New Organisms and Other Matters Bill

Government Bill

Explanatory note

General policy statement

The amendments made by this Bill implement a series of changes to the Hazardous Substances and New Organisms Act 1996 (**HSNO**), the Medicines Act 1981, and the Agricultural Compounds and Veterinary Medicines Act 1997, focused on providing a practical framework for proceeding with caution in the management of new organisms (including genetically modified organisms) while preserving opportunities. The changes form part of the Government's response to the Report of the Royal Commission on Genetic Modification.

The amendments—

- ensure comprehensive and strict regulation by extending HSNO to regulate human cells and the regeneration of animals not present in New Zealand from tissue:
- streamline the process of approving low risk genetic modification work within contained laboratories by providing for approval of such modifications on a project rather than organism basis:
- streamline procedures for assessment and approval of animal or human medicines that are or contain low risk new organisms, including approvals to deal with emergency situations:
- extend the grounds on which the Minister may call in specific applications to include significant cultural, ethical, and spiritual effects:
- provide for the ability to approve the release of new organisms with conditions imposed within a cautious and case-by-case framework. This new category of release provides that—

- every application considered needs to meet the minimum standards as set out in section 36 of HSNO when conditions are imposed:
- a broad range of conditions may be imposed with guidance provided in HSNO:
- the present procedures in HSNO for a release, including the use of a full public process, be used when the conditions or status of a release approval change:

- strengthen the machinery for enforcement and incentives to comply with HSNO in relation to new organisms by specifying that one agency (the Ministry of Agriculture and Forestry) is responsible for all enforcement for new organisms. There is also provision for strict civil liability for harm caused by those in breach of HSNO and a civil penalty regime for the same breaches of HSNO.

In addition, changes to improve the overall effectiveness of the operation of HSNO for new organisms are proposed. These amendments include improving the operability of the law by clarifying the circumstances and procedures for protection of confidential supporting information, completing the transfer of controls on animals in zoos and similar facilities, and amending operational details such as providing more realistic time limits and procedures for dealing with containment decisions.

This Bill also implements changes to meet the Government's stated intention to better reflect the Treaty relationship between Māori and the Crown in HSNO.

All of the amendments in the Bill come into force on the day after the date on which the Bill receives the Royal assent.

Clause by clause analysis

Clause 1 is the Title clause.

Part 1
Preliminary provisions

Clause 2 is the commencement clause. The Bill comes into force on the day after the date on which it receives the Royal assent.

Clause 3 sets out the purpose of the Bill.

Part 2
Hazardous Substances and New Organisms Act 1996

This Part contains amendments to the Hazardous Substances and New Organisms Act 1996. In this part of the analysis, references to sections are to sections of that Act.

Clause 5 amends section 2, which defines terms used in the Act. The amendments insert a number of new terms and amend a number of current definitions. Of particular note,—

- the new definition of **human cells** and the amendment to **organism** means that **organism** includes a human cell:
- the new definition of **regenerative tissue** and the substituted definition of **develop** means that development includes the regeneration of an organism from regenerative tissue:
- the substituted definition of **develop** includes the fermentation of micro-organisms that are new organisms and the amendment to the definition of **field test** to omit the reference to large-scale fermentation of micro-organisms means that approvals for the fermentation of micro-organisms will proceed in the normal way as approvals for the development of new organisms in containment.

Clause 6 amends section 2A, which defines **new organism**. The amendments—

- clarify that an organism is not a new organism if an approval has been granted under section 38 to release an organism of the same taxonomic classification or an organism of the same taxonomic classification has been prescribed as not a new organism:
- provide that a new organism does not cease to be a new organism because it is subject to a conditional release approval under *new section 38C*.

Clause 7 amends section 11, which sets out the powers, functions, and duties of the Environmental Risk Management Authority (**ERMA**). A new function is inserted to approve containment standards for containment facilities. Before exercising the function, ERMA must consult representatives of the classes of persons who are likely to have an interest in the containment standards.

Clause 8 amends section 16 which requires the Minister, when considering whether a person is suitable to be appointed as a member of ERMA, to ensure that the membership includes a balanced

mix of knowledge and experience in matters likely to come before it. The amendment clarifies that *matters* include matters relating to the Treaty of Waitangi and tikanga Māori.

Clause 9 amends section 19, which authorises ERMA to delegate certain powers. The amendments—

- authorise the delegation to any person of the power to conduct rapid assessments under *new sections 42A and 42B* (inserted by *clause 20*), which relate to projects for low-risk genetic modification and to assessment of adverse effects of importing a genetically modified organism into containment:
- authorise the delegation to the responsible chief executive of the power—
    - to approve an application under *new section 38H(1)(b)* to release a qualifying organism:
    - to determine under *new section 38H(3)* whether a medicine is a qualifying medicine or whether a veterinary medicine is a qualifying veterinary medicine.

Clause 10 inserts a new Part 4A which establishes a committee to be called Nga Kaihautu Tikanga Taiao. The function of the committee is to provide advice and assistance to ERMA on matters of policy and process. The advice and assistance must be given from the Māori perspective and come within terms of reference set by ERMA for the committee.

Clause 11 amends section 25, which contains the prohibition on importing, developing, field testing, or releasing a new organism except in accordance with an approval issued under the Act. The amendments provide that,—

- if an organism has a conditional release approval, no further approvals are required for the conditional release of the organism:
- the prohibition on the importation of a new organism does not apply to regenerative tissue:
- the prohibition applies to a new organism that is subject to an innovative agricultural compound application under the Agricultural Compounds and Veterinary Medicines Act 1997 and an innovative medicine application under the Medicines Act 1981.

