances of the special emergency, the applicant can provide to the Authority in the time available.

"(3) The Authority may decline the application only if it is satisfied that—
"(a) the agricultural compound or medicine is not necessary for use in the special emergency; or
"(b) if the application relates to a hazardous substance, the proposed plan does not adequately control the adverse effects of the hazardous substance; or
"(c) if the application relates to a new organism, the proposed plan does not adequately control the adverse effects of the new organism or any inseparable organism (including, but not limited to, adequate control of the organism if the organism is likely to establish an undesirable self-sustaining population, taking into account the ease of destroying such a population).

"49G **Controls attaching to approval of application**

If the Authority approves an application under **section 49F**, the Authority must impose the control that the agricultural compound or medicine may be released only if the special emergency is dealt with in accordance with the specified plan, and the plan includes—

"(a) the measures that must be taken to avoid, remedy, or mitigate any actual or potential adverse effects from the use of the agricultural compound or medicine:

"(b) the requirements for the disposal of the agricultural compound or medicine and any waste products:

"(c) the requirements for the eradication or control of any new organism.

"49H **Notification or publication of approval of application**

"(1) An approval under **section 49F** and the reasons for the approval must be notified or published in the *Gazette*.

"(2) The notified or published approval—

"(a) must describe the special emergency to which it relates; and

"(b) must specify where a copy of the plan for dealing with the use of the agricultural compound or medicine in the special emergency may be inspected or obtained; but

"(c) need not specify what the approval has been granted for.

"(3) If the approval is only notified in the *Gazette*,—

"(a) the notice must specify where a copy of the approval may be inspected or obtained; and

"(b) the Authority must make copies of the approval available for inspection free of charge, and for purchase at a reasonable cost, at the head office of the Authority and at any other places that the Authority determines as necessary or appropriate.

"49I **Effect of approval of release**

"(1) An approval for the importation, release, or use of an agricultural compound or medicine in a special emergency is limited to the importation, release, or use of the agricultural compound or medicine in the special emergency.

"(2) If an approval relates to a new organism, the organism does not cease to be a new organism because it is released in accordance with the approval.

"49J **Duration of approval**

An approval under **section 49F** takes effect on the day specified in the approval, and expires on the earlier of—

"(a) the date of expiry (if any) of the special emergency specified by a responsible Minister in—

"(i) the declaration declaring the special emergency; or

"(ii) a later declaration declaring that the special emergency has ceased; or

"(b) the date of expiry (if any) specified by the Authority in the approval, which must not be later than the date of expiry of the special emergency; or

"(c) if **paragraph (a) or paragraph (b)** does not apply, 2 years after the date on which the approval is granted.

"49K **Consequences of expiry of approval**

On the expiry of an approval under **section 49F** that relates to a hazardous substance or new organism, the hazardous substance or new organism must be disposed of unless, before the expiry of the approval, the applicant has, under any other provision of this Act, been granted an approval."

**27 Prohibited organisms**

(1) Section 50(1), (3), and (4) is amended by omitting the words "the Second Schedule to this Act", and substituting in each case the expression "**Schedule 2**".

(2) Section 50 of the principal Act is amended by repealing subsection (2), and substituting the following subsections:

"(2) The Governor-General may, by Order in Council made on the recommendation of the Minister, amend **Schedule 2** to—

"(a) add a new organism that the Authority has, under subsection (3), recommended to the Minister be included in the schedule:

"(b) add a new organism, or group or groups of new organisms, that have adverse effects on the health and safety of people or the environment:

"(c) remove an organism or group of organisms, but only if the organism was inserted by Order in Council.

"(2A) **Subsection (2)** applies subject to section 141.

"(2B) An organism in **Schedule 2** that is prescribed as not a new organism in regulations made under section 140(1)**(ba)** is to be treated as if it had been removed from that Schedule."

### 28 Transhipment of substances and organisms

Section 51(2)(a) of the principal Act is amended by omitting the words "the Second Schedule to this Act", and substituting the expression "**Schedule 2**".

### 29 Applications required to be publicly notified

(1) Section 53(1) is amended by inserting, after paragraph (a), the following paragraph:

"(ab) an application under **section 38A** for a conditional release approval for a new organism:".

(2) Section 53(1)(b) of the principal Act is amended by inserting, after the words "section 35", the words "or **section 38H**".

