

# **Hazardous Substances and New Organisms Amendment Bill**

Government Bill

As reported from the Primary Production Committee

## **Commentary**

### **Recommendation**

The Primary Production Committee has examined the Hazardous Substances and New Organisms Amendment Bill and recommends by majority that it be passed. We recommend all amendments unanimously.

### **Introduction**

The Hazardous Substances and New Organisms (HSNO) Amendment Bill would amend the Hazardous Substances and New Organisms Act 1996.

The bill would implement policy changes arising from the regulatory review of agricultural and horticultural products by the Ministry for Regulation in late 2024.<sup>1</sup> The review made recommendations intended to improve access to agricultural and horticultural products for farmers, growers, and businesses, while continuing to manage risks to the environment and to the health and safety of people and communities. The bill would give effect to the recommendations that relate to the HSNO Act. (Other recommendations are addressed in the Agricultural Compounds and Veterinary Medicines Amendment Bill, on which we are reporting separately.) The bill would also strengthen the overall operation of the regulatory systems for hazardous substances and new organisms by improving regulatory processes, certainty, transparency, and oversight.

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<sup>1</sup> Ministry for Regulation, Agricultural and horticultural products regulatory review.

The bill is intended to improve application and regulatory processes, public participation, compliance and enforcement, and emergency provisions. The bill's main changes would:

- streamline application, approval, and reassessment processes for hazardous substances and new organisms
- strengthen the Environmental Protection Authority's (the Authority) regulatory and operational powers, including through levies, regulations, notices, and use of recognised international regulatory assessments
- amend provisions relating to public participation, adverse events, biosecurity responses, and decision-making processes
- strengthen compliance, monitoring, enforcement, and information-sharing arrangements.

### **“Denewed organism”**

Many submitters questioned the meaning of the term “denewed”. Section 25C of the bill defines a “denewed organism” for the limited purpose of that section only (to identify that the general prohibition on importing, releasing, or developing a new organism does not apply to an organism that is prescribed as not a new organism). We understand that the term is already used informally by the Authority and the Ministry for Cities, Environment, Regions and Transport when referring to organisms that are no longer regulated as new organisms.

The term, which appears only twice in the bill as introduced, was chosen because it is distinctive and signals a specific statutory definition. It also indicates that an organism has ceased to be new for the purposes of the Act.

We were advised that overseas jurisdictions do not commonly use the term. However, many jurisdictions do not regulate new organisms as a separate statutory category in the same way that New Zealand does. The bill would not change the criteria for determining an organism as not new. It would only change the process for making those decisions.

### **Legislative scrutiny**

As part of our consideration of the bill, we have examined its consistency with principles of legislative quality. We wish to bring the House's attention to issues relating to clauses 148 (which was also commented on by the Regulations Review Committee) and 155. We discuss these in more detail later in this commentary.

### **Proposed amendments**

This commentary covers the main amendments we recommend to the bill as introduced. We do not discuss minor or technical amendments.

## **Meaning of “new organism”**

Clause 5 would amend the meaning of “new organism” in section 2A of the Act to clarify the status of migratory species. Under clause 5, an organism that belongs to a migratory species would not be a new organism if the migratory species was present in New Zealand from time to time before 29 July 1998, and the arrival in New Zealand of the species before that date occurred without human intervention.

The bill would allow approvals for activities involving new organisms in specific circumstances. Clause 70 would amend section 48 to allow approvals to authorise the release or use of a new organism in response to an adverse event. Clause 77 would amend section 49F to allow an approval under that section to authorise the release of a medicine or medical device that is, or contains, a new organism during a special emergency.

We consider that approvals under sections 48 and 49F should not affect an organism’s status as a new organism. We note that the Act does not expressly state this. We recommend amending clause 5, section 2A to make clear that an organism would not cease to be a new organism solely because it is subject to an approval under section 48 or 49F. This amendment would clarify the existing position, without changing which organisms are regulated as new organisms.

## **Delegation of powers**

Section 19 of the HSNO Act sets out the powers, functions, and duties that the Authority may delegate. Clause 12 of the bill would amend section 19 to expand the matters that the Authority can delegate to its chief executive. This would include a decision on any Part 5 application and any decision on a reassessment if the Part 5 application, or the application or decision to proceed with the reassessment, is not publicly notified. Clause 12 would also enable the Authority to delegate to the chief executive its power under proposed new section 141K to vary statutory time limits where additional time is needed to complete an assessment.

Submitters expressed concern that subdelegating the power to vary a time limit could reduce certainty and accountability in the approvals process. We agree that decisions to vary a time limit should remain subject to senior oversight within the Authority.

We note that new section 141K is not intended to manage routine information-gathering during an assessment. Separate mechanisms would pause time frames when applicants are asked to provide further information.

We recommend replacing proposed new section 19(5B) to clarify that, if the Authority delegates to its chief executive a power to vary a time limit on its own initiative, the chief executive may not sub-delegate that power. However, where an applicant requests a variation, we recommend amending section 19(8) to clarify that the chief executive could sub-delegate the power to vary the time limit, but only to Authority employees. We consider that these amendments would maintain accountability while allowing applicant-initiated requests to be managed efficiently.

## **Approval requirements for developing new organisms**

Section 25 of the Act restricts certain activities involving hazardous substances and new organisms unless the required approval has been obtained. Clause 23 would amend section 25 to align it with the new definition of “develop” provided for through clause 4. It would also exempt specified departments from requiring approval for certain biosecurity activities involving new organisms.

Submitters sought clarification about whether the exemption would cover trials, tests, and other research conducted for biosecurity purposes (which are also types of development in the new definition in clause 4). Some submitters were concerned that the limited breadth of the exemption provision might hinder the ability to respond to biosecurity incursions. Others considered that it could create uncertainty about which activities would require approval. We agree that this provision could be strengthened.

We therefore recommend amending clause 23 to replace proposed new section 25(1B) with new section 25(1B) and (1C). Our proposed new subsections would ensure that the exemption would cover trials, tests, and other research of, on, or using a new organism. The exemption would apply when the activity was carried out by the Ministry for Primary Industries or any other department recognised under the Biosecurity Act 1993. The activity would need to be for the purpose of identifying, managing, or eradicating a new organism.

We consider that our proposed new section 25(1B) would help to clarify the limits of the exemption. This is because it would exempt only those activities referred to in paragraphs (a)(iv) and (a)(v) of the amended definition of “develop”, and only where those activities are carried out for the purpose of identifying, managing, or eradicating a new organism. Activities covered by paragraphs (a)(i) to (a)(iii) of the definition of “develop”, as well as field testing, would continue to require approval.

## **Adverse events**

The bill would replace several provisions that apply during emergencies with a broader framework for responding to adverse events. The new concept of an adverse event is similar to the old concept of an emergency, except that it further supports preparedness for, and responses to, biosecurity incursions. It would provide for approvals, controls, and exemptions in specified circumstances.

Clause 68 of the bill would replace section 46 of the Act. The definition of an “adverse event” in new section 46 includes events currently contained in the definition of emergency (a declared state of emergency, an emergency under the Fire and Emergency New Zealand Act 2017, a hazardous substance or new organisms emergency declared under Part 9 of the Act, or a marine oil spill). The new definition would also include the arrival or establishment of an unwanted organism in New Zealand.

## **Arrival of an unwanted organism**

This bill is intended to assist with biosecurity practices by helping to prepare for the arrival of an unwanted organism. We understand that an organism is generally consid-

ered established once it has been present for some time and may be difficult or impossible to eradicate. The adverse event provisions are intended to support rapid responses to the arrival of new and unwanted organisms.

We therefore recommend amending proposed new section 46(e) to remove reference to the establishment in New Zealand of an unwanted organism from the definition of adverse event. The arrival of an unwanted organism would remain an adverse event for the purposes of applications and approvals to use a hazardous substance or new organism in an emergency. We also recommend a related consequential amendment in proposed new section 48A.

### ***Gazette notification***

Under new section 48A, proposed through clause 71, regulated response activities involving the release or use of a hazardous substance or new organism would generally be authorised once the Director-General of the Ministry for Primary Industries publishes a notice in the Gazette. The notice would be required to state the reasons why those activities are necessary.

We recommend amending new section 48A to allow regulated response activities to be authorised immediately if the Director-General is satisfied that they must be carried out without delay because of an immediate biosecurity-related threat. In these circumstances, the notice would need to be published in the Gazette as soon as practicable after the activity is authorised. This amendment would avoid delaying an urgent biosecurity response, while maintaining transparency through subsequent notification.

### **Transition from conditional to full release**

Clause 42 would insert new section 34B, which would create a simplified pathway from conditional release approval for a new organism to full release. It would allow the holder of a conditional release approval to apply to release a new organism without controls.

Submitters were concerned that the proposed pathway might not provide the scrutiny required for a full release application. They considered that an organism should be assessed against the relevant matters and criteria before its controls are removed. Some submitters also considered that the criteria for using the pathway should be set out in the Act rather than in delegated legislation.

We agree that applications to fully release an organism should be assessed against the matters and criteria for a full release approval. Existing section 34A already provides an appropriate pathway, by allowing the holder of a conditional release approval to apply for full release when that approval expires. We therefore consider that new section 34B is unnecessary, and recommend removing clause 42 from the bill. This would maintain the existing pathway and ensure that applications are assessed against the relevant matters and criteria for full release.

## **Determination of new organism**

Clause 27 would amend section 26 to expand the Authority's power to determine, on application, whether an organism is a new organism to enable it to identify the taxonomic classification of a new organism.

We recommend amending clause 27 to insert new section 26(1), which would allow the Authority, on application, to determine whether a group of organisms is a group of new organisms. This would allow organisms to be considered together in groups where appropriate.

As introduced, the bill could be read as giving the Authority a stand-alone power to determine the taxonomic classification of any organism or group of organisms. We consider that this power should form part of a determination that an organism, or group of organisms, is new. A separate application for a taxonomic classification should not be required.

We recommend inserting new section 26(1A) so that the Authority would be able to determine the taxonomic classification of any organism or group that it determines is new. This would preserve the Authority's discretion to identify the appropriate classification and clarify the scope of its determination.

## **Infringement fees**

The HSNO Act provides that the maximum infringement fee that may be prescribed for an offence against the Act is \$3,000. Clause 148 of the bill as introduced would increase the maximum infringement fee to \$12,000.

The Regulations Review Committee expressed concern that the existing maximum exceeds the level suggested by the Legislation Design and Advisory Committee's guidelines. The guidelines suggest that infringement fees should generally not exceed \$1,000.

The Regulations Review Committee also noted that clause 148 would not distinguish between individuals and others, such as commercial entities. We agree that a maximum fee of \$12,000 would be disproportionate for an individual. However, we consider that infringement fees should provide an effective deterrent. The Act has limited enforcement options short of prosecution, and low fees may not deter larger commercial entities.

We recommend amending clause 148 so that the maximum infringement fee that may be prescribed would be \$3,000 for an individual and \$12,000 in any other case. We consider that this approach would provide a more proportionate enforcement regime while maintaining an effective deterrent.

## **Transitional and savings provisions**

We note that the bill as introduced does not include any transitional or savings provisions. We consider that including these kinds of provisions would support a smooth transition for the bill coming into force. For example, these provisions would clarify

whether the existing or amended law applies to matters already under way when the relevant provisions in the bill come into force.

We recommend inserting new clause 156A and Schedule 1 into the bill (new Part 3 of the Act's Schedule 7) to give effect to these arrangements. We consider that our amendments would provide certainty for applicants and the Authority while avoiding unnecessary disruption to existing matters.

### **Applications and reassessments under Part 5**

Part 5 of the Act relates to the assessment of hazardous substances and new organisms. We recommend inserting several provisions into the bill to support arrangements for applications and reassessments under Part 5. These would provide that:

- the existing law would generally continue to apply to applications made before the relevant new provisions commence, if the applications have not been withdrawn or finally determined before those provisions commence
- the Authority's new discretion under section 26 to determine the appropriate taxonomic classification would apply to applications for the determination of a new organism that have not been finally determined before the new discretion commences
- new section 52B would apply to requests for information made after that section commences
- existing reassessment provisions in the Act would generally continue to apply to reassessments already under way when new section 63 and some key amendments commence
- new section 64, and amended section 64A, would apply to reassessments already under way, allowing the Authority to suspend or restrict certain activities while a reassessment is completed
- amended section 66 would apply to reassessments carried out under the existing law following those reassessments, ensuring that, if the Authority prohibits the use of a hazardous substance or requires its controlled disposal, that prohibition expressly ceases to apply if an approval relating to the hazardous substance is subsequently granted.

These arrangements would generally preserve the law that applied when an application was made or a reassessment began.

### **Organisms prescribed as not new organisms**

We also recommend transitional arrangements for organisms listed in the Hazardous Substances and New Organisms (Organisms Prescribed as Not New Organisms) Regulations 2009.

The Authority could prescribe these organisms as not new by a notice under new Part 5A. It could do so without complying with the preconditions and requirement to give reasons that would otherwise apply.

Our amendments would make it clear that, until a replacement notice is issued, the 2009 regulations would continue to apply to:

- the relevant exclusions from the meaning of “new organism” in section 2A
- the meaning of “denewed organism” in new section 25C.

These arrangements would expire on the earlier of three months after the repeal of the regulation-making power in section 140(1)(c), or the date on which the 2009 regulations are revoked.

We consider that these arrangements would enable organisms listed in the regulations to move into the new notice framework without unnecessary reassessment. They are also intended to preserve the organisms’ regulatory status during the transition.

### **Group standards under Part 6A**

Finally, we recommend inserting transitional and savings arrangements to ensure that the old law would generally continue to apply to:

- applications relating to group standards that were made, but not withdrawn or finally determined, before new provisions relating to notification and consultation, hearings, and other matters relating to group standards commenced
- a proposal to issue, amend, or revoke a group standard if the proposal has been notified but is not yet finally determined before the new provisions relating to notification and consultation, hearings, and other matters relating to group standards commenced.

New section 96Q, introduced through clause 137, would apply to a group standard amended or revoked after that section commenced, including one considered under the transitional provisions relating to group standards. It would state that compensation is not payable for loss arising from the amendment or revocation of a group standard.

The bill would replace section 65 of the Act, which specifies that no compensation is payable following reassessment. Our proposed transitional provisions state that the old section 65 would continue to apply to a group standard amended or revoked before it is replaced. Section 96Q would apply to group standards amended or revoked after section 65 is replaced.

We intend that these arrangements would avoid changing the applicable process after an application or proposal has begun. They would also clarify which compensation provision would apply.

### **Other matters considered**

As part of our consideration of this bill, we also discussed the following matters. While we do not recommend any drafting changes as a result, we consider it worth noting these matters.

### **Agricultural Compounds and Veterinary Medicines Amendment Bill**

We considered this bill alongside the Agricultural Compounds and Veterinary Medicines Amendment Bill (ACVM), which was referred to our committee for consideration with a similar timeframe. We wish to clarify the differences between these two bills, and how they would interact in practice.

Both of these bills responded to the Ministry for Regulation's regulatory review of agricultural and horticultural products, giving effect to the recommendations relevant to each Act.

The ACVM Act regulates the importation, manufacture, sale, and use of agricultural compounds and veterinary medicines to ensure they are fit for purpose and manages their risks to public health, trade in primary produce, animal welfare, and agricultural security. It also ensures agricultural compound residues are compliant with domestic residue standards and that sufficient consumer information is provided about them. The Ministry for Primary Industries is the primary regulator under that Act, responsible for assessing and deciding on applications to register agricultural compounds and veterinary medicines in New Zealand.

The ACVM bill aims to reduce barriers to accessing new agricultural products. It also aims to modernise and strengthen the regulatory system for agricultural compounds and veterinary medicines.

The purpose of the HSNO 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. The HSNO bill, as discussed previously in this commentary, aims to strengthen the regulatory systems for hazardous substances and new organisms. It would also improve regulatory processes, certainty, transparency, and oversight.

Agricultural compounds and veterinary medicines may contain hazardous substances or new organisms, and as such might require approvals under both the HSNO Act and the ACVM Act.

#### *Relationship between the ACVM Act and the HSNO Act*

Any hazardous substance or new organism that is also an agricultural compound (or part thereof) must first be approved under the HSNO Act. While product applications through the ACVM Act could be considered at the same time as an application for approval under the HSNO Act, they would ultimately require an approval under the HSNO Act before becoming registered under the ACVM Act. Neither bill would change this relationship between the two Acts.

### **Genetically modified organisms**

We heard from several submitters who raised concerns that modernising approval pathways under the HSNO Act could increase the likelihood of genetically modified organisms (GMOs), including gene-edited organisms, entering New Zealand. They suggested that the bill should explicitly confirm that it does not alter this particular

framework and that any new organisms involving genetic modification must continue to comply with the HSNO Act.

Submitters also told us that relying on assessments from recognised international regulators could lead to the approval of products that are inconsistent with New Zealand's GMO regulatory settings.

We were assured by advisers, multiple times, that the bill would not remove the requirement for GMOs that are new organisms to be regulated under the HSNO Act. Any such organism would continue to require approval under the Act before it could be imported, developed, field tested, or released, as applicable. The bill's provisions allowing greater reliance on assessments by recognised international regulators relate to hazardous substances rather than new organisms. Any decision under those provisions would still need to comply with other relevant requirements under the HSNO Act. We consider that no further changes are necessary.

We also received assurance from advisers that the amendments to the Act would not reduce the current standard for environmental release of GMOs.

### **Petition of GE Free NZ in Food and Environment: Pause the progress of the Hazardous Substances and New Organisms Amendment Bill**

Alongside this bill, we also considered the petition of GE Free NZ in Food and Environment. It was presented to the House on 29 July 2026 by Scott Willis and transferred to us on 6 August 2026. The petition requests:

That the House of Representatives pause the progress of the Hazardous Substances and New Organisms Amendment Bill until after the Government has undertaken public consultation on the proposed Regulations and Schedule 2-type exclusions; and urge the Government to undertake such consultation.

The petitioner raised concerns similar to those raised by other submitters. We heard from GE Free NZ in Food and Environment during our hearings. We have no further matters to bring to the attention of the House.

## **Appendix**

### **Committee process**

The Hazardous Substances and New Organisms Amendment Bill was referred to this committee on 14 May 2026. The House instructed us to report the bill back no later than 17 September 2026. We invited the Minister for the Environment to provide an oral submission on the bill. She did so on 25 June 2026.

We called for submissions on the bill with a closing date of 15 June 2026. We received and considered submissions from 175 interested groups and individuals. We heard oral evidence from 18 submitters. We wish to acknowledge the efforts of all submitters and thank them for their engagement.

Advice on the bill was provided by the Ministry for Cities, Environment, Regions and Transport, and by the Environmental Protection Authority. The Office of the Clerk provided advice on the bill's legislative quality. The Parliamentary Counsel Office assisted with legal drafting. The Regulations Review Committee reported to us on the powers contained in clause 148.

We considered the bill alongside the petition of GE Free NZ in Food and Environment: Pause the progress of the Hazardous Substances and New Organisms Amendment Bill. The petition was signed by 2,451 people on the Parliament website. It was presented to the House by Scott Willis on 29 July 2026 and transferred to us on 6 August 2026.

### **Committee membership**

Miles Anderson (Chairperson)

Steve Abel

Rachel Boyack

Mark Cameron

Dana Kirkpatrick

Hon Jo Luxton

Suze Redmayne

### **Related resources**

The documents we received as advice and evidence are available on the Parliament website.



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**Key to symbols used in reprinted bill**

**As reported from a select committee**

text inserted unanimously

~~text deleted unanimously~~



*Hon Nicola Grigg*

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| 147                                                                                       | New subpart 1 heading in Part 10 inserted                                                                        | 88        |
| <b>Subpart 1—Orders in Council</b>                                                        |                                                                                                                  |           |
| 148                                                                                       | Section 140 amended (Regulations)                                                                                | 88        |
| 149                                                                                       | Section 140A amended (Persistent organic pollutants)                                                             | 89        |
| 150                                                                                       | Section 140B repealed (Schedule 1AA may be amended or substituted)                                               | 89        |
| 151                                                                                       | Section 141 amended (Procedure for making Orders in Council)                                                     | 89        |
| 152                                                                                       | New subpart 2 heading in Part 10 inserted                                                                        | 89        |
| <b>Subpart 2—Material incorporated by reference</b>                                       |                                                                                                                  |           |
| 153                                                                                       | Section 141F amended (Requirement to consult on proposal to amend or replace material incorporated by reference) | 89        |
| 154                                                                                       | New subparts 3 and 4 of Part 10, new subpart 5 heading in Part 10, and new section 141R inserted                 | 90        |
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| 141K                                                                                      | Variation of time limits generally                                                                               | 90        |
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| <b>Part 2</b>                                                                             |                                                                                                                  |           |
| <b>Other amendments</b>                                                                   |                                                                                                                  |           |
| 155                                                                                       | Schedule 1AA repealed                                                                                            | 95        |
| 156                                                                                       | Schedule 2 amended                                                                                               | 95        |
| <u>156A</u>                                                                               | <u>Schedule 7 amended</u>                                                                                        | <u>95</u> |
| 157                                                                                       | Consequential amendment related to Part 1                                                                        | 96        |

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| <u>New Part 3 inserted into Schedule 7</u> |     |
| Schedule                                   | 102 |
| Consequential amendment                    |     |

**The Parliament of New Zealand enacts as follows:**

**1 Title**

This Act is the Hazardous Substances and New Organisms Amendment Act **2026**.

**2 Commencement**

5

- (1) This Act comes into force on a date or dates set by Order in Council.
- (2) However, the following provisions come into force on the day after Royal assent:
  - (a) **section 4(1)** (to the extent that it inserts definitions of approval, transshipment application, and unwanted organism), **(3), (4)** (to the extent that it repeals a definition of environmental medium), **(5), and (11)**: 10
  - (b) **sections 5(2) and (5), 6, 8, ~~10~~, to 11, 12(1) to (3) and (8), 13, 14(1), (2), and (4), 16, 18, 19(1), 20, 21, 23(1), 24, 35(1) and (2), 37(1), (2), and (4), 41(1), 43(1) and (3), 44, 45, 46(1) to (3), ~~49~~, 50(2), 51(1) and (2), 58(1) and (2), 65, 69(1) and (4), 84(1) and (2), 102(1), 115 to 117, 120, 122, 124, 126 to 130, 132, 135(1) and (2), 138 to 142, 144, 145, 146(2), 148(2) and (3), 149, 150, and 155.** 15
- (3) Any part of this Act that has not come into force 2 years after Royal assent comes into force then. 20
- (4) An Order in Council made under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

**3 Principal Act**

This Act amends the Hazardous Substances and New Organisms Act 1996.

**Part 1** 25  
**Main amendments**

**4 Section 2 amended (Interpretation)**

- (1) In section 2(1), insert in their appropriate alphabetical order:
 

**approval** has the meaning given in **section 27**

**large-scale fermentation** means fermentation, in 1 or more vessels that are capable of holding a total volume that is greater than 10 litres

30

**qualifying medical device** means a medical device (as defined in section 3A of the Medicines Act 1981) that—

- (a) is or contains a new organism; and
- (b) is determined under section 38I(3) to be a qualifying medical device

**temporary hazardous substance approval** means an approval under **section 29AB**

**transhipment application** means an application for approval under section 51 to tranship a hazardous substance or new organism through New Zealand

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

- (2) In section 2(1), replace the definition of **develop** with:

**develop**, in relation to a new organism,—

- (a) means any of the following:
  - (i) genetically modify an organism:
  - (ii) regenerate the new organism from biological material of that organism that cannot, without human intervention, be used to reproduce that organism:
  - (iii) in the case of a new organism that is a micro-organism, carry out large-scale fermentation using that organism:
  - (iv) deliberately isolate, aggregate, multiply, breed, propagate, grow, raise, or otherwise use the new organism:
  - (v) carry out trials, tests, or other research of, on, or using the new organism; but
- (b) does not include field testing of the new organism

- (3) In section 2(1), definition of **enforcement officer**, replace “or 99(3)” with “, 99(3), or **99A(4)**”.