Clause 12 amends section 27, which defines the different types of approval that can be given under the Act. The amendments insert references to—

- a conditional release approval, which is an approval under *new section 38B* (as inserted by *clause 18*) to import for release, or to release from containment, a new organism with controls:
- an approval to import for release, release, or use under *new section 49E* (as inserted by *clause 26*) an agricultural compound or medicine in a special emergency.

Clause 13 inserts a *new section 27A*, which sets out the requirements for describing new organisms in the types of approval in section 27 that relate to new organisms.

Clause 14 repeals section 29A, which provides for approvals for innovative agricultural compounds and medicines.

Clause 15 amends section 34, which prohibits a person importing for release or releasing from containment a new organism without approval. The section sets out the requirements for an application for approval. A drafting amendment is made to recognise that an application can also be made under *new section 38A* (as inserted by *clause 18*) to import for release or release from containment a new organism with controls.

Clause 16 inserts a *new section 34A* to provide for an application for release of a new organism to be made at or after the time for applying for a conditional release approval for the new organism.

Clause 17 amends section 38, which provides for the approval of an application made under section 34 if the application is not approved under the rapid assessment procedure in section 35. The amendment widens the scope of section 38 so that it applies to an application made under section 34 that is declined under any other section of the Act.

Clause 18 inserts *new sections 38A to 38J*. *New sections 38A to 38G* deal with the conditional release of new organisms. Under *new section 38A*, a person may apply to ERMA for a conditional release approval to import for release, or to release from containment, a new organism with controls. Under *new section 38B*, ERMA may, with the agreement of the applicant, treat an application made under section 34 as if it were an application made under *new section 38A*. ERMA may approve the application under *new section 38C*, which sets out the criteria for determining an application. *New section 38D*

sets out a non-exhaustive list of controls that may be imposed on a conditional release approval. *New section 38E* specifies the duration of a conditional release approval which, depending on the circumstances, may be a date or the happening of an event. *New section 38F* requires a new organism to be destroyed on the expiry of a conditional release approval unless another approval has been granted under the Act. *New section 38G* sets out the extent to which ERMA, on its own initiative or on application, may review the controls it has imposed on a conditional release approval.

New sections 38H to 38J deal with the release of qualifying organisms, ie qualifying medicines and qualifying veterinary medicines being medicines that are or contain new organisms that meet the criteria specified in *new section 38H(2)*. Under *new section 38H*, ERMA may make a rapid assessment of an application made under section 34 that relates to a qualifying organism and approve the importation for release or release from containment of the qualifying organism with or without controls. An approval under *new section 38H* is not an approval to use the qualifying organism until the medicine or veterinary medicine has been approved for use under the Medicines Act 1981 or the Agricultural Compounds and Veterinary Medicines Act 1997. *New section 38I* clarifies the procedure to be followed if ERMA delegates to a responsible chief executive the function of assessing and approving an application to release a qualifying organism. *New section 38J* provides a non-exhaustive list of the types of controls that can be imposed on an approval to release a qualifying organism.

Clause 19 amends section 39, which deals with the importation, development, or field testing of a new organism into containment for certain purposes. The amendments—

- widen the first purpose from the development of any genetically modified organism to the development of any new organism:
- substitutes a *new subsection (2)*, which adds a reference to *new section 38H*:
- adds a *new subsection (3)*, which provides for applications after a conditional release approval for approval to put the organism into containment.

Clause 20 inserts *new sections 42A and 42B. New section 42A* provides an alternative rapid assessment for applications to develop a new organism in containment. The alternative is limited to

developments in projects for low-risk genetic modification. *New section 42B* gives ERMA a discretion to make a rapid assessment of applications to import a new organism in containment and approve an application if satisfied that the criteria for low-risk genetic modification specified in regulations under section 41.

Clause 21 substitutes a *new section 43* about the additional matters ERMA must have regard to when considering an application under section 40(1)(b) to develop a new organism in containment. The current section requires consideration of the matters in or under sections 37 and 41. The new section limits consideration of the matters under section 41 to applications to genetically modify an organism. Consideration of the matters in section 37 continues to apply to all applications.

Clause 22 repeals section 44A(4) consequential on omitting reference to the fermentation of micro-organisms in the definition of **field test** in section 2.

Clause 23 amends section 45, which provides for the approval of an application relating to a new organism under section 40 that is declined under the rapid assessment provisions of section 42. The amendments—

- widen the scope of the section to include applications declined under *new section 42A or new section 42B* (as inserted by *clause 20*):
- generalise the test of balancing beneficial effects and adverse effects (currently limited to the hypothetical escape of the organism):
- insert additional criteria relating to the escape of the organism.

Clause 24 inserts a *new section 45B*, which relates to animals in circuses or zoological gardens that are subject to deemed approvals under the transitional provisions of the Act. The amendments will authorise ERMA to apply containment controls and other controls it considers appropriate to these animals.

Clause 25 amends section 49 which provides that the Act does not apply to a hazardous substance or new organism required for use in an emergency if the emergency or use was not foreseeable. The amendment is of a drafting nature and excludes from the scope of the section the provisions of *new sections 49A to 49K*, which deal with agricultural compounds and medicines in a special emergency. The

new sections apply whether or not the special emergency or use of the compound or medicine was foreseeable.

Clause 26 inserts *new sections 49A to 49K* to provide for the rapid assessment and approval of applications to import for release, release, or use in a special emergency an agricultural compound or a medicine that is or contains a hazardous substance or a new organism. A special emergency is an adverse event (which includes, but is not limited to, an event or emergency specified in section 46(1)) declared to be a special emergency by the responsible Minister under the Hazardous Substances and New Organisms Act 1996, the Biosecurity Act 1993, the Conservation Act 1987, the Fisheries Act 1996, the Health Act 1956, or the Medicines Act 1981. An approval is limited to the importation, release, or use of the agricultural compound or medicine in the special emergency. On the expiry of the approval, the new organism must be disposed of unless, before the expiry, the applicant has been granted an approval under another provision of the Act.