(3) Section 53(1)(c) of the principal Act is amended by adding the words ", if the application has not been approved under **section 38H**".

(4) Section 53(2)(b) of the principal Act is amended by adding the words "or **section 42A or section 42B**".

**New (unanimous)**

(5) Section 53(4)(c) of the principal Act is amended by repealing subparagraph (ii), and substituting the following subparagraph:

"(ii) any local authority (within the meaning of the Local Government Act 2002) if, in the opinion of the Authority, the local authority is likely to have an interest in the application."

### 30 Information held on behalf of applicant

(1) Section 55(3) of the principal Act is amended by repealing paragraph (a), and substituting the following paragraph:

"(a) any information is held by the Authority relating to any application made under this Act in respect of a hazardous substance or new organism; and".

(2) Section 55(3)(b) of the principal Act is amended by omitting the words "That substance", and substituting the words "the substance or organism that is the subject of the application".

**New (unanimous)**

(2A) Section 55(4) of the principal Act is amended by inserting,—

(a) after the words "hazardous substances", the words "or new organisms"; and

(b) after the word "substance", the words "or organism".

(3) Section 55(4A) of the principal Act is amended by repealing paragraph (a), and substituting the following paragraph:

"(a) any information is held by the Authority relating to any application made under this Act in respect of a hazardous substance or new organism; and".

(4) Section 55(4A)(b) of the principal Act is amended by omitting the words "That substance", and substituting the words "the substance or organism that is the subject of the application".

**New (unanimous)**

(5) Section 55(4B) of the principal Act is amended by inserting,—

(a) after the words "hazardous substances", the words "or new organisms"; and

(b) after the word "substance", the words "or organism".

(6) Section 55(7) of the principal Act is amended by omitting the expression "(4A)(b)", and substituting the expression "(4B)(b)".

## 31 Authority to withhold information

(1) Section 57(2) of the principal Act is amended by omitting the words "immediately notify", and substituting the words "make all reasonable efforts to contact and notify immediately".

(2) Section 57 of the principal Act is amended by repealing subsection (4), and substituting the following subsection:

"(4) The Authority may release the information or withhold the information in accordance with the Official Information Act 1982 if—

"(a) the Authority has complied with subsection (2); and

"(b) the time limit specified in subsection (3) has expired."

**32 Further information**

Section 58(1)(c) of the principal Act is amended by inserting, after the words "field test,", the words "conditionally release,".

**33 Time limits and waivers**

(1) Section 59(1)(a) is amended by omitting the words "section 28A or section 35 or section 42 of this Act", and substituting the expression "paragraph (b)".

(2) Section 59(1) is amended by omitting paragraph (b), and substituting the following paragraph:

"(b) if any of sections 28A, 35, **38H**, 42, **42A**, or **42B** apply to the application,—

"(i) make a rapid assessment of the application within 10 working days after receipt of the application; and

"(ii) if the application is not approved under one of those sections, publicly notify the application, if required under this Act, within 10 working days of the Authority's decision."

(3) Section 59(2) of the principal Act is amended by omitting the words "not later than 15 working days", and substituting the words "as soon as reasonably practicable but not later than 30 working days".

**34 Grounds for reassessment of a substance or organism**

(1) Section 62(1) of the principal Act is amended by inserting, after the word "containment", the words "**(*or*)** any conditionally released new organism, any qualifying organism released with controls,".

(2) Section 62(4) of the principal Act is amended by omitting the expression "42", and substituting the expression "**38C**, **38H**, 42, **42A**, **42B**,".

### 35 Reassessment

(1) Section 63(2) of the principal Act is amended by inserting, after paragraph (c), the following paragraphs:

"(ca) sections **38A to 38D** and 54 to 61 apply with all necessary modifications to a reassessment of a conditional release approval:

**New (unanimous)**

"(cb) **sections 38H to 38K** and 54 to 58 apply with all necessary modifications to a reassessment of a qualifying organism released with controls:".

(2) Section 63 of the principal Act is amended by adding the following subsection:

"(3) However, a reassessment of a (*conditional release approval for a qualifying medicine or a qualifying veterinary medicine*) qualifying organism released with controls is not required to be publicly notified in accordance with section 53."