- (4) In section 2(1), repeal the definitions of **environmental medium** and **environmentally sound disposal**.

- (5) In section 2(1), definition of **field test**, delete “, but from which the organism, or any heritable material arising from it, could be retrieved or destroyed at the end of the trials”.

- (6) In section 2(1), definition of **qualifying medicine**, replace paragraph (b) with:

- (b) is determined under section 38I(3) to be a qualifying medicine

- (7) In section 2(1), definition of **qualifying organism**, after “qualifying medicine”, insert “, qualifying medical device,”.

- (8) In section 2(1), definition of **qualifying veterinary medicine**, replace paragraph (b) with:

- (b) is determined under section 38I(3) to be a qualifying veterinary medicine

- (9) In section 2(1), replace the definition of **release** with:
- release**, in relation to a new organism, means—
- (a) move the organism, or allow the organism to move or be moved, within New Zealand without containment; but
  - (b) does not include moving the organism, or allowing the organism to move or be moved, into containment
- (10) In section 2(1), definition of **risk species**, after “under”, insert “**Part 5A** or”.
- (11) In section 2(1), definition of **Stockholm Convention**, paragraph (a), delete “, a copy of the English text of which is set out in Schedule 1AA”.
- 5 Section 2A amended (Meaning of term new organism)**
- (1) After section 2A(1)(a), insert:
- (aa) an organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species by a notice under **Part 5A**:
- (2) In section 2A(1)(b), after “risk species”, insert “by regulations made under section 140”.
- (3) ~~In section 2A(2)(a)(i), replace “section 35” with “section 34B, 35,”.~~
- (4) In section 2A(2)(a)(iii) and (b)(iii), after “prescribed”, insert “by a notice under **Part 5A**”.
- (5) After section 2A(2)(c), insert:
- (d) the organism belongs to a migratory species that was present in New Zealand from time to time before 29 July 1998, or immediately before that date, and whose arrival in New Zealand before that date occurred without human intervention.
- (6) After section 2A(2A)(c), insert:
- (d) it is subject to an approval granted under section 48 or 49F.
- 6 Section 3 amended (Act to bind the Crown)**
- (1) Before section 3(1), insert:
- General*
- (2) In section 3(1), replace “shall bind” with “binds”.
- (3) Before section 3(2), insert:
- Hazardous substances controlled by Minister of Defence*
- (4) In section 3(2), replace “shall not” with “does not”.
- (5) Replace section 3(3) to (7) with:
- (3) The Chief of Defence Force must ensure that codes of practice developed by the Chief of Defence Force are in place for hazardous substances that are controlled by the Minister of Defence and contained in any weapons system.

- (4) The codes of practice must—
  - (a) be based on the relevant EPA controls; or
  - (b) meet the relevant requirements prescribed by EPA notices issued under section 75.
- (4A) The codes of practice may incorporate or adapt any relevant international code of practice. 5
- (5) The Chief of Defence Force must ensure that methods of controlling hazardous substances that are controlled by the Minister of Defence and not contained in any weapons system—
  - (a) are based on the relevant EPA controls; or 10
  - (b) meet the relevant requirements prescribed by EPA notices issued by the Authority under section 75.
- (5A) The Chief of Defence Force may comply with **subsection (5)** by following the relevant code of practice approved by the Authority under section 79.
- (6) The Secretary of Defence must arrange for the following to be assessed and audited (as and when required by the Minister of Defence, or in accordance with a programme of audit and assessment approved by that Minister): 15
  - (a) the codes of practice referred to in **subsection (3)**; and
  - (b) the methods referred to in **subsection (5)**.
- (6A) Section 24(2)(e) of the Defence Act 1990 is to be applied in relation to the findings of that assessment and audit and the Secretary of Defence must submit the report of those findings to the Minister, in addition to the Minister of Defence. 20
- (7) Any person may report to the Authority—
  - (a) a failure to comply with a code of practice referred to in **subsection (3)**; or 25
  - (b) a failure to use a method referred to in **subsection (5)**.
- (6) In section 3(8), replace “breach of an EPA control relating to a hazardous substance under the control of the Minister of Defence” with “failure to comply with a code of practice referred to in **subsection (3)**, or a failure to use a method referred to in **subsection (5)**,”. 30

**7 Section 9 amended (Methodology to be used)**

Replace section 9(4) with:

- (4) A reference in this section to a decision under Part 5 does not include a reference to—
  - (a) any decision relating to an application for a temporary hazardous substance approval; or 35

|           |                                                                                                                                                                                       |    |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
|           | (b) any decision relating to the reassessment of a hazardous substance that is the subject of a temporary hazardous substance approval, including—                                    |    |
|           | (i) a decision under section 62 as to whether there are grounds to reassess the hazardous substance; and                                                                              |    |
|           | (ii) a decision to proceed with the reassessment under <b>subpart 9 of Part 5</b> .                                                                                                   | 5  |
| <b>8</b>  | <b>Section 11 amended (Powers, functions, and duties of Authority)</b>                                                                                                                |    |
|           | Replace section 11(1)(fa) with:                                                                                                                                                       |    |
|           | (fa) approve forms for applications under this Act:                                                                                                                                   |    |
| <b>9</b>  | <b>Section 17 renumbered as section 10A and repositioned (Restriction on Ministerial direction)</b>                                                                                   | 10 |
|           | Renumber section 17 as <b>section 10A</b> and reposition it after section 10.                                                                                                         |    |
| <b>10</b> | <b>New subpart 1 heading in Part 4 inserted</b>                                                                                                                                       |    |
|           | After section 17, insert:                                                                                                                                                             |    |
|           | Subpart 1—Committees and subcommittees                                                                                                                                                | 15 |
| <b>11</b> | <b>New subpart 2 heading in Part 4 inserted</b>                                                                                                                                       |    |
|           | After section 18C, insert:                                                                                                                                                            |    |
|           | Subpart 2—Delegations                                                                                                                                                                 |    |
| <b>12</b> | <b>Section 19 amended (Delegation by Authority)</b>                                                                                                                                   |    |
| (1)       | Repeal section 19(2)(a), (bd), and (ca).                                                                                                                                              | 20 |
| (2)       | In section 19(2)(b), delete “other”.                                                                                                                                                  |    |
| (3)       | Replace section 19(2)(ba) with:                                                                                                                                                       |    |
|           | (ba) the power under section 38I(1) to assess and approve an application that relates to a qualifying organism to the responsible chief executive:                                    |    |
| (4)       | In section 19(2)(bb), replace “or veterinary medicine is a qualifying medicine” with “, medical device, or veterinary medicine is a qualifying medicine, qualifying medical device,”. | 25 |
| (5)       | In section 19(2)(bc), after “qualifying medicines”, insert “, qualifying medical devices,”.                                                                                           |    |
| (6)       | Replace section 19(2)(cb) and (cc) with:                                                                                                                                              | 30 |
|           | (cb) the power to hear and decide any application under Part 5, if it is not publicly notified under <b>section 53</b> , to its chief executive:                                      |    |
|           | (cc) the power to proceed with and decide on any reassessment under <b>subpart 9 of Part 5</b> , if the application for the reassessment, or the decision                             |    |

|           |                                                                                                                                                                                                                                      |    |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
|           | to proceed with the reassessment, is not publicly notified under <b>section 53</b> , to its chief executive:                                                                                                                         |    |
| (7)       | Repeal section 19(2)(e).                                                                                                                                                                                                             |    |
| (8)       | In section 19(2)(g), after “section 99(3)(a)”, insert “or <b>99A(4)</b> ”.                                                                                                                                                           |    |
| (9)       | After section 19(2)(ha), insert:                                                                                                                                                                                                     | 5  |
| (i)       | the power under <b>section 141K</b> to vary a time limit imposed under this Act to its chief executive.                                                                                                                              |    |
| (10)      | Replace section 19(5B) with:                                                                                                                                                                                                         |    |
| (5B)      | <del>However, if the delegate is the chief executive of the Authority and the power or function is a specified power or function, the chief executive may only delegate the power or function to an employee of the Authority.</del> | 10 |
| (5B)      | However, the chief executive of the Authority—                                                                                                                                                                                       |    |
| (a)       | <u>may delegate a specified function or power only to an employee of the Authority; and</u>                                                                                                                                          |    |
| (b)       | <u>may not delegate a power under <b>section 141K</b> to vary a time limit on the Authority’s own initiative that is delegated to that chief executive under <b>subsection (2)(i)</b>.</u>                                           | 15 |
| (11)      | After section 19(7), insert:                                                                                                                                                                                                         |    |
| (8)       | In this section, <del>specified power or function or power</del> means— <u>any of the following functions or powers that are delegated to the chief executive of the Authority under this section:</u>                               | 20 |
| (a)       | <del>a power or function or power</del> <u>under section 26 that relates to hazardous substances; or:</u>                                                                                                                            |    |
| (b)       | <u>a power referred to in <b>subsection (2)(cb), (cc)</b>, or (d):</u>                                                                                                                                                               |    |
| (c)       | <u>a power referred to in <b>subsection (2)(i)</b> to vary a time limit (but only to the extent that it is a power to vary a time limit on an application of a person).</u>                                                          | 25 |
| <b>13</b> | <b>New subpart 3 heading in Part 4 inserted</b>                                                                                                                                                                                      |    |
|           | In Part 4, after section 19, insert:                                                                                                                                                                                                 |    |
|           | Subpart 3—Registers                                                                                                                                                                                                                  | 30 |
| <b>14</b> | <b>Section 20 amended (Obligation to prepare and maintain register)</b>                                                                                                                                                              |    |
| (1)       | Replace the heading to section 20 with “ <b>Register of applications for approvals, etc</b> ”.                                                                                                                                       |    |
| (2)       | Repeal section 20(3).                                                                                                                                                                                                                |    |
| (3)       | Replace section 20(4) with:                                                                                                                                                                                                          | 35 |

- (4) The register must also record, for each approval to import a new organism for release or to release a new organism from containment that is granted under section 38, whether or not the Authority—
- (a) has been notified under **section 38AAC** of the organism's release; or
  - (b) has waived the requirement for that notification.

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- (4) Replace section 20(5) with:

- (5) The Authority must make the register available on an Internet site maintained by or on behalf of the Authority.

**15 New section 20AA inserted (Register of decisions under Part 5A)**

After section 20, insert:

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**20AA Register of decisions under Part 5A**

- (1) The Authority must keep a register that records the following matters:
- (a) each organism that is prescribed under **Part 5A** as not a new organism for the purposes of this Act:
  - (b) each organism—
    - (i) that is not prescribed as not a new organism for the purposes of this Act; and
    - (ii) that an authorised maker (within the meaning of **section 73E**) has declined, on an application made under **Part 5A**, to prescribe as not a new organism for the purposes of this Act:
  - (c) for each organism that is referred to in **paragraph (a) or (b)**, a link to the statement of reasons that is required to be published under **section 73J** for prescribing, or declining to prescribe, the organism as not a new organism:
  - (d) each species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed under **Part 5A** as a risk species for the purposes of **section 2A(1)(aa)**:
  - (e) each species, subspecies, infrasubspecies, variety, strain, or cultivar—
    - (i) that is not prescribed as a risk species for the purposes of **section 2A(1)(aa)**; and
    - (ii) that an authorised maker (within the meaning of **section 73E**) has declined, on an application made under **Part 5A**, to prescribe as a risk species for the purposes of **section 2A(1)(aa)**:
  - (f) for each species, subspecies, infrasubspecies, variety, strain, or cultivar that is referred to in **paragraph (d) or (e)**, a link to the statement of reasons that is required to be published under **section 73J** for prescribing, or declining to prescribe, the species, subspecies, infrasubspecies, variety, strain, or cultivar as a risk species.

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| Hazardous Substances and New Organisms Amendment Bill                      |                                                                                                                                                                                                                 |    |
|----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| Part 1 cl 16                                                               |                                                                                                                                                                                                                 |    |
| (2)                                                                        | The Authority must make the register publicly available on an Internet site maintained by or on behalf of the Authority.                                                                                        |    |
| <b>16</b>                                                                  | <b>Section 20A amended (Register of exposure limits for substances with toxic or ecotoxic properties)</b>                                                                                                       |    |
|                                                                            | Replace section 20A(3) with:                                                                                                                                                                                    | 5  |
| (3)                                                                        | The Authority must make the register publicly available on an Internet site maintained by or on behalf of the Authority.                                                                                        |    |
| <b>17</b>                                                                  | <b>Section 20B repealed (Publication of decisions)</b>                                                                                                                                                          |    |
|                                                                            | Repeal section 20B.                                                                                                                                                                                             |    |
| <b>18</b>                                                                  | <b>New subpart 4 heading in Part 4 inserted</b>                                                                                                                                                                 | 10 |
|                                                                            | In Part 4, above section 20C, insert:                                                                                                                                                                           |    |
| Subpart 4—Work plans                                                       |                                                                                                                                                                                                                 |    |
| <b>19</b>                                                                  | <b>Section 20C amended (Reassessments work plan)</b>                                                                                                                                                            |    |
| (1)                                                                        | Replace the heading to section 20C with “ <b>Work plan for reassessments of hazardous substances</b> ”.                                                                                                         | 15 |
| (2)                                                                        | After section 20C(4), insert:                                                                                                                                                                                   |    |
| (5)                                                                        | Subsection (4)(a) does not require the Authority to ensure that the work plan gives highest priority for reassessments of hazardous substances that are the subject of temporary hazardous substance approvals. |    |
| <b>20</b>                                                                  | <b>New subpart 5 of Part 4 inserted</b>                                                                                                                                                                         | 20 |
|                                                                            | After section 20C, insert:                                                                                                                                                                                      |    |
| Subpart 5—Levies of persons who import or manufacture hazardous substances |                                                                                                                                                                                                                 |    |
| <b>20D</b>                                                                 | <b>Meaning of specified persons</b>                                                                                                                                                                             |    |
|                                                                            | In this subpart, <b>specified persons</b> means—                                                                                                                                                                | 25 |
| (a)                                                                        | persons who import hazardous substances; and                                                                                                                                                                    |    |
| (b)                                                                        | persons who manufacture hazardous substances.                                                                                                                                                                   |    |
| <b>20E</b>                                                                 | <b>Levy of specified persons</b>                                                                                                                                                                                |    |
|                                                                            | Every specified person must pay a levy prescribed by the regulations made under this subpart to—                                                                                                                | 30 |
| (a)                                                                        | the Authority; or                                                                                                                                                                                               |    |
| (b)                                                                        | a prescribed person on behalf of the Crown (being a person who is prescribed by the regulations made under this subpart).                                                                                       |    |

**20F Interest on unpaid levy**

- (1) A person who owes a levy under this subpart is liable to pay to the Authority or the prescribed person interest assessed at the rate and applied by the method (if any) prescribed by the regulations made under this subpart.
- (2) The interest is payable on—
  - (a) any unpaid levy; and
  - (b) any unpaid instalment payment in respect of any levy; and
  - (c) any unpaid interest that has been charged already.

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**20G Levy regulations**

- (1) The Governor-General may, by Order in Council made on the recommendation of the Minister, make regulations providing for the levies.

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**Guidance note**

See **sections 20H and 20I** for procedural requirements with which the Minister must comply before making a recommendation under this section.

- (2) Levies must be prescribed on the basis that the following costs should be met fully out of the levies:
  - (a) a portion of the costs of the Authority in performing or exercising its functions, duties, and powers under this Act relating to hazardous substances, where the size of the portion to be met by levies under this Act is determined by the Minister; and
  - (b) the costs of collecting the levy money.
- (3) Levies may be prescribed on the basis that any actual cost that could have been, but has not been, recovered as a levy shortfall for a year may be recovered (along with any financing charge) over any period of up to 5 years.
- (4) The regulations may do any 1 or more of the following:
  - (a) specify the amount of levies, or the method of calculating or ascertaining the amount of levies:
  - (b) include in levies, or provide for the inclusion in levies of, any shortfall in recovering the actual costs:
  - (c) refund, or provide for refunds of, any over-recovery of the actual costs:
  - (d) provide for the payment and collection of levies (which may include providing for instalment payments):
  - (e) provide for interest under **section 20F**:
  - (f) provide different levies for different specified persons or different classes of specified persons:
  - (g) specify the financial year or part financial year to which a levy applies, and apply that levy to that financial year or part financial year and each subsequent financial year until the levy is revoked or replaced:

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| <ul style="list-style-type: none"> <li>(h) require payment of a levy for a financial year or part financial year, irrespective of the fact that the regulations may be made after that financial year has commenced:</li> <li>(i) require specified persons to keep, and give to the Authority or another person, records and information to enable amounts of levy payable by the specified persons to be accurately calculated:</li> <li>(j) specify the form and manner in which, and the times at which, those records and information must be kept or given:</li> <li>(k) specify requirements for a person to verify that those records and information are correct before giving them to the Authority or any other person:</li> <li>(l) exempt any class of specified person from paying a levy:</li> <li>(m) provide for waivers or refunds of the whole or any part of a levy for any case or class of cases:</li> <li>(n) provide for anything that this subpart says may or must be provided for by regulations made under this subpart:</li> <li>(o) provide for anything incidental that is necessary for carrying out, or giving full effect to, this subpart.</li> </ul> | <p>5</p> <p>10</p> <p>15</p> |
| <p>(5) Regulations made under this section are secondary legislation (<i>see</i> Part 3 of the Legislation Act 2019 for publication requirements).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <p>20</p>                    |
| <b>20H Consultation before making recommendation</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                              |
| <ul style="list-style-type: none"> <li>(1) Before making a recommendation for regulations under this subpart, the Minister must— <ul style="list-style-type: none"> <li>(a) consult the Authority on the proposed regulations; and</li> <li>(b) consult specified persons who the Minister considers are likely to be affected by the proposed regulations or representatives of those persons.</li> </ul> </li> <li>(2) A failure to consult as required by this section does not affect the validity of any regulations made under this subpart.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <p>25</p>                    |
| <b>20I Exemption from paying levy</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                              |
| <i>Exemption of class of specified persons</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                              |
| <ul style="list-style-type: none"> <li>(1) Before making a recommendation for regulations under <b>section 20G(4)(l)</b>, the Minister must— <ul style="list-style-type: none"> <li>(a) have regard to the purpose of the levy; and</li> <li>(b) be satisfied that the extent of the exemption is no broader than is reasonably necessary to address the matters that gave rise to the proposed exemption.</li> </ul> </li> <li>(2) If the Minister makes a recommendation for regulations under <b>section 20G(4)(l)</b>, the Minister’s reasons for making the recommendation (including</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>30</p> <p>35</p>          |

why the exemption is appropriate) must be published together with the regulations.

*Exemption of individual or named specified persons*

(3) The Minister may exempt any specified person from the requirement to pay a levy under this subpart. 5

(4) Before granting an exemption under this section, the Minister must—

(a) have regard to the purpose of the levy; and

(b) be satisfied that the extent of the exemption is no broader than is reasonably necessary to address the matters that gave rise to the proposed exemption. 10

**20J Miscellaneous provisions relating to levies**

(1) If a person is in 2 or more classes of specified persons in respect of which different levies have been prescribed by the regulations made under this subpart, the person must pay each of those levies (unless the regulations provide otherwise). 15

(2) The amount of any unpaid levy and of any interest under **section 20F** are recoverable in any court of competent jurisdiction as a debt due to the Authority, or to any other person prescribed for the purposes of this subsection by regulations made under this subpart, on behalf of the Crown.

(3) The Authority, or any other person prescribed for the purposes of this subsection by regulations made under this subpart, must ensure that each levy payment is paid into a Crown Bank Account and separately accounted for. 20

Subpart 6—Other financial provisions

**21 Section 24 renumbered and repositioned (Power to request information)**

Renumber section 24 as **section 11A** and reposition it after section 11. 25

**22 Cross-heading above section 25 replaced**

Replace the cross-heading above section 25 with:

Subpart 1—Restriction or prohibition of import and other activities

**23 Section 25 amended (Restriction of import, manufacture, development, field testing, or release)** 30

(1) In section 25(1), delete “or in accordance with Parts 11 to 16”.

(2) Replace section 25(1B) with:

(1B) ~~Despite subsection (1)(b), the following departments or their agents may isolate, aggregate, multiply, breed, propagate, grow, raise, or otherwise use a new organism for the purpose of identifying, managing, or eradicating that organism:~~ 35

**Hazardous Substances and New Organisms Amendment  
Bill**

Part 1 cl 24

- (a) ~~the department responsible for administering the Biosecurity Act 1993;~~  
(b) ~~any departments that are recognised by the responsible Minister under section 101(2) of that Act.~~
- (1B) Despite subsection (1)(b), any of the specified departments or their agents may develop a new organism, for the purpose of identifying, managing, or eradicating the new organism, in 1 or more of the following ways: 5
- (a) by isolating, aggregating, multiplying, breeding, propagating, growing, raising, or otherwise using that organism:  
(b) by carrying out trials, tests, or other research of, on, or using that organism. 10
- (1C) The specified departments are—
- (a) the department responsible for administering the Biosecurity Act 1993; and  
(b) any departments that are recognised by the responsible Minister under section 101(2) of that Act. 15
- (3) In section 25(2), delete “, develop”.
- (4) Replace section 25(6) with:
- (6) A person may do a thing specified in subsection (1)(a) or (b) in relation to any hazardous substance or new organism that is or has been the subject of any of the following kinds of application only if the person has applied for and been granted an approval under this Act to do the thing: 20
- (a) an application made under this Act if the Authority is required under Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997 (as applied by **section 141R(2)**) to protect confidential information (within the meaning of **section 141R(6)**) provided in support of that application that is about the hazardous substance or new organism: 25
- (b) an innovative medicine application:  
(c) an innovative TNP application.
- (5) In section 25(7), replace “section 55(3) or (4)” with “**section 141R(1) or (2)**”. 30
- 24 Section 25B amended (Prohibition on storage of persistent organic pollutants)**
- (1) Replace the heading to section 25B with “**Prohibition of storage of persistent organic pollutants and exception**”.
- (2) Repeal section 25B(2)(b). 35
- 25 Sections 25C and 25D replaced**
- Replace sections 25C and 25D with:

**25C Prohibited organisms**

- (1) The importation, release, or development of any organism specified in Schedule 2 (other than a denewed organism) is prohibited.
- (2) However, the development of any new organism specified in Schedule 2 that is present in New Zealand and that the Authority considers to be a vagrant is permitted in accordance with an approval granted under section 45. 5
- (3) 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 (4)**, recommended to the Minister be included in that schedule: 10
  - (b) add a new organism, or a 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 a group of organisms, but only if the organism or group was inserted by Order in Council.

**Guidance note** 15

See section 141 for procedural requirements with which the Minister must comply before making a recommendation under **subsection (3)**.