Clause 27 amends section 50, which prohibits the importation or release of organisms specified in *Schedule 2*. The amendments repeal subsection (2) (which permits an organism to be added on the recommendation of the Minister) and substitute a *new subsection (2)*, which—

- provides for an organism or group of organisms to be added if they may have adverse effects on the health and safety of people or the environment:
- provides for the removal of an organism or group or groups of organisms, but only if the organism or organisms were inserted by Order in Council.

The amendments also insert a *new subsection (2B)* which provides that an organism in *Schedule 2* that is prescribed as not a new organism ceases to be a prohibited organism.

Clause 28 makes a drafting amendment to section 51.

Clause 29 amends section 53, which provides for the public notification of applications. The amendments add references to applications for approval under *new sections 38A, 42A, and 42B*.

Clause 30 amends section 55, which deals with information held by ERMA that relates or may relate to applications. The amendments extend the protection afforded to commercially sensitive information in hazardous substances applications to new organism applications.

Clause 31 amends section 57, which deals with requests for information supplied in relation to an application. The amendments relate to a person's failure to respond to a notice from ERMA that it has received a request for information. The amendments—

- require ERMA not only to give the notice but also to make all reasonable efforts to contact the person:
- require ERMA, after the time limit specified in the section, to release or withhold the information in accordance with the Official Information Act 1982.

Clause 32 makes a drafting amendment to section 58.

Clause 33 amends section 59 and specifies time limits for various matters under the Act. The amendments—

- insert references to *new sections 38H, 42A, and 42B*:
- require ERMA to publicly notify its decision as soon as reasonably practicable but not later than 30 working days after a hearing.

Clause 34 amends section 62, which deals with reassessing new organisms in containment and hazardous substances. The amendments insert references to conditionally released new organism and to *new sections 38C, 38H, 42A, and 42B*.

Clause 35 amends section 63, which specifies which groups of sections apply to the reassessment of different types of approval. The amendment inserts new provisions relating to conditional release approvals.

Clause 36 amends section 68, which authorises the Minister to call in and decide applications that have significant economic, environmental, international, or health effects or significant effects in an area in which ERMA lacks sufficient knowledge or experience. The amendment adds reference to significant cultural, ethical, and spiritual effects.

Clause 37 amends section 69, which deals with the time limit and notification in relation to a Ministerial direction to call in an application under section 68. The amendment requires the Minister to give a direction within 30 working days after the date on which ERMA gives public notice of the application.

Clause 38 amends section 71, which deals with the conduct of an inquiry by ERMA after receiving a notice of a Ministerial call in. The amendments are of a drafting nature.

Clause 39 amends section 73, which deals with the decision and notification of it in relation to a Ministerial call in. The amendment is of a drafting nature.

Clause 40 amends section 97, which specifies that certain persons are responsible for enforcing the provisions of the Act in certain circumstances. The amendment clarifies that reference to the provisions of the Act include controls imposed under the provisions of the Act.

Clause 41 inserts a *new section 97A*, which makes the enforcement agency responsible for ensuring that the provisions of the Act are enforced in respect of new organisms. The enforcement agency is the chief executive of the department of State responsible for the administration of the Biosecurity Act 1993.

Clause 42 makes drafting amendments to section 98.

Clause 43 inserts a *new section 98A*, which gives the chief executives of the Ministry for the Environment and of ERMA the same functions, powers, duties, and protections that enforcement officers have under the Act.

Clause 44 makes a drafting amendment to section 99.

Clause 45 makes a drafting amendment to section 103(1)(c).

Clause 46 amends section 106, which provides for the form and content of compliance orders. The amendments—

- omit the requirement that the compliance period must not start earlier than 4 days after the order is served:
- omit the requirement that the order must state the last day on which an appeal can be lodged.

Clause 47 makes a drafting amendment to section 114.

Clause 48 inserts a *new Part 7A* providing for pecuniary penalties and civil liability.

New sections 124A to 124F provide for pecuniary penalties to be imposed for breaches of the Act relating to new organisms. *New section 124B* confers jurisdiction on the Court to make pecuniary penalty orders, but requires the Court not to make an order if it is satisfied that the person concerned did not know, and could not reasonably have known, of the breach. *New section 124C* specifies the maximum amount of a pecuniary penalty that can be ordered, providing separately for individuals and bodies corporate. *New section 124D* authorises the Court, instead of or in addition to a

pecuniary penalty order, to order that a person mitigate or remedy the adverse effects of the breach (or pay the costs of this being done) or to order that the new organism involved in the breach be destroyed or to make both orders. *New section 124E* deals with the standard of proof and certain procedural matters in proceedings for a pecuniary penalty order. *New section 124F* deals with the relationship between proceedings for a pecuniary penalty and criminal proceedings in respect of the same, or substantially the same, act or omission. Primacy is accorded to the completion of criminal proceedings.

New sections 124G and 124H deal with civil liability for harm due to acts or omissions of persons while in breach of certain provisions of the Act relating to new organisms. *New section 124G* makes a person liable in damages for any loss or damage caused by any act or omission of the person while doing certain things involving a new organism in breach of the Act. The section clarifies that a person is liable whether or not the person intended the act, omission, or breach or was taking reasonable care when the act, omission, or breach occurred. The section also clarifies that proceedings under this section are in addition to, and not in substitution for any other cause of action.

