

The Hazardous Substances and New Organisms Act

Existing Law and Proposed Amendments

This version of HSNO comprises the existing Act (including the amendments made under the 2002 HSNO Amendment Act) and the changes Government has proposed under the **New Organisms and Other Matters Bill 2003**. In this document, Government proposals contained in the Bill feature as redline insertions. Square, italicised brackets indicate the clauses in the Bill that introduce the amendments.

This version of the Act does not include:

- Changes to the Medicines Act 1981 and to the Agricultural Compounds and Veterinary Medicines Act 1997 proposed by Government in the Bill
- Changes to the Second Schedule of the HSNO Act
- Sections related to hazardous substances (sections 28-33 and 74-96)
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BE IT ENACTED by the Parliament of New Zealand as follows

PART I – PRELIMINARY

1. Short Title and Commencement

- (1) This Act may be cited as the Hazardous Substances and New Organisms Act 1996.
- (2) This Act shall come into force on a date to be fixed by the Governor-General by Order in Council; and one or more Orders in Council may be made fixing different dates for different provisions and for different purposes.

2. Interpretation-

- (1) In this Act, unless the context otherwise requires,-

“**Advertisement**” means any publication to the community or to any section of the community of any words, whether written or printed, spoken, or in any electronic form, or of any pictorial representation or design or device, used to promote the sale of any hazardous substance; and “to advertise” has a corresponding meaning:

“**Aerodrome**” has the same meaning as in section 2 of the Civil Aviation Act 1990:

“**Aircraft**” has the same meaning as in section 2 of the Civil Aviation Act 1990:

“**Amenity values**” means those natural or physical qualities and characteristics of an area that contribute to people's appreciation of its pleasantness, aesthetic coherence, and cultural and recreational attributes:

[“**approved form**” means a form approved by the Authority under section 11(fa)]

“**Authority**” means the Environmental Risk Management Authority established under section 14 of this Act:

“**Bioaccumulation**” means accumulation within the tissues of living organisms:

“**Building**” has the same meaning as in section 3 of the Building Act 1991:

“**By-product**” means an incidental or secondary product made in the manufacture of another product:

“**Carrier**”, in relation to a craft, means the owner or charterer of the craft; and, where the owner or charterer is not in New Zealand, includes the agent in New Zealand of the owner or charterer or, if there is no such agent in New Zealand, the person in charge

“**Code of practice**” means any document issued or approved in accordance with section 78 of this Act:

“**Compound**” means any chemical combination of chemical elements:

“conditional release approval means an approval under section 38C [Clause 5 (1) of the Bill]

“conditionally released new organism means a new organism that is subject to a conditional release approval [Clause 5 (1) of the Bill]

“**Container**” means any vessel or structure, whether moveable or fixed, in which hazardous substances may be cased, covered, enclosed, contained, or packed; and-

- (a) Includes,-
 - (i) Any vessel (other than part of a vehicle's fuel system) which forms an integral part of any vehicle; and
 - (ii) Any stationary container; and
 - (iii) Any package;

(b) Does not include any landfill:

“**Containment**” means restricting an organism or substance to a secure location or facility to prevent escape; and includes, in respect of genetically modified organisms, field testing and large scale fermentation:

“**Containment facility**” means,-(b) In relation to genetically modified organisms, a facility which complies with the controls imposed by an approval granted under ~~section 42 or 45 of this Act any of sections 42, 42A, 42B, or 45~~ [Clause 5 (2) of the Bill]:

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

“**Controller**” means the person for the time being in charge of a location or facility:

“**Controls**” means any obligations or restrictions imposed on any hazardous substance or new organism, or on any person in relation to any hazardous substance or new organism, by this or any other Act or any regulations, rules, codes, or other documents made in accordance with the provisions of this or any other Act for the purposes of controlling the adverse effects of that substance or organism on people or the environment:

“**Customs officer**” means any person holding office as an officer of Customs under the Customs Act 1966:

“**Craft**” means any form of aircraft, ship, or other vehicle or vessel capable of being used to transport any substance to or from New Zealand from or to any country outside New Zealand:

~~“**Develop**”, in relation to organisms, means genetic modification of any organism; but does not include field testing:~~

~~(a) In relation to a hazardous substance,—~~

- ~~(i) Treating the substance in such a way that it is no longer a hazardous substance; or~~
- ~~(ii) Discharging the substance into the environment as waste; or~~
- ~~(iii) Exporting the substance as waste from New Zealand:~~

~~(b) In relation to a new organism,—~~

- ~~(i) Rendering the organism biologically inactive in such a manner as to prevent the occurrence of any future biological activity; or~~
- ~~(ii) Exporting the organism from New Zealand:~~

~~“**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”.[Clause 5 (3) of the Bill]~~

“**Distribution system**” has the same meaning as in section 2 of the Gas Act 1992:

“**Ecotoxic**” means capable of causing ill health, injury, or death to any living organism:

“**Effect**” includes-

- (a) Any potential or probable effect; and
- (b) Any positive or adverse effect; and
- (c) Any temporary or permanent effect; and
- (d) Any past, present, or future effects; and

- (e) Any acute or chronic effect; and
- (f) Any cumulative effect which arises over time or in combination with other effects:

“Enforcement officer” means an enforcement officer appointed under section 98 or section 99(3) of this Act:

“Environment” includes-

- (a) Ecosystems and their constituent parts, including people and communities; and
- (b) All natural and physical resources; and
- (c) Amenity values; and
- (d) The social, economic, aesthetic, and cultural conditions which affect the matters stated in paragraphs (a) to (c) of this definition or which are affected by those matters:

“Environmental user charge” means an amount of money payable per unit mass of a hazardous substance:

“Explosive” means capable of sudden expansion owing to a release of internal energy; and includes the capability to generate-

- (a) Deflagration; or
- (b) Pyrotechnic effects,-

and “explosion” has a corresponding meaning:

“Exportation” has the same meaning as in section 2 of the Customs Act 1966; and “to export” has a corresponding meaning:

“Field test” means, in relation to an organism, the carrying on of trials on the effects of the organism under conditions similar to those of the environment into which the organism is likely to be released, but from which the organism, or any heritable material arising from it, could be retrieved or destroyed at the end of the trials; ~~and includes large-scale fermentation of microorganisms~~ [Clause 5 (4) of the Bill]:

“Firework” means an object containing small quantities of hazardous substances with explosive properties enclosed in a case of paper or similar material of such a strength, construction, and character that the ignition or explosion of one such firework will not cause the explosion en masse of similar fireworks kept or carried with it, and whose sole or principal effect is not percussive or vertical or horizontal flight:

“Gas appliance” has the same meaning as in section 2 of the Gas Act 1992:

“Gas installation” has the same meaning as in section 2 of the Gas Act 1992:

[**“genetic element”**, in relation to a new organism, means-

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

“Genetically modified organism” means, unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material-

- (a) Have been modified by in vitro techniques; or
- (b) Are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques:

“**Hazard classification**” means a combination of the hazardous property of a substance and the level or type of hazard related to that property prescribed in accordance with section 74 of this Act:

“**Hazardous substance**” means, unless expressly provided otherwise by regulations, any substance-

- (a) With one or more of the following intrinsic properties:
 - (i) Explosiveness:
 - (ii) Flammability:
 - (iii) A capacity to oxidise:
 - (iv) Corrosiveness:
 - (v) Toxicity (including chronic toxicity) :
 - (vi) Ecotoxicity, with or without bioaccumulation; or
- (b) Which on contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased) generates a substance with any one or more of the properties specified in paragraph (a) of this definition:

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

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

[Clause 5 (1) of the Bill]

"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: *[Clause 5 (1) of the Bill]*

“**Identification**” means the provision of any information about a substance or organism which-

- (a) Clearly identifies the chemical or biological nature of the substance or organism:
- (b) Specifies the nature and degree or type of hazard intrinsic to the substance or organism:
- (c) Describes precautions to be taken by persons managing hazardous substances to avoid injury to people or environmental damage:
- (d) Directly or indirectly aids in managing any hazardous effect of a hazardous substance:(e) Identifies and specifies the means of contacting any person knowledgeable in the management of the substance:

“**Import**”, in relation to new organisms, has the same meaning as in section 2(1) of the Biosecurity Act 1993:

“**Importation**”, in relation to hazardous substances, has the same meaning as in section 47 of the Customs Act 1966; and “to import”, in relation to those substances, has a corresponding meaning:

“**Inseparable organism**” means any organism which is unable to be separated from any other organism:

“**Intrinsic values**”, in relation to ecosystems, means those aspects of ecosystems and their constituent parts which have value in their own right, including-

- (a) Their biological and genetic diversity; and
- (b) The essential characteristics that determine an ecosystem's integrity, form, functioning, and resilience:

[“**laboratory**” means a vehicle, room, building, or any other structure set aside and equipped for scientific experiments or research, for teaching science, or for the development of chemical or medicinal products]

“**Landfill**” means any premises used for the lawful deposit or disposal of waste materials into or onto land:

“**Lifecycle**”, in relation to a substance, means the time for which the substance is in existence from (and including) its manufacture or importation to its disposal:

“**Manufacture**”, in relation to a hazardous substance, includes the mining or extraction of any hazardous substance:

“**Member**” means a member of the Authority:

“**Minister**” means the Minister for the Environment:

“**Motor vehicle**” has the same meaning as in section 2(1) of [the Land Transport Act 1998]:

“**Natural and physical resources**” has the same meaning as in section 2(1) of the Resource Management Act 1991:

[“**New organism**” has the meaning given to it by section 2A:]

“**Organism**”-

~~(a) Does not include a human being or a genetic structure derived from a human being:~~

~~(a) does not include a human being:~~

~~(ab) includes a human cell: [Clause 5 (5) of the Bill]~~

(b) Includes a micro-organism:

(c) Includes a genetic structure, ~~other than a genetic structure derived from a human being~~ other than a human cell [Clause 5 (6) of the Bill], that is capable of replicating itself, whether that structure comprises all or only part of an entity, and whether it comprises all or only part of the total genetic structure of an entity:

~~(ca) includes regenerative tissue: [Clause 5 (7) of the Bill]~~

(d) Includes an entity (other than a human being) declared to be an organism for the purposes of the Biosecurity Act 1993:

(e) Includes a reproductive cell or developmental stage of an organism:

“**Person**” includes the Crown:

“**Place of work**” has the same meaning as in section 2(1) of the Health and Safety in Employment Act 1992:

“**Port of entry**” has the same meaning as in the Customs Act 1966:

[“**premises**” includes a dwelling, building, aircraft, ship, carriage, vehicle, box, receptacle, and place]

“**prescribed** means prescribed by regulations made under this Act [Clause 5 (1) of the Bill]

[“**Public health**” has the same meaning as in section 6(1) of the New Zealand Public Health and Disability Act 2000]

[“**public notice**” means-

- (a) a method determined by the Authority under section 53A; or
- (b) if section 53A does not apply or no method has been determined under that section, a notice published in 1 or more daily newspapers circulating in the main metropolitan areas together with such other public notice (if any) as the Authority or Minister thinks fit]

“**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) [Clause 5 (1) of the Bill]

“**qualifying organism** means a new organism that is or is contained in a qualifying medicine or qualifying veterinary medicine: [Clause 5 (1) of the Bill]

“**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) [Clause 5 (1) of the Bill]

“**Rail service vehicle**” and “**light rail vehicle**” have the same meanings as in section 2(1) of the Transport Services Licensing Act 1989:

“**Railway line**” has the same meaning as in section 2(1) of the Transport Services Licensing Act 1989:

“**regenerative tissue** means biological material from a new organism that cannot, without human intervention, be used to reproduce the organism [Clause 5 (1) of the Bill]

“**Regulations**” means regulations in force under this Act:

“**Release**”, in relation to new organisms, means to allow the organism to move within New Zealand free of any restrictions other than those imposed in accordance with the Biosecurity Act 1993 or the Conservation Act 1987:

[“**research and development**”, in relation to a hazardous substance, means systematic investigation or experimentation activities that involve innovation or technology transfer for the purpose of gaining knowledge about the properties or uses of that substance]

“**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 [Clause 5 (1) of the Bill]

“**Risk species**” means any species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species under section 140 of this Act:

“**Road**” has the same meaning as in section 2(1) of [the Land Transport Act 1998]:

“**Serious harm**” has the same meaning as in the First Schedule to the Health and Safety in Employment Act 1992:

“**Serious environmental damage**” means any environmental damage prescribed under section 140 of this Act:

“**Ship**” has the same meaning as in section 2(1) of the Maritime Transport Act 1994:

“**Stationary container**” means any building or part of a building, or vessel supported by or incorporated in any building, which is expressly designed to contain any hazardous substance:

“**Substance**” means-

- (a) Any element, defined mixture of elements, compounds, or defined mixture of compounds, either naturally occurring or produced synthetically, or any mixtures thereof:
- (b) Any isotope, allotrope, isomer, congener, radical, or ion of an element or compound which has been declared by the Authority, by notice in the Gazette, to be a different substance from that element or compound:
- (c) Any mixtures or combinations of any of the above:
- (d) Any manufactured article containing, incorporating, or including any hazardous substance with explosive properties:

“**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**” [Clause 5 (1) of the Bill]

“**Territorial authority**” has the same meaning as in section 2(1) of the Local Government Act 1974:

[“**Test certificate**” means a certificate issued by a test certifier in accordance with section 82:]

“**Toxic**” means capable of causing ill-health in, or injury to, human beings:

“**Tracking system**” means a system established under regulations made under section 76 of this Act:

“**Transferable permit**” means any permit to import or manufacture a hazardous substance issued in accordance with a transferable permit scheme:

“**Transferable permit scheme**” means any scheme established in accordance with section 87 of this Act:

“**Transshipment**” means the importation into New Zealand of a hazardous substance or new organism solely for the purpose of export within 20 working days to another destination outside New Zealand:

“**Treaty of Waitangi (Te Tiriti o Waitangi)**” has the same meaning as the word “Treaty” as defined in section 2 of the Treaty of Waitangi Act 1975:

“**Weapons system**” means any ammunition, explosive, or propellant; and includes any platform designed to carry any combination thereof:

“**Working day**” means any day except-

- (a) A Saturday, a Sunday, Good Friday, Easter Monday, Anzac Day, Labour Day, the Sovereign's birthday, and Waitangi Day; and
 - (b) A day in the period commencing on the 20th day of December in any year and ending with the 15th day of January in the following year.
- (2) For the purposes of paragraph (a) of the definition of the term “substance” in section 2(1) of this Act, the definition of any mixture of elements or mixture of compounds may include a range of percentages of the elements or compounds making up the substance.

[2A. **Meaning of term**

“**New organism**”-

- (1) A new organism is-

- (a) An organism belonging to a species that was not present in New Zealand immediately before 29 July 1998:
- (b) An organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation:
- (c) An organism for which a containment approval has been given under this Act:
- (ca) an organism for which a conditional release approval has been given: [Clause 6(1) of the Bill]
- (d) A genetically modified organism:
- (e) An organism that belongs to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.

~~(2) An organism ceases to be a new organism when an approval has been given in accordance with this Act for the importation for release or release from containment of an organism of the same kind as the organism.~~

(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. [Clause 6(2) of the Bill]

- (3) Despite the provisions of this section, an organism present in New Zealand before 29 July 1998 in contravention of the Animals Act 1967 or the Plants Act 1970 is a new organism.
- (4) Subsection (3) does not apply to the organism known as rabbit haemorrhagic disease virus, or rabbit calicivirus.]