- (4) 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 Schedule 2, where the Authority is satisfied that— 20
  - (a) the organism is likely to have any of the effects described in section 36; and
  - (b) any likely adverse effects that may occur should the organism escape from containment would outweigh any likely beneficial effects of allowing the organism to be imported into containment. 25
- (5) The Authority, when making a recommendation under **subsection (4)**, may advise the Minister that a group of organisms should be included in Schedule 2 if it is difficult for persons to distinguish between high-risk and low-risk members of that group. 30
- (6) In this section, **denewed organism** ~~mean—means~~ an organism that is prescribed as not a new organism in ~~regulations made under section 140(1)(c) or a notice made under~~ **Part 5A**.
- (7) An order made under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements). 35

**26 New subpart 2 heading in Part 5 inserted**

In Part 5, above section 26, insert:

Subpart 2—Determination of new organisms and hazardous substances, definitions, etc

**27 Section 26 amended (Determination of new organism or hazardous substance)**

Replace section 26(1) and (2) with:

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(1) ~~The Authority may, on application by any person, determine either or both of the following:~~

(a) ~~whether or not an organism is a new organism:~~

(b) ~~any 1 or more taxonomic classifications, as the Authority thinks fit, for an organism or a group of organisms.~~

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(1) The Authority may, on application by any person, determine whether or not—

(a) an organism is a new organism; or

(b) a group of organisms is a group of new organisms.

(1A) If the Authority determines that an organism is a new organism, or that a group of organisms is a group of new organisms, it may also determine any 1 or more taxonomic classifications that the Authority thinks fit for the organism or group of organisms.

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(2) ~~The A~~ determination under this section must be published on an Internet site maintained by or on behalf of the Authority.

**28 Section 27 replaced (Types of approval)**

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Replace section 27 with:

**27 Meaning of approval**

In this Act, **approval** means any of the following:

(a) an approval to import or manufacture a hazardous substance, otherwise than into or in containment (*see* sections 28A, 29, and **29AB**):

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(b) an approval to import a hazardous substance into containment or to manufacture a hazardous substance in containment (*see* sections 30 and 32):

(c) an approval to import for release or release from containment a new organism that is not a qualifying organism without controls (*see ~~sections 34B,~~ sections 35 and 38*):

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(d) an approval to import for release or release from containment a qualifying organism with controls (*see* section 38I) or without controls (*see* sections 38 and 38I):

(e) a conditional release approval to import for release or release from containment a new organism with controls (*see* sections 38BA and 38C):

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- (f) an approval to import a new organism into containment, or to develop or field test a new organism in containment (*see* sections 39, 42 to **42C**, and 45):
- (g) an approval to do 1 or more of the following (*see* section 48):
  - (i) import a hazardous substance for release or use in response to an adverse event: 5
  - (ii) import a new organism for release or use in response to an adverse event:
  - (iii) ~~release or use~~ a hazardous substance from containment in response to an adverse event: 10
  - (iv) ~~release or use~~ a new organism from containment in response to an adverse event:
  - (v) use any hazardous substance in response to an adverse event in a manner that would otherwise contravene the provisions of this Act or any regulations or any EPA notice: 15
- (h) an approval to do any 1 or more of the following in a special emergency (*see* section 49F):
  - (i) import an agricultural compound, a medicine, or a medical device for release:
  - (ii) manufacture an agricultural compound, a medicine, or a medical device that is or contains a hazardous substance otherwise than in containment: 20
  - (iii) release an agricultural compound, a medicine, or a medical device from containment:
  - (iv) use an agricultural compound, a medicine, or a medical device in a manner that would contravene this Act or any regulations or any EPA notice: 25
- (i) an approval to tranship a hazardous substance or new organism through New Zealand (*see* section 51).

**29 Section 27A amended (Approvals at any taxonomic classification) 30**

In section 27A(1), replace “section 27(b), (ba), (bb), or (c)” with “**section 27(c), (d), (e), or (f)**”.

**30 Section 28 and cross-heading replaced**

Replace section 28 and the cross-heading above section 28 with:

### Subpart 3—Approvals for hazardous substances

#### *Approvals for hazardous substances except containment approvals*

#### **28 Application for approval to import or manufacture hazardous substance**

- (1) A person intending to import or manufacture a hazardous substance otherwise than into or in containment must, before importing or manufacturing that substance, apply under this section for, and be granted, an approval under section 28A or 29 to import or manufacture that substance. 5
- (2) However, **subsection (1)** does not apply to the person if—
  - (a) an approval under section 28A or 29 already allows the importation or manufacture of that substance; or 10
  - (b) the person applies under **section 29A** for, and is granted, an approval under **section 29AB** that allows the person to import or manufacture the substance and that approval is in force.
- (3) An application under this section must—
  - (a) be in the approved form; and 15
  - (b) contain, or be accompanied by, the information prescribed by the regulations; and
  - (c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration. 20
- (4) An applicant under this section may withdraw the application at any time by written notice to the Authority.

#### **31 Section 28A amended (Rapid assessment for importation or manufacture of hazardous substances)**

- (1) Replace section 28A(1) with: 25
  - (1) The Authority may make a rapid assessment of the adverse effects of importing or manufacturing a hazardous substance if an application under **section 28** to import or manufacture the substance requests that the Authority make a rapid assessment of those effects.
- (2) Replace section 28A(3) to (6) with: 30
- (3) The Authority must not approve a hazardous substance under this section solely because it is satisfied of the matter in subsection (2)(ab) if it considers that the application, if approved, will result in—
  - (a) significant cultural, economic, environmental, ethical, or health effects in or for New Zealand; or 35
  - (b) significant effects for New Zealand's international obligations; or

- (c) significant effects in an area in which the Authority lacks sufficient knowledge or expertise.
- (4) Sections 77 to 77B apply to any hazardous substance approved under this section.
- (5) The Authority must not determine the application under section 29 if the Authority decides—

  - (a) to decline to make a rapid assessment under this section; or
  - (b) to make a rapid assessment but not to approve the hazardous substance under this section.

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- (6) However, nothing in this section prevents an applicant from—

  - (a) withdrawing the application under **section 28** before the Authority declines to make a rapid assessment or declines to approve the hazardous substance under this section; or
  - (b) making a new application under **section 28**.

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### 32 Section 29 amended (Determination of applications) 15

- (1) In section 29(1), replace “any” with “an”.
- (2) After section 29(1), insert:

#### Guidance note

This section does not apply to an application for approval made under **section 28** that requests that the Authority make a rapid assessment of the adverse effects of importing or manufacturing a hazardous substance (see section 28A). 20

### 33 New sections 29A to 29AC inserted

After section 29, insert:

#### 29A Application for temporary hazardous substance approval

- (1) A person may apply under this section for an approval under **section 29AB** (a **temporary hazardous substance approval**) to import or manufacture a hazardous substance for a use specified in the application if—

  - (a) the person has applied under **section 28** to carry out that importation or manufacture for the specified use; and
  - (b) the Authority has notified the person under **section 52** that the application under **section 28** is complete; and
  - (c) the determination of the application under **section 28** is pending; and
  - (d) the specified use of the hazardous substance has been lawfully authorised by at least 2 international regulators.

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- (2) A person may not apply for a temporary hazardous substance approval if—

  - (a) the person has requested, in their application under **section 28**, that the Authority make a rapid assessment under section 28A; and

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- (b) the Authority's determination as to whether to make the rapid assessment or approve the hazardous substance is pending.
- (3) A determination relating to an application is pending if—

  - (a) the applicant has not withdrawn the application; and
  - (b) the application has not lapsed under **section 52B**; and
  - (c) the application has not been finally determined.
- (4) An application under this section must—

  - (a) be in the approved form; and
  - (b) contain, or be accompanied by, the information prescribed by the regulations; and
  - (c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration.
- (5) An applicant under this section may withdraw the application at any time by written notice to the Authority.
- (6) The application is to be treated as withdrawn if, before the application is determined under **section 29AB**, the application under **section 28**—

  - (a) is withdrawn by the applicant; or
  - (b) lapses under **section 52B**; or
  - (c) is determined under section 29.

**29AB Determination and content of temporary hazardous substance approval**

- (1) The Authority may grant an application under **section 29A** for a temporary hazardous substance approval only if—

  - (a) the Authority is satisfied that the approval would have an identified benefit for New Zealand for the duration of the approval; and
  - (b) controls will be imposed on the approval; and
  - (c) the Authority is satisfied that, for the duration of the approval, those controls would be sufficient to manage the risks associated with the specified use for which the approval would allow the hazardous substance to be imported or manufactured.
- (2) Without limiting **subsection (1)(b)**, a temporary hazardous substance approval must include a control to the effect that the person to whom the approval has been granted may, for the duration of the approval,—

  - (a) use the hazardous substance only if that use is the specified use; or
  - (b) supply the hazardous substance only if the person takes all reasonably practicable steps to ensure that any resupply is only for the specified use.
- (3) Sections 77 to 77B apply to any hazardous substance approved under this section.

- (4) In this section, **specified use**, in relation to an approval, means the use specified in the approval.

**29AC Duration of temporary hazardous substance approval**

A temporary hazardous substance approval expires on the earliest of the following:

- (a) the date specified as the expiry date in the approval (being a date that is no later than 4 years after the date on which the approval is granted);
- (b) when the person to whom the approval is granted withdraws the application under **section 28** (the **related section 28 application**) that is referred to in **section 29A**;
- (c) when the related section 28 application—
  - (i) lapses under **section 52B**; or
  - (ii) is determined under section 29.

**34 Section 29B amended (Applications relating to persistent organic pollutants)**

In section 29B(1)(b), replace “environmentally sound disposal” with “disposal in accordance with directions issued under **section 73A** (environmentally sound disposal of persistent organic pollutants)”.

**35 Section 30 amended (Importing hazardous substances in containment)**

- (1) Replace the heading to section 30 with “**Importing or manufacturing hazardous substances into or in containment**”.
- (2) In section 30, replace “manufacture or importation of any hazardous substance in containment” with “importation into containment, or the manufacture in containment, of any hazardous substance”.
- (3) Replace section 30(c) with:
  - (c) use in response to an adverse event (within the meaning of **section 46**), a special emergency declared under section 49B, or an emergency declared under any other Act; or

**36 Section 31 amended (Application for hazardous substance containment approval)**

Replace section 31(1) to (3) with:

- (1) A person intending to import into containment, or manufacture in containment, any hazardous substance must, before importing or manufacturing that substance, apply under this section for, and be granted, an approval to import or manufacture that substance.
- (2) An application under this section must—
  - (a) be in the approved form; and

- (b) contain, or be accompanied by, the information prescribed by the regulations; and
    - (c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration.
- 5
- 37 Section 33 amended (Exemptions from Act for small-scale research on hazardous substances)**
- (1) Replace the heading to section 33 with “**Small-scale research on hazardous substances: exemption for use and sale**”.
  - (2) Before section 33(1), insert:
- 10
- Exemption*
- (3) Replace section 33(1)(b) with:
- (b) the use does not create or involve a declined hazardous substance; and
- (4) After section 33(1), insert:
- 15
- Restriction on sale*
- (5) After section 33(2), insert:
  - (3) In this section, **declined hazardous substance**—
- (a) means a hazardous substance that is the subject of—
    - (i) an application for approval that is declined; or
    - (ii) an approval that is revoked under **section 63**; but
  - (b) does not include a hazardous substance that—
    - (i) is the subject of an approval that is in force (except if the hazardous substance is prescribed for the purposes of this subparagraph); or
    - (ii) is the subject of an application for a temporary hazardous substance approval that is declined (except if the hazardous substance is prescribed for the purposes of this subparagraph); or
    - (iii) is the subject of a temporary hazardous substance approval that is revoked under **section 63** (except if the hazardous substance is prescribed for the purposes of this subparagraph); or
    - (iv) is prescribed for the purposes of this subparagraph.
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- 25
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- (4) In this section, a reference to a hazardous substance that is prescribed is a reference to a hazardous substance that is, or that belongs to a class that is, prescribed by an EPA notice issued under section 76A.
- 38 New subpart 4 in Part 5 inserted**
- 35
- After section 33, insert:

Subpart 4—Approvals for new organisms

*Importation for release or release from containment generally*

**33A Application required**

Every person intending to import for release or to release from containment any new organism must, before importation or release, apply to the Authority under section 34 or 38A for, and be granted, an approval to import or release the organism.

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**39 Cross-heading above section 34 replaced**

Replace the cross-heading above section 34 with:

*Importation for release or release from containment (other than conditional release)*

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**40 Section 34 amended (Application for approval to import or release)**

(1) Replace the heading to section 34 with “**Application for approval other than conditional release approval, etc**”.

(2) Replace section 34(1) with:

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(1) A person may apply to the Authority for an approval (other than a conditional release approval) to import for release or to release from containment a new organism.

(3) Replace section 34(2) and (3) with:

(2) An application under this section must—

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(a) be in the approved form; and

(b) contain, or be accompanied by, the information prescribed by the regulations; and

(c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration.

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**41 Section 34A amended (Applications for conditional release and for release in respect of same new organism)**

(1) Replace the heading to section 34A with “**Deemed section 34 application: release of new organism at expiry of conditional release approval**”.

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(2) After section 34A(1), insert:

(1A) The application must—

(a) be in the approved form; and

(b) contain, or be accompanied by, the information prescribed by the regulations; and

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- (c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration.

**42 New section 34B inserted (Approval to release without controls: simplified transition from conditional release approval)**

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After section 34A, insert:

**34B Approval to release without controls: simplified transition from conditional release approval**

- (1) Any person may apply to the Authority for approval under this section to release, without controls, a new organism to which a conditional release approval applies.
- (2) An application under this section must—
- (a) be in the approved form; and
- (b) contain, or be accompanied by, the information prescribed by the regulations; and
- (c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration.
- (3) The Authority may grant the application only if the Authority is satisfied that the criteria prescribed by an EPA notice for the purposes of this section are met.
- (4) If the application is granted,—
- (a) the approval takes immediate effect; and
- (b) the conditional release approval expires with immediate effect; and
- (c) the new organism may be released without controls.
- (5) An applicant under this section may withdraw the application at any time by written notice to the Authority.

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**43 Section 35 amended (Rapid assessment of risk for importation of new organisms)**

- (1) In the heading to section 35, after “**organisms**”, insert “**(other than qualifying organisms)**”.

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- (2) Replace section 35(1) with:

- (1) The Authority may make a rapid assessment of the adverse effects of importing a new organism (other than a genetically modified new organism) for release if an application under section 34 to import the new organism for release requests that the Authority make a rapid assessment under this section of those effects.

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- (3) In section 35(2)(a) and (3)(a), delete “as defined in the Biosecurity Act 1993”.

- (4) After section 35(5), insert:
- (6) This section does not apply to an application under section 34 that relates to a qualifying organism (*see* section 38I(1) to (2)).
- 44 Section 36 amended (Minimum standards)**
- In section 36, replace “shall decline the application” with “must decline an application made under section 34 referred to in section 38(1)”. 5
- 45 Section 37 heading amended (Additional matters to be considered)**
- In the heading to section 37, after “considered”, insert “for decision under section 38”.
- 46 Section 38 amended (Determination of applications to import or release)** 10
- (1) In the heading to section 38, replace “to import or release” with “under section 34 generally”.
- (2) Repeal section 38(1)(b)(i).
- (3) After section 38(1)(b), insert:
- Guidance note**

See section 36 (minimum standards), which sets out circumstances in which the Authority must decline the application.
- (4) Repeal section 38(3) to (4). 15
- 47 New sections 38AA to 38AAC inserted**
- After section 38, insert: 20
- 38AA Duration of section 38 approval generally**

(1) This section applies to an approval granted under section 38 but does not apply to an approval that is expressed to take effect when a conditional release approval expires.

(2) The approval expires— 25

(a) on the applicable expiry date; or

(b) if the organism is released before the applicable expiry date, when the organism is released.

(3) The **applicable expiry date** is the latest of the following dates: 30

(a) the date that is 5 years after the date of the approval:

(b) if an application is made under **section 38AAB** to extend the approval,—

(i) the date on which the Authority determines the application if the Authority refuses it, but only if that date is after the date on which the approval would otherwise expire; or 35

- (ii) the date determined by the Authority if the Authority grants the application.

### **38AAB Application for extension of section 38 approval generally**

- (1) This section applies to an approval to which **section 38AA** applies.
- (2) On an application made by any person before the date on which the approval would otherwise expire, the Authority may extend the approval if the approval—
  - (a) has not been extended before; or
  - (b) has been extended fewer than 3 times.
- (3) **Section 52(5)** does not apply in relation to the application and, accordingly, the date on which the application is made is the date on which it is lodged with the Authority (whether or not it is complete, within the meaning of **section 52(3)**).
- (4) The application must—
  - (a) be in the approved form; and
  - (b) contain, or be accompanied by, the information prescribed by the regulations; and
  - (c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration.
- (5) The approval continues in force until the Authority determines the application.
- (6) However,—
  - (a) **subsection (5)** does not reduce the period for which the approval would otherwise remain in force under **section 38AA**; and
  - (b) if the Authority grants the application, the approval continues in force until the date that the Authority determines.
- (7) If the Authority grants the application, the date determined by the Authority must not be later than 5 years after the date on which the approval would have expired but for **subsections (5) and (6)(b)**.

### **38AAC Notification of release in accordance with section 38 approval**

- (1) This section applies to an approval to import a new organism for release, or to release a new organism from containment, that is granted under section 38.
- (2) A person who releases an organism in accordance with the approval must notify the Authority within 1 month after the date of release.

- (3) A person is not required to notify the Authority under this section if the Authority waives the requirement for notification.

**Guidance note**

See **section 20(4)**, which requires the Authority to record in the register kept under section 20 whether or not it has been notified under this section or has waived the requirement for notification.

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**48 Section 38A amended (Application for approval to import or release new organism with controls)**

Replace section 38A(2) and (3) with:

- (2) An application under this section must—
- (a) be in the approved form; and
  - (b) contain, or be accompanied by, the information prescribed by the regulations; and
  - (c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration.

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**49 Section 38B amended (Application under section 34 may be treated as application under section 38A)**

In section 38B, delete “, and sections 38A, 38BA, 38C, and 53(1)(ab) apply accordingly”.

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**50 Section 38BA amended (Rapid assessment of risk for importation or release of new organisms with controls)**

- (1) Replace section 38BA(1) with:
- (1) The Authority may make a rapid assessment of the adverse effects of importing for release, or releasing from containment, a new organism (other than a genetically modified organism) if an application under section 38A in respect of the new organism requests that the Authority make a rapid assessment of those effects.
- (2) In section 38BA(2)(a), delete “as defined in the Biosecurity Act 1993”.

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**51 Section 38E amended (Duration of conditional release approval)**

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- (1) Replace section 38E(1) with:
- (1) A conditional release approval that expressly states that it does not expire expires on the close of the latest date on which the controls imposed on the approval expressly expire.
- (2) Replace section 38E(2)(c) with:
- (c) the close of the latest date on which the controls imposed on the approval expressly expire.

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- (3) After section 38E(2), insert:
- (3) Despite anything else in this section, if an application is made under **section 38F** to extend a conditional release approval, the date on which the conditional release approval expires is,—
- (a) if the Authority refuses the application, the date on which the Authority determines the application, but only if that date is after the date on which the approval would otherwise expire; or
- (b) if the Authority grants the application, the date determined by the Authority.
- 52 Section 38F replaced (Consequences of expiry of conditional release approval)**
- Replace section 38F with:
- 38F Application for extension**
- (1) On an application made by any person before the date on which a conditional release approval would otherwise expire, the Authority may extend the approval if the approval—
- (a) has not been extended before; or
- (b) has been extended fewer than 3 times.
- (2) **Section 52(5)** does not apply in relation to the application and, accordingly, the date on which the application is made is the date on which it is lodged with the Authority (whether or not it is complete, within the meaning of **section 52(3)**).
- (3) The application must—
- (a) be in the approved form; and
- (b) contain, or be accompanied by, the information prescribed by the regulations; and
- (c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration.
- (4) The approval continues in force until the Authority determines the application.
- (5) However,—
- (a) **subsection (4)** does not reduce the period for which the approval would otherwise remain in force under section 38E; and
- (b) if the Authority grants the application, the approval continues in force until the date that the Authority determines.
- (6) If the Authority grants the application, the date determined by the Authority must not be later than 5 years after the date on which the approval would have expired but for **subsections (1) and (5)(b)**.

**53 Section 38G amended (Review of controls on conditional release approval)**

- (1) Replace section 38G(1) and (2) with:
- (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 97A, review the controls that it has imposed on the conditional release approval. 5
- (1A) Following the review, the Authority may—
- (a) amend a control so that it better meets the objective of the control; or
  - (b) amend or replace a subject-to-review control if the amendment or replacement is consistent with the potential consequences of the review identified in the subject-to-review control; or 10
  - (c) remove a control requiring the disposal of the new organism to which the approval applies if the Authority considers that the control is not necessary to prevent any adverse effect on human health or safety or the environment; or
  - (d) impose, amend, or replace a control requiring the disposal of the new organism to which the approval applies if the Authority considers that— 15
    - (i) imposing, amending, or replacing the control is necessary to prevent any adverse effect on human health or safety or the environment; or
    - (ii) amending or replacing the control (if applicable) will not increase the likelihood of any adverse effect on human health or safety or the environment. 20
- (1B) Nothing in **subsection (1A)(d)** limits the discretion of the Authority under **subsection (1A)(a) or (b)**. 25
- (2) An application under this section must—
- (a) be in the approved form; and
  - (b) contain, or be accompanied by, the information prescribed by the regulations; and
  - (c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration. 30
- (2A) An applicant under this section may withdraw the application at any time by written notice to the Authority.
- (2) In section 38G(3), replace “section 67A” with “**section 73C**”.
- (3) After section 38G(3), insert: 35
- (4) In this section, **subject-to-review control** means a control that includes a review requirement that specifies the circumstances in which the control is to be reviewed and the potential consequences of the review.

**54 Section 38I amended (Assessment of applications for release of qualifying organisms)**

- (1) Before section 38I(1), insert:

*Rapid assessment*

- (2) After section 38I(1), insert:

5

- (1A) An approval granted under this section is not an approval—

- (a) to use a qualifying medicine or qualifying medical device until the medicine or device 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.

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- (3) Before section 38I(3), insert:

*Determination of whether medicine, etc, is qualifying medicine, etc*

- (4) In section 38I(3), replace “qualifying organism is or is contained in a qualifying medicine or a qualifying veterinary medicine” with “medicine, medical device, or veterinary medicine that is or contains a new organism is a qualifying medicine, qualifying medical device, or qualifying veterinary medicine”.

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- (5) In section 38I(3)(a), after “veterinary medicine”, insert “, or the intended purpose of the medical device,”.

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- (6) In section 38I(3)(b), replace “qualifying” with “new”.

- (7) After section 38I(3), insert:

**Guidance note**

See **paragraph (b)** of the definitions of qualifying medical device, qualifying medicine, and qualifying veterinary medicine in section 2(1).

See *also* definition of qualifying organism in section 2(1).

25

- (8) In section 38I(4), replace “qualifying organism is or is contained in a qualifying medicine or a qualifying veterinary medicine” with “medicine, medical device, or veterinary medicine that is or contains a new organism is a qualifying medicine, qualifying medical device, or qualifying veterinary medicine”.

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- (9) In section 38I(4)(a) and (b), replace “qualifying organism” with “new organism”.