### 36 Minister's power to call in applications with significant effects

Section 68 of the principal Act is amended by repealing subsection (1), and substituting the following subsection:

"(1) The Minister may direct that he or she will decide an application under this Act if the Minister considers that the decision on the application will have—

"(a) significant cultural, economic, environmental, ethical, health, international, or spiritual effects; or

"(b) significant effects in an area in which the Authority lacks sufficient knowledge or experience."

### 37 Notification of Minister's direction

Section 69(1) of the principal Act is amended by omitting the words "15 working days after receipt, by the Authority, of the application", and substituting the words "30 working days

after the date on which the Authority gives public notice of the application".

**38 Conduct of inquiry by Authority**

Section 71 of the principal Act is amended by repealing subsection (4), and substituting the following subsection:

"(4) The Authority—

"(a) must hold an inquiry in public; and

"(b) must consider—

"(i) all matters under this Act relevant to the application; and

"(ii) the Minister's reasons for giving the direction under section 68."

**39 Minister to decide application and notify decision**

Section 73(3) of the principal Act is amended by omitting the words "Part VI of".

**New (unanimous)**

**39A Part 5A repealed**

(1) Part 5A of the principal Act is repealed.

(2) Section 9 of the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002 is consequentially repealed.

**40 Enforcement of Act**

Section 97 of the principal Act is amended by inserting, after the word "Act" in the first place where it occurs, the words "(including any controls imposed on approvals granted under this Act)".

**41 New section 97A inserted**

The principal Act is amended by inserting, after section 97, the following section:

"97A **Enforcement of Act in respect of new organisms**

"(1) The enforcement agency must ensure that the provisions of this Act are enforced in respect of new organisms.

"(2) For the purpose of complying with **subsection (1)**, the enforcement agency may appoint enforcement officers in accordance

with this Act who may exercise also the powers of inspectors under the Biosecurity Act 1993 that may be exercised in respect of an unwanted organism, and the provisions of that Act apply with all necessary modifications.

"(3) A person who may exercise powers under the Biosecurity Act 1993 in respect of unwanted organisms may also exercise those powers under that Act in respect of new organisms whether or not the person is appointed as an enforcement officer under this Act.

**New (unanimous)**

"(3A) Without limiting **subsection (2)**, the provisions of the Biosecurity Act 1993 that apply, with all necessary modifications, for the purposes of this section include sections 162A, 163, and 164 of that Act.

"(4) In this section,—

"**enforcement agency** means the chief executive of the department of State responsible for the administration of the Biosecurity Act 1993

"**unwanted organism** has the same meaning as in section 2(1) of the Biosecurity Act 1993."

**42 Co-ordination of inspection**

Section 98(1) and (3) of the principal Act is amended by omitting the words "section 97 of this Act" in each place where they occur, and substituting in each case the words "section 97 or **section 97A**".

**43 New section 98A inserted**

The principal Act is amended by inserting, after section 98, the following section:

"98A **Chief executives of Ministry and Authority to have functions, powers, duties, and protections of enforcement officers**

"(1) For the purposes of this Act, a chief executive has the same functions, powers, duties, and protections that enforcement officers have under this Act.

"(2) In **subsection (1)**, **chief executive** means—

"(a) the chief executive of the department of State responsible for the administration of this Act:

"(b) the chief executive of the Authority."

**44 Supervision of inspection**

Section 99(1) of the principal Act is amended by omitting the words "section 97 of this Act", and substituting the words "section 97 or **section 97A**".

**45 Powers of entry for inspection**

Section 103(1)(c) of the principal Act is amended by omitting the words "the conditions", and substituting the words "compliance with the conditions or controls on any hazardous substance or new organism".

**46 Form and content of compliance order**

(1) Section 106(d) of the principal Act is amended by omitting the words ", which shall not be less than 4 days from the time at which the notice is served".

(2) Section 106(f) of the principal Act is amended by omitting the words "and the last day on which a notice of appeal can be lodged".

(3) Section 106 of the principal Act is amended by adding, as subsection (2), the following subsection:

"(2) The period referred to in paragraph (1)(d) of this section must—

"(a) commence at the time the notice is served; and

"(b) be reasonable, having regard to the circumstances giving rise to the compliance order."