New section 124H sets out 3 defences to the liability under *new section 124G*. The first relates to saving or protecting life or health, or preventing serious damage to property, or avoiding an actual or likely adverse effect on the environment. The second relates to events outside the control of the person and the event could not have reasonably been foreseen or provided against. In relation to the first and second defences, the person must also have taken reasonable steps to mitigate or remedy the effects of the breach. The third is that the person did not know, and could not reasonably have known, of the breach.

New section 124I applies for the purposes of *new sections 124B and 124G*. It provides that, in certain circumstances, a person is to be treated as in breach of the Act or as having done or omitted to do an act if the person's director, employee, or agent is in breach of the Act or has done or omitted to do the act. The new section also specifies the extent to which a defence to the breach that is available to the director, employee, or agent is also available to the other person.

Clause 49 amends section 140, which authorises the making of regulations. The amendments—

- authorise the making of regulations prescribing organisms that are not new organisms:
- authorise the making of regulations that prescribe controls for conditionally released new organisms.

Clause 50 repeals the Second Schedule (which lists prohibited new organisms for which no approval to import, develop, field test, or release can be given) and substitutes a *new Schedule 2*. The new schedule omits organisms that are already present in New Zealand in an uncontained environment, and corrects errors in the names of other organisms.

Part 3
Agricultural Compounds and Veterinary Medicines Act 1997

This Part contains amendments to the Agricultural Compounds and Veterinary Medicines Act 1997. In this part of the analysis, references to sections are to sections of that Act.

Clause 52 amends section 12. The amendments parallel those made to the Hazardous Substances and New Organisms Act 1996 by *clause 31*.

Clause 53 amends section 15, which gives the Director-General a discretion to waive the requirement to notify an application to register a trade name product. The amendments—

- insert a reference to a special emergency declared under *new section 49B* of the Hazardous Substances and New Organisms Act 1996 as inserted by *clause 26*; and
- permit the Director-General to waive the requirement to notify an application if the trade name product does not contain a new organism and the Minister has advised the Director-General that an emergency has arisen under the Act and that the Minister agrees to the Director-General considering whether to grant a waiver.

Part 4
Medicines Act 1981

This Part contains amendments to the Medicines Act 1981. In this part of the analysis, references to sections are to sections of that Act.

Clause 55 inserts new definitions into section 2.

Clause 56 inserts *new sections 24A to 24G*. *New section 24A* provides that the Director-General of Health may grant a conditional release approval under *new section 38C* of the Hazardous Substances and New Organisms Act 1996 for a qualifying new medicine if he or she has the consent of the Minister of Health and is acting under a delegation from ERMA. *New section 24B* applies where the Director-General declines to grant an approval. The Director-General must inform ERMA and provide information to ERMA to assist it in making a decision, and the Minister must not consent to the distribution of the medicine unless the Minister receives advice from ERMA that it has approved the release of the medicine.

New section 24C defines terms for the purposes of *new sections 24D to 24G*, in particular **responsible Minister** and **special emergency**, which are defined to have the same meaning as in *new section 49A* of the Hazardous Substances and New Organisms Act 1996 (as inserted by *clause 26*). *New section 24D* gives a responsible Minister power to approve the distribution or use in a special emergency a medicine that is or contains a hazardous substance or new organism. *New section 24E* provides for the notification of an approval. *New section 24F* provides for the duration of an approval under *new section 24D*. Under *new section 24G*, on the expiry of the approval, the medicine must not be distributed or used unless, before the expiry, an approval under other provisions of the Act has been obtained.

Clauses 57 to 60 amend sections 25, 26, 28, and 29, which contain certain exemptions from restrictions on manufacturing, distributing, or selling medicines without approval. The amendments provide that the exemptions do not apply to medicines that are qualifying new medicines.

Regulatory impact and business compliance cost statement

Statement of problem and need for action

Proceeding cautiously while preserving opportunities

The 2-year moratorium on the Environmental Risk Management Authority (**ERMA**) considering applications to release new genetically modified organisms (**GMOs**), agreed to by Parliament in October 2001, expires in October 2003. In its response to the report of the Royal Commission on Genetic Modification, the Government agreed with the major theme of "a precautionary approach" to genetic modification that "preserved options for the future". The

main legislation covering the regulation of new organisms (including GMOs), the Hazardous Substances and New Organisms Act 1996 (**HSNO**), does not fully achieve this objective and needs to be addressed before October 2003.

HSNO provides for controls on the development of GMOs in contained conditions and for the release of new organisms into the environment without any conditions. However, there is no intermediate level of control. This reduces the opportunities for proceeding with caution with genetic modification because new organisms with potential benefits can not be released outside containment with conditions attached to that release.

Improvements to HSNO

HSNO has been in operation for new organisms since 1998, and during that time experience has shown that there are improvements that could be made in the way the Act operates. Some anomalies have shown up in the Act, and some of these have added extra costs to applications. ERMA has found some of the timelines contained in the Act are not realistic. Examples of these are the timelines for ERMA to publicly notify its decisions and to allow the authority to order prompt compliance where enforcement officers have issued a compliance order for breach of the regulations.

Other areas have added unnecessary costs to the application process. At the moment, for example, researchers must make a separate application for every new low-risk GMO developed in the laboratory during a particular research project rather than being able to make a single application for the project as a whole. In the case of medicines, dual approvals are required from Medsafe (in the case of human medicines), or the Agricultural Compounds and Veterinary Medicines (**ACVM**) unit (in the case of animal products), as well as from ERMA for all medicines containing GMOs or living organisms – including those considered to pose a low risk to the environment and public safety.