- (10) After section 38I(4)(a), insert:

- (aa) any effect of the medical device or new organism on the person in, on, or for whom the device is being used (within the meaning of the Medicines Act 1981):

35

- (11) Replace section 38I(5) with:

- (5) In this section,—

|            |                                                                                                                                                                                                                                                                                                                                                                                 |    |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
|            | <b>medical device</b> has the same meaning as in section 3A of the Medicines Act 1981                                                                                                                                                                                                                                                                                           |    |
|            | <b>medicine</b> means a medicine or new medicine within the meaning of section 3 of the Medicines Act 1981                                                                                                                                                                                                                                                                      |    |
|            | <b>veterinary medicine</b> has the same meaning as in section 2(1) of the Agricultural Compounds and Veterinary Medicines Act 1997.                                                                                                                                                                                                                                             | 5  |
| <b>55</b>  | <b>Section 38J replaced (Procedure for assessing and approving application by responsible chief executive)</b>                                                                                                                                                                                                                                                                  |    |
|            | Replace section 38J with:                                                                                                                                                                                                                                                                                                                                                       |    |
| <b>38J</b> | <b>Procedure for assessing and approving application by responsible chief executive</b>                                                                                                                                                                                                                                                                                         | 10 |
| (1)        | This section applies if the Authority has delegated to the responsible chief executive its power under section 38I(1) to assess and approve an application that relates to a qualifying organism.                                                                                                                                                                               |    |
| (2)        | The responsible chief executive must be paid the charge fixed by the Authority for the assessment and approval of the application.                                                                                                                                                                                                                                              | 15 |
| (3)        | The responsible chief executive must determine whether the medicine is a qualifying medicine, the medical device is a qualifying medical device, or the veterinary medicine is a qualifying veterinary medicine, as the case may be.                                                                                                                                            |    |
| (4)        | If the responsible chief executive is satisfied that the medicine is a qualifying medicine, the medical device is a qualifying medical device, or the veterinary medicine is a qualifying veterinary medicine, the responsible chief executive may, with or without controls, approve the importation for release, or the release from containment, of the qualifying organism. | 20 |
| <b>56</b>  | <b>Section 38K amended (Controls)</b>                                                                                                                                                                                                                                                                                                                                           | 25 |
| (1)        | In section 38K(1)(a), after “qualifying medicine”, insert “, qualifying medical device,”.                                                                                                                                                                                                                                                                                       |    |
| (2)        | In section 38K(1)(b), replace “the qualifying medicine or” with “or using the qualifying medicine, qualifying medical device,”.                                                                                                                                                                                                                                                 |    |
| (3)        | In section 38K(1)(c), replace “the qualifying medicine or” with “or use the qualifying medicine, qualifying medical device,”.                                                                                                                                                                                                                                                   | 30 |
| (4)        | Replace section 38K(1)(d) with:                                                                                                                                                                                                                                                                                                                                                 |    |
|            | (d) controls concerning the persons in relation to whom the qualifying medicine or qualifying medical device may be administered or used:                                                                                                                                                                                                                                       |    |
| <b>57</b>  | <b>Section 38L amended (Review of controls for qualifying organisms)</b>                                                                                                                                                                                                                                                                                                        | 35 |
| (1)        | Replace section 38L(2) with:                                                                                                                                                                                                                                                                                                                                                    |    |
| (2)        | An application under this section must—                                                                                                                                                                                                                                                                                                                                         |    |

| Hazardous Substances and New Organisms Amendment Bill                                                                                                                                                                                                                                                                                                                                                             |    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| Part 1 cl 58                                                                                                                                                                                                                                                                                                                                                                                                      |    |
| <ul style="list-style-type: none"> <li>(a) be in the approved form; and</li> <li>(b) contain, or be accompanied by, the information prescribed by the regulations; and</li> <li>(c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in <b>paragraph (b)</b> that the regulations require to be verified by a statutory declaration.</li> </ul> | 5  |
| (2A) An applicant under this section may withdraw the application at any time by written notice to the Authority.                                                                                                                                                                                                                                                                                                 |    |
| (2) In section 38L(3), replace “section 67A” with “ <b>section 73C</b> ”.                                                                                                                                                                                                                                                                                                                                         |    |
| <b>58 Section 39 amended (Importation or development of new organisms in containment)</b>                                                                                                                                                                                                                                                                                                                         | 10 |
| (1) Replace the heading to section 39 with “ <b>Importation into, or development or field testing in, containment</b> ”.                                                                                                                                                                                                                                                                                          |    |
| (2) In section 39(1), replace “importation, development, or field testing of any new organism into containment” with “importation of any new organism into containment, or the development or field testing of any new organism in containment,”.                                                                                                                                                                 | 15 |
| (3) In section 39(1)(c), replace “in an emergency” with “in response to an adverse event”.                                                                                                                                                                                                                                                                                                                        |    |
| <b>59 Section 40 amended (Application for containment approval for new organisms)</b>                                                                                                                                                                                                                                                                                                                             | 20 |
| Replace section 40(2) and (3) with:                                                                                                                                                                                                                                                                                                                                                                               |    |
| (2) To avoid doubt, an application under this section for approval to develop a new organism that is specified in Schedule 2 and that the Authority considers to be a vagrant may be made whether or not the new organism is present in New Zealand.                                                                                                                                                              | 25 |
| <b>Guidance note</b><br>However, importing a new organism specified in Schedule 2 is prohibited under <b>section 25C</b> .                                                                                                                                                                                                                                                                                        |    |
| (3) An application under this section must—                                                                                                                                                                                                                                                                                                                                                                       | 30 |
| <ul style="list-style-type: none"> <li>(a) be in the approved form; and</li> <li>(b) contain, or be accompanied by, the information prescribed by the regulations; and</li> <li>(c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in <b>paragraph (b)</b> that the regulations require to be verified by a statutory declaration.</li> </ul> | 35 |

- 60 Section 42 amended (Rapid assessment of adverse effects for development of genetically modified organisms)**
- (1) Replace section 42(1) with:
- (1) The Authority may make a rapid assessment of the adverse effects of developing a genetically modified organism in containment if an application under section 40 to develop the organism in containment requests that the Authority make a rapid assessment under this section of those effects. 5
- (2) After section 42(2), insert:
- (3) This section does not apply in relation to the development in containment of a genetically modified organism— 10
- (a) that is a new organism specified in Schedule 2; and
- (b) that the Authority considers to be a vagrant.
- 61 Section 42A amended (Rapid assessment of projects for low-risk genetic modification)**
- (1) Repeal section 42A(1). 15
- (2) In section 42A(2), replace “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” with “a specified application that requests the Authority to make a rapid assessment of the adverse effects of carrying out the project to which the application relates, the Authority may make a rapid assessment of those effects”. 20
- (3) After section 42A(3), insert:
- (4) This section does not apply in relation to the development in containment of a genetically modified organism— 25
- (a) that is a new organism specified in Schedule 2; and
- (b) that the Authority considers to be a vagrant.
- (5) In this section, **specified application**, in relation to a project, means an application under section 40 to develop a new organism in containment as part of a project.
- 62 Section 42B amended (Rapid assessment of adverse effects for importation of genetically modified organisms into containment)** 30
- Replace section 42B(1) with:
- (1) The Authority may make a rapid assessment of the adverse effects of importing a genetically modified organism into containment if an application under section 40 to import the organism into containment requests that the Authority make a rapid assessment under this section of those effects. 35

**63 Section 42C replaced (Rapid assessment of adverse effects for development in containment, etc, of certain new organisms)**

Replace section 42C with:

- 42C Rapid assessment of adverse effects of importing, developing, or field testing (other than genetically modified organism)** 5
- (1) The Authority may make a rapid assessment of the adverse effects of importing a new organism (other than a genetically modified organism) into containment, or of developing or field testing a new organism (other than a genetically modified organism) in containment, if an application under section 40 to import the organism into containment, or to develop or field test the organism in containment, requests that the Authority make a rapid assessment under this section of those effects. 10
- (2) If the Authority is satisfied that the importation, development, or field testing meets the prescribed criteria for low-risk importation, development, or field testing, the Authority may— 15
- (a) approve the application; and
- (b) impose any controls that the Authority thinks fit for each of the matters specified in Part 2 of Schedule 3.
- (3) The **prescribed criteria** for low-risk importation, development, or field testing are the criteria prescribed by an EPA notice for the purposes of this section. 20
- (4) This section does not apply in relation to the development in containment of a new organism—
- (a) that is specified in Schedule 2; and
- (b) that the Authority considers to be a vagrant.

**64 Section 43 amended (Additional matters to be considered when application made for developing new organisms in containment)** 25

In section 43, insert as subsection (2):

- (2) If the application is for approval to develop a new organism in containment that is specified in Schedule 2 and that the Authority considers to be a vagrant, the Authority must also have regard to any adverse effects of the development of the organism and of any of its offspring, progeny, or descendants. 30

**65 Section 44 amended (Additional matters to be considered on applications for importing and field testing of organisms)**

- (1) After section 44(b), insert: 35
- (c) the ability of any heritable material arising from the organism to escape from containment if it is a genetically modified organism.
- (2) In section 44, insert as subsection (2):

- (2) The Authority, when making a decision under section 45 on the application, may have regard to the ability of any heritable material arising from the organism to escape from containment if it is not a genetically modified organism.

**66 Section 45 amended (Determination of application)**

- (1) Replace section 45(1) with: 5
- (1) After considering any application for approval made under section 40, the Authority (if the application is not approved under section 42, 42A, 42B, or **42C**) may, in its discretion, approve the application if—
- (a) the application is for 1 or more of the purposes specified in section 39(1); and 10
  - (b) the Authority is satisfied, after taking into account all the effects of the organism and any inseparable organism (including the matters referred to in section 43 or 44, as applicable), that the beneficial effects of having the organism in containment outweigh the adverse effects of the organism and any inseparable organism; and 15
  - (c) the Authority is satisfied—
    - (i) that the organism can be adequately contained; and
    - (ii) that, in the case of a new organism that is specified in Schedule 2 and that the Authority considers to be a vagrant, the organism and any offspring, progeny, or descendants of the organism will not escape from containment. 20
- (1A) Without limiting the circumstances in which the Authority may, in its discretion, decline the application, the Authority must decline the application if any of the matters set out in **subsection (1)(a), (b), and (c)** are not met.
- (2) In section 45(4), replace “In taking into account the adverse effects of the organism under subsection (1)(a)(ii)” with “In determining the adverse effects of the organism for the purposes of **subsection (1)(b)**”. 25

**67 New section 45AA inserted (Controls required for development of prohibited organism that is vagrant)**

After section 45A, insert: 30

**45AA Controls required for development of prohibited organism that is vagrant**

- (1) This section applies to an approval under section 45 to develop in containment a new organism that is specified in Schedule 2 and that the Authority considers to be a vagrant.
- (2) The approval must include controls— 35
- (a) to ensure that, if the organism is not already in a containment facility, the organism is placed in and contained in a containment facility; and

- (b) to restrict the number or quantity of offspring, progeny, or descendants that may be in containment at the facility; and
- (c) to ensure that, after the end of the development of the organism, the organism and any offspring, progeny, or descendants resulting from that development continue to be in containment in a containment facility or are disposed of.

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**68 Section 46 and cross-heading replaced**

Replace section 46 and the cross-heading above section 46 with:

**Subpart 5—Emergencies and other adverse events**

*Use of hazardous substances and new organisms in response to adverse events*

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**46 Definition of adverse event**

For the purposes of **sections 46A to 49**, **adverse event** means—

- (a) a state of emergency declared under the Civil Defence Emergency Management Act 2002; or
- (b) an emergency within the meaning of section 6 of the Fire and Emergency New Zealand Act 2017; or
- (c) a hazardous substance or new organisms emergency declared under Part 9; or
- (d) a marine oil spill within the meaning of section 281 of the Maritime Transport Act 1994; or
- (e) the arrival or establishment in New Zealand of an organism that is an unwanted organism.

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**46A Adverse event, etc, must be foreseeable**

A person may make an application under section 47, and be granted an approval under section 48, for the importation, release, or use of a hazardous substance or new organism in connection with an adverse event only if both of the following are foreseeable:

25

- (a) the adverse event:
- (b) the release or use (as the case may be) in response to the adverse event.

**Guidance note**

However, see **section 49**.

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**69 Section 47 amended (Application for approval to use a hazardous substance or new organism in an emergency)**

- (1) Replace the heading to section 47 with “**Application for approval**”.

- (2) In section 47(1)(a) and (b), replace “release in an emergency” with “release or use in response to an adverse event”.
  - (3) In section 47(1)(c) to (e), replace “in an emergency” with “in response to an adverse event”.
  - (4) In section 47(1), replace “shall” with “must”. 5
  - (5) Replace section 47(2) and (3) with:
    - (2) An application under this section must—
      - (a) be in the approved form; and
      - (b) contain, or be accompanied by, the information prescribed by the regulations; and 10
      - (c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration.
- 70 Section 48 amended (Determination of applications)**
- (1) Replace section 48(1)(a) with: 15
    - (a) the substance or organism is not necessary for release or use in response to an adverse event; or
  - (2) Replace section 48(2) with:
    - (2) When approving an application under section 47, the Authority must impose the following controls: 20
      - (a) that the organism or substance concerned only be released or used for a specified type of adverse event:
      - (b) that the organism or substance may only be released or used if the adverse event is dealt with in accordance with a specified plan that includes— 25
        - (i) the measures that must be taken to avoid, remedy, or mitigate any actual or potential adverse effects from the release or use of that substance or organism; and
        - (ii) the requirements for disposing of the hazardous substance (if applicable) and any waste products; and 30
        - (iii) the requirements for eradication or control of the new organism (if applicable).
- 71 Section 49 replaced (Exemptions from provisions of Act in emergencies)**
- Replace section 49 with:
- 48A Release and use in response to adverse event involving unwanted organism** 35
- (1) This section applies to an approval under section 48 that authorises any 1 or more of the following activities (the **regulated response activities**) in response

**Hazardous Substances and New Organisms Amendment  
Bill**

Part 1 cl 71

- to an adverse event that is the arrival ~~or establishment~~ in New Zealand of an unwanted organism:
- (a) the release of any hazardous substance from containment in response to the adverse event:
  - (b) the release of any new organism from containment in response to the adverse event: 5
  - (c) the use of any hazardous substance in response to the adverse event in a manner that would otherwise contravene the provisions of this Act or any regulations or any EPA notice.
- (2) ~~A regulated response activity is authorised in response to the arrival or establishment in New Zealand of the unwanted organism only after the relevant chief executive gives notice in the *Gazette* stating that the activity is necessary for 1 or more of the following purposes:~~ 10
- (a) ~~minimising the impact of the organism on natural and physical resources, human health, and overseas market access for New Zealand products:~~ 15
  - (b) ~~controlling the spread of the organism:~~
  - (e) ~~reducing the geographical distribution of the organism:~~
  - (d) ~~eradicating the organism:~~
- (2) A regulated response activity is authorised in response to the arrival in New Zealand of the unwanted organism only after the relevant chief executive— 20
- (a) is satisfied that the activity is necessary for 1 or more of the following purposes:
    - (i) minimising the impact of the organism on natural and physical resources, human health, and overseas market access for New Zealand products: 25
    - (ii) controlling the spread of the organism:
    - (iii) reducing the geographical distribution of the organism:
    - (iv) eradicating the organism; and
  - (b) gives notice in the *Gazette* stating that the activity is necessary and the purpose or purposes for which it is necessary. 30
- (2A) However, the regulated response activity is authorised, with immediate effect, on the relevant chief executive being satisfied that the activity needs to be carried out without delay because of an immediate biosecurity-related threat.
- (2B) In that case, the notice must be published in the *Gazette* as soon as practicable after the regulated response activity is authorised. 35
- (3) The relevant chief executive must arrange for ~~that notice~~ a notice under this section to be published, as soon as practicable after it has been published in the

|           |                                                                                                                                                                                                                                                                |    |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
|           | <i>Gazette</i> , on an Internet site maintained by or on behalf of the department of State responsible for the administration of the Biosecurity Act 1993.                                                                                                     |    |
| (4)       | In this section, <b>relevant chief executive</b> means the chief executive of the department of State that is responsible for the administration of the Biosecurity Act 1993.                                                                                  | 5  |
| <b>49</b> | <b>Exemption from provisions of Act for response to adverse event</b>                                                                                                                                                                                          |    |
| (1)       | Nothing in this Act applies to any hazardous substance or new organism that is required for release or use in responding to an adverse event if the adverse event or the release or use of the substance or organism in the adverse event was not foreseeable. | 10 |
| (2)       | This section is subject to <b>section 25C</b> and sections 49A to 49L.                                                                                                                                                                                         |    |
| <b>72</b> | <b>Cross-heading above section 49A amended</b>                                                                                                                                                                                                                 |    |
|           | In the cross-heading above section 49A, replace “ <i>and medicines</i> ” with “ <i>, medicines, and medical devices</i> ”.                                                                                                                                     |    |
| <b>73</b> | <b>Section 49A amended (Interpretation)</b>                                                                                                                                                                                                                    | 15 |
| (1)       | In section 49A, replace the definition of <b>adverse event</b> with:<br><b>adverse event</b> includes, but is not limited to, an adverse event within the meaning of <b>section 46</b>                                                                         |    |
| (2)       | In section 49A, definition of <b>interested government agency</b> , replace “or medicine” with “ <i>, medicine, or medical device</i> ”.                                                                                                                       | 20 |
| (3)       | In section 49A, insert in its appropriate alphabetical order:<br><b>medical device</b> means a medical device (as defined in section 3A of the Medicines Act 1981) that is or contains a hazardous substance or new organism                                   |    |
| <b>74</b> | <b>Section 49C amended (Application of sections 49D to 49K)</b>                                                                                                                                                                                                |    |
|           | In section 49C(b), replace “or medicine” with “ <i>, medicine, or medical device</i> ”.                                                                                                                                                                        | 25 |
| <b>75</b> | <b>Section 49D amended (Application for approval to use agricultural compound or medicine in special emergency)</b>                                                                                                                                            |    |
| (1)       | In the heading to section 49D, replace “ <b>or medicine</b> ” with “ <i>, medicine, or medical device</i> ”.                                                                                                                                                   |    |
| (2)       | In section 49D(2)(a), replace “or medicine for release” with “ <i>, medicine, or medical device for release</i> ”.                                                                                                                                             | 30 |
| (3)       | In section 49D(2)(b), replace “or medicine that is” with “ <i>, medicine, or medical device that is or contains</i> ”.                                                                                                                                         |    |
| (4)       | In section 49D(2)(c), and (d) and (3)(b), replace “or medicine” with “ <i>, medicine, or medical device</i> ”.                                                                                                                                                 | 35 |

| Hazardous Substances and New Organisms Amendment Bill |                                                                                                                                                                         |
|-------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Part 1 cl 76                                          |                                                                                                                                                                         |
| <b>76</b>                                             | <b>Section 49E amended (Contents of application)</b>                                                                                                                    |
| (1)                                                   | In section 49E(2)(a), (b), (e), (i), and (j), replace “or medicine” with “, medicine, or medical device” in each place.                                                 |
| (2)                                                   | In section 49E(2)(c) and (g), replace “use of the agricultural compound or medicine” with “release or use of the agricultural compound, medicine, or medical device”. 5 |
| (3)                                                   | In section 49E(2)(f), replace “or medicine have been approved for use” with “, medicine, or medical device has been approved for release or use”.                       |
| <b>77</b>                                             | <b>Section 49F amended (Determination of applications)</b>                                                                                                              |
|                                                       | In section 49F(3)(a), replace “or medicine is not necessary for use” with “, medicine, or medical device is not necessary for release or use”. 10                       |
| <b>78</b>                                             | <b>Section 49G amended (Controls attaching to approval of application)</b>                                                                                              |
| (1)                                                   | In section 49G, replace “or medicine may be released” with “, medicine, or medical device may be released or used”.                                                     |
| (2)                                                   | In section 49G(a), replace “use of the agricultural compound or medicine” with “release or use of the agricultural compound, medicine, or medical device”. 15           |
| (3)                                                   | In section 49G(b), replace “or medicine” with “, medicine, or medical device” in each place.                                                                            |
| <b>79</b>                                             | <b>Section 49H amended (Notification or publication of approval of application)</b> 20                                                                                  |
|                                                       | In section 49H(2)(b), replace “use of the agricultural compound or medicine” with “release or use of the agricultural compound, medicine, or medical device”.           |
| <b>80</b>                                             | <b>Section 49I amended (Effect of approval of release)</b>                                                                                                              |
|                                                       | In section 49I(1), replace “or medicine” with “, medicine, or medical device” in each place. 25                                                                         |
| <b>81</b>                                             | <b>Section 49L amended (Rapid assessment and approval of other hazardous substances in special emergencies)</b>                                                         |
|                                                       | In section 49L(2), replace “or a medicine” with “, a medicine, or a medical device”. 30                                                                                 |
| <b>82</b>                                             | <b>Section 50 and cross-heading repealed</b>                                                                                                                            |
|                                                       | Repeal section 50 and the cross-heading above section 50.                                                                                                               |
| <b>83</b>                                             | <b>Cross-heading above section 51 replaced</b>                                                                                                                          |
|                                                       | Replace the cross-heading above section 51 with:                                                                                                                        |
| Subpart 6—Transshipment through New Zealand 35        |                                                                                                                                                                         |

**84 Section 51 amended (Transshipment of substances and organisms)**

- (1) Before section 51(1), insert:

*Act not applicable to approved transshipment*

- (2) In section 51(1), replace “shall apply” with “applies”.

- (3) Replace section 51(2) with:

5

*Restriction on transshipment*

- (2) A person must apply for, and be granted, an approval under this section before they tranship a hazardous substance or new organism through New Zealand.

*Application*

- (3) An application under this section must—

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- (a) be in the approved form; and
- (b) contain, or be accompanied by, the information prescribed by the regulations; and
- (c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration.

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*Withdrawal of application*

- (4) An applicant under this section may withdraw the application at any time by written notice to the Authority.

*Determination of application*

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- (5) The Authority—

- (a) must decline an application made under this section for approval to tranship any new organism specified in Schedule 2; and
- (b) may, within any period determined in accordance with the regulations,—
  - (i) decline an application made under this section for approval to tranship any hazardous substance or new organism that the Authority considers 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 an application made under this section with any controls that the Authority thinks fit.

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**85 Sections 52 to 53C and cross-heading above section 52 replaced**

Replace sections 52 to 53AA and the cross-heading above section 52 with:

Subpart 7—Procedure relating to applications, etc, and to decisions

*Completeness check*

**52 Notification that application is complete or incomplete**

- (1) The Authority must, in writing and within the prescribed period, notify an applicant for an approval, a review, or a reassessment under this Part as to whether their application is complete. 5
- (2) The **prescribed period** is the period that—
  - (a) starts on the first working day after the application is lodged; and
  - (b) ends on the day that is determined in accordance with the regulations.
- (3) An application is **complete** only if— 10
  - (a) the application is in the approved form; and
  - (b) the application contains, or is accompanied by, any prescribed information that the regulations require to be contained in or accompany the application; and
  - (c) the application contains, or is accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration; and 15
  - (d) any charge fixed by the Authority under section 21 for carrying out the completeness check has been paid to the Authority; and 20
  - (e) any charge fixed by the Authority under section 21 for assessing and determining the application that the Authority requires to be paid before commencing the assessment has been paid to the Authority.
- (4) This section does not apply to an application that is made by the chief executive of the Authority. 25
- (5) An application is not to be treated for any purpose under this Act as having been made or received by the Authority until the day on which the Authority notifies the applicant that the application is complete.
- (6) In this section and in **section 52A**, **applicant** does not include the chief executive of the Authority. 30

**52A Return of incomplete application**

- (1) When the Authority notifies an applicant that an application is incomplete, the Authority must give written reasons for its decision that the application is incomplete.
- (2) The Authority must return the incomplete application when, or soon as is reasonably practicable after, it notifies the applicant that the application is incomplete. 35

- (3) If, after an application has been returned as incomplete, the application is lodged again with the Authority, the application is to be treated as a new application.