**47 Penalties**

Section 114 of the principal Act is amended by inserting, after subsection (6), the following subsection:

"(6A) To avoid doubt, the Court may make an order under either or both of subsection (5) and subsection (6) against the same person in respect of the same offence."

**48 New Part 7A inserted**

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

## "Part 7A
## "Pecuniary penalties and civil liability for breaches relating to new organisms

"124A **Interpretation**

In this Part, unless the context otherwise requires,—

"**Court** means the High Court

"**enforcement agency** means the chief executive of the department of State responsible for the administration of the Biosecurity Act 1993.

*"Pecuniary penalties*

"124B **Pecuniary penalty order**

"(1) The enforcement agency may apply to the Court for an order that a person pay to the Crown a pecuniary penalty under this Act.

"(2) The Court may make the order if it is satisfied that the person—

"(a) developed, field tested, imported, or released a new organism in breach of this Act; or

"(b) possessed or disposed of any new organism imported, manufactured, developed, or released in breach of this Act; or

"(c) failed to comply with any controls relating to a new organism—

"(i) imposed by any approval granted under this Act; or

"(ii) specified in regulations made under this Act.

"(3) The Court must not make the order if (*it is satisfied*) the person satisfies the Court that the person did not know, and could not reasonably have known, of the breach.

"124C **Amount of pecuniary penalty**

"(1) The Court must not make an order for the payment of a pecuniary penalty that exceeds,—

"(a) in the case of an individual, $500,000; or

"(b) in the case of a body corporate, the greater of—

"(i) $10,000,000; or

"(ii) if it can be readily ascertained and if the Court is satisfied that the contravention occurred in the course of producing a commercial gain, 3 times the value of any commercial gain resulting from the contravention; or

"(iii) if the commercial gain cannot be readily ascertained, 10% of the turnover of the body corporate and all of its interconnected bodies corporate (if any).

"(2) In determining an appropriate penalty under this section, the Court must have regard to all relevant matters, including—

"(a) the nature and extent of the breach:

"(b) the nature and extent of any loss or damage suffered by any person or to the environment as a result of the breach:

"(c) the circumstances in which the breach took place:

"(d) whether or not the person has previously been found in proceedings under this Act to have engaged in any similar conduct:

"(e) the steps taken by the person to bring the breach to the attention of the enforcement agency:

"(f) the steps taken by the person to avoid, remedy, or mitigate the effects of the breach.

"(3) In this section, **interconnected** and **turnover** have the same meaning as in the Commerce Act 1986.

"124D **Other orders instead of or in addition to pecuniary penalty order**

"(1) At the conclusion of proceedings for an order for the payment of a pecuniary penalty under **section 124B**, the Court may, instead of or in addition to making the order, make—

"(a) an order that the person mitigate or remedy any adverse effects on people or the environment—

"(i) caused by or on behalf of the person; or

"(ii) relating to any land that the person owns or occupies; or

"(b) an order to pay the costs of mitigating or remedying the adverse effects specified in **paragraph (a)**.

"(2) At the conclusion of proceedings for an order for the payment of a pecuniary penalty under **section 124B**, the Court may,

instead of or in addition to making the order, make an order for the destruction of the new organism involved in the breach.

"(3) To avoid doubt, the Court may make an order under either or both of **subsections (1)** and **(2)** against the same person in respect of the same breach.

"124E **Standard of proof and procedural matters**

In proceedings for an order under **section 124B**,—

"(a) the standard of proof is the standard of proof that applies in civil proceedings; and

"(b) the enforcement agency may, by order of the Court, obtain discovery and administer interrogatories.

"124F **Relationship between concurrent proceedings for pecuniary penalty and criminal proceedings**

"(1) Criminal proceedings under this Act may be started against a person whether or not proceedings for an order under **section 124B** have been started against the person for the same act or omission or substantially the same act or omission in respect of which the criminal proceedings have been started.

"(2) Uncompleted proceedings for an order under **section 124B** must be stayed if criminal proceedings are started or have already been started against the person for the same act or omission or substantially the same act or omission in respect of which the order is sought.

"*Civil liability for acts and omissions while in breach*

"124G **Civil liability**

"(1) A person is liable in damages for any loss or damage caused by any act or omission of the person while—

"(a) developing, field testing, importing, or releasing a new organism in breach of this Act:

"(b) possessing or disposing of any new organism imported, manufactured, developed, or released in breach of this Act; or

"(c) failing to comply with any controls relating to a new organism—

"(i) imposed by any approval granted under this Act; or

"(ii) specified in any regulations made under this Act.