ERMA has also found problems with the operation of some aspects of HSNO, and sought more clarity around the decision-making process in some areas to allow it to make more accurate assessments of the risks posed by new organisms on a case-by-case basis. Currently, for example, the Authority can only make decisions on risk at the species level, which is not practicable for organisms such as bacteria, where some sub-species or strains within the same species are highly toxic to humans and animals while others are harmless.

The Zoological Gardens Regulations 1997, which cover the containment of zoo and circus animals, expire in July this year. HSNO needs to be amended to take account of this change.

The emerging science of biotechnology (including genetic modification) has been developing rapidly and continues to do so. When HSNO was developed, some technologies that are today a reality had not been anticipated, meaning some areas are not covered by the legislation. An example of this is the regeneration of animals from tissue samples.

Biotechnology, as with any new technology, raises ethical, cultural, and social issues. HSNO does not fully reflect these concerns as it stands at the moment.

More appropriately reflect the Treaty relationship

The Royal Commission was critical of the current wording of HSNO as regards the Treaty of Waitangi relationship between Māori and the Crown and wanted HSNO amended so it was clear that effect was to be given to the principles of the Treaty.

Many Māori who made submissions during the public consultation on the amendment of the Act were of the view that their opinions were not taken seriously or considered early enough in the decision-making process on the development and release of new organisms. Many sought enhanced Māori membership on ERMA.

Applicants are required to consult with Māori well before an application is lodged with the IBSC or ERMA. Both Māori and applicants have expressed concerns about the practical operation of this consultation at present.

Statement of the public policy objectives

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.

Statement of the feasible options to achieve the desired objective and the benefits of the proposal

Proceeding cautiously while preserving opportunities

Options

Status quo

The current provisions of HSNO for release of a new organism require ERMA to consider the application on the assumption that there can be no conditions attached to the release. HSNO currently requires the following considerations in relation to a new organisms release:

- minimum standards – no organism may be considered for release if it is likely to cause significant adverse effects:
- additional matters – an organism is less likely to be released where it is likely to establish an undesirable self-sustaining population and, if it did, where it would be difficult to then eradicate:
- if the above 2 tests are 'passed', an organism may be released only if, on balance, the positive effects outweigh the negative.

HSNO prohibits the organisms listed in the Second Schedule from being imported, developed, or released in New Zealand.

HSNO provides a statutory strict liability regime for criminal offending, but no means by which individuals can be compensated for harm. However, under existing civil liability laws, a person harmed may be able to seek compensation on grounds such as negligence or nuisance.

Non-regulatory means

As HSNO requires a positive decision for the release of any new organism, there are no non-regulatory measures that can achieve the objectives to enable a cautious release of new organisms while maintaining a robust risk management system.

Regulatory means – preferred option

A range of regulatory measures is provided in the Bill for the release of new organisms, including GMOs, that allows for an intermediate level of approval for release (known as **conditional release**). This is supported by enforcement and an enhanced liability regime to ensure compliance.

Deciding when conditional release is possible

The first step in constructing the new approval is to determine the process for arriving at a decision. The options in a decision to release with conditions are to—

- require that the minimum standards test be passed assuming conditions are operative:
- require an organism to pass the minimum standards test without consideration of the conditions to be applied (status quo):
- provide for the minimum standards test to be passed assuming conditions are operative, and with consideration of whether or not the new organism could be recovered or eradicated if desired.

The third option is the preferred option because it provides for the advantages of the first option with the added requirement to consider the feasibility of mitigation, for example, by eradicating the organisms, in cases where conditions fail, thus reducing potential costs.

Criteria for conditions and level of prescription

The second and new step is to determine when and what conditions should be applied. As organisms are enormously varied in their nature and potential effects, the only realistic option is to impose conditions on a case-by-case basis – eg, conditions on large animals will be vastly different from those that could be applied to micro-organisms. However, there are general matters that can be considered in imposing conditions, although not all will be used in every case. The options are to—

- give ERMA full discretion in choosing and applying conditions:
- provide a non-exclusive list of matters and allow ERMA discretion to apply them or any other appropriate condition on a case-by-case basis:
- list matters that must be addressed in every case.

The second option is preferred, thus providing transparency and flexibility in decision making, and greater certainty to the applicant.

Additional safeguards

In addition, the Bill provides a new measure for addition of types of 'intrinsic risk characteristics' (as well as a named organism) to the

prohibited organisms listed in the Second Schedule of HSNO. This prohibits certain organisms from entry to New Zealand, and prevents ERMA from considering applications for these organisms. The likely effect will be to remove from consideration some types of new organisms (and so any risks that arise from their possible approval) but there may be lost opportunities, through removal of organisms from consideration that might otherwise be used, for example, in research. The Bill also allows for a simpler mechanism to remove organisms from the prohibited list.

Enforcement and liability

There is nothing unique about the likely effectiveness of current liability rules in the GM context to warrant a special liability regime for GM activities. Nor is there reason to expect that the costs and benefits of the liability regime are materially different in the GM context. Liability rules may be less effective in certain situations, such as where the harm is to many individuals or the environment. At that point, the regulatory regime, such as HSNO, has an important role in encouraging precaution and it is important that there are strong incentives to comply with the regulatory regime.

Therefore the preferred option is to amend HSNO to include a statutory strict civil liability rule to enable individuals to seek compensation for harm caused by activities in breach of certain provisions of HSNO relating to new organisms; and a civil penalty regime to enable civil penalties to be recovered by the State for breaches of certain provisions of HSNO relating to new organisms. This would strengthen incentives to comply with the regulatory regime without any additional compliance costs for businesses.

The Ministry of Agriculture and Forestry will be the agency responsible for all enforcement activity related to new organisms.