*Further information*

**52B Request to applicant for further information** 5

- (1) The Authority may, by written notice given to an applicant, request the applicant to supply any further information relating to the application that is specified in the notice.
- (2) If the applicant fails to comply with the request within the period determined in accordance with the regulations, the application lapses. 10

**52C Authority may commission report, etc**

- (1) For the purpose of assisting the Authority in performing its functions in relation to an application, a review, or a reassessment under this Part, the Authority may—
- (a) commission a report or seek advice from any person, including, for example, a review of any information provided by the applicant (if any); or 15
  - (b) obtain any relevant information from any source on the substance or organism that is the subject of the application, review, or reassessment.
- (2) If the Authority receives information under this section, the Authority must give written notice to each of the following that the information is available for inspection: 20
- (a) the applicant (if any):
  - (b) every person who made a submission on the application, review, or reassessment in response to public notification or consultation under **section 53 or 53A**. 25
- (3) However, the Authority is not required to give notice relating to information that has been withheld in accordance with section 9(2)(b) of the Official Information Act 1982.
- (4) A notice under this section must be given within a period that is determined in accordance with the regulations before— 30
- (a) the Authority determines the application or makes a decision on the review or reassessment; or
  - (b) any hearing of the application, review, or reassessment commences.
- (5) If the Authority requests a report, advice, or any other information under this section, it may postpone, for a period that it considers is reasonable,— 35
- (a) its determination of the application or decision on the review or reassessment; or

|           |                                                                                                                                                                                                                                                                                              |    |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
|           | (b) any hearing of the application, review, or reassessment.                                                                                                                                                                                                                                 |    |
| (6)       | However, the Authority may postpone its determination or decision, or any hearing, only if it considers that the requested information relates to an area in which it lacks sufficient knowledge or expertise.                                                                               |    |
|           | <i>Notification and consultation</i>                                                                                                                                                                                                                                                         | 5  |
| <b>53</b> | <b>Public notification of applications, etc (except if approved under rapid assessment provisions)</b>                                                                                                                                                                                       |    |
|           | <i>Applications, etc, that Authority may publicly notify</i>                                                                                                                                                                                                                                 |    |
| (1)       | This section applies to each of the following:                                                                                                                                                                                                                                               |    |
|           | <i>Applications relating to hazardous substances</i>                                                                                                                                                                                                                                         | 10 |
| (a)       | an application under <b>section 28</b> for approval to import or manufacture a hazardous substance, but only if the application has not requested that the Authority make a rapid assessment under section 28A of the adverse effects of importing or manufacturing the hazardous substance: |    |
|           | <i>Applications, etc, relating to new organisms</i>                                                                                                                                                                                                                                          | 15 |
| (b)       | an application under section 34 to import for release, or to release from containment, any new organism, but only if the application has not been approved under section 35 or 38I:                                                                                                          |    |
| (c)       | an application under section 38A for a conditional release approval for a new organism, but only if the application has not been approved under section 38BA:                                                                                                                                | 20 |
| (d)       | an application for a review, or a decision of the Authority to conduct a review on its own initiative, under section 38G of any controls imposed on a conditional release approval:                                                                                                          |    |
| (e)       | an application for a review, or a decision of the Authority to conduct a review on its own initiative, under section 38L of any controls imposed on an approval under section 38I relating to a qualifying organism:                                                                         | 25 |
| (f)       | an application under section 40 in respect of a new organism, but only if the application has not been approved under section 42, 42A, 42B, or <b>42C</b> :                                                                                                                                  | 30 |
|           | <i>Applications relating to adverse events</i>                                                                                                                                                                                                                                               |    |
| (g)       | an application under section 47 to import for release, release from containment, or use a hazardous substance or new organism in response to an adverse event:                                                                                                                               |    |
|           | <i>Reassessments</i>                                                                                                                                                                                                                                                                         | 35 |
| (h)       | an application for a reassessment, or a decision of the Authority to proceed with a reassessment on its own initiative, under <b>subpart 9</b> .                                                                                                                                             |    |
| (2)       | As soon as practicable after receiving the application or making the decision,—                                                                                                                                                                                                              |    |

- 5

The Authority must ensure that any relevant application or decision that it is required to publicly notify under this section is publicly notified within any period that is determined in accordance with the regulations.

- 10

The Authority must notify the Minister as soon as practicable after it determines that it is required to publicly notify a relevant application or decision under this section.

## 30

See **section 68(1A)**, which relates to the Minister's power to call in applications with significant effects.

- 35

**53A Consultation about certain applications, etc, with affected persons**

- (1) This section applies to any matter to which **section 53** applies that is not to be publicly notified under that section, and to any transshipment application, that the Authority considers will have 1 or more of the following effects:
  - (a) significant cultural, economic, environmental, ethical, health, or international effects; or 5
  - (b) significant effects in an area in which the Authority lacks sufficient knowledge or expertise.
- (2) The Authority must—
  - (a) do everything reasonably practicable to consult all persons who, in its opinion, are likely to be directly affected by the Authority’s decision on the application, review, or reassessment; and 10
  - (b) give those persons a reasonable opportunity to make submissions and comments to the Authority on the application, review, or reassessment; and 15
  - (c) consider all submissions and comments received before approving or declining the application, or completing and making a decision on the review or reassessment.
- (3) Nothing in this section prevents the Authority from consulting any person before making a decision on the application, review, or reassessment (whether or not the Authority is required to consult under this section). 20

**53B Notification of departments, Crown entities, and local authorities generally**

*Application of section*

- (1) This section applies to each of the following: 25
  - (a) any application under this Part (except an application for a relevant review);
  - (b) any decision of the Authority to proceed with a reassessment on its own initiative under **subpart 9**.

*Requirement to notify* 30

- (2) As soon as practicable after receiving the application or making the decision, the Authority must notify—
  - (a) any department or Crown entity that, in the opinion of the Authority, is likely to have an interest in the application or decision; and
  - (b) if that application or decision relates to a new organism,— 35
    - (i) the Department of Conservation; and
    - (ii) any local authority that, in the opinion of the Authority, is likely to have an interest in the application or decision; and

- (c) if the application or decision relates to a hazardous substance, WorkSafe.  
*Decision on application or reassessment*
- (3) The Authority must have particular regard to any information the Department of Conservation or WorkSafe gives to the Authority in response to notification under **subsection (2)(b) or (c)** before the Authority— 5
- (a) makes a decision on the application (except as provided by **paragraph (b)**); or
- (b) completes and makes a decision on the reassessment, in the case of an application for a reassessment or a decision to proceed with a reassessment. 10
- Definition*
- (4) In this section, **relevant review** means—
- (a) a review under section 38G of any controls imposed on a conditional release approval; or
- (b) a review under section 38L of any controls imposed on an approval under section 38I relating to a qualifying organism. 15
- 53C Notification of departments and Crown entities about certain reviews**
- (1) This section applies to an application for a relevant review, or a decision of the Authority to conduct a relevant review on its own initiative, if the application or decision is not to be publicly notified under **section 53**. 20
- (2) As soon as practicable after receiving the application or making the decision, the Authority must notify—
- (a) any department or Crown entity that, in the opinion of the Authority, is likely to have an interest in the application or decision; and
- (b) the Department of Conservation (but only in the case of an application for a review, or a decision to conduct a review, under section 38G of any controls imposed on a conditional release approval). 25
- (3) In this section, **relevant review** has the same meaning as in **section 53B**.
- 86 Section 54 amended (Submission on application)**
- (1) In the heading to section 54, replace “**application**” with “**publicly notified matter**”. 30
- (2) Replace section 54(1) with:
- (1) Any person may make a written submission to the Authority on any matter that is publicly notified under **section 53**.
- (3) In section 54(3), after “applicant”, insert “(if any)”. 35
- 87 Sections 55 to 59A replaced**
- Replace sections 55 to 59A with:

*Timing, etc, and notification of decisions*

**55 Periods for assessment and determination**

- (1) The Authority must assess and determine an application for an approval, a review, or a reassessment under this Part within any period determined in accordance with the regulations. 5
- (2) The Authority must complete a rapid assessment under section 28A, 35, 38BA, 38I, 42, 42A, 42B, **42C**, or 49F (including section 49F as applied by section 49L) within any period determined in accordance with the regulations.

**56 Joint processing of related applications so heard and decided on together**

- (1) This section applies if— 10
  - (a) the Authority receives applications (**related applications**) in respect of hazardous substances that are, or include, related chemicals or substances; and
  - (b) at least 1 of the applications is publicly notified in accordance with **section 53** or required to be consulted on by **section 53A**; and 15
  - (c) the Authority considers that decisions on the applications should be made on the same date.
- (2) The Authority may extend a time limit that is imposed under this Act and that applies in relation to the related applications to ensure that— 20
  - (a) they are heard (if more than 1 application is to be heard) at the same time and place; and
  - (b) decisions on the applications are made on the same date.
- (3) However, the Authority may not extend the time limit beyond the latest date that applies in relation to the related applications.

**Guidance note** 25

See also **sections 141K and 141L**.

**57 Decision to be written and copy given to applicant, etc, and submitters**

- (1) The Authority's decision on an application, a review, or a reassessment under this Part, including its reasons for the decision, must be recorded in writing.
- (2) The Authority must give a copy of the decision to— 30
  - (a) the applicant (if any); and
  - (b) any persons who have made submissions in response to any public notification or consultation under **section 53 or 53A** in respect of the application, review, or reassessment.

**58 Decision to be publicly notified**

- (1) The Authority must publicly notify its decision on an application, a review, or a reassessment under this Part by no later than any date determined in accordance with the regulations.
- (2) The Authority may withhold any information relating to a transshipment application if, in its opinion, the information could pose a risk to national safety and security.

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**88 Section 60 replaced (Obligation to hold hearing)**

Replace section 60 with:

Subpart 8—Hearings

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**60 Decision to hold hearing**

- (1) The Authority must hold a hearing in respect of an application, a review, or a reassessment under this Part if the Authority—
  - (a) has publicly notified under **section 53**, or has consulted under **section 53A** on, the application or (if applicable) the decision to conduct or proceed with the review or reassessment on its own initiative; and
  - (b) considers that a hearing would be likely to assist it in determining or making a decision on the application, review, or reassessment.
- (2) For the purposes of deciding whether a hearing would be likely to assist it in determining or making a decision on the application, review, or reassessment, the Authority must take into account whether, in its opinion, a hearing would be likely to provide it with any relevant information that is additional to—
  - (a) the information that has been provided by the applicant (if any), including under **section 52B**; and
  - (b) any submissions or comments made in response to the public notification or consultation.
- (3) This section does not apply in relation to any application or reassessment that is the subject of a direction of the Minister under section 68.

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**Guidance note**

Under section 71, the Authority is required to inquire into any application or reassessment that the Minister has called in under section 68. **Sections 60A** to 61 apply in relation to the conduct of the inquiry.

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**60A Date of hearing and notice about hearing**

If a hearing in respect of an application, a review, or a reassessment is required to be held, the Authority must—

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- (a) fix a date for commencement of the hearing that is no later than any date determined in accordance with the regulations; and

- (b) give notice of that fixed date and of the time and place of the hearing to each of the following:
- (i) the applicant (if any):
  - (ii) any person who made a submission in respect of the application, review, or reassessment in response to the public notification or consultation under **section 53 or 53A** and stated that they wish to be heard.

5

**Guidance note**

*See also—*

- **section 52C**, which enables the Authority to postpone a hearing until after information requested under that section is received and requires the Authority to notify any applicants and submitters if the Authority receives information under that section; and
- **section 56**, which allows the Authority to extend time limits applying to related applications in respect of hazardous substances so that those applications can be heard together.

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**60B Information obtained under section 52C**

Any information obtained under **section 52C** may be considered at any hearing that the Authority conducts.

**89 Section 61 amended (Provisions relating to hearings)**

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- (1) In the heading to section 61, replace “**Provisions**” with “**Other provisions**”.
- (2) Replace section 61(1) with:
  - (1) This section applies if the Authority is required to hold a hearing in respect of an application, a review, or a reassessment.
- (3) In section 61(3), replace “For the purpose of considering any application, the” with “The”.
- (4) In section 61(4), replace “in relation to any such consideration and any decision on any matter” with “for the purposes of the hearing and the Authority’s consideration and decision on the application, review, or reassessment that is the subject of the hearing”.
- (5) Replace section 61(7) and (8) with:
  - (7) The Authority must hold any hearing in respect of an application, a review, or a reassessment in public if the application, or any decision of the Authority to conduct the review or proceed with the reassessment on its own initiative, is publicly notified under **section 53**.
  - (7A) The Authority must establish a procedure that is appropriate and fair in the circumstances and may—
    - (a) permit cross-examination; or
    - (b) permit questions in clarification; or

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|
| <p>(c) permit only the members of the Authority to question any person.</p> <p>(8) At the hearing, the applicant (if any), and any person who made a submission in response to the public notice or consultation under <b>section 53 or 53A</b> and stated that they wish to be heard,—</p> <p>(a) may speak (either personally or through a representative); and</p> <p>(b) may call evidence.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 5                                                              |
| <p>(6) In section 61(9), replace “he or she wished” with “they wish”.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                |
| <p><b>90 New subpart 9 heading in Part 5 inserted</b></p> <p>In Part 5, after section 61, insert:</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |
| <p>Subpart 9—Reassessments</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 10                                                             |
| <p><b>91 Section 62 amended (Grounds for reassessment of substance or organism)</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                |
| <p>(1) In section 62(1)(c), delete “released with controls”.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                |
| <p>(2) After section 62(2), insert:</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                |
| <p>(2A) The Authority must—</p> <p>(a) record a decision under this section, including its reasons for the decision, in writing; and</p> <p>(b) give a copy of the written decision to the person who made the request; and</p> <p>(c) give public notice of the decision as soon as practicable after making the decision.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 15<br><br><br><br><br>20                                       |
| <p>(3) Replace section 62(3) with:</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                |
| <p>(3) For the purposes of subsection (1),—</p> <p>(a) an organism has <b>previously been assessed by the Authority</b> if—</p> <p style="padding-left: 20px;">(i) it is the subject of a conditional release approval (<i>see</i> sections 38BA and 38C); or</p> <p style="padding-left: 20px;">(ii) it is a qualifying organism that is the subject of an approval granted under section 38I for the release of the organism with controls; or</p> <p style="padding-left: 20px;">(iii) it is the subject of an approval granted under any of sections 42 to <b>42C</b> or 45 relating to a new organism in containment; or</p> <p style="padding-left: 20px;">(iv) it is the subject of an approval granted under section 48; or</p> <p style="padding-left: 20px;">(v) it is the subject of a decision of the Minister under section 73 to grant an approval under any of sections 38BA, 38C, 38I, 42 to <b>42C</b>, 45, and 48; and</p> <p>(b) a hazardous substance has <b>previously been assessed by the Authority</b> if it is the subject of—</p> | 25<br><br><br><br><br><br><br><br><br><br>30<br><br><br><br>35 |

- (i) an approval granted under any of sections 28A, 29, **29AB**, 32, and 48; or
- (ii) a decision of the Minister under section 73 to grant an approval under any of those sections.

**92 New section 62A inserted (Authority may proceed with reassessment)** 5

After section 62, insert:

**62A Authority may proceed with reassessment**

- (1) The Authority may, on an application made by any person or on its own initiative, proceed with—
  - (a) either of the following after making a decision under section 62(2): 10
    - (i) a full reassessment of a hazardous substance or new organism under **section 63**:
    - (ii) a modified reassessment of a hazardous substance or new organism under section 63A; or
  - (b) a modified reassessment of a hazardous substance under section 63C or 63D. 15
- (2) However, the Authority may proceed with a modified reassessment only if the Authority is satisfied that the preconditions specified in section 63A, 63C, or 63D (as the case may be) are met.
- (3) An application under this section must— 20
  - (a) be in the approved form; and
  - (b) contain, or be accompanied by, any prescribed information that the regulations require to be contained in or accompany the application; and
  - (c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration. 25
- (4) An applicant under this section may withdraw the application at any time by written notice to the Authority.

**93 Section 63 replaced (Reassessment)** 30

Replace section 63 with:

**63 Full reassessment**

- (1) A provision specified in column 1 of the following table is to be applied to an application for a reassessment under this section of a matter specified opposite in column 2:

| Column 1                    | Column 2 |
|-----------------------------|----------|
| Provision to be applied     | Matter   |
| <i>Hazardous substances</i> |          |

|           | <b>Column 1<br/>Provision to be applied</b>                                                                                                                                | <b>Column 2<br/>Matter</b>                                                                                                                                                                                                                                |    |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
|           | 1 Section 29                                                                                                                                                               | Hazardous substance subject of approval under section 28A or 29                                                                                                                                                                                           |    |
|           | 2 <b>Section 29AB</b>                                                                                                                                                      | Hazardous substance subject of temporary hazardous substance approval                                                                                                                                                                                     |    |
|           | 3 Sections 30 and 32<br><i>New organisms</i>                                                                                                                               | Hazardous substance subject of approval under section 32                                                                                                                                                                                                  |    |
|           | 4 Sections 38BA to 38D                                                                                                                                                     | New organism subject of conditional release approval ( <i>see</i> sections 38BA and 38C)                                                                                                                                                                  |    |
|           | 5 Sections 38I to 38K                                                                                                                                                      | Qualifying organism subject of approval under section 38I for release with controls                                                                                                                                                                       |    |
|           | 6 Sections 39 and 42 to <b>45AA</b><br><i>Hazardous substances and new organisms: adverse events</i>                                                                       | New organism in containment subject of approval under section 42, 42A, 42B, <b>42C</b> , or 45                                                                                                                                                            |    |
|           | 7 Section 48                                                                                                                                                               | Hazardous substance or new organism subject of approval under section 48 for release or use in response to adverse event (within the meaning of <b>section 46</b> )                                                                                       |    |
| (2)       | A provision specified in column 1 of the table is to be applied—                                                                                                           |                                                                                                                                                                                                                                                           |    |
|           | (a)                                                                                                                                                                        | as if a reference in that provision to an application for approval were a reference to the application for reassessment; and                                                                                                                              |    |
|           | (b)                                                                                                                                                                        | with any other necessary modifications.                                                                                                                                                                                                                   |    |
| (3)       | On completing a reassessment under this section, the Authority may—                                                                                                        |                                                                                                                                                                                                                                                           | 5  |
|           | (a)                                                                                                                                                                        | decide that the approval concerned may continue (with or without any variations); or                                                                                                                                                                      |    |
|           | (b)                                                                                                                                                                        | revoke the approval concerned.                                                                                                                                                                                                                            |    |
| (4)       | Nothing in this section—                                                                                                                                                   |                                                                                                                                                                                                                                                           |    |
|           | (a)                                                                                                                                                                        | prevents a person from making a new application for an approval under this Part; or                                                                                                                                                                       | 10 |
|           | (b)                                                                                                                                                                        | in the case of the reassessment of a hazardous substance that is the subject of a temporary hazardous substance approval, affects an application that the holder of the approval has made in respect of the hazardous substance under <b>section 28</b> . | 15 |
| (5)       | In this section, <b>application for a reassessment</b> includes a decision of the Authority to proceed with a reassessment on its own initiative.                          |                                                                                                                                                                                                                                                           |    |
| <b>94</b> | <b>Section 63A amended (Modified reassessment procedure for amendments to approvals of hazardous substances)</b>                                                           |                                                                                                                                                                                                                                                           |    |
| (1)       | In the heading to section 63A, delete “ <b>of hazardous substances</b> ”.                                                                                                  |                                                                                                                                                                                                                                                           | 20 |
| (2)       | Replace section 63A(1) and (2) with:                                                                                                                                       |                                                                                                                                                                                                                                                           |    |
| (1)       | The preconditions that the Authority must be satisfied are met before proceeding with a reassessment of a hazardous substance or new organism under this section are that— |                                                                                                                                                                                                                                                           |    |

**Hazardous Substances and New Organisms Amendment  
Bill**

Part 1 cl 95

- (a) a reassessment of the hazardous substance or new organism under **section 63** is not appropriate because the reassessment will involve only a specific aspect of the approval concerned; and
- (b) the amendment is not a minor or technical amendment to which **section 73C** applies. 5
- (2) On completing a reassessment of a hazardous substance under this section, the Authority—
- (a) may vary 1 or more of the following:
- (i) the EPA controls applying in relation to the hazardous substance;
- (ii) the description of the hazardous substance: 10
- (iii) the hazard classification of the hazardous substance; or
- (b) may decline to vary any of the matters referred to in **paragraph (a)**; but
- (c) may not revoke an approval in respect of the hazardous substance.
- (2A) On completing a reassessment of a new organism under this section, the Authority— 15
- (a) may vary or decline to vary any controls applying in relation to the new organism; but
- (b) may not revoke an approval in respect of the new organism.
- (3) Repeal section 63A(3).
- (4) In section 63A(6), replace “The Authority may approve or decline an application for reassessment under this section as it considers appropriate after taking” with “In making a decision under **subsection (2) or (2A)**, the Authority must take”. 20
- (5) In section 63A(6)(a), replace “reassessment” with “decision”.
- (6) Repeal section 63A(7) and (8). 25
- 95 Section 63B replaced (Proposal for group standard may be consulted on in same way as reassessment)**
- Replace section 63B with:
- 63B Proposal for group standard may be consulted on as if part of reassessment** 30
- (1) This section applies if—
- (a) the Authority decides to reassess a hazardous substance under section 63A and the application, or the decision to proceed with the reassessment on its own initiative, is not required to be publicly notified in accordance with **section 53**; and 35
- (b) the Authority is required to consult in accordance with **section 53A** on the application or the decision to proceed with the reassessment; and

- (c) the Authority proposes (whether on an application or on its own initiative) to issue, amend, or revoke a group standard that applies to the hazardous substance on similar grounds for deciding under section 62 that grounds exist to reassess the substance.
- (2) The Authority may consult on the following matters, in accordance with **section 53A**, as if they were part of the reassessment: 5
- (a) the proposal to issue, amend, or revoke the group standard; and
- (b) the Authority’s assessment of the matters referred to in section 96C(1)(a), (b), (d), and (e) applying in relation to the group standard (if the group standard is proposed to be issued or amended). 10
- (3) If the Authority consults in accordance with **subsection (2)**, **section 96E** does not apply.
- 96 Section 63C amended (Modified reassessment to change controls in other cases)**
- (1) In the heading to section 63C, after “cases”, insert “relating to hazardous substances”. 15
- (2) Replace section 63C(1) with:
- (1) The preconditions that the Authority must be satisfied are met before proceeding with a reassessment of a hazardous substance under this section are that—
- (a) a reassessment of the hazardous substance under **section 63** is not appropriate because the reassessment will involve only a specific aspect of the approval concerned; and 20
- (b) the amendment is not a minor or technical amendment to which **section 73C** applies; and
- (c) the reassessment is necessary because of a change to a hazard classification system established under section 74, controls in regulations, EPA controls, or controls under the Health and Safety at Work Act 2015. 25
- (3) In section 63C(2), replace “A reassessment under this section” with “On completing a reassessment under this section, the Authority”.
- (4) In section 63C(2)(a)(iii), replace “but” with “or”. 30
- (5) Replace section 63C(2)(b) with:
- (b) may decline to vary any of the matters referred to in paragraph (a); but
- (c) may not revoke an approval in respect of the hazardous substance.
- (6) Repeal section 63C(3).
- (7) In section 63C(6), replace “The Authority may approve or decline an application for reassessment under this section as it considers appropriate after taking” with “In making a decision under subsection (2), the Authority must take”. 35
- (8) Repeal section 63C(7) to (9).