"(2) A person is liable under **subsection (1)** whether or not—
"(a) the person intended the act, omission, or breach; or
"(b) the person was taking reasonable care when the act, omission, or breach occurred.

"(3) To avoid doubt, proceedings under this section are in addition to, and not in substitution for, any other cause of action.

"124H **Defences to liability under section 124G**

"(1) A person is not liable under **section 124G** if the person proves 1 or more of the defences specified in **subsection (2)** in relation to the breach.

"(2) The defences are—
"(a) that—
"(i) the breach was necessary for the purpose of—
"(A) saving or protecting life or health; or
"(B) preventing serious damage to property; or
"(C) avoiding an actual or likely adverse effect on the environment; and
"(ii) the conduct of the defendant was reasonable in the circumstances; and
"(iii) the defendant took steps that were reasonable in all the circumstances to mitigate or remedy the effects of the breach after it occurred; or
"(b) that the breach was due to an event beyond the control of the defendant (including natural disaster, mechanical failure, or sabotage) and—
"(i) the event could not reasonably have been foreseen or been provided against by the defendant; and
"(ii) the defendant took steps that were reasonable in all the circumstances to mitigate or remedy the effects of the breach after the event occurred; or
"(c) that the defendant did not know, and could not reasonably have known, of the breach.

**New (unanimous)**

"*Liability for acts and omissions of others*

"124I **Breaches, acts, and omissions by directors, employees, or agents**

"(1) This section applies for the purposes of **sections 124B and 124G**.

"(2) A body corporate is to be treated as in breach of this Act or as having done or omitted to do an act if—

"(a) a director, employee, or agent of the body corporate, acting within the scope of his or her actual or apparent authority, is in breach of this Act or has done or omitted to do an act; or

"(b) any other person, at the direction or with the consent or agreement (whether express or implied) of a director, employee, or agent of the body corporate, given within the scope of the actual or apparent authority of the director, employee, or agent, is in breach of this Act or has done or omitted to do an act.

"(3) A person (**person A**) who is not a body corporate is to be treated as in breach of this Act or as having done or omitted to do an act if—

"(a) an employee or agent of person A, acting within the scope of his or her actual or apparent authority, is in breach of this Act or has done or omitted to do an act; or

"(b) any other person, at the direction or with the consent or agreement (whether express or implied) of an employee or agent of person A, given within the scope of the actual or apparent authority of the employee or agent, is in breach of this Act or has done or omitted to do an act.

"(4) If a person in breach of this Act has a defence to the breach under **section 124H**, the defence is also available to another person if the breach is to be treated under **subsection (2)** or **subsection (3)** as also the breach of the other person.

"(5) However, the defence under **section 124H(2)(c)** is not available to the other person unless the other person also proves that he or she did not know, and could not reasonably have known, of the breach by the person.

"(6) If the Court is prevented by **section 124B(3)** from making an order under that section against a person in breach of this Act and the breach is to be treated under **subsection (2) or subsection (3)** of this section as also the breach of another person, the Court must not make an order under **section 124B** against the other person if it is satisfied that the other person did not know and could not reasonably have known of the breach."

**49 Regulations**

(1) Section 140(1) of the principal Act is amended by inserting, after paragraph (b), the following paragraph:

"(ba) prescribing organisms that are not new organisms for the purposes of this Act:".

(2) Section 140(1) of the principal Act is amended by inserting, after paragraph (f), the following paragraphs:

"(fa) prescribing controls for any conditionally released new organism or any qualifying organism released with controls, to avoid or mitigate any adverse effects on the physical or chemical nature of the environment:

"(fb) prescribing controls for any conditionally released new organism or any qualifying organism released with controls, to avoid or mitigate illness or injury to people or animals (other than the persons or animals referred to in **section 38H(4)(a) and (b)**) or damage to the environment or chattels:".

(3) Section 140 of the principal Act is amended by inserting, after subsection (2), the following subsection:

"(2A) Regulations may be made under subsection (1)**(ba)** only if the Minister has considered—

"(a) whether the organism has formed a self-sustaining population in New Zealand; and

"(b) whether any person is attempting to manage, control, or eradicate the organism under any Act."