3. Act to bind the Crown-

- (1) Except as provided in subsections (2) to (8) of this section, this Act shall bind the Crown.
- (2) Subject to subsections (3) to (8) of this section, this Act shall not apply to any hazardous substance controlled by the Minister of Defence.
- (3) The Chief of Defence Force shall develop codes of practice for hazardous substances controlled by the Minister of Defence and contained in any weapons system.
- (4) The codes of practice developed under subsection (3) of this section-
 - (a) Shall meet the requirements prescribed by regulations made in accordance with section 75 of this Act; and

- (b) May incorporate or adapt any relevant international code of practice.
- (5) The Chief of Defence Force-
 - (a) Shall ensure that methods of controlling all hazardous substances not contained in any weapons system and controlled by the Minister of Defence conform to the relevant requirements prescribed by regulations made in accordance with section 75 of this Act; and
 - (b) May comply with the requirements by following the relevant code of practice approved under section 79 of this Act.
- (6) The Secretary of Defence shall audit the controls on hazardous substances under the control of the Minister of Defence in accordance with section 24(2) (e) of the Defence Act 1990, and report the results to the Minister and the Minister of Defence.
- (7) Any person may report to the Authority a breach of the requirements required to be met by any regulations in relation to hazardous substances under the control of the Minister of Defence.
- (8) Where an incident occurs which involves any hazardous substance under the control of the Minister of Defence and the incident is not being investigated under the Armed Forces Discipline Act 1971, the Authority may, after consultation with the Minister and the Minister of Justice and the Minister of the Crown who is responsible for the Department for Courts, direct an inquiry to be held before a District Court Judge.
- (9) To assist the Judge, the Authority may appoint 2 or more people with skills or knowledge relevant to the subject-matter of the inquiry.
- (10) The Judge may hold the inquiry at any times and places the Judge appoints, and shall report on the cause of the incident to the Authority.
- (11) The Judge has all the powers of a Commission of Inquiry under the Commissions of Inquiry Act 1908; and subject to subsections (9) and (10) of this section, that Act shall apply accordingly.

PART II - PURPOSE OF ACT

4. Purpose of Act-

The purpose of this Act is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms.

5. Principles relevant to purpose of Act-

All persons exercising functions, powers, and duties under this Act shall, to achieve the purpose of this Act, recognise and provide for the following principles:

- (a) The safeguarding of the life-supporting capacity of air, water, soil, and ecosystems:
- (b) The maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing and for the reasonably foreseeable needs of future generations.

6. Matters relevant to purpose of Act-

All persons exercising functions, powers, and duties under this Act shall, to achieve the purpose of this Act, take into account the following matters:

- (a) The sustainability of all native and valued introduced flora and fauna:
- (b) The intrinsic value of ecosystems:

- (c) Public health:
- (d) The relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga:
- (e) The economic and related benefits to be derived from the use of a particular hazardous substance or new organism:
- (f) New Zealand's international obligations.

7. Precautionary approach-

All persons exercising functions, powers, and duties under this Act, including but not limited to, functions, powers, and duties under sections [28A,] 29, 32, 38, 45, and 48 of this Act, shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

8. Treaty of Waitangi-

All persons exercising powers and functions under this Act shall take into account the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

9. Methodology to be used-

- (1) The Governor-General may from time to time, by Order in Council, establish a methodology (which includes an assessment of monetary and non-monetary costs and benefits) for making decisions under Part V of this Act; and the Authority shall consistently apply that methodology when making such decisions.
- (2) Before making any recommendation for the purpose of making any Order in Council under subsection (1) of this section, the Minister shall request the Authority to-
 - (a) Develop a proposed methodology; and
 - (b) Establish a process that the Minister considers gives the public adequate time and opportunity to make submissions on the proposed methodology to the Authority; and
 - (c) Advise the Minister of any submissions received, and any comments the Authority wishes to make on the submissions, or the proposed methodology,-and the Minister shall have regard to those submissions and comments.
- (3) A failure to comply with subsection (2) of this section shall not affect the validity of any Order in Council made under subsection (1) of this section.
- (4) Notwithstanding section 59 of this Act, the Authority shall not proceed to determine any application made under Part V of this Act until an Order in Council has been made under subsection (1) of this section.
- (5) No decision of the Authority under Part V of this Act shall be challenged on the adequacy or otherwise of the methodology developed and applied under subsection (1) of this section.

PART III - POWERS, FUNCTIONS, AND DUTIES

10. Powers, functions, and duties of Minister-

The Minister may-

- (a) Appoint members of the Authority in accordance with the provisions of section 15 and section 16 of this Act:
- (b) Issue policy direction in accordance with the provisions of section 17 of this Act:
- (c) Decide any application made under ... this Act in accordance with the provisions of sections 68 to 73 inclusive of this Act:

- (d) Carry out any powers, functions, and duties conferred on the Minister by or under this Act.

11. Powers, functions, and duties of Authority-

The Authority may-

- (a) Advise the Minister on any matter relating to the purpose of this Act, including, but not limited to,-
- (i) The extent to which persons are complying with the provisions of this Act:
 - (ii) Inconsistencies or conflicts between any controls placed on hazardous substances and new organisms under this Act and any controls placed on any hazardous substance and new organisms under any other Act:
 - (iii) The consideration and investigation of the use of environmental user charges in accordance with section 96 of this Act:
- (b) Monitor and review-
- (i) The extent to which the Act reduces adverse effects on the environment or people from hazardous substances or new organisms:
 - (ii) The enforcement of this Act including, but not limited to, the exercise of any power under section 103 of this Act by any enforcement officer:
- (c) Promote awareness of the adverse effects of hazardous substances and new organisms on people or the environment and awareness of the prevention or safe management of those effects:
- (d) Contribute to and cooperate with international forums and carry out international requirements as directed by the Minister:
- (e) Enquire into any incident or emergency involving a hazardous substance or a new organism:
- (f) Keep such registers relating to hazardous substances and new organisms as may be required by this Act or as may be necessary to administer this Act:
- (i) [(fa) approve forms for applications under Part V:]
 - (ii) **(fb) approve standards for containment facilities:** [Clause 7(1) of the Bill]
- (g) Carry out any powers, functions, and duties conferred on it by or under this Act or any other enactment.

(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. [Clause 7(2) of the Bill]

12. Powers, functions, and duties of enforcement officers-

Any enforcement officer may, in relation to the powers, functions, and duties specified in the enforcement officer's warrant of appointment,-

- (a) Give advice and information on the provisions of this Act:
- (b) Promote and monitor compliance with the provisions of this Act:
- (c) Provide information to the Authority if requested to do so by the Authority:
- (d) Carry out any powers, functions, and duties conferred on enforcement officers by or under this Act.

13. General duty-

- (1) Every person who imports, possesses, or uses a hazardous substance or new organism shall ensure that-

- (a) Any adverse effect caused by an act or omission of that person in relation to that substance or organism on any other person or the environment is avoided, remedied, or mitigated; and
 - (b) No action or omission by that person will contravene any requirement or control on that substance or organism imposed by this Act.
- (2) The duty imposed in accordance with subsection (1) of this section is not of itself enforceable against any person, and no person is liable to any other person for a breach of that duty.
 - (3) Notwithstanding subsection (2) of this section, a compliance order may be served on any person requiring that person to cease or prohibiting that person from commencing anything done or to be done by or on behalf of that person that in the opinion of the enforcement officer relates to any hazardous substance or new organism and is or is likely to be dangerous to such an extent that it has or is likely to have an adverse effect on the health and safety of people or the environment.

PART IV - ENVIRONMENTAL RISK MANAGEMENT AUTHORITY

14. Establishment of Authority-

- (1) There is hereby established an Authority to be called the Environmental Risk Management Authority.
- (2) The Authority shall be a body corporate with perpetual succession and a common seal, and shall have and may exercise all the rights, powers, and privileges, and may incur all the liabilities and obligations, of a natural person of full age and capacity.
- (3) The common seal of the Authority shall be judicially noticed in all Courts and for all purposes.

15. Membership of Authority-

The Authority shall consist of no fewer than 6, nor more than 8, members who shall be appointed by the Minister.

16. Eligibility for appointment as member of Authority-

- (1) When considering whether a person is suitable to be appointed as a member of the Authority, the Minister shall ensure that the membership includes a balanced mix of knowledge and experience in matters likely to come before the Authority.
- (2) **In subsection (1), matters includes matters relating to the Treaty of Waitangi and tikanga Maori.** *[Clause 8 of the Bill]*

17. Compliance with policy directions-

- (1) Subject to subsection (2) of this section, in the exercise of its functions, powers, and duties, the Authority shall have regard to the policy of the Government in relation to the control of hazardous substances and new organisms, and shall comply with any general directions relating to that policy given to it in writing signed by the Minister.
- (2) No policy direction given to the Authority by the Minister shall apply to the exercise of any power, duty, or function of the Authority under Part V of this Act.
- (3) As soon as practicable after any such direction is given, the Minister shall publish in the Gazette and lay before the House of Representatives a copy of that direction.

18. Further provisions applying in respect of Authority-

The provisions set out in the First Schedule to this Act shall apply in respect of the Authority.

19. Delegation by Authority-

- (1) The Authority may, in writing, delegate to any person, any of the Authority's functions, powers, or duties under this Act, on such conditions as the Authority thinks fit, except-
 - (a) The fixing of charges under section 21 of this Act; and
 - (b) Except as provided in subsection (2) of this section, any decision making power; and
 - (c) This power of delegation.
- (2) The Authority may delegate, on such terms and conditions as the Authority thinks fit,-
 - (a) The power to conduct a rapid assessment under ~~section 35 or section 42 of this Act~~ any of sections 35, 42, 42A, or 42B [Clause 9 (1) of the Bill] to any person, whether or not that person is a member of the Authority;
 - (b) The power to hear and decide any other application made under Part V of this Act to any committee appointed for that purpose in accordance with the First Schedule to this Act.
 - (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; [Clause 9(2) of the Bill]
 - [(c) the power to decide any application for permission or other matter under Parts XI to XVI to-
 - (i) any employee of the Ministry of Agriculture and Forestry, or of any person specified in section 97, with relevant experience in the subject matter of the application; or
 - (ii) if there is no employee with that relevant experience, any other person with that relevant experience, whether or not that person is a member of the Authority;
 - [(d) the power to conduct a rapid assessment under section 28A to its chief executive;
 - [(e) the power to hear and decide any application made under section 31 to its chief executive;
 - [(f) the power to hear and decide an application made under section 83 for approval as a test certifier to any person, whether or not that person is a member of the Authority;
 - [(g) the power to appoint an enforcement officer under section 99(3) (a) to its chief executive.]
- (3) Every decision made in accordance with a delegation under subsection (2) of this section shall be treated in all respects as though it were a decision of the Authority.
- (4) Every person purporting to act under a delegation under this section is presumed to be acting in accordance with its terms in the absence of evidence to the contrary.
- (5) A delegation under this section shall be revocable at will, and no such delegation shall prevent the performance or exercise of any function, power, or duty by the Authority.
- [(6) Every delegation under subsection (2) must be available for public inspection at the office of the Authority during ordinary office hours.]

20. Obligation to prepare and maintain register-

- (1) The Authority shall keep a register of all applications made to the Authority.
- (2) The register shall specify-
 - (a) The name and address of the applicant;
 - (b) A sufficient description of the substance or organism to uniquely identify that substance or organism;
 - (c) The purpose of the application;
 - (d) Whether the application was approved or declined;
 - (e) Any controls attached to the approval by the Authority;

- (f) All the controls on a hazardous substance, whether the controls are imposed under this Act or any other Act.
- (3) The register shall also record the details of any list of low risk organisms issued by the Authority.
- (4) Any decision by the Authority to approve the importation for release or development of any organism as a low risk organism (other than an organism which is listed as a low risk organism), shall also be included in the register.
- (5) Every person shall have the right to inspect the register during the ordinary office hours of the Authority.

21. Charges-

- (1) The Authority may from time to time-
 - (a) Fix the charges-
 - (i) On a scale of charges for exercising or performing any function, power, or duty under this Act; or
 - (ii) Based on the time involved in exercising or performing any function, power, or duty under this Act-
so as to recover the actual and reasonable costs incurred in the exercise of that function, power, or duty; and
 - (b) Specify the persons liable to pay the charge.
- (2) Before any charges are fixed pursuant to subsection (1) of this section, the Authority shall-
 - (a) Publicly notify the charges it proposes to fix and the persons who are liable to pay the charge; and
 - (b) Allow such period of time as the Authority thinks fit for any person who may be liable to pay the proposed charge to comment in writing to the Authority on whether or not the proposed charges are reasonable; and
 - (c) Consider any comments received in accordance with paragraph (b) of this subsection.
- (3) The Authority shall, after fixing any charges in accordance with this section, publicly notify the charges.
- (4) Where the Authority fixes a scale of charges or a charge based on time, the Authority shall provide an estimate of the full charge payable by any person upon request by that person.
- (5) Any charge payable under this section by any person in respect of the completed exercise or performance of any function, power, or duty by the Authority shall, until paid in full and remitted to the Authority, constitute a debt due to the Authority, and may be recovered in any Court of competent jurisdiction.

22. Payments in advance-

- (1) The Authority may estimate the charge payable in respect of the exercise or performance of any function, power, or duty and require that estimated charge or part of that estimated charge to be paid in full before the Authority exercises or performs the function, power, or duty to which that charge relates.
- (2) Where the actual and reasonable costs of exercising or performing any function, power, or duty,-
 - (a) Exceed the amount paid in advance, the difference between the amount paid and the actual and reasonable costs shall be a debt and the provisions of section 21(5) of this Act shall apply:
 - (b) Are less than the amount paid in advance, the Authority shall refund the difference between the amount paid and the actual and reasonable costs.

23. Fees for local authorities-

Any local authority may prescribe fees by bylaw or resolution in accordance with section 690A of the Local Government Act 1974 for the exercise or performance by the territorial authority of any power, function, or duty under this Act.

24. Power to request information-

The Authority may from time to time request any person who in the Authority's opinion is able to give any information relating to any significant incident or emergency or likely significant incident or emergency involving a hazardous substance or new organism which is the subject of an inquiry by the Authority under section 11(e) of this Act, to furnish to the Authority any such information and to produce any documents or papers or things which in the Authority's opinion relate to any such matter and which may be in the possession or under the control of that person.

Part 4A

Nga Kaihautu Tikanga Taiao

[Part 4A, Sections 24A – 24D introduced in Clause 10 of the Bill]

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 Maori perspective and come within terms of reference set by the Authority for Nga Kaihautu Tikanga Taiao.

24C Appointment and remuneration of members and chair

- (1) The Authority must appoint not fewer than 4 and not more than 8 members of Nga Kaihautu Tikanga Taiao.
- (2) The Authority must appoint 1 of the members to be the chairperson of Nga Kaihautu Tikanga Taiao.
- (3) The members of Nga Kaihautu Tikanga Taiao are entitled to be paid remuneration at a rate set by the Authority.

24D Review of terms of reference

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

PART V - ASSESSMENT OF HAZARDOUS SUBSTANCES AND NEW ORGANISMS

Prohibition of Import, Etc, and Types of Approval

[25AA. This Part subject to Part 5A-

This Part applies subject to Part 5A.]

25. Prohibition of import, manufacture, development, field testing, or release-

- (1) No-
 - (a) Hazardous substance shall be imported, or manufactured:
 - (b) New organism shall be imported, developed, field tested, or released- otherwise than in accordance with an approval issued under this Act or in accordance with Parts XI to XVI of this Act.
- (2) No approval shall be issued to import, develop, field test, or release any new organism specified in ~~the Second Schedule to this Act~~Schedule 2 [Clause 11(1) of the Bill].
- ~~(3) Where any organism has received approval for importation into containment then, notwithstanding that the organism in containment remains a new organism, no further approval shall be required for any subsequent importations into containment of such an organism.~~
- (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. [Clause 11(2) of the Bill]

26. Determination of new organism [or hazardous substance]-

- (1) The Authority may, by notice in the Gazette, on application by any person, determine whether or not any organism is a new organism[, or (without limiting any regulations made under section 74(b)) whether or not any substance is a hazardous substance].
- (2) Before issuing such a determination, the Authority shall have regard to-
 - (a) Any information held by the Authority; and
 - (b) Any information held by any department listed in the First Schedule to the State Sector Act 1988 and any Crown entity listed in the Fourth Schedule to the Public Finance Act 1989; and
 - (c) Any information provided by the applicant.
- (3) Any determination issued by the Authority under subsection (1) of this section may be revoked or reissued on receipt of further information by the Authority.

