



## PROACTIVE RELEASE COVERSHEET

<b>Minister</b>	Hon Nicola Grigg	<b>Portfolio</b>	Environment
<b>Name of package</b>	Briefing: Second briefing on delegated HSNO Act policy decisions to inform drafting instructions for a HSNO Amendment Bill	<b>Date to be published</b>	5 June 2026

### List of documents that have been proactively released

<b>Date</b>	<b>Title</b>	<b>Author</b>
19 March 2026	Second briefing on delegated HSNO Act policy decisions to inform drafting instructions for a HSNO Amendment Bill	Ministry for the Environment

**Information redacted** **NO**

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**Summary of reasons for redaction**

N/A



## BRIEFING

### Second briefing on delegated HSNO Act policy decisions to inform drafting instructions for a HSNO Amendment Bill

<b>Date:</b>	19 March 2026	<b>Priority:</b>	Urgent
<b>Security classification:</b>	In Confidence	<b>Tracking number:</b>	BRF-7020

	Action sought	Response by
Hon Penny SIMMONDS <b>Minister for the Environment</b>	<b>Agree</b> to delegated decisions on the hazardous substance and new organisms policy to inform the drafting instructions.	25 March 2026
Hon Andrew Hoggard <b>Minister for Food Safety</b>		

#### Action for Minister for the Environment's Office staff

**Forward** this briefing to: Minister for Food Safety for joint decisions.

#### Appendices and attachments

None

#### Contact at Ministry for the Environment for telephone discussion (if required)

Name	Position	Telephone	1st contact
Glenn Wigley	General Manager	027 491 7806	
Sarah Kenward	Manager	027 288 9374	✓
Richard Souness	Author		

#### The following departments/agencies have been consulted

None

- Minister's office to complete:
- |  |   |                                    |
|--|---|------------------------------------|
| <input type="checkbox"/> Noted               | <input type="checkbox"/> Approved             | <input type="checkbox"/> Declined  |
| <input type="checkbox"/> Overtaken by Events | <input type="checkbox"/> Needs change         | <input type="checkbox"/> Seen      |
|  | <input type="checkbox"/> See Minister's Notes | <input type="checkbox"/> Withdrawn |

#### Minister's Comments



## BRIEFING

### Second briefing on delegated HSNO Act policy decisions to inform drafting instructions for a HSNO Amendment Bill

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## Purpose

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This briefing seeks decisions to inform drafting instructions for a Hazardous Substances and New Organisms Amendment Bill (the Bill), which will amend the Hazardous Substances and New Organisms Act 1996 (the Act).

## Key points

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- In May 2025, Cabinet made policy decisions on the Agricultural and Horticultural Products Regulatory Review Omnibus Bill to amend the Hazardous Substances and New Organisms Act 1996 (the Act), including the following decisions [ECO-25-MIN-0075 and CAB-25-MIN-0171 refers (see attached)]:
  - *authorised the Minister for the Environment to take final decisions on the matters listed in paragraphs 10 to 13 (recommendation 14);*
  - *authorised the Minister for the Environment to take final detailed decisions on the levy (recommendation 17);*
  - *authorised joint Ministers to make final decisions on minor and technical issues and make changes consistent with the policy intent described in the paper under ECO-25-SUB-0075 on any issues that arise during the drafting process (recommendation 46).*
- The Ministry provided the Parliamentary Counsel Office (PCO) with drafting instructions in July and December 2025, and PCO has supplied a draft Bill with additional queries. Further delegated decisions are required to give effect to the policy agreed by Cabinet and to improve workability. These include changes to application processes, definitions and delegations, and a range of technical fixes.
- There are also decisions that, subject to your agreement, will need to be taken to Cabinet, to rescind previous Cabinet decisions [CAB-25-MIN-0171 refers]. These include changes impacted by the continued regulation of genetically modified organisms under the Act, and we are changing our approach to repealing some regulations to align with best practice. Officials discussed these with you on 10 and 17 February when investigating the interplay

between the HSNO amendments and the Gene Technology Bill. These are different to what Cabinet agreed.

## Recommended action

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### Recommended actions for the Minister for the Environment

<p>The Ministry for the Environment recommends that you:</p> <p><b>Note</b> in May 2025, Cabinet decided on the direction of policy decisions to amend the Hazardous Substances and New Organisms Act 1996 [CAB-25-MIN-0171]</p>	<p><i>Noted</i></p>
<p><b>Note</b> in May 2025, Cabinet authorised final decisions on the matters listed in recommendations 10 – 13, and on the levy (recommendation 17) be delegated to the Minister for the Environment [CAB-25-MIN-0171]</p>	<p><i>Noted</i></p>
<p><b>Agree</b> to introduce the tiered application pathway structure for hazardous substances via regulations, supported by set application requirements in the Act</p>	<p><i>Agree / Disagree</i></p>
<p><b>Agree</b> to remove the ability for the Environmental Protection Authority to waive a requirement of the Act, or a regulation or a Notice concerning the time within, but retain the option to extend or reduce timeframes (reconsideration of decision in BRF-6205 (see attached))</p>	<p><i>Agree / Disagree</i></p>
<p><b>Agree</b> that the applicant becomes responsible for selecting the appropriate application pathway when applying for hazardous substances and new organism approvals</p>	<p><i>Agree / Disagree</i></p>
<p><b>Agree</b> to include in the regulation making ability, the power to specify the information the Authority requires to accompany an application</p>	<p><i>Agree / Disagree</i></p>
<p><b>Agree</b> to decisions for the design of the hazardous substances levy to go into the Bill:</p> <ul style="list-style-type: none"> <li>a. The levy will be introduced via regulations</li> <li>b. Waivers, exemptions and refunds will be provided for in the Bill; and</li> <li>c. Record-keeping and reporting requirements will be provided for in the Bill</li> </ul>	<p><i>Agree / Disagree</i></p> <p><i>Agree / Disagree</i></p> <p><i>Agree / Disagree</i></p>