**50 New Schedule 2 substituted**

The principal Act is amended by repealing the Second Schedule, and substituting the **Schedule 2** set out in the **Schedule**.

**New (unanimous)**

**50A Transitional provision: human cell research in containment**

(1) This section applies to a genetically modified human cell if, at the commencement of this section, the genetically modified human cell—

(a) is present in New Zealand; and

(b) is in a containment facility approved under section 39 of the Biosecurity Act 1993.

**New (unanimous)**

(2) A genetically modified human cell to which this section applies must be treated as if it had been approved under section 45 of the principal Act, immediately before the commencement of **Part 1 of the New Organisms and Other Matters Act 2003**, as an importation into containment or a development in containment as the case may be.

(3) **Subsection (2)** ceases to apply to a genetically modified human cell after 1 year after the commencement of this section unless, before the expiry of that period, the holder of the genetically modified human cell gives the Authority a notice in writing identifying—

(a) the genetically modified human cell; and

(b) the nature and range of the genetic modification; and

(c) the containment facility in which the genetically modified human cell is held.

(4) The Authority may, by notice in writing to the holder of the genetically modified human cell,—

(a) impose controls under section 45(2):

(b) require the holder of the genetically modified human cell to supply to the Authority such further information relating to the cell as is specified in the notice.

# Part 3
# Agricultural Compounds and Veterinary Medicines Act 1997

### 51 Agricultural Compounds and Veterinary Medicines Act 1997 called principal Act in this Part

In this Part, the Agricultural Compounds and Veterinary Medicines Act 1997[2] is called "the principal Act".

[2] 1997 No 87

### 52 Director-General to withhold information

(1) Section 12(2) of the principal Act is amended by omitting the words "immediately notify", and substituting the words "make all reasonable efforts to contact and notify immediately".

(2) Section 12 of the principal Act is amended by repealing subsection (4), and substituting the following subsection:

"(4) The Director-General may release the information or withhold the information in accordance with the Official Information Act 1982 if—

"(a) the Director-General has complied with subsection (2); and

"(b) the time limit specified in subsection (3) has expired."

### 53 Waiver of notification

Section 15 of the principal Act is amended by repealing subsection (2), and substituting the following subsections:

"(2) The Director-General may waive the requirement to notify an application in accordance with section 14 if, in the Director-General's opinion, a trade name product is likely to be required for use in—

"(a) a biosecurity emergency declared under section 144 of the Biosecurity Act 1993; or

"(b) a special emergency declared under **section 49B** of the Hazardous Substances and New Organisms Act 1996.

"(3) The Director-General may waive the requirement to notify an application in accordance with section 14 if—

"(a) the trade name product is not, and does not contain, a hazardous substance or new organism (within the meaning of the Hazardous Substances and New Organisms Act 1996); and

"(b) the Minister has advised the Director-General in writing that—

"(i) an emergency has arisen under this Act; and

"(ii) the Minister agrees to the Director-General considering whether to grant a waiver; and

"(c) the Director-General is of the opinion that the trade name product is likely to be required for use in the emergency."

## Part 4
## Medicines Act 1981

### 54 Medicines Act 1981 called principal Act in this Part

In this Part, the Medicines Act 1981[3] is called "the principal Act".

[3] 1981 No 118

**55 Interpretation**

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

"**ERMA** means the Environmental Risk Management Authority established under the Hazardous Substances and New Organisms Act 1996

"**new organism** has the same meaning as in section 2A of the Hazardous Substances and New Organisms Act 1996

"**qualifying new medicine** means a new medicine that—

"(a) is or contains a new organism; and

"(b) meets the criteria set out in **section 38H(3)** of the Hazardous Substances and New Organisms Act 1996

"**qualifying organism** means a new organism that is or is contained in a qualifying new medicine".

**New (unanimous)**

**55A New section 5A inserted**

The principal Act is amended by inserting, after section 5, the following section:

"5A **Relationship with Hazardous Substances and New Organisms Act 1996**

In relation to medicines that are or contain hazardous substances or new organisms, the requirements of this Act are additional to the requirements of the Hazardous Substances and New Organisms Act 1996."