27. Types of approval-

In this Act, the term "approval" means any of the following:

- (a) An approval to import or manufacture a hazardous substance for release:

- (b) An approval to import for release or release from containment any new organism:
 - (ba) a conditional release approval to import for release or release from containment a new organism. [Clause 12(1) of the Bill]
- (c) An approval to import any new organism into containment, field test any new organism in containment, develop any new organism in containment:
- (d) An approval to import any hazardous substance into containment or manufacture any hazardous substance in containment:
- (e) An approval to import or manufacture any hazardous substance for release in an emergency, import any new organism for release in an emergency, or release any new organism from containment in an emergency.
- (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. [Clause 12(2) of the Bill]

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. [Clause 13 of the Bill]

~~[29A. Approvals for innovative agricultural compounds and medicines]~~

- ~~(1) Despite sections 28(1) and 28A, no person may import or manufacture a hazardous substance that is the subject of-~~
 - ~~(a) an innovative agricultural compound application; or~~
 - ~~(b) an innovative medicine application-~~~~unless that person has made an application for approval to import or manufacture that substance and that application has been approved under section 28A or section 29.~~
- ~~(2) Subsection (1) 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.~~
- ~~(3) In this section,-~~
 - ~~(a) innovative agricultural compound application has the same meaning as in section 72 of the Agricultural Compounds and Veterinary Medicines Act 1997;~~
 - ~~(b) innovative medicine application has the same meaning as in section 23A of the Medicines Act 1981.] [Clause 14 of the Bill]~~

Assessment of New Organisms for Importation or Release

34. Application for approval to import or release-

- (1) Every person intending-
 - (a) To import for release; or
 - (b) To release from containment-

any new organism shall, before importation or release, apply under this section or under section 38A, [Clause 15(1) of the Bill] to the Authority for approval to import or release.

- (2) Every application under this section [Clause 15(2) of the Bill] shall be in [an approved form] and shall include-
- (a) Any information prescribed; 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 such 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 potential use for the organism.
- (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.

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. [Clause 16 of the Bill]

35. Rapid assessment of risk for importation of new organisms -

- (1) Where the Authority receives an application under section 34 of this Act to import a new organism that is not a genetically modified organism for release, the Authority may make a rapid assessment of the adverse effects of importing that organism in accordance with subsections (2) and (3) of this section.
- (2) If the Authority is satisfied that-
 - (a) The organism is not an unwanted organism as defined in the Biosecurity Act 1993; and
 - (b) It is highly improbable that the organism, after release,-
 - (i) Could form self-sustaining populations anywhere in New Zealand, taking into account the ease of eradication; or
 - (ii) Could displace or reduce a valued species; or
 - (iii) Could cause deterioration of natural habitats; or
 - (iv) Will be disease-causing or be a parasite, or be a vector or reservoir for human, plant, or animal disease; or
 - (v) Will have any adverse effects on human health and safety or the environment,- the Authority may approve the application without controls.
- (3) If the Authority is satisfied that-
 - (a) The organism is an unwanted organism as defined in the Biosecurity Act 1993; or

(b) The organism is likely to fail the minimum standards specified in section 36 of this Act-

the Authority may, subject to subsection (5) of this section, decline the application.

- (4) If the Authority considers that the application should not be approved under subsection (2) of this section, then the application may be determined under section 38 of this Act.
- (5) Where any person appointed by the Authority to conduct a rapid assessment of risk declines an application under subsection (3) of this section, the applicant may request the Authority to continue the assessment and determine the application in accordance with section 38 of this Act.

36. Minimum standards-

The Authority shall decline the application, if the new organism is likely to-

- (a) Cause any significant displacement of any native species within its natural habitat; or
- (b) Cause any significant deterioration of natural habitats; or
- (c) Cause any significant adverse effects on human health and safety; or
- (d) Cause any significant adverse effect to New Zealand's inherent genetic diversity; or
- (e) Cause disease, be parasitic, or become a vector for human, animal, or plant disease, unless the purpose of that importation or release is to import or release an organism to cause disease, be a parasite, or a vector for disease.

37. Additional matters to be considered-

The Authority, when making a decision under section 38 of this Act, shall have regard to-

- (a) The ability of the organism to establish an undesirable self-sustaining population; and
- (b) The ease with which the organism could be eradicated if it established an undesirable self-sustaining population.

38. Determination of applications to import or release-

(1) If an application made under section 34 of this Act is not granted under section 35 ~~of this Act or any other section~~ [Clause 17(1) of the Bill], the Authority may, in its discretion,-

- (a) Approve the application if-
- (i) The organism meets the minimum standards set out in section 36 of this Act; and
- (ii) After taking into account all the effects of the organism, the effects of any inseparable organism and the matters in section 37 of this Act, the positive effects of the organism outweigh the adverse effects of the organism and any inseparable organism; or
- (b) Decline the application if-
- (i) The organism fails to meet the said minimum standards; or
- (ii) After taking into account all the effects of the organism, the effects of any inseparable organism, and the matters in section 37 of this Act, the adverse effects of the organism and any inseparable organism outweigh the positive effects; or
- (iii) Insufficient information is available to enable the Authority to assess the adverse effects of the organism.

~~(2) Any approval to import an organism for release, or to release an organism from containment, shall be granted without controls.~~

- (2) An approval under subsection (1) must be granted without controls. [Clause 17(2) of the Bill]
- (3) Any approval to import an organism for release or to release an organism from containment shall lapse 5 years after the date of the approval unless-
- (a) The organism is sooner released; or
 - (b) The Authority, following an application by any person before the expiry of the time limit, extends the time limit for a further period of up to 5 years.
- (3A) However, subsection (3) does not apply to an approval under this section that takes effect on the expiry of a conditional release approval. [Clause 17(3) of the Bill]
- (4) Every person who releases an organism in accordance with an approval given under this section within 5 years after the date of that approval shall, unless the requirement is waived by the Authority, notify the Authority within one month after the date of release.
- (5) The Authority shall give its decision in writing, including reasons for the decision, give written notice of the decision to the applicant and every person who made a submission, and publicly notify it.

Conditional release of new organisms

[Sections 38A –38J are introduced in Clause 18 of the Bill]

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 67 A.

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 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.

38 I. 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.

Containment Approval for New Organisms

39. Importation or development of new organisms in containment-

- (1) The Authority may approve the importation, development, or field testing of any new organism into containment for the following purposes:
 - (a) The development of any ~~genetically modified~~ new [Clause 19(1) of the Bill] organism:
 - (b) Field testing any new organism:
 - (c) Maintaining a new organism for use in an emergency (as defined in section 46 of this Act) :
 - (d) The conservation of any genetic material:
 - (e) The public display of any organism including, but not limited to, display in a circus or zoological garden:
 - (f) Maintaining a new organism in containment to produce antigens, biopesticides, biopharmaceuticals, enzymes, hormones, or vaccines for release:
 - (g) Maintaining new organisms in containment for diagnostic purposes:
 - (h) Such other purposes as the Authority thinks fit.

~~(2) Any decision by the Authority, under section 38 of this Act, to decline any application to import any new organism or release any new organism from containment shall not prevent the Authority from approving the importation of any new organism into containment, the field testing of any genetically modified organism in containment, or the development of any new organism in containment, for any purpose specified in subsection (1) of this section.~~

(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 I 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 I or more of the purposes specified in subsection (1).

[Clause 19(2) of the Bill]

40. Application for containment approval for new organisms-

- (1) Every person intending-
 - (a) To import into containment any new organism; or
 - (b) To develop any new organism in containment; or
 - (c) To field test any new organism in containment-shall, before importing or developing or testing, apply to the Authority for approval to import or develop that new organism.
- (2) Every application shall be in [an approved form] and shall include any information prescribed, 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 such consideration, information about the containment system for the organism, and,-
 - (a) For the development of a genetically modified organism,-
 - (i) The identification of the organism; and

- (ii) The description of the project and the experimental procedures to be used; and
 - (iii) The details of the biological material to be used; and
 - (iv) The expression of foreign [nucleic acid material]; and
 - (v) All the possible adverse effects of the organism on the environment:
- (b) For field testing and large scale fermentation of a genetically modified organism, -
- (i) The identification of the organism; and
 - (ii) The purposes of the field testing and large scale fermentation; and
 - (iii) The genetic modifications of the organism to be tested; and
 - (iv) The nature and method of field trials and the experimental procedures to be used; and
 - (v) All the possible adverse effects of the organism on the environment.
- (3) The Authority may, by written notice given to the applicant, require the applicant to verify an application by statutory declaration.
- (4) An applicant may, by written notice to the Authority, withdraw the application at any time.

41. Assessment of adverse effects of developing genetically modified organisms -

The Governor-General may, from time to time, by Order in Council, make regulations-

- (a) Specifying the procedures and methods for assessing the probability that an adverse effect will occur from genetic modification of an organism:
- (b) Specifying the probability that adverse effects will occur from specified development procedures:
- (c) Specifying the circumstances in which genetic modification of an organism is a low risk genetic modification.

42. Rapid assessment of adverse effects for development of genetically modified organisms -

- (1) Where the Authority receives an application under section 40 of this Act to develop a genetically modified organism in containment, the Authority may make a rapid assessment of the adverse effects of developing that organism.
- (2) If the Authority is satisfied that any development meets the criteria for a low-risk genetic modification specified in regulations made under section 41 of this Act, the Authority may approve the application and impose such controls providing for each of the matters specified in the Third Schedule to this Act as the Authority thinks fit.

[Sections 42A and 42B are introduced in Clause 20 of the Bill]

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).

~~43. Additional matters to be considered when application made for developing new organisms in containment-~~

~~The Authority, in making a decision under section 45 of this Act, on an application made under section 40(1) (b) of this Act, shall have regard to-~~

- ~~(a) The matters set out in regulations made under section 41 of this Act; and~~
- ~~(b) The matters in section 37 of this Act.~~

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. [Clause 21 of the Bill]

44. Additional matters to be considered on applications for importing and field testing of organisms-

The Authority, when making a decision under section 45 of this Act, on an application made under section 40(1) (a) or (c) of this Act, shall have regard to-

- (a) The matters in section 37 of this Act; and
- (b) The ability of the organism to escape from containment.

[44A. Additional matters to be considered for certain developments and field tests-

- (1) This section applies to an application-

- (a) to develop a new organism in containment that is a genetically modified organism, to the extent that the development does not take place in a containment structure:
- (b) to field test a new organism in containment if the new organism is a genetically modified organism.
- (2) In deciding whether to approve or decline an application, the Authority must take into account-
 - (a) any adverse effects of developing or field testing the organism on-
 - (i) human health and safety; and
 - (ii) the environment, in particular ecosystems and their constituent parts; and
 - (b) any alternative method of achieving the research objective that has fewer adverse effects on the matters referred to in paragraph (a) than the development or field test; and
 - (c) any effects resulting from the transfer of any genetic elements to other organisms in or around the site of the development or field test.
- (3) The matters referred to in subsection (2) are in addition to the matters referred to in sections 44 and 45.
- ~~(4) In this section, field test does not include large scale fermentation of microorganisms inside a containment structure.] [Clause 22 of the Bill]~~

45. Determination of application-

- (1) After considering any application for approval made under section 40 of this Act, the Authority (if the application is not approved under ~~section 42 of this Act~~ section 42 or section 42A or section 42B) [Clause 23(1) of the Bill] may, in its discretion,-
 - (a) Approve the application if-
 - (i) The application is for one of the purposes specified in section 39(1) of this Act; and
 - (ii) After taking into account all the effects of the organism and any inseparable organism, including, but not limited to, the effects on the matters in section 43 of this Act (for applications made under section 40(1) (b) of this Act) or the matters in section 44 of this Act (for applications made under section 40(1) (a) or (c) of this Act), the beneficial effects of having the organism in containment outweigh the adverse effects of the organism and any inseparable organism ~~should the organism escape~~ [Clause 23(2) of the Bill]; and
 - (iii) The Authority is satisfied that the organism can be adequately contained; or
 - (b) Decline the application in any other case.
- [(2) An approval under this section-
 - (a) must include controls that provide for each of the applicable matters specified in the Third Schedule; and
 - (b) may include controls that provide for any other matters in order to give effect to the purpose of this Act.]
- (3) The Authority shall give its decision in writing, including reasons for the decision, give written notice of the decision to the applicant and every person who made a submission, and publicly notify the decision.
- (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. [Clause 23(3) of the Bill]

[45A. Controls required for certain developments and for all field tests-

- (1) This section applies to an approval under section 45-
 - (a) to develop a new organism in containment that is a genetically modified organism, to the extent that the development does not take place in a containment structure; or
 - (b) to field test a new organism in containment if the new organism is a genetically modified organism.
- (2) An approval-
 - (a) must include controls to ensure that, after the end of the development or field test, the organism and any heritable material from the organism is removed or destroyed; and
 - (b) may include controls to ensure that, after the end of the development or field test and after heritable material is removed or destroyed, some or all of the genetic elements remaining from the organism are removed or destroyed.
- (3) In subsection (2), destroyed includes leaving genetic elements to break down or become inactive at the site of the development or field test.]

(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. [Clause 24 of the Bill]

Use of Hazardous Substances and New Organisms in Emergencies

46. Meaning of emergency-

- (1) For the purposes of section 30(c) and sections 47 to 49 of this Act, "emergency" means-
 - (a) An event involving the release of a new organism for which a national pest management strategy has been approved under section 68 of the Biosecurity Act 1993; or
 - [(b) a state of emergency declared under the Civil Defence Emergency Management Act 2002; or]
 - (c) An emergency as defined in section 2 of the Fire Service Act 1975; or
 - (d) An emergency declared under Part IX of this Act; or
 - (e) A marine oil spill emergency under the Maritime Transport Act 1994.
- (2) Sections 47 and 48 of this Act apply to every foreseeable emergency where the importation, release, or use of the hazardous substance or new organism in that emergency is also foreseeable.

47. Application for approval to use a hazardous substance or new organism in an emergency-

- (1) Every person intending to-
 - (a) Import any hazardous substance for release in an emergency; or
 - (b) Import any new organism for release in an emergency; or
 - (c) Release any new organism from containment in an emergency; or
 - (d) Release any hazardous substance from containment in an emergency; or
 - (e) Use any hazardous substance in an emergency in a manner which would otherwise contravene the provisions of this Act or any regulations-shall, before importation or release or use, apply to the Authority for approval to import or release or use.
- (2) Every application shall be in [an approved form] and shall include-
 - (a) Information to identify the substance or organism; and
 - (b) Information showing that the hazardous substance or new organism is necessary to deal with an emergency; and
 - (c) A proposed plan for dealing with the use of the substance or organism in the emergency; and
 - (d) All information relating to the effects of the substance or organism; and
 - (e) Such other information as may be prescribed.
- (3) The Authority may, by written notice given to the applicant, require the applicant to verify an application by statutory declaration.
- (4) An applicant may, by written notice to the Authority, withdraw the application at any time.

48. Determination of applications-

- (1) The Authority may approve or decline an application under section 47 of this Act, but may only decline the application if it is satisfied that-
 - (a) The organism or substance is not necessary for use in the emergency; or
 - (b) If the application relates to a substance, the proposed plan does not adequately control the adverse effects of the substance; or
 - (c) If the application relates to a new organism, the proposed plan does not adequately control the adverse effects of the 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).
- (2) When approving the substance or organism in accordance with subsection (1) of this section, the Authority shall impose the following controls:
 - (a) That the substance or organism only be released when an emergency has been declared under this Act or declared in accordance with the provisions of any other Act:
 - (b) That the organism or substance only be released for a specified type of emergency:
 - (c) That the organism or substance may only be released if the emergency is dealt with in accordance with a specified plan which includes:
 - (i) The measures which must be taken to avoid, remedy, or mitigate any actual or potential adverse effects from the use of that substance or organism:
 - (ii) The requirements for the disposal of the hazardous substance and any waste products:
 - (iii) The requirements for the eradication or control of any new organism.