It is expected that business would only begin any application process in situations where they anticipate a clear economic benefit, even allowing for the cost of meeting any conditions that may be imposed. In addition, conditions on an approval will require checking for compliance. Compliance and enforcement activity is a cost to the Government which is budgeted for in the agriculture budget.

The new category of conditional release and measures supporting it impact on people in the vicinity of conditional releases, especially in the case of organic farmers, and also for any non-GM human food producers. They will be protected by the successful operation of the

new provisions. However, the costs and benefits to non-GM users have not been quantified but may include activity such as testing for the presence of GM organisms. Also, breaches of conditions may mean they are faced with costs, for example due to contamination issues. The new liability provisions will provide additional mechanisms by which any breaches can be addressed.

Summary

Compared to the status quo of having only field trials and general release approvals, conditional release with an enhanced liability regime under the above preferred options is considered to—

- provide greater flexibility in the use of new organisms (including GMOs) that are assessed by ERMA to generate a positive net benefit:
- increase the economic benefits from application of this new technology by allowing managed use of organisms unlikely to meet the requirements for full release:
- minimise the risks of negative impacts, including on those for whom GMOs are an affront to their cultural, spiritual or ethical values:
- provide a higher level of environmental and public health and safety protection available through the use of conditions on releases.

Costs could be incurred if the new organism has unforeseen impacts or impacts that cannot adequately be controlled, even with the conditions imposed at the time of release. These costs may be on individuals in the form of non-GM users or across the community as a whole.

Improvements to HSNO

Status quo	**Preferred option**
Streamline process	
All medicines containing a new organism must get two approvals, from ERMA for environmental safety, and from: a. Medsafe for human medicines b. Agricultural Compounds and Veterinary Medicines Unit (ACVM) for animal medicines.	Streamline approvals by providing a rapid assessment process in the HSNO Act for animal and human medicines containing new organisms that meet low risk criteria, and allowing the decision to be delegated. Reduces costs for applicants while at the same time providing comprehensive coverage for foreseeable situations.

Status quo	**Preferred option**
Government agencies are required to obtain a prior approval through the public processes of HSNO for any agricultural compound, animal or human medicine containing a new organism needed in a health or bio-security emergency and this may cause delays.	Provide a fast-track approval system, requiring only consultation with affected government agencies, for animal and human medicines, vaccines, and pesticides containing new organisms needed in an emergency – the procedure to be strictly limited to emergency use only. Avoids any delay in providing an emergency response.
Approval of research to develop "low-risk" GMOs (i.e. organisms considered to present minimal risks to people and the environment **and** contained in a registered containment facility – a laboratory or glasshouse) are usually made by Institutional Biological Safety Committees (**IBSCs**) under delegation from ERMA. However, ERMA must approve imports of the same low-risk GMOs, a complex and time-consuming process given the low level of risk.	Allow IBSCs to approve import of low risk organisms into containment on a case-by-case basis. This is to apply **only** to imports for the institution represented by the IBSC. Provides cost savings to applicants.
Researchers must make an application for each individual new organism developed during a single research project.	Allowing approval on a 'project' basis for low-risk development in containment provides cost savings to applicants and encourages compliance.
Clarify and update processes	
An organism is defined taxonomically as one belonging to a 'species.'	Change the definition of new organism so that it is not limited to 'species'. Improves ERMA's ability to assess risks posed by a given organism.
Large-scale fermentation can only be assessed as a field test and for processes over 10 litres, thus it is based on volume not on risk.	Allow assessment of fermentation of micro-organisms by risk and not volume. Allows ERMA to use the most appropriate assessment methods.
ERMA must notify its decisions within 15 days of the conclusion of a hearing or its considerations.	Extend the deadline before which ERMA must notify its decisions. Provides more appropriate and realistic timelines for decision making.
Compliance orders state a period within which a remedial action must be taken (this is currently not less than 4 days).	Remove 4-day requirement for compliance orders. Allows enforcement agencies to determine the most appropriate time period for compliance.
All organisms that were not present in New Zealand before 29 July 1998 are considered new organisms, even when they are naturally introduced to New Zealand or have arrived as accidental 'hitchhikers'.	Allow regulations to declare organisms no longer new if this proves to be the case under certain circumstances. Avoids unnecessary restrictions, and applications for release, for organisms already here.
Applications for containment of organisms are determined in accordance with section 45 which requires ERMA to take account of effects of the organism and whether it can be adequately contained.	Clarifies the decision-making path when ERMA considers approvals for new organisms in containment to include both risks of escape and impact of controls to prevent that risk. Makes it clear how ERMA should arrive at its decisions.
Zoo and circus animals are managed under the transitional provisions of HSNO and the Zoological Gardens Regulations which expire on 28 July 2003.	Include zoo and circus animals in HSNO and allow ERMA to make and vary all the necessary controls. Brings organisms that would not be otherwise released into a consistent framework with other new organisms.

Status quo	**Preferred option**
'Future-proof' by closing regulatory gaps	
Human cells are not included in the definition of an 'organism'.	Approval will be required to import genetically-modified human cells or to genetically modify human cells or tissues in New Zealand. Applies only to certain developments using human cells in culture. Any therapeutic procedures are covered by health-ethics committees and other legislation. Any procedures involving the genetic modification of people will be addressed by the proposed human assisted reproductive technology legislation. Brings these into line with other similar developments.
Tissue regeneration is not covered in the definition of 'develop'.	Definitions in HSNO will cover regeneration of an organism from tissues, cells or other genetic material when that organism would be a new organism to New Zealand. Ensuring organisms new to New Zealand that may in future be developed using this technology will be covered by legislation.
Ministerial call-in applies for significant economic, environmental, international and health effects as well as in cases where it is judged ERMA lacks sufficient knowledge or experience to decide the case.	The matters on which the Minister for the Environment can exercise call-in powers will be extended to include significant cultural, ethical and spiritual issues, but without further defining the terms. Provides the Minister with the desired call-in ability without the constraint of defined terms, and provides certainty on the matters that may be considered for call-in.