**56 New sections 24A to 24G inserted**

The principal Act is amended by inserting, after section 24, the following headings and sections:

"*Qualifying new medicines*

"24A **Assessment of qualifying new medicines**

The Director-General may grant (*a conditional release*) an approval under **section (*38C*) 38H** of the Hazardous Substances and New Organisms Act 1996 for the release of a qualifying new medicine if he or she—

"(a) has the consent of the Minister to do so; and

"(b) is acting under a delegation from ERMA given under section 19 of that Act.

"24B **Procedure if Director-General declines to grant (*conditional release*) approval**

If the Director-General declines to grant (*a conditional release*) an approval because the new organism is not a qualifying new medicine, then—

"(a) the Director-General must—

"(i) (*must*) inform ERMA that the new medicine is not a qualifying new medicine; and

"(ii) provide ERMA with a copy of all information (from assessing the safety, quality, and efficacy of the new medicine) that the Director-General considers may assist ERMA in deciding whether to approve or decline the application under the Hazardous Substances and New Organisms Act 1996; and

"(b) the Minister must not consent under section 20 (*of this Act*) or give provisional consent under section 23 to the distribution, sale, or advertising of the medicine unless the Minister receives written advice from ERMA that the medicine has been approved for release under the Hazardous Substances and New Organisms Act 1996.

"*Approval of medicines required for use in special emergency*

"24C **Interpretation**

In **sections 24D to 24G**, unless the context otherwise requires,—

"**hazardous substance** has the same meaning as in section 2(1) of the Hazardous Substances and New Organisms Act 1996

"**responsible Minister** has the same meaning as in **section 49A** of the Hazardous Substances and New Organisms Act 1996

"**special emergency** has the same meaning as in **section 49A** of the Hazardous Substances and New Organisms Act 1996.

"24D **Approval of medicines required for use in special emergency**

"(1) An application may be made to the Minister for approval to distribute (*or use*) , sell, or advertise in a special emergency a medicine that is or contains a hazardous substance or new organism.

"(2) The Minister may approve an application under **subsection (1)** with or without (*controls*) conditions, as long as the Minister is satisfied that—

"(a) the special emergency has been declared and has not come to an end; and

"(b) the medicine is required for the special emergency; and

"(c) the application complies with **subsection (3)**.

"(3) An application under **subsection (1)** must—

"(a) be accompanied by the prescribed application fee (if any); and

"(b) be in a form approved by the Director-General; and

"(c) be accompanied by any information that the Minister considers is necessary for determining whether or not to approve the application.

**Struck out (unanimous)**

"(4) An approval granted under this section is in addition to, and not in substitution for, any approval required under the Hazardous Substances and New Organisms Act 1996.

"24E **Notification or publication of approval**

The approval of an application under **section 24D** must be notified in the *Gazette*.

"24F **Duration of approval**

An approval of an application under **section 24D** takes effect on the day specified in the approval, and expires on the earlier of—

"(a) the date of expiry (if any) of the special emergency specified by the responsible Minister in—

"(i) the declaration declaring the special emergency; or

"(ii) a later declaration declaring that the special emergency has ceased; or

"(b) the date of expiry (if any) specified by the responsible Minister in the approval, which must not be later than the date of expiry of the special emergency; or

"(c) if **paragraph (a)** or **paragraph (b)** does not apply, 2 years after the date on which the approval is granted.

"24G **Consequences of expiry of approval**

On the expiry of an approval of an application under **section 24D**, the medicine to which the approval applies must not be distributed or used unless authorised by or under any other provision of this Act."

**Struck out (unanimous)**

**57 Exemptions for practitioners and others**

Section 25 of the principal Act is amended by inserting, after subsection (3), the following subsection:

"(3A) This section does not apply to medicines that are qualifying new medicines."

**58 Exemptions for pharmacists**

Section 26(4) of the principal Act is amended by inserting, after the word "medicine", the words "(not being a qualifying new medicine)".

**59 Exemptions in respect of herbal remedies**

Section 28 of the principal Act is amended by adding the following subsection:

"(3) This section does not apply to a herbal remedy that is a qualifying new medicine."

**60 Exemption for medicine required by medical practitioner**

Section 29 of the principal Act is amended by adding the following subsection:

"(4) This section does not apply to a medicine that is a qualifying new medicine."