- (3) The Authority shall give its decision in writing, including reasons for the decision, give written notice of the decision to the applicant, and publicly notify it.

49. Exemptions from provisions of Act in emergencies-

Subject to ~~section 50 of this Act~~ sections 49A to 50 [Clause 25 of the Bill], nothing in this Act shall apply to any hazardous substance or new organism required for use in an emergency where-

- (a) The emergency; or
(b) The use of the substance or organism in the emergency-
was not foreseeable.

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

[Sections 49A – 49K are introduced in Clause 26 of the Bill]

"49A Interpretation

In sections 498 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
 - (c) 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 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.

Prohibited List Organisms

50. Prohibited organisms-

- (1) The importation or release or development of any organism specified in ~~the Second Schedule to this Act~~ Schedule 2 [Clause 27(1) of the Bill] is prohibited.
- ~~(2) Subject to section 141 of this Act, the Governor-General may, from time to time, by Order in Council, on the recommendation of the Minister, add any organism to the Second Schedule to this Act.~~
- (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.
[Clause 27(2) of the Bill]
- (3) The Authority may, after declining any application made under this Act in relation to an organism, recommend to the Minister that an Order in Council be made to include the organism in ~~the Second Schedule to this Act~~ Schedule 2 [Clause 27(1) of the Bill], where the Authority is satisfied that-
 - (a) The organism is likely to have any of the effects described in section 36 of this Act; and
 - (b) Any likely adverse effects which may occur should the organism escape from containment would outweigh any likely beneficial effects of allowing the organism to be imported into containment.
- (4) The Authority, when making a recommendation under subsection (3) of this section, may advise the Minister that a group of organisms should be included in ~~the Second Schedule to this Act~~ Schedule 2 [Clause 27(1) of the Bill] if it is difficult for persons to distinguish between high-risk and low-risk members of that group.
- (5) Every Order in Council made under this section shall be deemed to be a regulation for the purposes of the Regulations (Disallowance) Act 1989.

Transshipment

51. Transshipment of substances and organisms-

- (1) Nothing in this Act shall apply to any hazardous substance or new organism transhipped through New Zealand where any person has-
 - (a) Received approval from the Authority to tranship the hazardous substances or new organism; and
 - (b) Complied with any controls that the Authority has imposed on the transshipment.
- (2) The Authority-
 - (a) Shall decline approval to tranship any organism specified in the ~~Second Schedule~~ Schedule 2 [Clause 28 of the Bill] to this Act:
 - (b) May, within 10 working days after receipt of the application-

- (i) Decline approval to tranship any hazardous substance or new organism if the Authority considers that the substance or organism cannot be adequately contained so as to prevent the environment from being exposed to the substance or organism or any adverse effects of the substance or organism; or
- (ii) Approve the transhipment of any hazardous substance or new organism with such controls as the Authority thinks fit.

Procedure for Assessment

52. Applicant may be required to provide further information-

- (1) Where the Authority considers that an applicant is able to provide further relevant information, the Authority may, by written notice given to the applicant not later than 10 working days after the receipt of the application, require the applicant to supply such further information relating to the application as is specified in the notice.
- (2) Where the applicant fails to comply with any request made in accordance with subsection (1) of this section within 1 year after the date of the request, the application shall lapse.

53. Applications required to be publicly notified-

- (1) The following applications shall be publicly notified by the Authority:
 - (a) An application, under section 28 of this Act, to import for release or manufacture for release any hazardous substance[, if the application has not been approved under section 28A]:
(ab) an application under section 38A for a conditional release approval for a new organisms: [Clause 29(1) of the Bill]
 - (b) An application, under section 34 of this Act, to import for release any new organism, if the application has not been approved under section 35 or section 38H [Clause 29(2) of the Bill] of this Act:
 - (c) An application, under section 34 of this Act, to release any new organism from containment, if the application has not been approved under section 38H [Clause 29(3) of the Bill]:
 - (d) An application, under section 40 of this Act, to field test a genetically modified organism:
 - (e) An application under section 47 of this Act to import, release, or use a hazardous substance or a new organism in an emergency.
- [(2) The Authority may, if it considers that there is likely to be significant public interest, publicly notify any application under section 40 to –
 - (a) import into containment any new organism or develop any new organism (other than a genetically modified organism) in containment; or
 - (b) develop any genetically modified organism in containment, if that application has not been approved in accordance with section 42 or section 42A or section 42B.] [Clause 29(4) of the Bill]
- (3) The public notice shall state-
 - (a) That any person may make a written submission on the application; and
 - (b) A closing date for receipt of submissions by the Authority . . . ; and
 - (c) The place where the application and accompanying information may be viewed, and the address for service of the Authority and the applicant unless that information has been withheld-

- (i) In accordance with the Official Information Act 1982; or
 - (ii) In accordance with . . . this Act.
- (4) The Authority shall, upon receipt of the application, notify-
 - (a) The Minister; and
 - (b) Any department listed in the First Schedule to the State Sector Act 1988 and any Crown entity listed in the Fourth Schedule to the Public Finance Act 1989 which, in the opinion of the Authority, is likely to have an interest in the application; and
 - (c) If the application is an application for approval of a new organism, -
 - (i) The Department of Conservation; and
 - (ii) Any Regional Council if, in the opinion of the Authority, that Council is likely to have an interest in the application.

[53A. Method of public notification-

- (1) The Authority may, if it thinks fit, determine a method of public notification of the applications referred to in section 53.
- (2) The method must, in the Authority's opinion, be a means of providing effective public notification at reasonable cost.
- (3) Before determining a method of public notification under subsection (1), the Authority must-
 - (a) publicly notify the method it proposes to determine; and
 - (b) allow the period of time that the Authority thinks fit for any person who may be affected by the proposed method to comment in writing to the Authority on whether the proposed method is reasonable; and
 - (c) consider any comments made in accordance with paragraph (b).
- (4) The Authority must, as soon as practicable after determining a method of public notification in accordance with this section, publicly notify the method in accordance with paragraph (b) of the definition of public notice in section 2(1).]

54. Submission on application-

- (1) Any person may make a written submission on any publicly notified application to the Authority.
- (2) The submission-
 - (a) Shall state the reasons for making the submission;
 - (b) May state any decision sought; and
 - (c) Shall state whether the person making the submission wishes to be heard.
- (3) The Authority shall forward a copy of every submission to the applicant as soon as reasonably practicable after receipt of it by the Authority.

55. Information held on behalf of applicant-

- (1) Where any person-
 - (a) Supplies any information to the Authority; and
 - (b) The information is likely to relate to an application for approval; and
 - (c) The relevant application has not yet been lodged with the Authority, -
the information shall be held by the Authority on behalf of that person; and the provisions of the Official Information Act 1982 shall not apply to that information until the relevant application has been received by the Authority.

(2) Where any information supplied under subsection (1) of this section is held by the Authority on behalf of any person, that information shall be returned upon request.

(3) Where-

~~(a) — Any information is held by the Authority relating to any application made under section 28 or section 31 or section 47 of this Act in respect of a hazardous substance; and~~

(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 [Clause 30(1) of the Bill]

(b) ~~That substance~~ the substance or new organism that is the subject of the application [Clause 30(2) of the Bill] is also the subject of an innovative medicine application as defined in section 23A of the Medicines Act 1981; and

(c) That information includes trade secrets or information that has commercial value that would be, or would be likely to be, diminished by disclosure,-

the provisions of sections 23A to 23C of the Medicines Act 1981, with the necessary modifications, shall apply to that information as if the information were confidential supporting information as defined in section 23A of that Act.

(4) The provisions of sections 23A to 23C of the Medicines Act 1981, with the necessary modifications, shall also apply to the Authority in respect of the information referred to in subsection (3) of this section as if the Authority were the Minister of Health, and as if references in those sections to applications were references to applications in respect of hazardous substances; but-

(a) The protected period (as defined in section 23A of the Medicines Act 1981) shall be the same period for which the information is protected under the Medicines Act 1981; and

(b) The Authority may disclose the information to any prescribed person or organisation or prescribed class of persons or organisations; and

(c) The Authority shall provide a summary of the effects of any substance in respect of which subsection (3) of this section applies where an application for approval is required to be publicly notified in accordance with section 53 of this Act.

[(4A) Where-

~~(a) — Any information is held by the Authority relating to any application made under section 28 or section 31 or section 47 in respect of a hazardous substance; and~~

(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 [Clause 30(3) of the Bill]

(b) ~~That substance~~ The substance or organism that is the subject of the application [Clause 30(4) of the Bill] is also the subject of an innovative agricultural compound application as defined in Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997; and

(c) That information includes trade secrets or information that has commercial value that would be, or would be likely to be, diminished by disclosure,-

the provisions of Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997, with the necessary modifications, apply to that information as if the information were confidential supporting information as defined in that Part of that Act.

[(4B) The provisions of Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997, with the necessary modifications, apply to the Authority in respect of the information referred to in subsection (4A) as if the Authority were the Director-General, and as if references in those sections to applications were references to applications in respect of hazardous substances; but-

- (a) The protected period (as defined in Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997) is the same period for which the information is protected under the Agricultural Compounds and Veterinary Medicines Act 1997; and
- (b) The Authority may disclose the information to any prescribed person or organisation or prescribed class of persons or organisations; and
- (c) The Authority must provide a summary of the effects of any substance in respect of which subsection (4A) applies where an application for approval is required to be publicly notified in accordance with section 53 of this Act.]

(5), (6) Repealed

- (7) The Governor-General may, from time to time, by Order in Council, make regulations prescribing persons or organisations or classes of persons or organisations for the purposes of subsections (4) (b) and [(4A) (b)] of this section.

56. Consideration of information withheld under Official Information Act 1982-

Any information withheld from any person in accordance with section 9(2) (b) of the Official Information Act 1982 may be considered by the Authority in reaching a decision under this Act.

57. Authority to withhold information-

- (1) Where, in the Authority's opinion, any information which has been supplied to the Authority in respect of any application may be able to be withheld under section 9(2) (b) of the Official Information Act 1982, that information shall not be released to any person when any application is publicly notified.

(2) Where-

- (a) The Authority receives a request to release any information held by the Authority under the Official Information Act 1982; and
- (b) The information to which the request relates,-
 - (i) In the Authority's opinion, may be able to be withheld under section 9(2) (b) of that Act; or
 - (ii) Has been classified as commercially sensitive by the person who gave the information to the Authority,-

the Authority shall ~~immediately notify~~ make all reasonable efforts to contact and notify immediately [Clause 31(1) of the Bill] the person who gave the information to the Authority that a request to release the information has been received.

- (3) Where a person receives notice from the Authority under subsection (2) of this section, that person shall, within 10 working days of receipt of the notice, respond to the Authority stating whether that person believes that the information should be withheld under section 9(2) (b) of the Official Information Act 1982 and give reasons for that person's belief.

~~(4) Where a person fails to respond to the Authority within the time stated in subsection (3) of this section, the Authority may release the information without further reference to that person.~~

(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. [Clause 31(2) of the Bill]

58. Further information-

- (1) The Authority-
 - (a) May commission a report or seek advice from any person on any matters raised in relation to the application, including a review of any information provided by the applicant:
 - (b) May obtain any existing relevant information on the substance or organism which is the subject of the application from any source:
 - (c) Shall consult with all departments or Crown entities notified of the application in accordance with section 53(4) of this Act and, where any application is for approval to import, develop, field test, **conditionally release**, [Clause 32 of the Bill] or release a new organism, have particular regard to any submissions made by the Department of Conservation.

[(1A) Any report, advice, or other information obtained under subsection (1) may be considered at any hearing conducted by the Authority.]

- (2) Where the Authority obtains further information under subsection (1) of this section, the Authority, at least [10] working days before commencement of the hearing or consideration, as the case may be, of the application, shall notify the applicant and every person who made a submission that the information is available for inspection, unless that information has been withheld in accordance with section 9(2) (b) of the Official Information Act 1982.
- (3) Where information is requested in accordance with subsection (1) of this section, the Authority may postpone the hearing or consideration of the application until the information has been received.

59. Time limits and waivers-

- (1) The Authority shall,-
 - (a) Where public notification of an application is required by section 53 of this Act, publicly notify that application within 10 working days of receipt unless ~~section [28A or section] 35 or section 42 of this Act~~ **paragraph (b)** [Clause 33(1) of the Bill] applies to that application:
 - ~~(b) — Where section [28A or section] 35 or section 42 of this Act applies to the application,~~
 - ~~(i) — Carry out a rapid assessment under section [28A or section] 35 or section 42 of this Act within 10 working days after receipt of the application; and~~
 - ~~(ii) — Where a further assessment of the application is required under Part V of this Act, and public notification of the application is required by section 53 of this Act, publicly notify the application within 10 working days of the Authority's decision under section [28A or section] 35 or section 42 of this Act:~~
 - (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. [Clause 33(2) of the Bill]
 - (c) Allow 30 working days from the date of public notification for the receipt of submissions:
 - (d) Fix a date for commencement of the hearing or (where there is no hearing) for consideration of the application, being not more than [30] working days after the receipt of the application or the closing date for submissions, whichever is the later:

- (e) Give the applicant at least 10 working days' notice of the commencement date and the time and place of the hearing or consideration of the application:
 - (f) Give every person who has made a submission on the application and who has stated his or her wish to be heard, at least 10 working days' notice of the commencement date and the time and place of the hearing.
- (2) The Authority shall publicly notify its decision ~~not later than 15 working days~~ as soon as reasonably practicable but not later than 30 working days [Clause 33(3) of the Bill] after the conclusion of the hearing or, where there is no hearing, the consideration of the application.
- (3) A person may apply to the Authority to-
- (a) Waive a requirement of this Act or a regulation concerning-
 - (i) The time within which any action shall be carried out; or
 - (ii) The information that shall be supplied; or
 - (b) Give a direction concerning-
 - (i) The time within which any action shall be carried out; or
 - (ii) The terms, including terms as to adjournment, costs, or other matters, on which any information shall be supplied.
- (4) The Authority shall not extend [or reduce] any time period or grant an application under this section to waive a requirement as to the time within which any action shall be carried out unless it is satisfied that-
- (a) The applicant and the persons making submissions consent to that waiver; or
 - (b) Any of those parties who have not so consented will not be unduly prejudiced.
- (5) Subject to subsection (4) of this section, the Authority may at any time extend [or reduce] any time limit under this Act whether or not-
- (a) An application has been made under this section; or
 - (b) That time limit has expired,-
- but in all cases must ensure the matter is carried out as promptly as is reasonable in the circumstances.

60. Obligation to hold hearing-

A hearing of any application need not be held unless-

- (a) The Authority considers that a hearing is necessary; or
- (b) The applicant has made a written request to the Authority for a hearing; or
- (c) A person who has made a submission stated in that submission that he or she wishes to be heard and has not subsequently advised that he or she does not wish to be heard.

61. Provisions relating to hearings-

- (1) The Authority shall consider and decide any application, other than an application which is the subject of a Ministerial direction under section 68 of this Act.
- (2) The Authority shall keep a record of all proceedings before it.
- (3) For the purpose of considering any application, the Authority shall have the same powers as are conferred on a Commission of Inquiry by the Commissions of Inquiry Act 1908; and sections 4, 4B, 4D, 6, 7, 9, 11, and 12 of that Act shall apply accordingly.
- (4) The members of the Authority shall have, in relation to any such consideration and any decision on any matter, the same immunities and privileges as are possessed by a District Court Judge.