- 97 Section 63D amended (Modified reassessment to align classifications)**
- (1) In the heading to section 63D, replace “**classifications**” with “**hazard classifications or controls**”.
- (2) Replace section 63D(1) with:
- (1) The preconditions that the Authority must be satisfied are met before proceeding with a reassessment of a hazardous substance under this section are that—
- (a) a reassessment of the hazardous substance under **section 63** is not appropriate because the reassessment will involve only a specific aspect of the approval concerned; and
- (b) the amendment is not a minor or technical amendment to which **section 73C** applies; and
- (c) the reassessment is necessary to change a hazard classification or control to align with—
- (i) the equivalent of a hazard classification or control that has been set by an international regulator; or
- (ii) a hazard classification or control of a related substance that was the subject of a decision of the Authority after the hazardous substance was approved by the Authority.
- (3) In section 63D(2), replace “A reassessment under this section” with “On completing a reassessment under this section, the Authority”.
- (4) In section 63D(2)(a)(iii), replace “but” with “or”.
- (5) Replace section 63D(2)(b) with:
- (b) may decline to vary any of the matters referred to in paragraph (a); but
- (c) may not revoke an approval in respect of the hazardous substance.
- (6) Repeal section 63D(3).
- (7) In section 63D(4), replace “The Authority may approve or decline an application for reassessment under this section as it considers appropriate after taking” with “In making a decision under subsection (2), the Authority must take”.
- (8) Repeal section 63D(5) to (7).
- 98 New section 63DA inserted (Modified reassessments of hazardous substances: application of sections 77 to 77B)**
- After section 63D, insert:
- 63DA Modified reassessments of hazardous substances: application of sections 77 to 77B**
- (1) This section applies if the Authority decides to vary any of the matters referred to in **section 63A(2)(a)**, 63C(2)(a), or 63D(2)(a) on completing a reassessment of a hazardous substance under section 63A, 63C, or 63D.

- (2) Section 77A applies as if the decision were an approval and, for that purpose, controls previously imposed under section 77A on the hazardous substance have effect as other specified controls under that section.
- (3) Section 77B applies if the hazardous substance has toxic or ecotoxic properties.
- (4) If the hazardous substance is the subject of an approval granted under section 28A or 29 (a **specified section**), section 77 applies as if the decision were an approval granted under the specified section.
- (5) Nothing in this section or in section 63A, 63C, or 63D limits section 77(2)(a).

**99 Section 64 replaced (Suspension of approvals during reassessment)**

Replace section 64 with:

**64 Suspension of use, etc, during reassessment: general**

- (1) This section applies if—
  - (a) an application for a reassessment, or a decision of the Authority to proceed with a reassessment on its own initiative, has been publicly notified under **section 53**; and
  - (b) the Authority has reasonable grounds to believe that there is a significant actual or imminent danger to human health or safety or to the environment from,—
    - (i) in the case of the reassessment of a hazardous substance, commencing or continuing to use the substance; or
    - (ii) in the case of the reassessment of a new organism, commencing or continuing the relevant activity authorised by the approval concerned.
- (2) The **relevant activity** is whichever 1 or more of the following is applicable:
  - (a) importing the new organism into containment;
  - (b) developing or field testing the new organism in containment;
  - (c) releasing or using the new organism.
- (3) The Authority may, by notice in the *Gazette*, direct that 1 or more of the following activities is prohibited until a decision is made following the reassessment of the hazardous substance or new organism:
  - (a) any use or further use of the hazardous substance;
  - (b) any importation or further importation into containment of the new organism;
  - (c) any development or field testing, or further development or field testing, in containment of the new organism;
  - (d) any release or further release of the new organism;
  - (e) any release or use, or further release or use, of the new organism in response to an adverse event (within the meaning of **section 46**).

- (4) The Authority must publish the notice on an Internet site maintained by or on behalf of the Authority as soon as practicable after the notice has been published in the *Gazette*.
- (5) This section does not apply if the reassessment applied for, or that the Authority has decided to proceed with on its own initiative, is the reassessment of a hazardous substance that is the subject of a temporary hazardous substance approval. 5

**64AA Suspension of use during reassessment: temporary hazardous substance approval**

- (1) This section applies if— 10
  - (a) a person has applied for, or the Authority has decided to proceed on its own initiative with, a reassessment of a hazardous substance that is the subject of a temporary hazardous substance approval; and
  - (b) the Authority has reasonable grounds to believe that there is a significant actual or imminent danger to human health or safety or to the environment from commencing or continuing to use the substance. 15
- (2) The Authority may, by notice in the *Gazette*, direct that any use or further use of the hazardous substance is prohibited until a decision is made following the reassessment of the hazardous substance.
- (3) The Authority must publish the notice on an Internet site maintained by or on behalf of the Authority as soon as practicable after the notice has been published in the *Gazette*. 20

**100 Section 64A amended (Temporary restriction of use during reassessment)**

- (1) In the heading to section 64A, after “use”, insert “, etc,”.
- (2) Replace section 64A(1) with: 25
  - (1) This section applies if—
    - (a) the Authority has publicly notified a decision under section 62(2) that grounds exist to reassess a hazardous substance or new organism; and
    - (b) a reassessment of the hazardous substance or new organism has not commenced or been completed; and 30
    - (c) the Authority has reasonable grounds to believe that there is an actual or imminent danger to human health or safety or to the environment from,—
      - (i) in the case of a hazardous substance, commencing or continuing to use the substance; or 35
      - (ii) in the case of a new organism, commencing or continuing the relevant activity authorised by the approval concerned; and

- (d) the Authority has consulted any persons who the Authority considers are likely to be affected if the Authority restricts an activity referred to in **paragraph (c)**.
- (1A) The Authority may, by notice in the *Gazette*, restrict 1 or more of the following activities in accordance with this section: 5
- (a) in the case of a hazardous substance, the use of the substance:
- (b) in the case of a new organism, the relevant activity that is authorised by the approval concerned.
- (1B) In this section, **relevant activity**, in relation to an approval in respect of a new organism, means whichever 1 or more of the following is applicable: 10
- (a) importing the new organism into containment:
- (b) developing or field testing the new organism in containment:
- (c) releasing or using the new organism.
- (3) In section 64A(2)(a), replace “a hazardous substance” with “the hazardous substance, or the carrying out of the relevant activity,”. 15
- (4) In section 64A(2)(b), after “substance”, insert “, or the carrying out of the relevant activity,”.
- (5) In section 64A(3)(a), after “substance”, insert “or the carrying out of the relevant activity”.
- (6) Replace section 64A(3)(b) with: 20
- (b) remains in force until the earliest of the following:
- (i) the date on which the Authority completes, and makes a decision on, a reassessment relating to the hazardous substance or new organism:
- (ii) the date on which the applicant (if any) withdraws the application for a reassessment: 25
- (iii) the date on which the Authority declines to proceed with an application (if any) for a modified reassessment relating to the hazardous substance or new organism because it is not satisfied that the preconditions for proceeding with the application are met: 30
- (iv) the date that is 1 year after the notice is published in the *Gazette*, if an application for reassessment of the hazardous substance or new organism has not been made, or if the Authority has not decided to proceed on its own initiative with a reassessment of the organism or substance, by that date. 35

**101 Section 65 replaced (No compensation following reassessment)**

Replace section 65 with:

- 65 No compensation for certain outcomes**
- No compensation is payable to any person for any loss arising from—
- (a) the revocation of an approval under **section 63**; or
  - (b) any variation under **section 63**, 63A, 63C, or 63D of any controls that attach to a hazardous substance or new organism; or
  - (c) any direction given under **section 64 or 64AA**; or
  - (d) any restriction imposed under section 64A.
- 102 Section 66 amended (Requirement for disposing of substances)**
- (1) Replace the heading to section 66 with “**Prohibition on use and requirement to dispose of substances**”.
  - (2) Replace section 66(1) with:
    - (1) This section applies if the Authority revokes an approval under **section 63** in respect of a hazardous substance.
    - (1A) The Authority may issue a direction, by notice in the *Gazette*,—
      - (a) prohibiting the use of the substance; or
      - (b) requiring the substance to be disposed of, at the owner’s expense, in accordance with the controls placed on it by the Authority and identified in the direction.
    - (1B) The prohibition on the use of the substance ceases to apply if—
      - (a) an approval to import or manufacture the hazardous substance is granted under section 28A, 29, or **29AB**; or
      - (b) an approval to import the hazardous substance into containment or manufacture the hazardous substance in containment is granted under section 32; or
      - (c) an approval in respect of the hazardous substance is granted under section 48 or 49F.
    - (1C) The Authority must publish the direction on an Internet site maintained by or on behalf of the Authority as soon as practicable after the direction has been published in the *Gazette*.
  - (3) In section 66(2), replace “subsection (1)” with “**subsection (1A)**” in each place.
- 103 Section 66A amended, renumbered as section 73A, and repositioned (Disposal of persistent organic pollutants)**
- (1) In the heading to section 66A, replace “**Disposal**” with “**Environmentally sound disposal**”.
  - (2) Replace section 66A(1) with:

- (1) The Authority may issue a direction, by notice, that specifies how persistent organic pollutants must be disposed of.
- (1A) The direction may also require persistent organic pollutants to be disposed of.
- (1B) The Authority must ensure that any direction that it issues under this section is not inconsistent with Article 6 of the Stockholm Convention.
- (3) Renumber section 66A as **section 73A** and reposition it after the **subpart 11 heading** in Part 5 (as inserted by **section 113**).

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#### 104 Sections 67 and 67A renumbered and repositioned

Renumber sections 67 and 67A as **sections 73B and 73C**, respectively, and reposition them after **section 73A** (as inserted by **section 103**).

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#### 105 Section 67B amended, renumbered as section 73D, and repositioned (Revoking duplicated approvals)

- (1) In the heading to section 67B, replace “**duplicated approvals**” with “**duplicated or spent approvals, etc**”.

- (2) Replace section 67B(1) with:

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- (1) The Authority may, by notice,—

- (a) revoke an approval, a deemed approval, or a group standard in respect of a substance if the Authority is satisfied that a corresponding approval (other than a deemed approval) applies that has the same or a substantially similar effect; or

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- (b) revoke an approval or a deemed approval in respect of a new organism if the Authority is satisfied that the approval or deemed approval is no longer in use.

- (3) After section 67B(3), insert:

- (4) In this section,—

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**corresponding approval** includes a group standard in respect of a hazardous substance to which this Part applies (*see* **sections 96AB(3)** and **96B(3)**)

**deemed approval** does not include a group standard.

- (4) Renumber section 67B as **section 73D** and reposition it after **section 73C** (as inserted by **section 104**).

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#### 106 Cross-heading above section 68 replaced

Replace the cross-heading above section 68 with:

Subpart 10—Minister’s call-in powers

#### 107 Section 68 amended (Minister’s power to call in applications with significant effects)

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- (1) In the heading to section 68, after “**applications**”, insert “**and reassessments**”.

- (2) In section 68(1), after “application”, insert “or reassessment” in each place.
  - (3) In section 68(1), replace “Act” with “Part”.
  - (4) Replace section 68(1A) with:
    - (1A) However, a direction under this section applies to an application or a reassessment that relates to any hazardous substances only if the application or (if applicable) the Authority’s decision to proceed with the reassessment on its own initiative is one to which **section 53(5)** applies. 5
  - (5) Replace section 68(3) with:
    - (3) The Minister, in the Minister’s discretion, may include in a relevant direction that applies to an application for an approval to release a new organism from containment, or the reassessment of a new organism that is the subject of a conditional release approval, a statement that specifies what is or is not significant, in the circumstances of the case, for the purposes of applying the following in respect of the application or ~~assessment~~ reassessment: 10
      - (a) in the case of an application, section 36, including as applied by ~~section 35(3)(b) and 38C(1)(a):~~ 15
      - (b) in the case of a reassessment, section 36, including as applied by section 38C(1)(a) (as applied by **section 63**).
- 108 Section 69 amended (Notification of Minister’s direction)**
- (1) In section 69(1), after “any application”, insert “or reassessment”. 20
  - (2) In section 69(1), replace “of the application” with “under **section 53** of the application or the Authority’s decision to proceed with the reassessment on its own initiative”.
  - (3) In section 69(2), after “application”, insert “or reassessment”.
- 109 Section 70 amended (Minister may appoint persons)** 25
- In section 70, after “application”, insert “or reassessment”.
- 110 Section 71 amended (Conduct of inquiry by Authority)**
- (1) In section 71(1), after “approval”, insert “or reassessment”.
  - (2) Replace section 71(2) with:
    - (2) The Authority may require further information under **section 52B** in respect of any application or reassessment to which the direction applies. 30
  - (3) In section 71(4)(b)(i), after “application”, insert “or reassessment”.
  - (4) Replace section 71(3) with:
    - (3) The Authority must give public notice of the inquiry in accordance with the regulations. 35
  - (3A) Without limiting **subsection (3)**,—

- (a) the public notice must state that any person may make a written submission on the application or reassessment to which the direction applies; and
  - (b) section 54 applies in relation to any written submission that is made in response to public notification under this section.

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- (3B) Sections **60A** to 61 apply in relation to the conduct of the inquiry and for that purpose—

  - (a) any reference in those sections to a hearing is to be treated as a reference to the inquiry; and
  - (b) any reference in those sections to a matter that is publicly notified under **section 53** is to be treated as a reference to the application or reassessment to which the direction applies; and
  - (c) any reference in those sections to a submission made in response to public notification under **section 53** is to be treated as a reference to a submission that is made, on the application or reassessment, in response to public notification under this section.

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**111 Section 72 amended (Authority to report to Minister)**

- (1) In section 72(1), after “application”, insert “or reassessment”.
- (2) In section 72(2)(a), after “approval”, insert “or reassessment”.

**112 Section 73 amended (Minister to decide application and notify decision) 20**

- (1) In the heading to section 73, after “**application**”, insert “**or reassessment**”.
- (2) In section 73(1), after “application”, insert “or reassessment” in each place.
- (3) In section 73(2), after “applicant”, insert “(if any)”.

**113 New subpart 11 heading in Part 5 inserted**

In Part 5, after section 73, insert: 25

Subpart 11—Other

**114 New Part 5A inserted**

After **section 73D** (as inserted by **section 105**), insert:

**Part 5A**

**Notices: risk species and organisms that are not new organisms 30**

**73E Definitions**

In this Part,—

|            |                                                                                                                                                                                                                                                     |    |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
|            | <b>authorised maker</b> , in relation to secondary legislation under this Part, means—                                                                                                                                                              |    |
|            | (a) the Authority; or                                                                                                                                                                                                                               |    |
|            | (b) a specified person who is authorised under <b>section 73F(1)(c)</b> to make the secondary legislation                                                                                                                                           | 5  |
|            | <b>specified person</b> means—                                                                                                                                                                                                                      |    |
|            | (a) the chief executive of the Authority; or                                                                                                                                                                                                        |    |
|            | (b) a committee appointed by the Authority under clause 14 of Schedule 5 of the Crown Entities Act 2004.                                                                                                                                            |    |
| <b>73F</b> | <b>Power to prescribe and to authorise to prescribe</b>                                                                                                                                                                                             | 10 |
| (1)        | The Authority may, by notice,—                                                                                                                                                                                                                      |    |
|            | (a) prescribe a species, or a subspecies, an infrasubspecies, a variety, a strain, or a cultivar, as a risk species for the purposes of <b>section 2A(1)(aa)</b> ; or                                                                               |    |
|            | (b) prescribe an organism as not a new organism for the purposes of this Act; or                                                                                                                                                                    | 15 |
|            | (c) authorise a specified person to prescribe, by notice,—<br>(i) a species, or a subspecies, an infrasubspecies, a variety, a strain, or a cultivar, as a risk species; or<br>(ii) an organism as not a new organism for the purposes of this Act. | 20 |
|            | <b>Guidance note</b>                                                                                                                                                                                                                                |    |
|            | Risk species may also be prescribed by regulations made under section 140. See section 2A(1)(b).                                                                                                                                                    |    |
|            | See sections 2A(2)(a)(iii) and (b)(iii) and <b>25C(1) and (6)</b> in relation to the effect of an organism being prescribed as not a new organism.                                                                                                  | 25 |
| (2)        | A notice made by the Authority under this section is secondary legislation ( <i>see</i> Part 3 of the Legislation Act 2019 for publication requirements).                                                                                           |    |
| (3)        | If a notice made by the Authority under this section authorises a specified person to prescribe any of the matters referred to in <b>subsection (1)(c)</b> ,—                                                                                       |    |
|            | (a) any notice made by the specified person that prescribes those matters is secondary legislation ( <i>see</i> Part 3 of the Legislation Act 2019 for publication requirements); and                                                               | 30 |
|            | (b) the notice made by the Authority must contain a statement to that effect.                                                                                                                                                                       |    |
| (4)        | The authorised maker may make secondary legislation under this section on the maker's initiative or on an application by another person.                                                                                                            | 35 |
| (5)        | An application under this section must—                                                                                                                                                                                                             |    |
|            | (a) be in the approved form; and                                                                                                                                                                                                                    |    |

- (b) contain, or be accompanied by, the information prescribed by the regulations.

### 73G Notification and consultation

- (1) Before deciding whether to make secondary legislation under this Part, the authorised maker must— 5
  - (a) notify each of the following:
    - (i) the Department of Conservation:
    - (ii) any department or Crown entity that, in the opinion of the authorised maker, is likely to have an interest in the proposal or application: 10
    - (iii) any local authority that, in the opinion of the authorised maker, is likely to have an interest in the proposal or application; and
  - (b) if the authorised maker considers that making the secondary legislation (or declining an application to make it) would have 1 or more of the relevant significant effects,— 15
    - (i) do everything reasonably practicable to consult all persons who, in its opinion, are likely to be directly affected if the secondary legislation is made; and
    - (ii) give those persons a reasonable opportunity to make submissions and give comments to the authorised person on the proposal or application. 20
- (2) The **relevant significant effects** are—
  - (a) significant cultural, economic, environmental, ethical, health, or international effects; or
  - (b) significant effects in an area in which the Authority lacks sufficient knowledge or expertise. 25
- (3) Nothing in this section prevents the authorised maker from consulting any person before deciding to make, or declining an application to make, the secondary legislation (whether or not the authorised maker is required to consult under this section). 30

### 73H Decision about prescribing risk species

- (1) In deciding whether to prescribe a species, or any subspecies, infrasubspecies, variety, strain, or cultivar, as a risk species, the authorised maker must consider all submissions and comments received about the relevant proposal or application in response to notification and any consultation under **section 73G**. 35
- (2) The authorised maker may prescribe a species, or any subspecies, infrasubspecies, variety, strain, or cultivar, as a risk species, under **section 73F** only if the authorised maker is satisfied that,—

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See **section 20AA**, which requires the Authority to keep a register that records matters relating to decisions under this Part.

## 25

Replace the Part 6 heading with:

## Part 6

## EPA controls and notices and other matters relating to Parts 5, 6A, and 7

## 30

After section 74, insert:

### Controls based on hazard classification

After section 75, insert:

*Other controls and prescribed matters*

**118 Section 76 amended (Authority may prescribe controls and requirements relating to hazardous substances)**

- (1) Replace the heading to section 76 with “**Controls and requirements relating to hazardous substances and new organisms**”. 5
- (2) In section 76(1), replace “prescribing EPA controls that do” with “that does”.
- (3) In section 76(1)(a) to (f), (i), and (j), replace “prescribe” with “prescribes”.
- (4) Replace section 76(1)(g) and (h) with:
  - (g) prescribes controls for any of the following to avoid or mitigate any adverse effects on the physical or chemical nature of the environment: 10
    - (i) any hazardous substance:
    - (ii) any conditionally released new organism:
    - (iii) any qualifying organism released with controls:
  - (h) prescribes controls to avoid or mitigate illness or injury to people or damage to the environment or chattels from any of the following: 15
    - (i) any hazardous substance:
    - (ii) any conditionally released new organism:
    - (iii) any qualifying organism released with controls:
- (5) After section 76(2), insert:
- (2A) Controls may not be prescribed under **subsection (1)(h)(iii)** in relation to a qualifying organism— 20
  - (a) to avoid or mitigate illness or injury to a person from being treated with a medicine that is or contains the qualifying organism; or
  - (b) to avoid or mitigate illness or injury to a person from the use in, on, or for the person of a medical device that is or contains the qualifying organism; or 25
  - (c) to avoid or mitigate illness or injury to an animal from being treated with a qualifying veterinary medicine that is or contains the qualifying organism.

**119 Section 76A amended (Authority may prescribe other matters relating to hazardous substances)** 30

- (1) Replace the heading to section 76A with “**Other prescribed matters relating to hazardous substances and new organisms**”.
- (2) After section 76A(a), insert:
  - (aa) prescribes the method of estimating the quantity of any organism imported or developed: 35
- (3) Repeal section 76A(b) and (c).

(4) In section 76A(e), after “substances”, insert “or new organisms”.

**120 New cross-heading above section 76B inserted**

After section 76A, insert:

*General provisions: issue and publication of EPA notices*

**121 Section 76C amended (Procedure for issuing EPA notices)**

5

(1) Replace section 76C(1)(c) with:

(c) consult the following:

- (i) any department or Crown entity that, in the opinion of the Authority, is likely to have an interest in the notice:
- (ii) any representative groups (industry or otherwise) or other persons that the Authority considers appropriate.

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(2) In section 76C(2)(b), after “substances”, insert “or new organisms”.

(3) In section 76C(7), replace “, (3), and (4)” with “and (3)”.

**122 New cross-heading above section 76E inserted**

After section 76D, insert:

15

*Hazardous substances: recognition of international regulators*

**123 Section 76E amended (Authority may recognise overseas bodies as international regulators)**

In section 76E(1), after “sections 28A”, insert “, **29A**,”.

**124 New cross-heading above section 77 inserted**

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After section 76E, insert:

*Controls attached to hazardous substances*

**125 Section 77 amended (EPA controls on hazardous substances)**

In section 77(1), replace “or section 29” with “, 29, or **29AB**”.

**126 Section 77B amended (Exposure limits for substances with toxic or ecotoxic properties)**

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In section 77B(6), insert in their appropriate alphabetical order:

**environmental hazards grouping** means the hazard grouping referred to as environmental hazards in the EPA notice, as currently in force, that establishes the hazard classification system and is issued under section 74

30

**environmental medium**,—

- (a) in relation to substances with toxic properties (which have a hazard classification under the health hazards grouping), means—

- (i) air, water, and soil; or
- (ii) a surface that a hazardous substance may be deposited onto:
- (b) in relation to substances with ecotoxic properties (which have a hazard classification under the environmental hazards grouping), means—
  - (i) water, soil, or sediment where these are in the natural environment; or
  - (ii) a surface that a hazardous substance may be deposited onto

5

**health hazards grouping** means the hazard grouping referred to as health hazards in the EPA notice, as currently in force, that establishes the hazard classification system and is issued under section 74

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**127 New cross-heading above section 78 inserted**

After section 77B, insert:

*Hazardous substances: codes of practice*

**128 Cross-heading above section 87 amended**

In the cross-heading above section 87, replace “*Transferable*” with “*Hazardous substances: transferable*”.