New (unanimous)

# Part 5
# Biosecurity Act 1993

**61 Biosecurity Act 1993 called principal Act in this Part**

In this Part, the Biosecurity Act 1993[4] is called "the principal Act".

[4] 1993 No 95

**62 New section 28B inserted**

The principal Act is amended by inserting, after section 28A, the following section:

"28B **Biosecurity clearance for certain new organisms and qualifying organisms**

Section 28 does not apply to—

"(a) a new organism that is subject to a conditional release approval granted under **section 38C** of the Hazardous Substances and New Organisms Act 1996; or

"(b) a qualifying organism approved for importation for release with controls under **section 38H** of that Act."

# Schedule

s 50

## New Schedule 2 substituted in principal Act

### Schedule 2

ss 25(2), 50(1) to (4)

### Prohibited new organisms

| | |
|---|---|
| 1 | Any snake of any species whatever. |
| 2 | Any venomous reptile, venomous amphibian, venomous fish, or venomous invertebrate. (In this item, **venomous** means capable of inflicting poisonous wounds harmful to human health.) |
| 3 | Any American grey squirrel (*Sciurus carolinensis gmelini*). |
| 4 | Any red squirrel (*Sciurus vulgaris*). |
| 5 | Any musquash (or muskrat) (*Ondatra zibethica*). |
| 6 | Any coypu or nutria (*Myocastor coypus*). |
| 7 | Any beaver (*Castor canadensis*). |
| 8 | Any gerbil (*Meriones unguiculatus*). |
| 9 | Any prairie dog (*Cyonomys* spp.). |
| 10 | Any pocket gopher (*Geomys* spp. and *Thomomys* spp.). |
| 11 | Any red or silver fox (*Vulpes vulpes*). |
| 12 | Any Arctic fox (*Alopex lagopus*). |
| 13 | Any mongoose (family Herpestidae) other than *Suricata suricatta*. |
| 14 | Any member of the family Mustelidae, subfamily Mustelinae, other than ferrets (*Mustela furo*), weasels (*Mustela nivalis*), and stoats (*Mustela erminea*), and subfamily Lutrinae, other than oriental small clawed otter (*Aonyx cineria*). |

## Schedule 2—continued

15 Any mole (family Talpidae).

16 Any member of the family Esocidae (eg, pikes, muskellunge).

17 Any member of the families Phalangeridae and Petauridae, other than the Australian brushtail possum (*Trichosurus vulpecula*).

18 Any stickleback (*Gasterosteus* spp.).

19 Any giant African snail (*Achatina* spp.).

20 Any predatory snail (*Euglandina rosea*).

21 Any cane toad (*Bufo marinus*).

22 Negro root (*Cassia occidentalis*).

23 Skeleton weed (*Chondrilla juncea*).

24 *Cymbopogon schoenanthus*.

25 *Cynanchum* (all species), eg, Indian swallowart.

26 Hairy thorn apple (*Datura metel*).

27 *Ephedra sinica*.

28 Leafy spurge (*Euphorbia esula*).

29 Star of Bethlehem, Pua-hoku (*Hippobroma longiflora*).

30 Poverty weed (*Iva axillaris*).

## Schedule 2—continued

**Struck out (unanimous)**

31 Loranthaceae (all species), eg, mistletoes.

**New (unanimous)**

31 Any member of the family Loranthaceae (eg mistletoe), other than *Alepis flavida, lleostylus micranthus, Peraxilla colensoi, Peraxilla tetrapetala, Trilepidea adamsii*, and *Tupeia antarctica*.

31A Any member of the genus *Korthalsella* other than *Korthalsella clavata, Korthalsella lindsayi* and *Korthalsella salicornioides*.

32 Butterbur (*Petasites hybridus*).

**Struck out (unanimous)**

33 Snakeweed, snakeroot (*Polygonum bistorta*).

34 Witchweed (all species) (*Striga*).

35 Strychnine (*Strychnos nux-vomica*).

36 *Tourrettia volubilis*.

37 Puncture vine (*Tribulus terrestris*).

## Legislative history

| | |
|---|---|
| 29 April 2003 | Introduction (Bill 47–1) |
| 6 May 2003 | First reading and referral to Education and Science Committee |

Wellington, New Zealand: Published under the authority of the House of Representatives—2003

47bar2.pag
29-AUG-03

*Price code: K*