- (5) Every summons to a witness to appear at a hearing shall be in [an approved form] and be signed by the person chairing the hearing.
- (6) All allowances for a witness shall be paid by the party on whose behalf the witness is called.
- (7) The Authority shall hold any [hearing of a publicly notified application] in public and shall establish a procedure that is appropriate and fair in the circumstances and may-
 - (a) Permit cross-examination; or
 - (b) Permit questions in clarification; or
 - (c) Permit only the members of the Authority to question any person.
- (8) At the hearing the applicant and any person who made submissions and stated that they wished to be heard may speak (either personally or through a representative) and call evidence.
- (9) Where any person who has stated that he or she wished to be heard fails to appear at the hearing, the Authority may nevertheless proceed with the hearing if it considers it fair and reasonable to do so.

62. Grounds for reassessment of a substance or organism-

- (1) -
 - (a) Any person; or
 - (b) The chief executive of the Authority-

may at any time request the Authority to decide whether there are grounds for reassessing any new organism in containment **or any conditionally released new organism** [Clause 34(1) of the Bill] or any hazardous substance where that organism or substance has previously been assessed by the Authority or where Parts XI to XVI of this Act apply to that substance or organism.
- (2) Where any request has been made under subsection (1) of this section, the Authority may decide that grounds exist to reassess that substance or organism after taking into account that-
 - (a) Significant new information relating to the effects of the substance or the organism has become available; or
 - (b) Another substance with similar or improved beneficial effects and reduced adverse effects has become available; or
 - (c) Information showing a significant change of use, or a significant change in the quantity manufactured, imported, or developed has become available.
- (3) The Authority shall give its decision under subsection (2) of this section in writing, with reasons, to the applicant.
- (4) For the purposes of subsection (1) of this section, "assessed by the Authority" means a decision under any of sections [28A,] 29, 32, **42, 38C, 38H, 42, 42A, 42B** [Clause 34(2) of the Bill], 45 or 48 of this Act or a decision by the Minister under section [73] of this Act, or a deemed assessment under section 160(1) (a) of this Act.

63. Reassessment-

- (1) Any person or the chief executive of the Authority may request the Authority to proceed with a reassessment following a decision under section 62(3) of this Act.
- (2) A reassessment under this section shall be deemed to be an application and shall be publicly notified in accordance with section 53 of this Act and-

- (a) Section 29 and sections 54 to 61 of this Act shall apply with all necessary modifications to a reassessment of a hazardous substance approved under [section 28A or] section 29 of this Act:
 - (b) Sections 30 and 32 of this Act shall apply with all necessary modifications to a reassessment of a hazardous substance approved under section 32 of this Act:
 - (c) Sections 39 to 45 and sections 54 to 61 of this Act shall apply with all necessary modifications to a reassessment of a new organism in containment approved under section 45 of this Act:
 - (ca) sections 38A to 38D and 54 to 61 apply with all necessary modifications to a reassessment of a conditional release approval: [Clause 35(1) of the Bill]
 - (d) Sections 47 and 48 and sections 54 to 61 of this Act shall apply with all necessary modifications to a reassessment of a hazardous substance or new organism for use in an emergency approved under section 48 of this Act.
- (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. [Clause 35(2) of the Bill]

64. Suspension of approvals during reassessment-

Where a decision to reassess any hazardous substance has been publicly notified under section 63(2) of this Act, and the Authority has reasonable cause to believe that there is significant actual or imminent danger to human health or safety or the environment from the continued use of the substance, the Authority, by notice in the Gazette, may direct that any further use of the substance is prohibited until such time as a decision has been made following the reassessment.

65. No compensation following reassessment-

Where any hazardous substance or new organism is reassessed in accordance with section 63 of this Act, no compensation shall be payable to any person for any loss where the Authority-

- (a) Declines to allow any further importation or manufacture of that substance; or
- (b) Declines to approve the release of any new organism from containment; or
- (c) Declines to approve any further importation, field testing, or development of any new organism in containment; or
- (d) Suspends any approval in accordance with section 64 of this Act; or
- (e) Varies the controls on any substance or organism.

66. Requirement for disposing of substances-

- (1) Where any hazardous substance has been reassessed in accordance with section 63 of this Act and the Authority has declined to allow any further importation or manufacture of that substance, the Authority may issue a direction, by notice in the Gazette, prohibiting the use of that substance and requiring that substance to be disposed of, at the owner's expense, in accordance with the controls placed on it by the Authority.
- (2) Where the use of any hazardous substance is prohibited in accordance with subsection (1) of this section, the Authority may, if it thinks fit, add to or vary the controls on disposal of that substance to control any additional adverse effects of disposal of that substance in accordance with subsection (1) of this section, disclosed during reassessment.

67. Authority to direct disposal of new organisms -

Following any decision to-

- (a) Decline approval to release any new organism from containment; or
- (b) Decline approval to import, field test, or develop any new organism, -

the Authority may direct, the owner of any such organism already in New Zealand to dispose of the organism at the owner's expense in accordance with the terms of the approval under which the organism was imported, field tested, or developed.

[67A. Minor or technical amendments to approvals-

The Authority may, of its own motion, amend any approval given by it under this Part if it considers that the alteration is minor in effect or corrects a minor or technical error.]

Minister's Call-in Powers

68. Minister's power to call in applications with significant effects-

~~(1) Where the Minister considers that the decision on any application under this Act will have-~~

- ~~(a) Significant economic effects; or~~
- ~~(b) Significant environmental effects; or~~
- ~~(c) Significant international effects; or~~
- ~~(d) Significant health effects; or~~
- ~~(e) Significant effects in an area in which the Authority lacks sufficient knowledge or experience,-~~

~~the Minister may direct that the Minister will decide the application.~~

(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. [Clause 36 of the Bill]

(2) The direction shall include the Minister's reasons for giving it.

(3) Where the application is for approval to release from containment any new organism, the Minister, in the Minister's discretion, may include in the direction given under subsection (1) of this section a statement specifying, in the circumstances of the particular case, what is or is not significant for the purposes of applying section 36 of this Act in respect of the application.

69. Notification of Minister's direction-

(1) A direction by the Minister under section 68 of this Act is not effective in respect of any application unless the direction is notified in the Gazette not later than ~~15 working days after receipt, by the Authority, of the application~~ 30 working days after the date on which the Authority gives public notice of the application. [Clause 37 of the Bill]

(2) The Minister shall forward a copy of the Gazette notice under subsection (1) of this section to the Authority; and the Authority shall inquire into and report on the application concerned under sections 71 and 72 of this Act.

70. Minister may appoint persons-

Where the Minister directs that the Minister will decide any application in accordance with section 68 of this Act, the Minister may appoint any person or persons with relevant knowledge or experience to sit with the Authority and exercise the power of a member of the Authority under sections 71 and 72 of this Act.

71. Conduct of inquiry by Authority-

- (1) On receipt of a notice under section 69 of this Act, the Authority shall inquire into any application for an approval to which a direction under section 68 of this Act applies.
- (2) The Authority may require further information under section 52 of this Act in respect of any application to which such a direction applies.
- (3) Sections 53 to 61 of this Act apply, with all necessary modifications, in respect of such an inquiry as if the conduct of the inquiry were the hearing of an application.
- ~~(4) Without limiting sections 53 to 61 of this Act (as applied by subsection (3) of this section),
 - ~~(a) Every inquiry shall be held in public; and~~
 - ~~(b) The matters to which the Authority shall have regard include all relevant matters under any of sections 36, 37, 41, and 43 of this Act, and the Minister's reasons for giving the direction under section 68 of this Act.~~~~
- (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.

[Clause 38 of the Bill]

72. Authority to report to Minister-

- (1) On completion of an inquiry under section 71 of this Act, the Authority shall, as soon as practicable, submit to the Minister a written report (including recommendations and reasons) on the application referred to it by the Minister.
- (2) After receiving a report from the Authority, the Minister shall ensure that-
 - (a) A copy of the report is sent to the applicant for any approval to which the report relates; and
 - (b) A copy of the report is sent to every person who made a submission.

73. Minister to decide application and notify decision-

- (1) When considering his or her decision on the application, the Minister shall have regard to-
 - (a) The report and recommendations of the Authority; and
 - (b) The reasons for calling in the application.
- (2) Within 20 working days after receiving a report from the Authority, the Minister shall give his or her decision in writing, including reasons for the decision, give written notice of the decision to the applicant and every person who made a submission, and publicly notify the decision.
- (3) Every decision by the Minister under this section may include such controls as may be imposed by the Authority under Part VI of *[Clause 39 of the Bill]* this Act, and shall have the same effect as a decision by the Authority.

PART 5A - [RESTRICTIONS ON APPROVING CERTAIN APPLICATIONS

[73A. Interpretation-

In this Part, unless the context otherwise requires,-

“medicine and new medicine” have the same meaning as in section 3 of the Medicines Act 1981

“restricted period” means the period beginning on 29 October 2001 and ending on the close of 29 October 2003

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

[73B. Application-

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

[73C. Authority must not consider or approve certain applications during restricted period-

- (1) If an application that subsection (2) applies to is made to the Authority during the restricted period (whether before or after the commencement of the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002) , the Authority-
 - (a) must not consider the application; and
 - (b) must not approve the application; and
 - (c) must return the application, and any fee accompanying it, to the applicant as soon as practicable.
- (2) This subsection applies to the following applications:
 - (a) an application to import a new organism for release:
 - (b) an application to release a new organism from containment.
- (3) However, subsection (2) does not apply to the following applications:
 - (a) an application to import a new organism for release or to release a new organism from containment if the organism is-
 - (i) a medicine or new medicine-
 - (A) to which the Minister of Health has given his or her consent or provisional consent under section 20 or section 23 of the Medicines Act 1981; or
 - (B) that is the subject of a clinical trial approved by the Director-General of Health under section 30 of that Act; or
 - (ii) the subject of an application to register a trade name product under section 9 or section 26 of the Agricultural Compounds and Veterinary Medicines Act 1997 and the organism will be a veterinary medicine used for therapeutic or prophylactic purposes:
 - (b) an application under section 47 of this Act.

[73D. Additional information required for certain applications-

- (1) This section applies to an application-
 - (a) referred to in section 73C(3) (a) ; and
 - (b) made during the restricted period.

- (2) An application must include information demonstrating that the new organism, and any inseparable organism, that the application relates to cannot persist viably in the physical environment beyond the human being or animal that is subject to treatment.
- (3) The information referred to in subsection (2) is in addition to other information required by or under this Act.
- (4) For the purposes of subsection (2), an organism cannot persist viably unless the organism can, without human intervention and other than on a temporary basis, regenerate or reproduce further generations of the same species of the organism.

[73E. Additional matters Authority must consider for certain applications-

- (1) This section applies to an application-
 - (a) referred to in section 73C(3) (a) ; and
 - (b) made during the restricted period.
- (2) In considering whether to approve or decline an application, the Authority must take into account-
 - (a) any adverse effects of the new organism on-
 - (i) human health and safety; and
 - (ii) the environment, in particular ecosystems and their constituent parts; and
 - (b) the information provided under section 73D(2) ; and
 - (c) the efficacy of the new organism as a medicine, new medicine, or veterinary medicine compared to a medicine, new medicine, or veterinary medicine that does not contain a genetically modified organism.
- (3) The matters referred to in subsection (2) are in addition to the matters that the Authority is required to take into account by or under this Act.
- (4) In subsection (2), efficacy means the ability of a medicine, new medicine, or veterinary medicine to produce the intended therapeutic effect, but does not include the potency of the medicine.

[73F. No compensation-

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

[73G. Expiry-

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

PART VII - INSPECTION, ENFORCEMENT, AND ANCILLARY POWERS

Inspection

97. Enforcement of Act-

The following persons shall ensure the provisions of this Act (including any controls imposed on approvals granted under this Act) [Clause 40 of the Bill] are enforced in the following situations:

- (a) The chief executive of the department of State that is for the time being responsible for the administration of the Health and Safety in Employment Act 1992 shall ensure that the provisions of this Act are enforced in any place of work:

- (b) The chief executive of the department of State that is for the time being responsible for the administration of the Gas Act 1992 shall ensure that the provisions of this Act are enforced in, on, at, or around any distribution system, gas installation, or gas appliance:
- (c) The Director of Land Transport Safety may enforce the provisions of this Act in or on any motor vehicle, on any road, in or on any rail service vehicle, or on any railway line:
- (d) The Commissioner of Police (after consultation with the Director of Land Transport Safety) shall ensure that the provisions of this Act are enforced in or on any motor vehicle, on any road, in or on any rail service vehicle, or on any railway line:
- (e) The Director of the Civil Aviation Authority shall ensure that the provisions of this Act are enforced in, on, or at any aircraft or [aerodrome]:
- (f) The Director of Maritime Safety shall ensure that the provisions of this Act are enforced in or on any ship:
- (g) The chief executive of the Ministry of Health shall ensure that the provisions of this Act are enforced where it is necessary to protect public health:
- (h) The chief executive of any territorial authority-
 - (i) Shall ensure that the provisions of this Act are enforced in or on any premises situated in the district of the territorial authority other than those premises specified in paragraphs (a) to (g) of this section:
 - (ii) May enforce the provisions of this Act in or on those premises specified in paragraphs (a) to (g) of this section where the territorial authority is in or on those premises for the purposes of enforcing the provisions of the Resource Management Act 1991:
 - (iii) Shall ensure that the provisions of this Act are enforced in or on those premises specified in paragraphs (a) to (g) of this section, where the function, power, or duty is transferred to the local authority in accordance with section 98 of this Act.
 - (iv) Shall ensure that the provisions of this Act are enforced in or on those premises specified in paragraphs (a) to (g) of this section in respect of any substances to which Part XIV of this Act applies.

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 all 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.**

[Clause 41 of the Bill]

98. Co-ordination of inspection-

- (1) Any person specified in ~~section 97 of this Act~~ section 97 or section 97A [Clause 42 of the Bill] may,-
 - (a) Appoint enforcement officers in accordance with section 100 of this Act to enforce the provisions of this Act; or
 - (b) Transfer the power to enforce the provisions of this Act in their area in accordance with subsections (2) to (7) of this section.
- (2) Any person who appoints any enforcement officers in accordance with subsection (1) of this section shall, each year, no later than one month before the commencement of the Authority's financial year, notify the Authority of the premises where that person will appoint enforcement officers in accordance with section 100 of this Act and the nature and level of inspection and enforcement to be provided by those enforcement officers.
- (3) Any person who has functions, powers, or duties under ~~section 97 of this Act~~ section 97 or section 97A may transfer all or any part of those functions, powers, or duties to another person specified in ~~section 97 of this Act~~ section 97 or section 97A [Clause 42 of the Bill], except that he or she may not transfer this power of transfer.
- (4) Repealed.
- (5) A person may not transfer any function, power, or duty under this section unless-
 - (a) The person has first-
 - (i) Notified the Authority in accordance with subsection (2) of this section; and
 - (ii) Notified the Authority where that person proposes to transfer the function to enforce the provisions of this Act to another person; and
 - (iii) Has received the approval of the Authority to the transfer in the case of a transfer between territorial authorities or the approval of the relevant Ministers to the transfer in the case of a transfer between other persons; and
 - (b) Both persons agree that the transfer is desirable on any of the following grounds:
 - (i) To ensure sufficient enforcement of this Act and to ensure that there is not unnecessary duplication of enforcement;
 - (ii) Efficiency;
 - (iii) Technical or special capability or expertise.
- (6) A transfer of functions, powers, or duties under this section shall be made by agreement between the authorities concerned and on such terms and conditions as are agreed.
- (7) A person to whom any function, power, or duty is transferred under this section may accept such transfer unless expressly forbidden to do so by the terms of any Act by or under which that person is appointed; and upon any such transfer, that person's functions, powers, and duties shall be deemed to be extended in such manner as may be necessary to enable the person to undertake, exercise, and perform the function, power, or duty.
- (8) Any transfer of any function, power, or duty under this section may be changed or revoked at any time by agreement between the transferee and transferor and upon notice to the Authority.