More appropriately reflect the Treaty relationship

Options

Status quo

HSNO currently reflects the Treaty relationship by stating, in section 8, that "all persons exercising powers and functions under this Act shall take into account the principles of the Treaty of Waitangi". In addition, ERMA is advised on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga, and the above section 8 issues by Nga Kaihautu Tikanga Taiao, a non-statutory advisory group. HSNO requires applicants to provide information on all possible adverse effects of an organism.

Non-regulatory means

Options to increase Māori participation at an earlier stage in the decision-making process include—

- establishing and supporting a national network of Institutional Biological Safety Committee Māori representatives, using

existing structures, to share information between institutions, regions, and hapu or iwi:

- encouraging pre-application discussions between iwi or hapu and prospective applicants.

Benefits will be a more structured and enhanced system for Māori involvement in decision making and hence applications that more appropriately address Māori interests. Māori would, through time, become better informed about the HSNO Act and the technologies it regulates, and applicants and ERMA would become better informed about tikanga Māori. The result would be better-informed decision-making.

There will be some financial costs to the Government involved in setting up and maintaining networks and their lines of communication, and in relationship-building between applicants and iwi or hapu.

There may be additional time and costs faced by applicants as they establish or build on existing relationships with iwi or hapu. These costs should reduce to some extent as communication systems are refined and relations improved.

Regulatory means

Options considered included—

- strengthen the wording of section 8 to 'give effect to' the principles of the Treaty:
- elevate the current section 6(d) (the relationship of Māori with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga) to become section 5(c), thus making it more prominent in the Act and a matter that must be recognised and provided for:
- add knowledge of the Treaty of Waitangi and tikanga Māori in the mix of skills considered for ERMA members:
- making Nga Kaihautu Tikanga Taiao a statutory advisory body to ERMA on the above matters of interest to Māori, and for ERMA to appoint the chair and members.

The statutory measures are to ensure greater weighting is accorded Māori views when a decision is made on an application. ERMA members, because of their greater knowledge, will be able to make better decisions. Nga Kaihautu Tikanga Taiao will have more visibility and their involvement in processes will be more transparent.

A combination of the third and fourth regulatory options and both the non-regulatory means is preferred.

Consultation

This Bill is based on decisions incorporating the submissions from an extensive public consultation on the discussion paper *Improving the Operation of the HSNO Act for New Organisms: Including Proposals in Response to Recommendations of the Royal Commission on Genetic Modification.* Officials encouraged submissions through meetings with many different stakeholder groups and at 7 hui. Over 1,000 submissions were received. Many of these were form or brief submissions from private individuals, but detailed submissions came from the agribusiness and forestry sector, environmental groups, the science and research community, Māori organisations, local authorities, religious and ethics groups, universities, legal organisations, organics producers, unions, and professional bodies.

A large number of submissions, many identical or nearly identical, commented on the need to retain a 'GE free status' for New Zealand. These comments varied from outright rejection of genetic modification through to recommendations that it be confined to certain uses, such as medical use. Another common theme was that genetic modification in the laboratory was acceptable but that the risks of moving any GM organism out of containment were too large.

Submissions from organics producer groups and the bee products industry expressed fears about the effects on their business if GM organisms were permitted out of the laboratory. Some of these submissions also sought measures to allow local authorities to create GE-free zones and recommended extended liability rules to encourage precaution in the use of GM organisms.

Submissions from those working in research, including medicines, felt regulation of GM work in the laboratory and in human and animal medicines was too restrictive and called for the process to be streamlined.

A theme of submissions from those involved directly or indirectly in agriculture or the seeds business was that the present regulation of new organisms is unnecessarily inhibiting economic growth. Submissions in this group also supported the provision of conditional release, but did not consider it necessary to extend liability rules.

Written submissions from Māori organisations and records from hui expressed a strong view that the level of consultation and time provided was inadequate given the complexity of the issues raised. This was coupled with a frustration about a paucity of information available to Māori and that Māori community views were not taken seriously or considered early enough either in policy formation or in decision making about genetic modification. Many submissions expressed opposition to genetic modification and sought strengthening of the obligations in law in respect of the Treaty of Waitangi.

Submitters generally proposed that the costs be borne by those who benefit. The research and business sectors considered that the Government should continue to support application costs because they considered there was a public benefit from introducing new technology. Other submitters considered that the applicants received all the benefits and proposed that they bear the full cost of applications, including the cost of checking compliance with conditions.

The following government agencies were consulted and actively involved in the preparation of this Bill: Ministry of Agriculture and Forestry, Department of Conservation, Ministry of Economic Development, Ministry of Foreign Affairs and Trade, Ministry of Health, Ministry of Justice, Department of Prime Minister and Cabinet, Ministry of Research Science and Technology, Te Puni Kōkiri, the Treasury, the Environmental Risk Management Authority, and the New Zealand Food Safety Authority.

Business compliance cost statement

Source of the compliance cost

Variable compliance costs will occur depending on the situation. In some situations, compliance costs will increase, for example,—

- costs of making a conditional release application, which may include costs of buying in specialist services, and training or employing new staff:
- users of conditionally released new organisms will be required to ensure compliance with control requirements:
- in the short term, the costs of identifying and understanding the regulatory requirements:
- other matters such as doing a pre-application assessment on the taxonomic level.