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**129 Cross-heading above section 95A replaced**

Replace the cross-heading above section 95A with:

*Hazardous substances: permissions*

**130 Cross-heading above section 96 amended**

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In the cross-heading above section 96, replace “*Environmental*” with “*Hazardous substances: environmental*”.

**131 Section 96 amended (Report on environmental user charges)**

In section 96(3)(f), replace “section 62” with “**subpart 9 of Part 5**”.

**132 Part 6A heading amended**

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In the Part 6A heading, after “**standards**”, insert “**for hazardous substances and products**”.

**133 New subpart 1 heading in Part 6A inserted**

Above section 96A, insert:

Subpart 1—Preliminary and general

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**134 New section 96AB inserted (Effect of group standards)**

After section 96A, insert:

**96AB Effect of group standards**

- (1) If a group standard applies to a hazardous substance or product, the substance or product must comply with the group standard.
- (2) However, in the case of a hazardous substance, if the hazardous substance also has an approval given under this Act, the substance may instead comply with the approval. 5
- (3) A hazardous substance to which section 96B(2)(a) applies is to be treated as having been approved by the Authority under section 29.

**135 Section 96B amended (Group standards)**

- (1) Replace the heading to section 96B with “**Power to issue, amend, or revoke group standards**”. 10
- (2) Replace section 96B(2)(b) and (c) with:
  - (b) a hazardous substance that has been approved under Part 5:
- (3) After section 96B(4), insert:
 

**Guidance note**

See **section 73D** (revoking duplicated or spent approvals, etc).

 15
- (4) After the guidance note (as inserted by **subsection (3)**) after section 96B(4), insert:
  - (4A) An application under this section must—
    - (a) be in the approved form; and 20
    - (b) contain, or be accompanied by, the information prescribed by the regulations; and
    - (c) contain, or be accompanied by, a statutory declaration that verifies any of the prescribed information referred to in **paragraph (b)** that the regulations require to be verified by a statutory declaration. 25

**136 Section 96C amended (When group standards may be issued or amended)**

- (1) Repeal section 96C(1)(c) and (h) and (2).
- (2) After section 96C(1)(e), insert:
 

(ea) have particular regard to any information that WorkSafe gives the Authority in response to notification under **section 96G**; and 30
- (3) Replace section 96C(3) with:
 

(3) However, the Authority may, on its own initiative, amend a group standard under section 96B without complying with subsection (1) if it considers that—

  - (a) the effect of the amendment is minor; or
  - (b) the amendment corrects a minor or technical error. 35

**137 Sections 96D to 96F replaced**

Replace sections 96D to 96F with:

**Subpart 2—Notification and consultation before decision**

**96D Application of subpart to minor amendments**

This subpart does not apply in relation to a group standard that the Authority amends under section 96B on its own initiative if it considers that—

- (a) the effect of the amendment is minor; or
- (b) the amendment corrects a minor or technical error.

**96E Public notification**

*Requirement to publicly notify* 10

(1) The Authority must, if it considers that there is likely to be significant public interest, publicly notify in 1 or more public notices—

- (a) an application under section 96B to issue, amend, or revoke a group standard; and
- (b) if the Authority proposes to issue or amend a group standard (whether on an application or on its own initiative),—
  - (i) the proposal; and
  - (ii) the Authority's assessment of the matters required under section 96C(1)(a), (b), (d), and (e) in relation to the group standard as proposed to be issued or amended; and

**Guidance note**

This section does not apply if **section 63B** applies and the Authority consults in accordance with **section 63B(2)**.

- (c) if the Authority proposes to revoke a group standard (whether on an application or on its own initiative), the proposal. 25

*Content of public notice*

(2) The public notice must state—

- (a) that any person may make a written submission on the application or proposal; and
- (b) a closing date for receipt of submissions by the Authority; and 30
- (c) the place or Internet site maintained by or on behalf of the Authority where the following (as applicable) may be viewed:
  - (i) the application and related information (except to the extent that any information in the application or in the related information is withheld in accordance with the Official Information Act 1982 or this Act); and 35

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|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
|               | <ul style="list-style-type: none"> <li>(ii) the proposal; and</li> <li>(iii) the assessment; and</li> <li>(d) the address for service of— <ul style="list-style-type: none"> <li>(i) the Authority; and</li> <li>(ii) the applicant (if any), except if that address is withheld in accordance with the Official Information Act 1982.</li> </ul> </li> </ul>                                                                                                               | 5                                |
| (3)           | The Authority must notify the Minister as soon as practicable after it decides to publicly notify an application or a proposal under this section.                                                                                                                                                                                                                                                                                                                          |                                  |
|               | <p><b>Guidance note</b></p> <p>See <b>section 68(1A)</b>, which (as modified by <b>section 96M</b>) applies in relation to an application under section 96B and relates to the Minister's power to call in applications with significant effects.</p>                                                                                                                                                                                                                       | 10                               |
|               | <i>Submissions</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                  |
| (4)           | Any person may make a written submission to the Authority on any application or proposal that is notified under this section.                                                                                                                                                                                                                                                                                                                                               | 15                               |
| (5)           | <p>The submission—</p> <ul style="list-style-type: none"> <li>(a) must state the reasons for making the submission; and</li> <li>(b) may state any decision sought; and</li> <li>(c) may state whether the person making the submission wishes to be heard.</li> </ul>                                                                                                                                                                                                      |                                  |
| (6)           | The Authority must forward to the applicant (if any) a copy of every submission as soon as is reasonably practicable after the Authority receives it.                                                                                                                                                                                                                                                                                                                       | 20                               |
|               | <b>96F Consultation about certain applications, etc, with affected persons</b>                                                                                                                                                                                                                                                                                                                                                                                              |                                  |
| (1)           | This section applies to any application, or any proposal of the Authority, to issue, amend, or revoke a group standard that—                                                                                                                                                                                                                                                                                                                                                |                                  |
|               | <ul style="list-style-type: none"> <li>(a) is not to be publicly notified under <b>section 96E</b>; and</li> <li>(b) that the Authority considers will have 1 or more of the following effects: <ul style="list-style-type: none"> <li>(i) significant cultural, economic, environmental, ethical, health, or international effects; or</li> <li>(ii) significant effects in an area in which the Authority lacks sufficient knowledge or expertise.</li> </ul> </li> </ul> | 25<br><br><br><br><br><br><br>30 |
| (2)           | <p>The Authority must—</p> <ul style="list-style-type: none"> <li>(a) do everything reasonably practicable to consult all persons who, in its opinion, are likely to be directly affected by the Authority's decision on the application or proposal; and</li> <li>(b) give those persons a reasonable opportunity to make submissions and comments to the Authority on the application or proposal; and</li> </ul>                                                         | 35                               |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| <ul style="list-style-type: none"> <li>(c) consider all submissions and comments received before making a decision on the application or proposal.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |    |
| <ul style="list-style-type: none"> <li>(3) Nothing in this section prevents the Authority from consulting any person before making a decision on the application or proposal (whether or not the Authority is required to consult under this section).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 5  |
| <p><b>96G Notification of departments and Crown entities</b></p> <p>The Authority must notify each of the following of any application, or proposal of the Authority, to issue, amend, or revoke a group standard:</p> <ul style="list-style-type: none"> <li>(a) any department or Crown entity that, in the opinion of the Authority, is likely to have an interest in the application or proposal:</li> <li>(b) WorkSafe.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 10 |
| <p>Subpart 3—Hearings before decision</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |    |
| <p><b>96H Application of subpart to minor amendments</b></p> <p>This subpart does not apply in relation to a group standard that the Authority amends under section 96B on its own initiative if it considers that—</p> <ul style="list-style-type: none"> <li>(a) the effect of the amendment is minor; or</li> <li>(b) the amendment corrects a minor or technical error.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 15 |
| <p><b>96I Requirement to hold hearing</b></p> <ul style="list-style-type: none"> <li>(1) The Authority must hold a hearing if— <ul style="list-style-type: none"> <li>(a) it considers that a hearing would be likely to assist it in— <ul style="list-style-type: none"> <li>(i) determining an application under section 96B; or</li> <li>(ii) deciding whether to proceed with a proposal to issue, amend, or revoke a group standard on its own initiative; and</li> </ul> </li> <li>(b) the Authority has publicly notified or consulted on the application or proposal under <b>section 96E or 96F</b>.</li> </ul> </li> <li>(2) For the purposes of determining whether a hearing would be likely to assist it in determining an application or in deciding whether to proceed with a proposal, the Authority must take into account whether, in its opinion, a hearing would be likely to provide it with any relevant information that is additional to the following: <ul style="list-style-type: none"> <li>(a) the information that has been provided by the applicant (if any):</li> <li>(b) any submissions and comments made in response to the public notification or consultation.</li> </ul> </li> <li>(3) This section does not apply in relation to an application that is the subject of a direction of the Minister under section 68, as applied by <b>section 96M</b>.</li> </ul> | 35 |

|                                                                                                                                                                                                                                                                                   |    |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| <b>Guidance note</b>                                                                                                                                                                                                                                                              |    |
| Under section 71, as applied by <b>section 96M</b> , the Authority is required to inquire into any application under section 96B that the Minister has called in. <b>Sections 96J to 96L</b> apply in relation to the conduct of the inquiry.                                     |    |
| <b>96J Date of hearing and notice about hearing</b>                                                                                                                                                                                                                               | 5  |
| If a hearing of the application or proposal is to be held, the Authority must give notice of the date for commencement of the hearing and of the time and place of the hearing to each of the following:                                                                          |    |
| (a) the applicant (if any):                                                                                                                                                                                                                                                       |    |
| (b) any person who made a submission in response to the public notification or consultation and stated that they wish to be heard.                                                                                                                                                | 10 |
| <b>Guidance note</b>                                                                                                                                                                                                                                                              |    |
| See also <b>section 96N</b> , which enables the Authority to postpone a hearing until after information requested under that section is received and requires the Authority to give notice to applicants and submitters if the Authority receives information under that section. |    |
| <b>96K Consideration of report, etc, obtained under section 96N</b>                                                                                                                                                                                                               |    |
| Any information obtained under <b>section 96N</b> may be considered at any hearing that the Authority conducts under this subpart.                                                                                                                                                |    |
| <b>96L Other provisions relating to hearings</b>                                                                                                                                                                                                                                  | 20 |
| <i>Application of section</i>                                                                                                                                                                                                                                                     |    |
| (1) This section applies if the Authority is required under <b>section 96I</b> to hold a hearing.                                                                                                                                                                                 |    |
| <i>Record of proceedings to be kept</i>                                                                                                                                                                                                                                           |    |
| (2) The Authority must keep a record of all proceedings before it.                                                                                                                                                                                                                | 25 |
| <i>Powers same as for Commission of Inquiry</i>                                                                                                                                                                                                                                   |    |
| (3) The Authority has the same powers as are conferred on a Commission of Inquiry by the Commissions of Inquiry Act 1908.                                                                                                                                                         |    |
| (4) Sections 4, 4B, 4D, 6, 7, 9, 11, and 12 of that Act apply accordingly.                                                                                                                                                                                                        |    |
| <i>Immunities and privileges</i>                                                                                                                                                                                                                                                  |    |
| (5) The members of the Authority have, for the purposes of the hearing, and the Authority's consideration of and decision on the application or proposal that is the subject of the hearing, the same immunities and privileges as are possessed by a District Court Judge.       | 30 |
| (6) <b>Subsection (5)</b> applies despite section 121 of the Crown Entities Act 2004.                                                                                                                                                                                             | 35 |

*Summons to appear*

- (7) Every summons to a witness to appear at a hearing must be in an approved form and be signed by the person chairing the hearing.

*Allowances for witnesses*

- (8) All allowances for a witness must be paid by the party on whose behalf the witness is called. 5

*Public hearings and other matters relating to proceedings*

- (9) The Authority must hold the hearing in public if the application or proposal is publicly notified under **section 96E**.
- (10) The Authority must establish a procedure that is appropriate and fair in the circumstances and may— 10
- (a) permit cross-examination; or
  - (b) permit questions in clarification; or
  - (c) permit only the members of the Authority to question any person.
- (11) At the hearing, the applicant (if any), and any person who made a submission in response to the public notice or consultation under **section 96E or 96F** and stated that they wish to be heard,— 15
- (a) may speak (either personally or through a representative); and
  - (b) may call evidence.
- (12) If any person who has stated that they wish to be heard fails to appear at the hearing, the Authority may proceed with the hearing if the Authority considers it fair and reasonable to do so. 20

Subpart 4—Other

**96M Minister's call-in power**

- (1) **Subpart 10 of Part 5** applies, with all necessary modifications, in relation to an application under section 96B in the same way that it applies in relation to an application under Part 5. 25
- (2) For that purpose,—
- (a) a reference in **section 68(1A)** to an application to which **section 53(5)** applies is to be treated as a reference to an application to which **section 96E(3)** applies; and 30
  - (b) a reference in section 69(1) to public notice given under **section 53** is to be treated as a reference to public notice given under **section 96E**; and
  - (c) a reference in section 71(1) to an application for approval is to be treated as a reference to an application under section 96B; and 35

- (d) **section 96E(4) to (6)** applies in relation to any written submission that is made in response to public notification under **section 71(3A)**, as applied by this section.
- (3) **Sections 96J to 96L** (the **specified sections**) apply in relation to the conduct of an inquiry under section 71 (as applied by this section) and for that purpose— 5
- (a) any reference in the specified sections to a hearing is to be treated as a reference to the inquiry; and
- (b) any reference in the specified sections to a matter that is publicly notified under **section 96E** is to be treated as a reference to the application to which the direction of the Minister under section 68 (as applied by this section) applies; and 10
- (c) any reference in the specified sections to a submission made in response to public notification under **section 96E** is to be treated as a reference to a submission that is made on the application in response to public notification under section 71 (as applied by this section). 15
- 96N Authority may commission report, etc**
- (1) For the purpose of assisting the Authority in performing its functions in relation to an application under section 96B or a proposal to issue, amend, or revoke a group standard on the Authority's own initiative, the Authority may— 20
- (a) commission a report or seek advice from any person, including, for example, a review of any information provided by the applicant (if any); or
- (b) obtain any relevant information from any source on the substance that is the subject of the application or proposal. 25
- (2) If the Authority receives information under this section, the Authority must give written notice to each of the following that the information is available for inspection:
- (a) the applicant (if any):
- (b) every person who made a submission on the application or proposal in response to public notification or consultation under **section 96E or 96F**. 30
- (3) However, the Authority is not required to give notice relating to information that has been withheld in accordance with section 9(2)(b) of the Official Information Act 1982. 35
- (4) If the Authority requests a report, advice, or any other information under this section, it may postpone, for a period that it considers is reasonable,—
- (a) its determination of the application or decision on the proposal; or
- (b) any hearing of the application or proposal.

- (5) However, the Authority may postpone its determination or decision or any hearing only if it considers that the requested information relates to an area in which it lacks sufficient knowledge or expertise.

**96O Decision to be written and copy given to applicant, etc**

- (1) This section applies to the following decisions of the Authority: 5
- (a) a decision to issue, amend, or revoke a group standard under section 96B on its own initiative:
  - (b) a decision on an application under section 96B:
  - (c) a decision to not proceed with a proposal to issue, amend, or revoke a group standard under section 96B on its own initiative if the proposal has been publicly notified or consulted on under **section 96E or 96F**. 10
- (2) The Authority’s decision, including its reasons for the decision, must be recorded in writing.
- (3) The Authority must give a copy of the decision to the applicant and any persons who have made submissions received under **section 96E or 96F**. 15

**96P Decision to be publicly notified**

The Authority must publicly notify each of the following decisions as soon as practicable after making the decision:

- (a) a decision of the Authority to issue, amend, or revoke a group standard under section 96B on its own initiative: 20
- (b) a decision of the Authority on an application under section 96B:
- (c) a decision of the Authority to not proceed with a proposal to issue, amend, or revoke a group standard under section 96B on its own initiative if the proposal has been publicly notified or consulted on under **section 96E or 96F**. 25

**96Q No compensation following amendment or revocation**

No compensation is payable to any person for any loss arising from the amendment or revocation of a group standard under this Part.

**138 Section 97 amended (Enforcement of Act)**

- (1) In the heading to section 97, after “Act”, insert “**in respect of hazardous substances**”. 30
- (2) In section 97(1), replace “The following persons shall ensure the provisions of this Act (including any controls imposed on approvals granted under this Act) are enforced in the following situations” with “The following provisions apply to the enforcement of the provisions of this Act (including any controls imposed by approvals granted under this Act) that relate to hazardous substances”. 35
- (3) In section 97(1)(d), (e) to (g), and (h)(i) and (iii), replace “shall” with “must”.

| Hazardous Substances and New Organisms Amendment Bill                                                                                                                                                                                                                                                                   |    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| Part 1 cl 139                                                                                                                                                                                                                                                                                                           |    |
| <b>139 Section 97A amended (Enforcement of Act in respect of new organism)</b>                                                                                                                                                                                                                                          |    |
| (1) In section 97A(2), after “modifications”, insert “(see sections 98 and 100)”.                                                                                                                                                                                                                                       |    |
| (2) In section 97A(5), repeal the definition of <b>unwanted organism</b> .                                                                                                                                                                                                                                              |    |
| <b>140 Section 97C amended (Sharing of information between Authority and enforcement agencies)</b>                                                                                                                                                                                                                      | 5  |
| Replace section 97C(3) with:                                                                                                                                                                                                                                                                                            |    |
| (3) In this section, <b>enforcement agency</b> means—                                                                                                                                                                                                                                                                   |    |
| (a) a person who is responsible for the enforcement of the provisions of this Act, as provided by section 97; or                                                                                                                                                                                                        |    |
| (b) the chief executive of the department of State responsible for the administration of the Biosecurity Act 1993; or                                                                                                                                                                                                   | 10 |
| (c) the New Zealand Customs Service.                                                                                                                                                                                                                                                                                    |    |
| <b>141 Section 99 amended (Supervision of inspection)</b>                                                                                                                                                                                                                                                               |    |
| Replace section 99(3) with:                                                                                                                                                                                                                                                                                             |    |
| (3) For the purposes of ensuring sufficient enforcement of the provisions of this Act (including any controls imposed by approvals granted under this Act), the Authority may—                                                                                                                                          | 15 |
| (a) appoint enforcement officers to enforce the provisions of this Act in such premises as the Authority thinks fit; or                                                                                                                                                                                                 |    |
| (b) authorise any chief executive of a department, Crown entity, or local authority to appoint enforcement officers to enforce the provisions of this Act in or on premises specified by the Authority.                                                                                                                 | 20 |
| <b>Guidance note</b>                                                                                                                                                                                                                                                                                                    |    |
| See also <b>section 99A</b> .                                                                                                                                                                                                                                                                                           |    |
| <b>142 New sections 99A and 99B inserted</b>                                                                                                                                                                                                                                                                            | 25 |
| After section 99, insert:                                                                                                                                                                                                                                                                                               |    |
| <b>99A Authority’s step-in power</b>                                                                                                                                                                                                                                                                                    |    |
| (1) This section applies if the Authority considers that—                                                                                                                                                                                                                                                               |    |
| (a) a person specified in section 97 is not performing or exercising the person’s functions, duties, or powers relating to the enforcement of the provisions of this Act (including any controls imposed by approvals granted under this Act) that relate to hazardous substances sufficiently (see section 99(1)); and | 30 |
| (b) it is necessary or desirable that the Authority do any of the following to achieve the purposes of this Act:                                                                                                                                                                                                        | 35 |

- (i) perform or exercise all or any of those functions, duties, or powers in place of the person:
- (ii) intervene in the performance or exercise of all or any of those functions, duties, or powers in place of the person in a case in which the person has already performed or exercised (but not yet completed the performance or exercise of) functions, duties, or powers in respect of the case: 5
- (iii) assist with the performance or exercise of all or any of those functions, duties, or powers.
- (2) The Authority may perform or exercise, or intervene in the performance or exercise of, all or any of the functions, duties, or powers in place of the person, but only if the Authority has consulted the person about the proposal to do so. 10
- (3) The Authority may assist with the performance or exercise of all or any of the functions, duties, or powers, but only with the prior agreement of the person.
- (4) For the purposes of **subsections (2) and (3)**, the Authority may appoint enforcement officers to enforce the provisions of this Act that relate to hazardous substances in any premises that the Authority thinks fit. 15
- (5) This section does not apply in relation to any functions, duties, or powers of—
  - (a) a territorial authority or its chief executive under this Act (*see* sections 97(1)(h) and 101); or 20
  - (b) a regional council or its chief executive (*see* section 97(2)).
- (6) In this section, **hazardous substance** has the same meaning as in section 99(4).
- 99B Authority may require information for purpose of section 99A**
- (1) The Authority may, by notice in writing given to a person specified in section 97, require the person to provide information that the Authority requires for the purpose of— 25
  - (a) deciding the matters referred to in **section 99A**; or
  - (b) performing or exercising, or intervening in or assisting with the performance or exercise of, all or any functions, duties, or powers under **section 99A**. 30
- (2) The notice must include the reason why the Authority requires the information.
- (3) The person must provide the required information by the date specified in the notice.
- (4) This section does not apply in relation to any functions, duties, or powers of—
  - (a) a territorial authority or its chief executive under this Act (*see* sections 97(1)(h) and 101); or 35
  - (b) a regional council or its chief executive (*see* section 97(2)).

**143 Section 109 amended (Offences)**

(1) Replace section 109(1)(d)(i) with:

- (i) manufactures, imports, uses, or disposes of a hazardous substance while the use of the hazardous substance is prohibited by a direction under **section 64 or 64AA**; or
- (ia) imports a new organism while the importation of the new organism into containment is prohibited by a direction under **section 64**; or
- (ib) develops or field tests a new organism while developing or field testing the new organism in containment is prohibited by a direction under **section 64**; or
- (ic) releases or uses a new organism while releasing or using the new organism is prohibited by a direction under **section 64**; or

(2) After section 109(1)(e)(vii), insert:

- (viii) any restriction imposed on an activity in respect of a new organism under section 64A; or

**144 Section 109A amended (Time for filing charging document)**

In section 109A(1), replace “6 months” with “12 months”.

**145 Section 109B amended (Extension of time for filing charging document)**

In section 109B(2) and (3)(a), (c), and (d), replace “6-month” with “12-month”.

**146 Section 114 amended (Penalties)**

- (1) In section 114(1A), after “section 109(1)(e)(vii)”, insert “or **(viii)**”.
- (2) In section 114(2), delete “, or section 156(1),”.

**147 New subpart 1 heading in Part 10 inserted**

In Part 10, above section 140, insert:

**Subpart 1—Orders in Council**

**148 Section 140 amended (Regulations)**

- (1) Repeal section 140(1)(c) to (f), (j), (k), and (m) and (2).
- (2) In section 140(1)(h), after “against this Act”, insert “and prescribing infringement fees (not exceeding \$3,000 in the case of an individual or \$12,000 in any other case) for those offences”.
- (3) In section 140(1)(i), delete “, and prescribing the infringement fees (not exceeding \$3,000) for each infringement offence, which may be different fees for different offences”.