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.

[Clause 43 of the Bill]

99. Supervision of inspection-

- (1) The Authority shall ensure that the provisions of this Act are enforced in all premises likely to contain a hazardous substance or new organism and shall advise the persons specified in ~~section 97 of this Act~~ section 97 or section 97A *[Clause 44 of the Bill]* and the Minister when the Authority considers that there is insufficient or unnecessary inspection and enforcement.
- (2) The Authority shall record all notifications made by persons in accordance with section 98 of this Act.
- (3) The Authority may from time to time, as the Authority thinks fit,-
 - (a) Appoint enforcement officers to enforce the provisions of this Act in such premises as the Authority thinks fit:
 - (b) Authorise the chief executive of-
 - (i) Any department specified in the First Schedule to the State Sector Act 1988:
 - (ii) Any Crown entity specified in the Fourth Schedule to the Public Finance Act 1989:
 - (iii) Any local authority-to appoint enforcement officers to enforce the provisions of this Act in or on any premises specified by the Authority.

100. Appointment of enforcement officers-

- (1) No person shall be appointed as an enforcement officer unless that person has the prescribed qualifications to carry out the powers, functions, and duties specified in the officer's warrant of appointment.
- (2) Any person who appoints any person other than an employee as an enforcement officer shall remain liable in every respect for the actions of that officer, while he or she is acting as such, as if that person were an employee of the appointer.
- (3) Every person who appoints an enforcement officer shall supply each officer with a warrant specifying the functions that the officer may carry out, and any such warrant may at any time be revoked by the person who issued it or by any successor in office of that person.
- (4) Where the chief executive of a territorial authority appoints an enforcement officer in accordance with this section, the chief executive may designate that officer as a "district hazardous substances officer".

101. Duty of territorial authorities-

- (1) If the Minister considers that any territorial authority is not exercising or performing any of its functions, powers, or duties under this Act to the extent that the Minister considers necessary to achieve the purposes of this Act, the Minister shall consult with the Minister of Local Government and may appoint, on such terms and conditions as the Minister thinks fit, the Authority to exercise or perform all or any of those functions, powers, or duties in place of the territorial authority.
- (2) Before making any appointment under subsection (1) of this section, the Minister shall give the territorial authority at least 20 working days' notice in writing of the Minister's intention to do so, specifying the reasons why the Minister considers such an appointment is necessary.

- (3) The notice shall invite the territorial authority to give to the Minister, within such period (being not less than 20 working days after the date of the notice) as may be specified in the notice, such written comments as the territorial authority wishes to make about any steps that the territorial authority is taking, or is intending to take, that may obviate the need for an appointment, and the Minister shall consider those comments and the need for making an appointment before making an appointment.
- (4) The Authority, if appointed under subsection (1) of this section to exercise or perform the functions, powers, or duties of a territorial authority under this Act, may do so as if it were the territorial authority; and the provisions of this Act shall apply accordingly.
- (5) All costs, charges, and expenses incurred by the Authority for the purposes of this section, in exercising or performing any functions, powers, or duties of a territorial authority under this Act, shall be recoverable from the territorial authority as a debt due to the Authority or may be deducted from any money payable to the territorial authority by the Authority.
- (6) In making any such appointment, the Minister shall specify the period for which the appointment is made, and it may from time to time be renewed.
- (7) Any appointment of the Authority under this section may be revoked at any time by the Minister.
- (8) In determining whether any appointment under this section should be renewed or whether a new appointment should be made, the Minister shall consider whether the territorial authority is capable of exercising its powers, functions, and duties under this Act, and, if the Minister considers the territorial authority is so capable, the territorial authority shall be directed by the Minister to resume those powers, functions, and duties.

102. Building Act 1991-

- (1) Where an enforcement officer believes that any building or sitework does not comply with the Building Act 1991, the enforcement officer shall, by notice in writing, give to the appropriate territorial authority details of the respects in which the building or sitework is believed not to comply.
- (2) For the purposes of this section, the terms “building”, “sitework”, and “territorial authority” have the meanings ascribed to them by the Building Act 1991.

103. Powers of entry for inspection-

- (1) Any enforcement officer may, at any reasonable time,-
 - (a) Go on, into, under, and over any premises [(excluding dwellings)]; or
 - (b) With the consent of the occupier, go on, into, under, and over a dwelling- for the purpose of inspection to-
 - (c) Monitor ~~the conditions-~~ compliance with the conditions or controls on any hazardous substance or new organism [Clause 45 of the Bill] in any premises where a hazardous substance or new organism approved under this Act is located; or
 - (d) Determine the nature of any substance or organism in the premises; or
 - (e) Determine whether or not any person is complying with a compliance order.
- (2) For the purposes of subsection (1) of this section, an enforcement officer may-
 - (a) Take samples of water, air, soil, any substance, or any organism; and
 - (b) Open containers or packages (including secured or sealed containers or packages) to inspect the contents; and
 - [(c) take photographs and measurements and make sketches and recordings; and]
 - (d) Take or remove any thing for analysis or testing; and

- (e) Conduct examinations, tests, inquiries, demonstrations, and inspections; and
 - [(ea) require that any place or thing specified by the enforcement officer is not disturbed for a reasonable time pending any examination, test, inquiry, demonstration, or inspection; and
 - [(eb) require the making of statements by the person in charge of the premises, in any form or manner specified by the enforcement officer, about conditions, material, or equipment relevant to the purpose of the inspection; and]
 - (f) Require the production of any documents relevant to the purpose of the inspection; and
 - (g) Take copies of the documents or information or extracts from those documents or information.
- (3) Where any enforcement officer has taken any thing in accordance with subsection 2(d) of this section, the enforcement officer shall give the occupier of the premises written notice of the things that have been taken, the reason for taking the things and where the things will be kept.
- (4) Within 5 working days of removing the thing the enforcement officer shall give the person in charge of the premises written notice stating-
- (a) Whether or not the thing will be returned or destroyed; and
 - (b) Either-
 - (i) The time and date of the return of the thing to the premises; or
 - (ii) The results of the analysis of the thing and why it is being destroyed.
- (5) Every enforcement officer exercising any of the powers conferred under this section shall, at the time of exercising that power, and thereafter on request, produce-
- (a) Evidence of that person's appointment as an enforcement officer; and
 - (b) Evidence of that person's identity.
- [(6) An enforcement officer may take any person with relevant experience or expertise on to the premises to assist the officer with the inspection.]
- (7) Nothing in this section shall limit or affect the privilege against self incrimination.

Compliance Orders

104. Scope of compliance order-

- (1) A compliance order may be served on any person by an enforcement officer-
- (a) Requiring that person to cease, or prohibiting that person from commencing, anything done or to be done by or on behalf of that person that, in the opinion of the enforcement officer,-
 - (i) Contravenes or is likely to contravene this Act, any regulations, or a control imposed by an approval under this Act; or
 - (ii) Relates to any hazardous substance or new organism and is or is likely to be dangerous, to such an extent that it has or is likely to have an adverse effect on the health and safety of people or the environment; or
 - (b) Requiring that person to do something that, in the opinion of the enforcement officer, is necessary to ensure that person complies with this Act, any regulations, controls imposed by an approval granted under this Act, or is necessary to avoid, remedy, or mitigate any actual or likely adverse effects on people or the environment resulting from any breach of any regulations or any controls imposed by an approval granted under this Act-

- (i) Caused by or on behalf of the person; or
 - (ii) Relating to any land of which the person is the owner or occupier.
- (2) A compliance order may be made subject to such conditions as are reasonable in the circumstances.

105. Compliance with compliance order-

Subject to the rights of appeal in section 125 of this Act, any person on whom a compliance order is served shall-

- (a) Comply with the order within the period specified in the order; and
- (b) Unless the order directs otherwise, pay all the costs and expenses of complying with the order.

106. Form and content of compliance order-

(1) Every compliance order shall be in the prescribed form and shall state-

- (a) The name of the person to whom it is addressed; and
- (b) The reasons for the order; and
- (c) The action required to be taken or ceased or not undertaken; and
- (d) The period within which the action shall be taken or cease, ~~which shall not be less than 4 days from the time at which the notice is served~~ [Clause 46(1) of the Bill]; and
- (e) The consequences of either not complying with the order or lodging a notice of appeal; and
- (f) The rights of appeal under section 125 of this Act ~~and the last day on which a notice of appeal can be lodged~~ [Clause 46(2) of the Bill]; and
- (g) The name and address of the agency whose enforcement officer served the order.

(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.

[Clause 46(3) of the Bill]

107. Service of compliance order-

- (1) Where a compliance order is to be served on a person, it may be served-
 - (a) By delivering it personally to the person (other than a Minister of the Crown) ; or
 - (b) By delivering it at the usual or last known place of residence or business of the person by any means, including by facsimile; or
 - (c) By sending it by pre-paid post addressed to the person at the usual or last known place of residence or business of that person.
- (2) Where a notice or other document is to be served on a body (whether incorporated or not) for the purposes of this Act, service on an officer of the body, or on the registered office of the body, in accordance with subsection (1) of this section shall be deemed to be service on the body.
- (3) Where a notice or other document is to be served on a partnership for the purposes of this Act, service on any one of the partners in accordance with subsection (1) of this section shall be deemed to be service on the partnership.
- (4) Where a notice or other document is sent by post to a person in accordance with subsection (1) (c) of this section, it shall be deemed, in the absence of proof to the contrary, to be received by the person at the time at which the letter would have been delivered in the ordinary course of the post.

108. Cancellation of compliance order-

- (1) For the purposes of this section, "relevant person" means the person or body who or which appointed the enforcement officer who served the compliance order.
- (2) Where a relevant person considers that a compliance order is no longer required, the relevant person may cancel the order at any time except where the order is subject to appeal under section 125 of this Act.
- (3) Where any relevant person delegates his or her power under this section, no person to whom the powers are delegated shall consider any application made under subsection (6) of this section, in respect of any compliance order which he or she has issued.
- (4) The chief executive of a territorial authority may delegate any of his or her powers, functions, or duties under this section.
- (5) The relevant person shall give written notice of a decision under subsection (2) of this section to cancel a compliance order to any person subject to the order.
- (6) Any person who is directly affected by a compliance order may apply in writing to the relevant person to change or cancel the order.
- (7) The relevant person shall, as soon as practicable, consider the application, having regard to the purpose for which the compliance order was given, the effect of a change or cancellation on that purpose, and any other matter the relevant person thinks fit; and the relevant person may confirm, change, or cancel the order.
- (8) The relevant person shall give written notice of the decision to the person who applied under subsection (6) of this section.
- (9) Where the relevant person, after considering an application made under subsection (6) of this section by a person who is directly affected by a compliance order, confirms the order or changes it in a way other than that sought by that person, that person may appeal to the District Court in accordance with section 125(3) of this Act against the whole or any part of the compliance order.
- (10) A compliance order may not be cancelled where the District Court has confirmed the order.

Enforcement

109. Offences-

- (1) Every person commits an offence against this Act who-
 - (a) Manufactures any hazardous substance in contravention of this Act; or
 - (b) Develops [or field tests] a new organism in contravention of this Act; or
 - (c) Knowingly imports or releases a new organism in contravention of this Act; or
 - (d) Knowingly, recklessly, or negligently-
 - (i) Manufactures, imports, develops, uses, or disposes of any hazardous substance or new organism where any approval is suspended in accordance with section 64 of this Act;
 - (ii) Possesses or disposes of any hazardous substance or new organism imported, manufactured, developed, or released in contravention of this Act; or
 - (e) Fails to comply with-
 - (i) Any controls imposed by any approval granted under this Act; or
 - (ii) Any controls specified in any regulations; or
 - (iii) Any requirement to obtain a test certificate specified in any regulations; or
 - (f) Fails to comply with any compliance order served under section 107 of this Act; or
 - (g) Fails to comply with any of the requirements of section 124 of this Act; or
 - (h) Fails without any lawful justification or excuse to obtain any transferable permit when required to do so by any Order in Council in force under this Act; or
 - (i) Being a manufacturer, developer, or importer of any hazardous substance or new organism knowingly fails to report any significant new information of any adverse effect of that hazardous substance or new organism; or

- (j) Knowingly personates any enforcement officer; or
 - (k) Wilfully obstructs any enforcement officer in the course of his or her duties; or
 - (l) Falsely informs a person that an emergency exists where that person knows the information to be false; or
 - (m) Knowingly labels any package or container in such a manner that the label could in an emergency wrongly indicate the presence of hazardous substances to an enforcement officer, fire services officer, or member of the Police.
- (2) Notwithstanding anything in the Summary Proceedings Act 1957, any information in respect of any offence against subsection (1) of this section may be laid by any person at any time within 120 working days after the time when the contravention giving rise to the information first became known, or should have become known, to that person.

110. Infringement offences-

In sections 111 to 113 of this Act-

"Infringement fee", in relation to an infringement offence, means the amount fixed by regulations made under section [140] of this Act, as the infringement fee for the offence:

"Infringement offence" means an offence specified as such in regulations made under section [140] of this Act.

111. Commission of infringement offence-

Where any person is alleged to have committed an infringement offence, that person may either-

- (a) Be prosecuted against for the alleged offence under the Summary Proceedings Act 1957; or
- (b) Be served with an infringement notice as provided for in section 112 of this Act.

112. Infringement notices-

- (1) Where an enforcement officer observes a person committing an infringement offence, or has reasonable cause to believe such an offence is being or has been committed by that person, an infringement notice may be issued in respect of that offence.
- (2) Any enforcement officer (not necessarily the officer who issued the notice) may deliver the infringement notice (or a copy of it) to the person alleged to have committed an infringement offence personally or by post addressed to that person's last known place of residence or business; and in that case for the purpose of the Summary Proceedings Act 1957, it (or the copy) shall be deemed to have been served on that person when it was posted.
- (3) Every infringement notice shall be in the prescribed form and shall contain the following particulars-
 - (a) Such details of the alleged infringement offence as are sufficient fairly to inform a person of the time, place, and nature of the alleged offence; and
 - (b) The amount of the infringement fee specified for that offence; and
 - (c) The address at which the infringement fee may be paid; and
 - (d) The time within which the infringement fee must be paid; and
 - (e) A summary of the provisions of section 21(10) of the Summary Proceedings Act 1957; and
 - (f) A statement that the person served with the notice has the right to request a hearing; and
 - (g) A statement of what will happen if the person served with the notice neither pays the infringement fee nor requests a hearing; and
 - (h) Such other particulars as are prescribed.

- (4) Where an infringement notice has been issued under this section, proceedings in respect of the offence to which the notice relates may be commenced in accordance with section 21 of the Summary Proceedings Act 1957; and in that case the provisions of that section shall apply with the necessary modifications.

113. Entitlement to infringement fees-

A territorial authority shall be entitled to retain all infringement fees received by it in respect of infringement offences where the infringement notice was issued by an enforcement officer employed by that authority.

114. Penalties-

- (1) Every person who commits an offence against paragraph (a) or paragraph (b) or paragraph (c) or paragraph (d) or paragraph (e) of section 109(1) of this Act is liable on summary conviction to imprisonment for a term not exceeding 3 months or a fine not exceeding \$500,000 and, if the offence is a continuing one, to a further fine not exceeding \$50,000 for every day or part of a day during which the offence has continued.
- (2) Every person who commits an offence against paragraph (f) or paragraph (g) or paragraph (h) or paragraph (i) of section 109(1) , or section 156(1) , of this Act is liable on summary conviction to a fine not exceeding \$50,000 and, if the offence is a continuing one, to a further fine not exceeding \$5,000 for every day or part of a day during which the offence has continued.
- (3) Every person who commits an offence against paragraph (j) or paragraph (k) or paragraph (l) or paragraph (m) of section 109(1) of this Act is liable on summary conviction to a fine not exceeding \$5,000.
- (4) Where any person is convicted of an offence against section 109 of this Act, the Court may, instead of or in addition to imposing any fine or term of imprisonment, revoke any transferable permit held by that person.
- (5) Where any person is convicted of an offence against section 109 of this Act, the Court may, instead of or in addition to imposing any fine or term of imprisonment, order the person to mitigate or remedy any adverse effects on people or the environment-
 - (a) Caused by or on behalf of the person; or
 - (b) Relating to any land of which the person is the owner or occupier-
or to pay the costs of doing so.
- (6) Where any person is convicted of an offence against section 109 of this Act, the Court may, instead of or in addition to imposing any fine or term of imprisonment, order the destruction of any new organism.
- (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. [Clause 47 of the Bill]
- (7) The continued existence of anything, or the intermittent repetition of any actions, contrary to any provision of this Act shall be deemed to be a continuing offence.