The Bill is intended to reduce compliance costs in other areas:

- streamlining the approval process for medicines that are or contain new organisms, for emergency situations, for low-risk organisms:
- clarifying large-scale fermentation approvals and declaring organisms no longer new.

Parties likely to be affected

The parties affected directly will be—

- applicants importing or developing new organisms for conditional release in New Zealand. The sector is broad and highly significant in the New Zealand economy, covering all areas of biologically based industries interested in the commercialisation of new organisms. For example, it would encompass all agricultural, horticultural, forestry, and fisheries industries:
- universities, CRIs, and some private companies conducting genetic research on low-risk GMOs. Only about 4 private companies appear to be currently involved in such work in New Zealand, with staff numbers ranging from about 10 to 200 researchers:
- applicants for (importers and manufacturers of) medicines that are or contain new organisms. Medsafe estimate that approximately 5 importers and manufacturers of human medicines might be expected to make application for new organism medicines. The Agricultural Compounds and Veterinary Medicines Group estimate about 5 applications from importers and manufacturers of new organism animal medicines.

Estimated compliance costs of the proposal

The costs of understanding the new procedures for an approval are considered small relative to the application itself, as the procedure will be similar to applications for field trials and for general release with which the industry is familiar.

The new cost of applications will vary depending on the type of approval sought, for example—

- a conditional release application is expected to be similar to other notified new organisms applications. To date, these

have ranged from an average of $47,000 to $84,000 depending on the type of application, with the costs presently shared between the applicant and the Government:

- an approval for release of a low-risk new organism medicine is expected to reduce from $47,000 (notified new organism release) to $5,000 (non-notified release):
- a large-scale fermentation application will reduce from the current range of $30,000–$60,000 for field tests to $3,000–$12,000 (non-notified development in containment) and $25,000–$35,000 (notified development). Large-scale fermentation (which are highly contained to prevent contamination and therefore prevent the organism from escaping) will be assessed as a development in containment.

It should be noted that the Government has decided to fund part of the costs of applications and decides the rate of this funding from time to time, which is currently on average 54% of the application cost.

The costs of meeting control requirements and achieving compliance have not been assessed. These will vary on a case-by-case basis, particularly for conditional releases.

Long-term implications of compliance costs

The compliance costs will remain for the period of the approval.

The application cost savings for certain applications continues into the future.

Over time, the costs of understanding the new process will reduce.

Level of confidence of compliance cost estimates

Based on the nature of the changes and ERMA's records of costs, there is a high level of confidence in the application cost estimates. As noted, other costs depend on the nature of individual applications.

Key compliance cost issues identified in consultation

No compliance costs of these proposals were identified in consultation.

Overlapping compliance requirements

The proposed changes clarify the interface between HSNO and the Medicines Act 1981, and between HSNO and the Agricultural Compounds and Veterinary Medicines Act 1997 (**ACVM**).

The Resource Management Act 1991 (the **RMA**) has not been used to control the use or effects of GMOs or new organisms to date. With the introduction of conditional release under HSNO, local authorities may be asked to consider introducing additional controls under the RMA. Section 32 of the RMA will require a local authority to demonstrate why any such controls are necessary and what effects they are addressing that have not already been dealt with under HSNO. However, conditional releases are a new provision, and the Ministry for the Environment will monitor how the interface between the RMA and HSNO is working.

Steps taken to minimise compliance costs

The purpose of much of this Bill is to reduce compliance costs. A communication strategy will be undertaken to inform applicants of the legislative changes and their potential obligations under the new legislation. ERMA will advise interested parties of any legislative changes, and their impacts, by means of seminars, information sheets, web publishing and individual attention. In addition, Medsafe and ACVM will ensure potential applicants receive information on the revised approval process through information sheets made available on websites, and through agency newsletters.

In terms of managing the information requirements at the time of application, ERMA already provides significant support to applicants, and this will apply to applicants for conditional release. Support is in the form of documentation such as application guides, including outlining information requirements and technical guides on risk assessment. All of these initiatives serve to educate and inform applicants so that compliance costs in preparing applications are minimised.

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.

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

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)**

"**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:

"(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".

(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 paragraph:

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

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

"(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.

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

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:".

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.

"(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 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.

"(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 on the date that section 55(3) to (6) ceases to apply either to the Authority or to any information held by the Authority in relation to the hazardous substance 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."

12 Types of approval

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

"(ba) a conditional release approval to import for release or release from containment a new 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)**, 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

"(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 the same taxonomic classification with the same genetic modification."

14 Approvals for innovative agricultural compounds and medicines

Section 29A of the principal Act is 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**); and

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

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

"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."

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 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 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)."

20 New sections 42A and 42B inserted

The principal Act is amended by inserting, after section 42, the following sections:

"42A **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 the importation of genetically modified organisms**

"(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 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

"(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 new organism, the 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**".

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".

(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".

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".

(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 paragraph:

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

(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 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".

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 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.

"(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", 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

"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 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.

"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 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 to avoid or mitigate illness or injury to people 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**.

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".

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 approval under **section 38C** 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 approval because the new organism is not a qualifying new medicine, then—

"(a) the Director-General—

"(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 to the distribution 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 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, 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.

"(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."

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."

s 50

Schedule
New Schedule 2 substituted in principal Act

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

Schedule 2
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*).

31 Loranthaceae (all species), eg, mistletoes.

32 Butterbur (*Petasites hybridus*).

Schedule 2—continued

33 Snakeweed, snakeroot (*Polygonum bistorta*).

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

35 Strychnine (*Strychnos nux-vomica*).

36 *Tourrettia volubilis*.

37 Puncture vine (*Tribulus terrestris*).

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

5072V14
28-APR-03
47bar1

Price code: K