- (4) In section 140(1)(l), delete “prescribing forms for the purpose of this Act that relate to new organisms and”.

**149 Section 140A amended (Persistent organic pollutants)**

Replace section 140A(1) and (2) with:

- |     |                                                                                                                                                                                                               |    |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| (1) | The Governor-General may, by Order in Council made on the recommendation of the Minister,—                                                                                                                    | 5  |
|     | (a) amend Schedule 2A by inserting, repealing, amending, or replacing any item in Schedule 2A; or                                                                                                             |    |
|     | (b) replace Schedule 2A.                                                                                                                                                                                      |    |
| (2) | Before recommending the making of an Order in Council under this section, the Minister must be satisfied that—                                                                                                | 10 |
|     | (a) the Order in Council would be consistent with New Zealand’s obligations under the Stockholm Convention; and                                                                                               |    |
|     | (b) in the case of an amendment that adds a hazardous substance to Schedule 2A, that substance exhibits the characteristics of a persistent organic pollutant that are specified in the Stockholm Convention. | 15 |

**Guidance note**

See section 141 for other procedural requirements with which the Minister must comply before making a recommendation under this section.

**150 Section 140B repealed (Schedule 1AA may be amended or substituted)** 20

Repeal section 140B.

**151 Section 141 amended (Procedure for making Orders in Council)**

- |      |                                                                                                                                                               |    |
|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| (1)  | In section 141(1), delete “(other than any Order in Council or part of an Order in Council made under section 9(1), 55(6), 140(1)(i), (j), or (m), or 140B)”. |    |
| (2)  | After section 141(1), insert:                                                                                                                                 | 25 |
| (1A) | Subsection (1) does not apply in respect of an Order in Council or part of an Order in Council made under—                                                    |    |
|      | (a) section 9(1), <b>20G</b> , or 140(1)(h), (i), or (l); or                                                                                                  |    |
|      | (b) section 140(1)(t) for the purpose of <b>section 141R(5)(b)</b> .                                                                                          |    |

**152 New subpart 2 heading in Part 10 inserted** 30

In Part 10, after section 141, insert:

Subpart 2—Material incorporated by reference

**153 Section 141F amended (Requirement to consult on proposal to amend or replace material incorporated by reference)**

- |     |                                |    |
|-----|--------------------------------|----|
| (1) | After section 141F(3), insert: | 35 |
|-----|--------------------------------|----|

(3A) **Subparts 2 and 3 of Part 6A** apply, with all necessary modifications, in relation to the proposed amendment, or replacement, of material incorporated by reference in a group standard as if the proposed amendment or replacement were an application or a proposal referred to in those subparts.

(2) Repeal section 141F(4)(a). 5

**154 New subparts 3 and 4 of Part 10, new subpart 5 heading in Part 10, and new section 141R inserted**

After section 141I, insert:

Subpart 3—Powers to waive, direct, and vary: supply of information and  
time limits 10

**141J Waivers and directions**

The Authority may, on the application of a person,—

- (a) waive a requirement as to the information that the person must supply under this Act; or
- (b) give a direction as to the terms on which the person must supply information under this Act. 15

**141K Variation of time limits generally**

- (1) The Authority may, on the application of a person or the Authority's own initiative, vary a time limit imposed under this Act.
- (2) The Authority may vary the closing date by which submissions made in response to public notification under **section 53, 71, 96E, or 96M** may be received only if satisfied that the specified persons— 20
  - (a) have consented to the variation; or
  - (b) have not consented to, but would not be unduly prejudiced by, the variation. 25
- (3) The **specified persons** are—
  - (a) the applicant (if any); and
  - (b) any persons whom the Authority—
    - (i) is aware have made a submission in response to the public notification; or 30
    - (ii) is satisfied are likely to make a submission in response to the public notification.
- (4) A time limit may be varied under this section—
  - (a) to a time limit that the Authority considers is reasonable in all the circumstances; and 35
  - (b) whether or not the time limit has expired.

**141L Extension of closing date: certain international agreements**

- (1) The Authority must extend (or further extend) the closing date by which submissions made in response to public notification under **section 53, 71, 96E, or 96M** may be received if a relevant CPTPP or TPP provision applies to—
  - (a) the application or other matter that is publicly notified under **section 53 or 96E**; or 5
  - (b) the application or reassessment that is the subject of the inquiry that is publicly notified under section 71 or **96M**.
- (2) The closing date may be extended to any date that the Authority considers appropriate to give effect to the relevant CPTPP or TPP provision. 10
- (3) The Authority may extend the closing date—
  - (a) on an application made by a person or on its own initiative; and
  - (b) whether or not the closing date has already passed.
- (4) **Section 141K** does not apply in relation to the extension of a closing date under this section. 15
- (5) In this section, **relevant CPTPP or TPP provision** means—
  - (a) Article 8.7.14 of the Trans-Pacific Partnership Agreement (done at Auckland on 4 February 2016) (technical barriers to trade: transparency: periods to comment on proposals); or
  - (b) that provision as incorporated into the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (done at Santiago, Chile, on 8 March 2018) by Article 1.1 of that agreement. 20

**141M Decisions under sections 141J to 141L: other**

The Authority must—

- (a) record a decision under any of **sections 141J to 141L**, including its reasons for the decision, in writing; and 25
- (b) give a copy of the written decision to the person (if any) who applied under that section; and
- (c) give public notice of the decision as soon as practicable after making the decision. 30

Subpart 4—Information to which Official Information Act 1982 applies

**141N Information relating to likely application**

- (1) This section applies if a person—
  - (a) supplies any information to the Authority; and
  - (b) the information is likely to relate to an application under this Act; and 35
  - (c) the relevant application has not yet been lodged with the Authority.

|             |                                                                                                                                                                                                                                                                                                                            |    |
|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| (2)         | The information must be held by the Authority on behalf of that person.                                                                                                                                                                                                                                                    |    |
| (3)         | The provisions of the Official Information Act 1982 do not apply to that information until the relevant application has been received by the Authority ( <i>see section 52(5)</i> ).                                                                                                                                       |    |
| <b>141O</b> | <b>Consideration of information withheld under Official Information Act 1982</b>                                                                                                                                                                                                                                           | 5  |
|             | Any information withheld by any person in accordance with section 9(2)(b) of the Official Information Act 1982 may be considered by—                                                                                                                                                                                       |    |
| (a)         | the Authority in reaching a decision under this Act; or                                                                                                                                                                                                                                                                    |    |
| (b)         | the Minister in reaching a decision under section 73 (including as applied by <b>section 96M</b> ).                                                                                                                                                                                                                        | 10 |
| <b>141P</b> | <b>Public notification: information involving trade secrets, etc, to be withheld</b>                                                                                                                                                                                                                                       |    |
| (1)         | If, in the Authority’s opinion, any information that has been supplied to the Authority in respect of any application under this Act may be able to be withheld under section 9(2)(b) of the Official Information Act 1982, that information must not be released to any person when any application is publicly notified. | 15 |
|             | <b>Guidance note</b><br><b>Sections 53, 71, 96E, and 96M</b> provide for public notification.                                                                                                                                                                                                                              |    |
| (2)         | In this section, a reference to an application includes a reference to any of the following:                                                                                                                                                                                                                               | 20 |
| (a)         | a review under section 38G or 38L, including a decision of the Authority to conduct the review on its own initiative:                                                                                                                                                                                                      |    |
| (b)         | a reassessment under <b>subpart 9 of Part 5</b> , including a decision of the Authority to proceed with the reassessment on its own initiative:                                                                                                                                                                            | 25 |
| (c)         | an inquiry under section 71 (including as applied by <b>section 96M</b> ):                                                                                                                                                                                                                                                 |    |
| (d)         | a proposal of the Authority to issue, amend, or revoke a group standard on its own initiative under Part 6A.                                                                                                                                                                                                               |    |
| <b>141Q</b> | <b>Requests under Official Information Act 1982 involving trade secrets, etc</b>                                                                                                                                                                                                                                           |    |
| (1)         | This section applies if—                                                                                                                                                                                                                                                                                                   | 30 |
| (a)         | the Authority receives a request under the Official Information Act 1982 to release any information held by the Authority in respect of an application under this Act; 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 the Official Information Act 1982; or                                                                                                                                                                                                      | 35 |

- (ii) has been classified as commercially sensitive by the person who gave the information to the Authority (the **information-giver**).
- (2) The Authority must make all reasonable efforts to, as soon as practicable, contact and notify the information-giver that the Authority has received a request to release the information. 5
- (3) Within 10 working days after a person receives a notice under this section, the person must respond to the Authority by—
  - (a) stating whether the person believes that the information should be withheld under section 9(2)(b) of the Official Information Act 1982; and
  - (b) giving reasons for that belief. 10
- (4) The Authority may, in accordance with the Official Information Act 1982, release the information or withhold the information if—
  - (a) the Authority has complied with **subsection (2)**; and
  - (b) the time limit applying under **subsection (3)** to the person receiving a notice has expired. 15
- (5) In this section, a reference to an application includes a reference to any of the following:
  - (a) a review under section 38G or 38L, including a decision of the Authority to conduct the review on its own initiative;
  - (b) a reassessment under **subpart 9 of Part 5**, including a decision of the Authority to proceed with the reassessment on its own initiative: 20
  - (c) an inquiry under section 71 (including as applied by **section 96M**);
  - (d) a proposal of the Authority to issue, amend, or revoke a group standard on its own initiative under Part 6A.

### Subpart 5—Other 25

#### **141R Disclosure and use of confidential information received with certain applications**

*Application of sections 23A to 23C of Medicines Act 1981*

- (1) Sections 23A to 23C of the Medicines Act 1981 apply (with all necessary modifications) to the Authority (as if it were the Minister of Health) in relation to confidential information received in respect of an application made under this Act if— 30
  - (a) the hazardous substance or new organism to which the application relates is, or has been, the subject of an innovative medicine application; and 35
  - (b) the confidential information is about that substance or organism; and
  - (c) the Minister of Health is, at the time that the Authority wants to disclose or use the information, required under section 23B of the Medicines Act

- 1981 to protect information provided in, or in relation to, the innovative medicine application.
- Application of Part 6 of Agricultural Compounds and Veterinary Medicines Act 1997*
- (2) Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997 applies (with the necessary modifications) to the Authority (as if it were the Director-General of the Ministry for Primary Industries) in relation to confidential information received in respect of an application made under this Act if—
- (a) either or both of the following apply:
- (i) the applicant has given the Authority written advice that, within 6 months after the application under this Act (the **HSNO application**) is made, the applicant intends to make an innovative TNP application in respect of the hazardous substance or new organism to which the HSNO application relates:
- (ii) the hazardous substance or new organism to which the HSNO application relates is, or has been, the subject of an innovative TNP application; and
- (b) the confidential information is about that substance or organism; and
- (c) in the case of a substance or an organism that is or has been the subject of an application referred to in **paragraph (a)(ii)**, the Director-General of the Ministry for Primary Industries is, at the time that the Authority wants to disclose or use the confidential information, required under Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997 to protect information provided in support of that application.
- (3) **Subsection (2)** ceases to apply in relation to confidential information about a hazardous substance or new organism that is referred to in **subsection (2)(a)(i)** 6 months after the relevant date if an innovative TNP application that applies to the substance or organism is not made under the Agricultural Compounds and Veterinary Medicines Act 1997 within that 6-month period.
- (4) The **relevant date** is,—
- (a) if the application under this Act is withdrawn or is returned under **section 52A** because it is incomplete,—
- (i) the date on which the application is withdrawn or returned (if no new and complete application is made within 6 months after the withdrawal or return); or
- (ii) if a new and complete application is made within 6 months after the withdrawal or return and is not withdrawn, the date on which the new and complete application is determined; or

|     |                                                                                                                                                                                                                                                                                                                             |    |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
|     | (iii) if a new and complete application is made within 6 months after the withdrawal or return and is withdrawn, the date on which the new and complete application is withdrawn; or                                                                                                                                        |    |
|     | (b) in any other case, the date on which the application under this Act is determined.                                                                                                                                                                                                                                      | 5  |
| (5) | Despite <b>subsections (2) and (3)</b> ,—                                                                                                                                                                                                                                                                                   |    |
|     | (a) if the Authority is required under <b>section 53</b> to publicly notify the application made under this Act, the Authority must make a summary of the effects of the hazardous substance or new organism available (in place of any confidential information contained in the application and related information); and | 10 |
|     | <b>Guidance note</b><br>See <b>section 53(4)(c)(ii)</b> , which requires the public notice to state the place or Internet site where the summary may be viewed.                                                                                                                                                             |    |
|     | (b) the Authority may disclose confidential information to prescribed persons or organisations or to persons or organisations within prescribed classes of persons or organisations.                                                                                                                                        | 15 |
| (6) | In this section,—                                                                                                                                                                                                                                                                                                           |    |
|     | <b>confidential information</b> means information that includes either or both of the following:                                                                                                                                                                                                                            | 20 |
|     | (a) trade secrets:                                                                                                                                                                                                                                                                                                          |    |
|     | (b) information with a commercial value that would, or would be likely to, be diminished by disclosure of the information                                                                                                                                                                                                   |    |
|     | <b>prescribed</b> means prescribed by the regulations.                                                                                                                                                                                                                                                                      |    |

## Part 2 25

### Other amendments

|             |                                                                                                  |    |
|-------------|--------------------------------------------------------------------------------------------------|----|
| <b>155</b>  | <b>Schedule 1AA repealed</b><br>Repeal Schedule 1AA.                                             |    |
| <b>156</b>  | <b>Schedule 2 amended</b><br>In the Schedule 2 heading, replace “50(1)–(4)” with “ <b>25C</b> ”. | 30 |
| <b>156A</b> | <b>Schedule 7 amended</b><br><u>In Schedule 7,—</u>                                              |    |
|             | (a) <u>insert the Part set out in <b>Schedule 1</b> of this Act as the last Part; and</u>        |    |
|             | (b) <u>make all necessary consequential amendments.</u>                                          |    |

**157 Consequential amendment related to Part 1**

Amend the legislation specified in the **Schedule** as set out in that schedule.

**Schedule 1**  
**New Part 3 inserted into Schedule 7**

**s 156A**

|                                                                                                |                                                                                                                                                             |    |
|------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| <b><u>Part 3</u></b>                                                                           |                                                                                                                                                             |    |
| <b><u>Provisions relating to Hazardous Substances and New Organisms Amendment Act 2026</u></b> |                                                                                                                                                             | 5  |
| <b><u>Subpart 1—Preliminary</u></b>                                                            |                                                                                                                                                             |    |
| <b><u>14</u></b>                                                                               | <b><u>Interpretation</u></b>                                                                                                                                |    |
| (1)                                                                                            | In this Part, <b>amendment Act</b> means the Hazardous Substances and New Organisms Amendment Act <b>2026</b> .                                             | 10 |
| (2)                                                                                            | In this Part,—                                                                                                                                              |    |
| (a)                                                                                            | a reference to a new provision is a reference to the provision as inserted or replaced by the amendment Act; and                                            |    |
| (b)                                                                                            | a reference to an old provision is a reference to the provision as in force immediately before it was replaced or repealed by the amendment Act.            | 15 |
| <b><u>Subpart 2—Part 5 of the Act</u></b>                                                      |                                                                                                                                                             |    |
| <b><u>Applications</u></b>                                                                     |                                                                                                                                                             |    |
| <b><u>15</u></b>                                                                               | <b><u>Pending application under old section 26</u></b>                                                                                                      |    |
|                                                                                                | New <b>section 26(1A)</b> extends to an application for a determination under old section 26(1) if the application—                                         | 20 |
| (a)                                                                                            | is made, is not withdrawn, and has not lapsed before the commencement of new <b>section 26(1A)</b> ; and                                                    |    |
| (b)                                                                                            | has not been finally determined immediately before that commencement.                                                                                       |    |
| <b><u>16</u></b>                                                                               | <b><u>Pending application for approval</u></b>                                                                                                              |    |
| (1)                                                                                            | This clause applies to an application for an approval under Part 5 of the Act if the application—                                                           | 25 |
| (a)                                                                                            | is made, is not withdrawn, and has not lapsed before the commencement of the new law; and                                                                   |    |
| (b)                                                                                            | the application has not been finally determined immediately before that commencement.                                                                       | 30 |
| (2)                                                                                            | The provisions of this Act that apply in relation to the application immediately before that commencement continue to apply in relation to the application. |    |

- (3) If 2 or more new laws are applicable and they commence on 2 or more dates, a reference in **subclauses (1) and (2)** to the commencement of the new law is to be treated as a reference to the earliest commencement.
- (4) In this clause, **new law** means—
- Application for any Part 5 approval* 5
- (a) in the case of any application for approval under Part 5 of the Act,—
- (i) new **sections 52 to 53A**; or
- (ii) new **section 55**; or
- (iii) new **sections 60 to 60B** and the amendments made to section 61 by the amendment Act; or 10
- (iv) the amendments made to sections 68 to 73 by the amendment Act; or
- Hazardous substance: application for approval (except containment approval)*
- (b) in the case of an application made under old section 28, the amendments made to section 28A by the amendment Act; or 15
- New organism: application for approval relating to release (except conditional release approval)*
- (c) in the case of an application made under section 34 (as in force immediately before that section is amended by the amendment Act), new section 35(1); or 20
- New organism: application for conditional release approval*
- (d) in the case of an application made under section 38A, new section 38BA(1); or
- New organism: application for approval to import, develop, etc, in or into containment* 25
- (e) in the case of an application made under section 40,—
- (i) new section 42(1); or
- (ii) the amendment made to section 42A(2) by the amendment Act; or
- (iii) new section 42B(1); or 30
- (iv) new **section 42C**; or
- Transshipment application*
- (f) in the case of an application made under section 51, new section 51(4) or (5)(b).

**17 Request to applicant for further information**

*General*

(1) New **section 52B** extends to any request that is made on or after the commencement of that section in relation to either of the following:

- (a) an application that is made under section 26 that has not been finally determined immediately before that commencement:
- (b) an application for approval under Part 5 of the Act to which **clause 16** applies.

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*Lapsing if request made under old law*

(2) However, if a request is made under old section 52(1) before the commencement of new **section 52B**, and the application has not lapsed under old section 52(2) before that commencement, old section 52(2) (instead of new **section 52B**) continues to apply in relation to the application.

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*Reassessments*

**18 General: new law applies to approvals whenever granted**

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The provisions of this Act relating to the reassessment of a hazardous substance or new organism apply in relation to the reassessment of a hazardous substance or new organism that is the subject of an approval that is in force, even if the approval is granted before any of those provisions are amended, replaced, or inserted by the amendment Act.

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**19 Commenced reassessments to be continued under old law**

Despite **clause 18**, the provisions of this Act relating to the reassessment of a hazardous substance or new organism, as in force immediately before the replacement or amendment of sections 63, 63A, 63C, and 63D by the amendment Act, continue to apply in relation to that reassessment if the reassessment has already commenced, but is not finally disposed of, before that replacement or amendment.

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**20 Suspension or temporary restriction of use, etc, during reassessment**

(1) Despite **clause 19**, new **section 64** and section 64A (as amended by the amendment Act) apply to the reassessment of a hazardous substance or a new organism, even if the reassessment has already commenced, but is not finally disposed of, before those sections commence.

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(2) For that purpose, in new **section 64(1)(a)**, a reference to the public notification of an application for a reassessment, or of a decision of the Authority to proceed with a reassessment, is to be treated as a reference to the public notification of the reassessment under old section 53.

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**21    No compensation following reassessment**

(1)    Old section 65 continues to apply in relation to a hazardous substance or new organism reassessed under any of the following sections (as in force immediately before their replacement or amendment by the amendment Act), including as applied by **clause 19**:

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- (a)    section 63;
- (b)    section 63A, 63C, or 63D.

(2)    For that purpose, in old section 65,—

- (a)    a reference to section 64 includes a reference to new **section 64**, as applied by **clause 20**; and
- (b)    a reference to section 64A includes a reference to section 64A, as amended by the amendment Act and applied by **clause 20**.

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**22    Prohibition on use and requirement for disposing of substances**

Despite **clause 19**, section 66, as amended by the amendment Act, extends to a hazardous substance that has been reassessed in accordance with old section 63 if the outcome of the reassessment is that the Authority declines to allow any further importation or manufacture of that substance.

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Subpart 3—Organisms prescribed as not new organisms

**23    Definition of 2009 regulations**

In this subpart, **2009 regulations** means the Hazardous Substances and New Organisms (Organisms Prescribed as Not New Organisms) Regulations 2009.

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**24    Expiry of clauses 25 to 27**

**Clauses 25 to 27** expire on the earlier of the following dates:

- (a)    3 months after the repeal of section 140(1)(c) by the amendment Act;
- (b)    the date on which the 2009 regulations are revoked by regulations made under section 140(1)(t).

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**25    2009 regulations continued**

The 2009 regulations—

- (a)    continue in force, for the purposes of **clauses 26 and 27**, until the expiry of this clause; and
- (b)    are revoked when this clause expires.

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**26    References to organism prescribed as not new organism**

(1)    In section 2A(2)(a)(iii) and (b)(iii), a reference to an organism that has been prescribed as not a new organism includes a reference to an organism that is prescribed as not a new organism in the 2009 regulations.

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- (2) In new **section 25C**, a reference to a denuded organism includes a reference to an organism that is prescribed as not a new organism in the 2009 regulations.

**27 Transition to Part 5A notice**

- (1) The authorised maker may, by notice under new **Part 5A** of this Act, prescribe any organism as not a new organism, that is prescribed as not a new organism in the 2009 regulations.

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- (2) New **sections 73G and 73I** do not apply in relation to a decision to make a notice under **subclause (1)**.

- (3) New **section 73J** does not apply in relation to any notice made under **subclause (1)**.

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Subpart 4—Part 6A of the Act

**28 Pending application relating to group standard**

- (1) This section applies to an application referred to in section 96B(4)(b) (for the issue, amendment, or revocation of a group standard) that—

(a) is made and not withdrawn before the commencement of new **subparts 2 to 4** of Part 6A of this Act; and

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(b) has not been finally determined immediately before that commencement.

- (2) The provisions of this Act that apply in relation to the application immediately before that commencement continue to apply in relation to it.

**29 Proposal to issue, amend, or revoke group standard on Authority's initiative**

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- (1) This section applies to a proposal of the Authority to issue, amend, or revoke a group standard if the proposal—

(a) is notified under old section 53(1A) or 53AA, or is or is required to be the subject of a hearing under section 61 (as in force before its amendment by the amendment Act), before the commencement of **subparts 2 to 4** of Part 6A; and

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(b) is not finally decided immediately before that commencement.

- (2) The provisions of this Act that apply in relation to the proposal immediately before that commencement continue to apply to it.

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**30 No compensation payable following amendment or revocation**

- (1) New **section 96Q** applies in relation to any group standard that is amended or revoked under Part 6A of the Act (including as applied by **clause 28 or 29**) on or after the commencement of that section.

- (2) Old section 65 continues to apply in relation to any group standard that is amended or revoked under section 96B(3) before old section 65 is replaced by the amendment Act.

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**Schedule  
Consequential amendment**

**s 157**

**Medicines Act 1981 (1981 No 118)**

In section 2(1), definition of **qualifying new medicine**, replace paragraph (b) with: 5

(b) is determined under section 38I(3) of the Hazardous Substances and  
New Organisms Act 1996 to be a qualifying medicine

**Legislative history**

11 May 2026  
14 May 2026

Introduction (Bill 304–1)  
First reading and referral to Primary Production Committee