115. Liability of employers and principals-

- (1) Subject to subsection (3) of this section, where any offence is committed against this Act by a person as the employee of another person, that offence shall, for the purposes of this Act, be treated as committed by that other person as well as by the first-mentioned person, whether or not it was done with that other person's knowledge or approval.

- (2) Where any offence is committed against this Act by a person acting as the agent of another person, that offence shall, for the purposes of this Act, be treated as committed by the principal unless it is done without the principal's express or implied authority.
- (3) In any proceedings (being proceedings for an offence against this Act or regulations) against any person in respect of any offence alleged to have been committed against this Act by an employee of that person, it shall be a defence for that person to prove-
 - (a) That-
 - (i) He or she did not know nor could reasonably be expected to have known that the offence was to be or was being committed; or
 - (ii) He or she took such steps as were reasonably practicable to prevent the commission of the offence; and
 - (b) That he or she took such steps as were reasonable in all the circumstances to remedy any effects of the act or omission giving rise to the offence.

116. Liability of directors and officers of bodies corporate-

Where any body corporate is convicted of an offence against this Act, every director and every person concerned in the management of the body corporate shall be guilty of the like offence if it is proved-

- (a) That the act that constituted the offence took place with his or her authority, permission or consent; and
- (b) That he or she knew or could reasonably be expected to have known that the offence was to be or was being committed and failed to take all reasonable steps to prevent or stop it.

117. Strict liability and defences-

- (1) In any prosecution for an offence specified in paragraph (a) or paragraph (b) or paragraph (e) or paragraph (f) or paragraph (g) of section 109(1) of this Act, it is not necessary to prove that the defendant intended to commit the offence.
- (2) It is a defence to prosecution of the kind referred to in subsection (1) of this section, if the defendant proves-
 - (a) That-
 - (i) The action or event to which the prosecution relates was necessary for the purposes of saving or protecting life or health, or preventing serious damage to property or 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 such steps as were reasonable in all the circumstances to mitigate or remedy the effects of the action or event after it occurred; or
 - (b) That the action or event to which the prosecution relates was due to an event beyond the control of the defendant, including natural disaster, mechanical failure, or sabotage, and in each case-
 - (i) The action or event could not reasonably have been foreseen or been provided against by the defendant; and
 - (ii) The defendant took such steps as were reasonable in all the circumstances to mitigate or remedy the effects of the action or event after it occurred; or
 - (c) That the action or event to which the prosecution related was within the defendant's control; but-
 - (i) The defendant had taken all reasonable steps to prevent the action or event; and

- (ii) The defendant took such steps as were reasonable in all the circumstances to mitigate or remedy the effects of the action or event after it occurred.
- (3) It is a defence to prosecution for any offence specified in section 109(1) (e) (ii) or (iii) of this Act that the defendant-
 - (a) Complied with any code of practice approved under section 79 of this Act as a method of achieving the controls that it is alleged that the defendant failed to comply with; or
 - (b) Was the holder of any current test certificate issued by any test certifier in accordance with section 82 of this Act, certifying that the controls that it is alleged that the defendant failed to comply with had been met,-unless the defendant had reason to believe that the code of practice . . . or the structure or goods covered by the test certificate did not meet the relevant controls.

118. Fines to be paid to territorial authority instituting prosecution-

- (1) Subject to subsection (2) of this section, where a person is convicted of an offence under section 109 of this Act and the Court imposes a fine, the Court shall, if the information for that offence was laid on behalf of a territorial authority, order that the fine be paid to that territorial authority.
- (2) There shall be deducted from every amount payable to a territorial authority under subsection (1) of this section, a sum equal to 10 percent thereof, and that sum shall be credited to the Crown Bank Account.
- (3) Notwithstanding anything in subsection (2) of this section, where any money awarded by a Court in respect of any loss or damage is recovered as a fine, and that fine is ordered to be paid to a territorial authority under subsection (1) of this section, no deduction shall be made under subsection (2) of this section in respect of that money.
- (4) Subject to subsection (2) of this section, an order of the Court made under subsection (1) of this section shall be sufficient authority for the Registrar receiving the fine to pay that fine to the territorial authority entitled to it under the order.
- (5) Nothing in section 73 of the Public Finance Act 1989 shall apply to any fine ordered to be paid to any territorial authority under subsection (1) of this section.

119. Search warrants-

- (1) Any District Court Judge or Justice of the Peace [or Community Magistrate] or any Registrar who is satisfied, on application in writing made on oath, that there are reasonable grounds for believing that there is, in or on or under or over any premises or any dwelling,-
 - (a) Any substance or organism that has been imported, manufactured, developed, released, held, transported, or disposed of in contravention of this Act; or
 - (b) Any documents or other records which there are reasonable grounds to believe may be evidence of the commission of any offence under this Act to which paragraph (a) of this subsection applies,-may issue a search warrant in the prescribed form.
- (2) Every search warrant shall be directed either to a member of the Police by name or to every member of the Police or to any enforcement officer by name, but in any of those cases, the warrant may be executed by any member of the Police.
- (3) On issuing a warrant, the Judge, Justice of the Peace, [Community Magistrate,] or Registrar may impose such reasonable conditions on its execution as he or she thinks fit.
- (4) Any member of the Police or any enforcement officer may call any person to assist him or her in the execution of a search warrant.

- (5) Every warrant shall, subject to any conditions imposed under subsection (3) of this section, authorise the member of the Police or the enforcement officer who is executing it, and any person called on by that member or officer to assist,-
- (a) To enter the premises or dwelling on one occasion within 14 days after the date of the issue of the warrant at any time that is reasonable in the circumstances; and
 - (b) To use such force, both for making entry (either by breaking open doors or otherwise) and for breaking open anything on the premises or dwelling, as is reasonable in the circumstances; and
 - (c) To search for and seize-
 - (i) Any substance or organism found on the premises or dwelling and believed on reasonable grounds to have been imported, manufactured, developed, released, held, transported, or disposed of in contravention of this Act; and
 - (ii) Any documents or other records which there are reasonable grounds to believe may be evidence of the commission of any offence under this Act; and
 - (d) To take any photographs, and make any drawings of any structure, container, packaging, or label where there are reasonable grounds to believe that the structure, container, packaging, or label is in breach of the provisions of this Act or regulations.
- (6) Any member of the Police or enforcement officer who executes a search warrant shall carry the warrant with him or her, and shall produce it for inspection-
- (a) On first entering the premises or dwelling, to the person appearing to be in charge of the premises or dwelling; and
 - (b) Whenever subsequently required to do so, on the premises or dwelling, by any other person appearing to be in charge of the premises or any part of the premises or dwelling.
- (7) Where the occupier of the premises or dwelling is not present at the time the search warrant is executed, the member of the Police or enforcement officer shall leave in a prominent place on the premises or dwelling a written statement of the time and date of the search, and of the member of the Police's or enforcement officer's name and the address of the Police station or other office to which enquiries should be made.
- (8) Where any substance or organism or books, documents, or other records is or are seized in execution of a search warrant, the member of the Police or enforcement officer executing the warrant shall leave in a prominent place on the premises or dwelling or send to the occupier, within 10 working days after the search, a written inventory of all things so seized.

120. Dealing with property seized by enforcement officers-

Section 199 of the Summary Proceedings Act 1957 applies, with the necessary modifications, to any property seized by any enforcement officer as if-

- (a) The reference in that section to section 198 of that Act were a reference to section 119 or section 137 of this Act; and
- (b) References in that section to a constable were references to an enforcement officer.

[121. Powers in respect of prohibited imports-

The importation of a hazardous substance in breach of this Act is the importation of a prohibited good under the Customs and Excise Act 1996, and the provisions of that Act apply accordingly.]

[122. Power to refuse entry to hazardous substance-

Where a customs officer has reasonable cause to believe that a hazardous substance is being imported in breach of this Act, that customs officer may direct that the hazardous substance remain on the ship or aircraft and leave New Zealand.]

123. Declaration that organism not genetically modified-

Any inspector (as defined in section 2(1) of the Biosecurity Act 1993) may require any person importing any organism to declare, by statutory declaration, that the organism is not a genetically modified organism.

124. Responsibilities of carrier and person in charge of any craft-

- (1) For the purposes of this Act, the carrier and the person in charge of any craft that berths, lands, or otherwise arrives in New Zealand from another country, or that is to so berth, land, or arrive, shall-
 - (a) Ensure that any documentation, required by regulations, in relation to all hazardous substances loaded onto that craft is available:
 - (b) On arrival of the craft at a port of entry or Customs airport, produce for inspection such documentation as a Customs officer may lawfully specify.
- (2) The carrier and the person in charge of a craft leaving New Zealand shall-
 - (a) Provide transportation from New Zealand, at the cost in respects of the carrier, of any hazardous substance on board the craft, or any other craft operated by the carrier when it arrived in New Zealand, which was not accompanied by the documentation required by regulations:
 - (b) In respect of any hazardous substance for which the carrier is obliged to provide transportation or the cost of transportation under paragraph (a) of this subsection, to pay all the costs (if any) incurred by the Crown in holding that substance before the removal of that substance from New Zealand.

PART 7A

PECUNIARY PENALTIES AND CIVIL LIABILITY FOR BREACHES

[Sections 124A to 124I are introduced in Clause 48 of the Bill]

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 have reasonably 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 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.

124 F 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.

PART VIII - APPEALS

125. Appeals-

- (1) In any case where the Authority-

- (a) Issues a transferable permit entitling the holder to import or manufacture less substance than the holder claimed to be entitled to import or manufacture; or
 - (b) Declines any application for a transferable permit; or
 - (c) Revokes any transferable permit; or
 - (d) Imposes any charge on any person to recover costs in accordance with section 21 of this Act; or
 - (e) Declines any application for approval as a test certifier in respect of any relevant controls in accordance with section 84 of this Act; or
 - (f) Revokes any approval to act as a test certifier in respect of any relevant controls in accordance with section 86 of this Act; or
 - (g) Suspends all or any part of any approval to act as a test certifier in accordance with section 86 of this Act; or
 - (h) Repealed.
 - (i) Declines any application under section 51 of this Act to tranship a substance or organism,-
any person directly affected may appeal against that decision to the District Court.
- (2) In any case where-
- (a) Any property is seized and retained pursuant to section 119 of this Act; or
 - (b) An application for compensation is declined in accordance with section 138 of this Act; or
 - (c) Costs are awarded in accordance with section 61 of this Act,-
the person directly affected may appeal against that decision to the District Court.
- [(2A) Where a customs officer directs in accordance with section 122 that a hazardous substance remains on a ship or aircraft, the person directly affected may appeal against that direction to the District Court.]
- (3) Any person on whom a compliance order is served may appeal to the District Court against the whole or any part of that order.
- (4) Any person who lodges a notice of appeal under subsection (3) of this section may apply to the District Court for a stay of the compliance order until the determination of the appeal.
- (5) The District Court shall not confirm a compliance order against which an appeal has been lodged where the person on whom the order was served was acting in accordance with-
- (a) Controls on any hazardous substance under this Act; or
 - (b) Conditions imposed on an approval granted under this Act.
- (6) Subject to subsection (7) of this section the decision of the Court on any appeal under this Act shall be final.
- (7) Any party to an appeal under this section may further appeal to the High Court on a question of law.

126. Appeal on question of law-

- (1) Any-
- (a) Party to any application for an approval or an application under section 26 of this Act or regulations; or
 - (b) Person who made submissions to the Authority on any application for an approval or an application under section 26 of this Act or regulations-

may appeal against the decision of the Authority to the High Court on a question of law, unless a right of appeal to the District Court against the decision is provided for in any other provision of this Act.

- (2) Any report and recommendation of the Authority under section 72 of this Act is deemed to be a decision for the purposes of Part X of the High Court Rules.
- (3) An appeal under this section shall be made in accordance with the High Court Rules, except to the extent that those rules are inconsistent with sections 127 to 134 of this Act.

127. Notice of appeal-

Before or immediately after the filing and service of a notice of appeal, the appellant shall serve a copy of the notice on-

- (a) The Authority; and
- (b) Every other party to the proceedings; and
- (c) Any other person who made a submission to the Authority.

128. Right to appear and be heard on appeal-

- (1) A party to any proceedings, or any person who made submissions to the Authority, and who wishes to appear and be heard on an appeal to the High Court, shall give notice of his or her intention to appear to-
 - (a) The appellant; and
 - (b) The Registrar of the High Court; and
 - (c) The Authority.
- (2) The notice to appear under subsection (1) of this section shall be served within 10 working days after the party or the person was served with the notice of appeal.

129. Parties to appeal before High Court-

- (1) The parties to an appeal before the High Court are the appellant, the Authority, and any person who gives notice of intention to appear under section 128 of this Act.
- (2) The Registrar of the High Court shall ensure that the parties to an appeal before the High Court are served with-
 - (a) A copy of every document which is filed or lodged with the Registrar of the High Court relating to the appeal; and
 - (b) Notice of the time and date set down for hearing the appeal.

130. Orders of High Court-

- (1) The High Court may, on application to it or on its own motion, make an order directing the Authority to lodge with the Registrar of the High Court all or any of the following things:
 - (a) Anything in the possession of the Authority relating to the appeal; and
 - (b) A report recording, in respect of any matter or issue the Court may specify, any of the findings of fact of the Authority which are not set out in its decision or report and recommendation; and
 - (c) A report setting out, so far as is reasonably practicable and in respect of any issue or matter the order may specify, any reasons or considerations to which the Authority had regard but which are not set out in its decision or report and recommendation.
- (2) An application under subsection (1) of this section shall be made,-

- (a) In the case of the appellant, within 20 working days after the date on which the notice of appeal is lodged; or
- (b) In the case of any other party to the appeal, within 20 working days after the date of the service on him or her of a copy of the notice of appeal.
- (3) The High Court may make an order under subsection (1) of this section only if it is satisfied that a proper determination of a point of law so requires; and the order may be made subject to such conditions as the High Court thinks fit.

131. Additional appeals on points of law-

- (1) When a party to an appeal, other than the appellant, wishes to contend that the decision or report and recommendation of the Authority or District Court is in error on other points of law, that party may lodge a notice to that effect with the Registrar of the High Court.
- (2) The notice under subsection (1) of this section shall be lodged within 20 working days after the date on which the respondent is served with a copy of the notice of appeal.
- (3) Sections 127 to 129 of this Act apply to a notice lodged under subsection (1) of this section, with all necessary modifications.

132. Extension of time -

On the application of a party to an appeal, the High Court may extend any period of time stated in sections 128 and 130 of this Act.

133. Date of hearing-

When a party to an appeal notifies the Registrar of the High Court-

- (a) That the notice of appeal has been served on all parties to the proceedings; and
- (b) Either-
 - (i) That no application has been lodged under section 130 of this Act; or
 - (ii) That any application lodged under section 130 of this Act has been complied with-

the appeal is ready for hearing and the Registrar shall arrange a hearing date as soon as practicable.

134. Appeals to Court of Appeal-

Section 144 of the Summary Proceedings Act 1957 applies in respect of a decision of the High Court under section 126 of this Act as if the decision has been made under section 107 of the Summary Proceedings Act 1957

PART IX - EMERGENCIES

135. Interpretation-

In this Part of this Act, unless the context otherwise requires,-

“**Emergency**” means-

- (a) Actual or imminent danger to human health or safety; or
- (b) A danger to the environment or chattels so significant that immediate action is required to remove the danger-
arising from a hazardous substance or new organism:

“Enforcement officer” includes any member of the Police, and any Chief Fire Officer or person exercising the powers of a Chief Fire Officer under section 28 or section 28A or section 29 of the Fire Service Act 1975.

136. Declaration of emergency-

- (1) Where any enforcement officer has reasonable grounds to believe that-
 - (a) There is an emergency; and
 - (b) Either,-
 - [(i) no state of emergency has been declared under the Civil Defence Emergency Management Act 2002; or]
 - (ii) The emergency is not being dealt with under the Fire Service Act 1975; or
 - (iii) No emergency has been declared under section 144 of the Biosecurity Act 1993; or
 - (iv) No other enforcement officer has declared an emergency under this Act; and
 - (c) All or any of the powers set out in section 137 of this Act should be exercised in order to-
 - (i) Enter any premises or dwelling; or
 - (ii) Remove the cause of the emergency; or
 - (iii) Stabilise the situation to limit the actual or likely adverse effects of the emergency; or
 - (iv) Protect the health and safety of people, chattels, or the environment from the actual or likely adverse effects of any emergency,-
the enforcement officer may declare a hazardous substance or new organisms emergency.
- (2) A hazardous substance or new organisms emergency shall be declared by the enforcement officer by-
 - (a) Identifying himself or herself to any persons in the vicinity; and
 - (b) Stating his or her authority to exercise emergency powers; and
 - (c) Announcing the nature of the emergency and the area likely to be affected.
- (3) Every enforcement officer shall notify-
 - (a) The person who appointed him or her as an enforcement officer, if he or she was appointed under section 98 of this Act; and
 - (b) The Authority-
of every occasion on which a hazardous substances or new organisms emergency is declared by that officer under this section.
- (4) Any emergency declared under this section shall cease-
 - (a) 48 hours after the time of declaration; or
 - [(b) when a state of emergency is declared under the Civil Defence Emergency Management Act 2002; or]
 - (c) When the emergency is treated by a Chief Fire Officer as an emergency under the Fire Service Act 1975; or
 - (d) When an emergency is declared under section 144 of the Biosecurity Act 1993,-
whichever is the sooner.
- (5) Where the conditions which caused the emergency to be declared under subsection (1) of this section still exist 48 hours after the time of declaration of the emergency and the emergency

has not been treated as an emergency under any of the provisions in paragraphs (b) , (c) , and (d) of subsection (4) of this section, one further declaration of emergency may be made under this Act and the provisions of subsection (4) of this section shall apply accordingly.

- (6) Any emergency declared under this section shall have effect over the area specified under subsection (2) (c) of this section.

137. Emergency powers-

- (1) When a hazardous substance or new organisms emergency has been declared under section 136 of this Act, any enforcement officer may-
- (a) Enter any premises or any dwelling at any time without complying with the provisions of section 103 or section 119 of this Act:
 - (b) Exercise any of the powers set out in section [103] of this Act:
 - (c) Exercise any of the powers set out in section 119(5) of this Act:
 - (d) Direct any person to stop any activity which may contribute to the emergency:
 - (e) Request any person, either verbally or in writing, to take any action to prevent or limit the extent of the emergency:
 - (f) Direct any person to leave any place in the vicinity of the emergency:
 - (g) Direct any person to refrain from entering the vicinity of the emergency:
 - (h) Requisition any property for use in the emergency:
 - (i) Destroy any property or any other thing in order to prevent or limit the extent of the emergency:
 - (j) Secure the site for up to 24 hours following the decision of the enforcement officer that the immediate danger is past.
- (2) If an enforcement officer enters any private property pursuant to the powers conferred by subsection (1) of this section, he or she shall advise the occupier of the property as soon as practicable.

138. Compensation for property requisitioned or destroyed-

- (1) Where any enforcement officer or any person acting at the request of an enforcement officer, made under section 137(1) (e) of this Act-
- (a) Requisitions any property from any person for use in an emergency; or
 - (b) Destroys any property in order to prevent or limit the extent of any emergency,-
- there shall be payable, on written application by any person having an interest in the property, by the organisation whose chief executive appointed the enforcement officer or (where the enforcement officer is a member of the Police) out of money appropriated by Parliament for the purpose, reasonable compensation for any loss or damage caused by the requisition or destruction of the property.
- (2) Compensation shall not be payable under this section to any person who caused or contributed substantially to the emergency which brought about the requisition or destruction.
- (3) Where there is any dispute as to the entitlement of any person to compensation under this section, or as to the amount of such compensation, or as to the liability of the Crown or any other person or organisation to pay any such compensation, the matter shall be determined by any court of competent jurisdiction.

139. Protection of enforcement officers and persons-

No action or proceedings shall be brought against any enforcement officer or any person acting at the request of an enforcement officer made under section 137(1) (e) of this Act, in respect of any actions taken by any such officer or person under this Part of this Act where that officer or that person has acted in good faith and with reasonable care.

PART X - MISCELLANEOUS PROVISIONS

140. Regulations-

- (1) Subject to section 141 of this Act, the Governor-General may from time to time, by Order in Council, make regulations for all or any of the following purposes:
 - (a) Prescribing organisms as genetically modified organisms for the purpose of this Act:
 - (b) Prescribing organisms as organisms which are not genetically modified for the purposes of this Act:
 - (ba) prescribing organisms that are not new organisms for the purposes of this Act: [*Clause 49(1) of the Bill*]
 - (c) Prescribing or providing for controls on compressed gases:
 - (d) Prescribing the method of estimating the quantity of any substance or organism to be imported or manufactured:
 - (e) Prescribing controls for any hazardous substance to avoid or mitigate any adverse effects on the physical or chemical nature of the environment:
 - (f) Prescribing controls to avoid or mitigate illness or injury to people or damage to the environment or chattels from any hazardous substance:
 - (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: [*Clause 49(2) of the Bill*]
 - [(g) prescribing requirements to be met by a laboratory, and during the storage, importation, or transportation of any hazardous substance, for the purposes of section 33:]
 - (h) Prescribing-
 - (i) Any species as a risk species where any subspecies, infrasubspecies, variety, strain, or cultivar of that species may have adverse effects on the health and safety of people or the environment; or
 - (ii) Any subspecies, infrasubspecies, variety, strain, or cultivar as a risk species where that subspecies, infrasubspecies, variety, strain, or cultivar may have adverse effects on the health and safety of people or the environment:
 - (i) Prescribing those offences under this Act that constitute infringement offences against this Act:
 - (j) Prescribing forms of infringement notices, and prescribing the infringement fees (not exceeding \$1,000) for each infringement offence, which may be different fees for different offences.
 - (k) Prescribing countries or organisations for the purposes of sections 28, 31, 34, and [40] of this Act:
 - (l) Prescribing information to be provided with any application for approval:
 - (m) Prescribing forms for the purposes of this Act:

- (n) Prescribing documentation to be issued in respect of any hazardous substance before importation into New Zealand:
 - (o) Prescribing qualifications for-
 - (i) Enforcement officers appointed under section 100 of this Act:
 - (ii) Test certifiers appointed under section 84 of this Act:
 - (p) Prescribing controls for by-products with hazardous properties, which result from the manufacture of any substance:
 - (q) Prescribing damage as serious environmental damage for the purposes of section 144 of this Act:
 - (r) Prescribing restrictions and prohibitions on the sale of specified fireworks:
 - (s) Providing for such other matters as are contemplated by or necessary for giving full effect to this Act and for its due administration.
- (2) Regulations may only be made under subsection (1) (p) of this section where the Authority has notified the Minister that the Authority has reviewed the controls on any by-product with hazardous properties under this Act or any other Act and has satisfied itself that those controls are not sufficient to achieve the purposes of this Act.
- (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. [Clause 49(3) of the Bill]
- (3) Any regulations made under this Act may provide for controls by reference to controls in regulations under any other Act:
- [4) Any regulations made under subsection (1) may require any person to obtain a test certificate at any specified time certifying that a specified requirement has been met.]

141. Procedure for making Orders in Council-

- (1) Before making any recommendation for the purpose of making any Order in Council under this Act (other than any Order in Council or part of an Order in Council made under section 9(1), section 55(7) , section [140(1) (i), (j) , (m) , or (n)], or section 160(1) (b), (c), or (d) of this Act) , the Minister shall-
- (a) Request the Authority to-
 - (i) Do everything reasonably practicable on its part to advise all persons, who or which in its opinion may be affected by any Order in Council made in accordance with the recommendation, of the proposed terms of the Order in Council; and
 - (ii) Give such persons a reasonable opportunity to make submissions on them to the Authority; and
 - (iii) Advise the Minister of any submissions received, and any comments the Authority wishes to make on the submissions or the proposed Order in Council; and
 - (b) Request the Authority to advise on the best international practices and standards for the safe management of hazardous substances and new organisms,-
and the Minister shall have regard to those submissions and comments received in accordance with paragraph (a) of this subsection and to the advice received in accordance with paragraph (b) of this subsection.

- (2) Subsection (1) (a) of this section shall not apply in respect of any Order in Council if the Minister considers it is desirable in the public interest that the Order in Council be made urgently.
- (3) A failure to comply with subsection (1) of this section shall not affect the validity of any Order in Council made under this Act.

[141A. Incorporation of material by reference

- (1) The following material may be incorporated by reference into any regulations or code of practice:
 - (a) standards, requirements, or recommended practices of international organisations:
 - (b) any document or other material that, in the opinion of the Minister (in the case of regulations) or the Authority (in the case of a code) , is too large or impractical to be printed as part of the regulations or code.
- (2) Any such material may be so incorporated in regulations or a code of practice either in whole or in part, and either unmodified or with such additions or variations as are specified in the regulations or code.
- (3) Any material incorporated in regulations or a code of practice by reference under subsection (1) (as it existed on the date of the inclusion but with such additions or variations (if any) as are specified in the regulations or code) is to be regarded for all purposes as forming part of the regulations or code.
- (4) If any material is incorporated in regulations or a code of practice by reference under subsection (1), the Minister (in the case of regulations) or the Authority (in the case of a code) must ensure that, so long as the material remains so incorporated, copies of the material are available-
 - (a) for inspection by members of the public free of charge; and
 - (b) for purchase by members of the public at a reasonable price-
at such place or places as the Minister or the Authority appoints.]

142. Relationship to other Acts-

- (1) Nothing in this Act shall affect the requirements of the Biosecurity Act 1993 in relation to any organism.
- (2) Every person exercising a power or function under the Resource Management Act 1991 relating to the storage, use, disposal, or transportation of any hazardous substance shall comply with the provisions of this Act and any regulations made under this Act.
- (3) Nothing in subsection (2) of this section shall prevent any person lawfully imposing more stringent requirements on the storage, use, disposal, or transportation of any hazardous substance than may be required by this Act or regulations made under this Act where such requirements are considered necessary by that person for the purposes of the Resource Management Act 1991.
- (4) Nothing in this Act shall apply to any resource consent, being-
 - (a) A land use consent relating to the storage, use, disposal, or transportation of any hazardous substance; or
 - (b) A coastal permit to do something that would otherwise contravene section 15 of the Resource Management Act 1991; or
 - (c) A discharge permit,-
where that resource consent was granted before the coming into force of any regulations made under this Act (other than regulations made under Parts XI to XVI of

this Act) until such time as the conditions on the resource consent are reviewed in accordance with section 128 of the Resource Management Act 1991.

- (5) For the purposes of this section, "resource consent" has the same meaning as in the Resource Management Act 1991.
- (6) Any controls prescribed under any other Act for any hazardous substance shall not contravene the provisions of regulations made under sections 75 and 76 of this Act unless-
 - (a) There is a provision in that other Act that expressly provides that controls made under that other Act for specified purposes may contravene the provisions of regulations made under this Act; and
 - (b) The controls are made for the purposes provided for in that Act.

143. Notification of hazardous substances injuries-

- [(1) In this section, hospital means a hospital care institution within the meaning of section 58(4) of the Health and Disability Services (Safety) Act 2001.]
- (2) If any person, upon admission to a hospital, is found to be suffering from any injury caused by a hazardous substance, the person for the time being in charge of the hospital shall give notice of the injury to the Medical Officer of Health.
- (3) The Medical Officer of Health shall ensure that information about any injury notified in accordance with subsection (2) of this section (not being information which identifies any individual person) is supplied to the Minister of Health.

144. Reporting of incidents-

- (1) Every person in charge of a substance involved in an incident resulting in serious harm to any person or serious environmental damage shall, unless an enforcement officer attended the incident or subsection (2) of this section applies, report that incident to an enforcement officer.
- (2) No person shall be obliged to report an incident to an enforcement officer under this Act where the incident is required to be reported under any other Act.

145. Ombudsmen Act 1975 amended-

Part II of the First Schedule to the Ombudsmen Act 1975 is hereby amended by inserting, in its appropriate alphabetical order, the following item:

"The Environmental Risk Management Authority. "

146. Authority to be Crown entity-

The Public Finance Act 1989 is hereby amended-

- (a) By inserting in the Fourth Schedule (as added by section 41 of the Public Finance Amendment Act 1992), in its appropriate alphabetical order, the following item:
"Environmental Risk Management Authority. ":
- (b) By inserting in the Fifth Schedule (as so added) , in its appropriate alphabetical order, the following item: "Environmental Risk Management Authority. ":
- (c) By inserting in the Sixth Schedule (as so added) , in its appropriate alphabetical order, the following item:"Environmental Risk Management Authority. "

147. Additional matters to be included in statement of intent-

- (1) The Authority shall, in addition to the matters specified in section 41D of the Public Finance Act 1989, include the following matters in the statement of intent prepared under that section:
 - (a) The methods (including financial and non-financial performance measures) by which the Authority intends to assess the extent to which it in fact meets the objectives specified in the statement of intent during that year:
 - (b) How the Authority intends to report on the extent to which it met or is meeting those objectives for that year and the dates by which interim reports, if any, will be given to the Minister:
 - (c) Financial forecasts for the 2 years following the year to which the performance agreement relates:
 - (d) Information on decisions under section 62 of this Act:
 - (e) Any new borrowings or financial leases, or similar liabilities that the Authority intends to incur during that year:
 - (f) A statement of the consideration given by the Authority when granting each approval of a hazardous substance of the reasons for and against imposing an environmental user charge as a control.
- (2) No provision specifying any liabilities the Authority intends to incur shall be included in a performance agreement under this section without the approval of the Minister of Finance.
- (3) Every statement of intent shall be accompanied by a written statement by the Authority estimating the effect that the matters set out in the statement of intent are likely to have on the management and use of hazardous substances and new organisms in the year to which the statement of intent relates and following years.

148. Additional reporting requirements-

The annual report delivered by the Authority in accordance with section 41L [sic] of the Public Finance Act 1989, shall include the following additional matters:

- (a) A report on the extent to which the Authority has met the objectives using the performance measures specified in the Statement of Intent in accordance with section 147 of this Act and information as to whether or not any interim reporting requirements were met:
- (b) An assessment of the extent to which this Act has contributed to the health and safety of people and the environment, including an assessment of any reduction in the likelihood that hazardous substances or new organisms will adversely affect people or the environment:
- (c) Information showing the number and type of incidents caused by inadequate management of hazardous substances or new organisms:
- (d) Information on decisions under section 62 of this Act:
- (e) Any other matters the Authority considers to be significant in the management and use of hazardous substances and new organisms, including the investigation and use of environmental user charges.

149. Amendments to other Acts-

The enactments specified in the Fourth Schedule to this Act are hereby amended in the manner indicated in that Schedule.

150. Repeals and revocations-

- (1) The enactments specified in the Fifth Schedule to this Act are hereby repealed.
- (2) The regulations and orders specified in the Sixth Schedule to this Act are hereby revoked.