## Recommended actions for Joint Ministers

The Ministry for the Environment recommends that you:	<b><i>Minister for the Environment</i></b>	<b><i>Minister for Food Safety</i></b>
<b>Note</b> in May 2025, Cabinet authorised joint Ministers to make detailed decisions to achieve the broad policy intent outlined in the paper and appendices under ECO-25-SUB-0075 (see attached) on any issues that arise during the drafting process [CAB-25-MIN-0171]	<i>Noted</i>	<i>Noted</i>
<b>Agree</b> to ask Cabinet to rescind the change to the definition of “incidentally imported new organism”	<i>Agree / Disagree</i>	<i>Agree / Disagree</i>
<b>Agree</b> to ask Cabinet to rescind the change to the definition of “organism”	<i>Agree / Disagree</i>	<i>Agree / Disagree</i>
<b>Agree</b> to ask Cabinet to rescind one of the proposed changes to the definition of “new organism” regarding a clarification that organisms that, through natural means, are no longer present in New Zealand, but can be introduced, are not new organisms	<i>Agree / Disagree</i>	<i>Agree / Disagree</i>
<b>Agree</b> to ask Cabinet to rescind the changes to section 26 to include a provision that allows for a decision to be made based on the ubiquity of an organism internationally and on the basis that the organism is otherwise new to science	<i>Agree / Disagree</i>	<i>Agree / Disagree</i>
<b>Agree</b> to ask Cabinet to rescind the changes to section 97A, which change the wording regarding the enforcement role in respect of new organisms	<i>Agree / Disagree</i>	<i>Agree / Disagree</i>
<b>Agree</b> to ask Cabinet to rescind the repeal of sections 147(1)(d), (e) and (f) and 148(c), (d) and (e) - Statement of Intent (SOI) and annual report provisions (minor and technical changes)	<i>Agree / Disagree</i>	<i>Agree / Disagree</i>
<p><b>Agree</b> to the following design features of the time-limited conditional approvals:</p> <p>a. Change the name to “temporary hazardous substances approval”</p>	<i>Agree / Disagree</i>	<i>Agree / Disagree</i>

<ul style="list-style-type: none"> <li>b. The EPA must consult with relevant government departments or Crown entities</li> <li>c. The EPA will be able to suspend the temporary hazardous substances approval while undertaking a reassessment</li> <li>d. The EPA will be able to modify and revoke the temporary hazardous substances approval following a reassessment.</li> <li>e. Compensation will not be available for any loss as a result of a change made to the approval.</li> </ul>	<p><i>Agree / Disagree</i></p> <p><i>Agree / Disagree</i></p> <p><i>Agree / Disagree</i></p> <p><i>Agree / Disagree</i></p>	<p><i>Agree / Disagree</i></p> <p><i>Agree / Disagree</i></p> <p><i>Agree / Disagree</i></p> <p><i>Agree / Disagree</i></p>
<p><b>Agree</b> to clarify the criteria of the international regulator rapid assessment pathway so that any international regulator assessment is sufficient and relevant to assess the effects of the substance in New Zealand</p>	<p><i>Agree / Disagree</i></p>	<p><i>Agree / Disagree</i></p>
<p><b>Agree</b> to allow people to apply for modified reassessments instead of deeming every reassessment to be an application, so the application can be treated like any other under the Act</p>	<p><i>Agree / Disagree</i></p>	<p><i>Agree / Disagree</i></p>
<p><b>Agree</b> to change the definition of “new organism” to clarify that any organism belonging to a migratory species that was present in New Zealand from time to time before the 29 July 1998, or immediately before that date is not a new organism</p>	<p><i>Agree / Disagree</i></p>	<p><i>Agree / Disagree</i></p>
<p><b>Agree</b> to include a new application pathway to develop vagrant contain prohibited new organisms in containment when they are found in New Zealand</p>	<p><i>Agree / Disagree</i></p>	<p><i>Agree / Disagree</i></p>
<p><b>Agree</b> to the following changes to emergency provisions:</p> <ul style="list-style-type: none"> <li>a. Rename an emergency for the purposes of sections 46 to 49 as an adverse event</li> <li>b. Extend hazardous substance containment approvals to cover adverse events, special emergencies and emergencies declared in any other Act</li> <li>c. Include references to medical devices alongside references to medicines in the special emergency provisions</li> </ul>	<p><i>Agree / Disagree</i></p> <p><i>Agree / Disagree</i></p> <p><i>Agree / Disagree</i></p>	<p><i>Agree / Disagree</i></p> <p><i>Agree / Disagree</i></p> <p><i>Agree / Disagree</i></p>
<p><b>Agree</b> to clarify data protection in respect of confidential information received in an application that relates to a hazardous substance or new organism which is, has</p>	<p><i>Agree / Disagree</i></p>	<p><i>Agree / Disagree</i></p>

been, or will be (within six months), the subject of an innovative TNP application under the ACVM Act		
<b>Agree</b> to align the powers and functions of new application types with existing delegations	<i>Agree / Disagree</i>	<i>Agree / Disagree</i>
<b>Agree</b> to defining “large-scale fermentation” as a consequence of the Cabinet decision on the definition of “develop”	<i>Agree / Disagree</i>	<i>Agree / Disagree</i>
<b>Agree</b> to the proposal to allow for new organisms contained in medical devices to be eligible for the same application pathways as new organisms contained in medicines	<i>Agree / Disagree</i>	<i>Agree / Disagree</i>
<b>Agree</b> to the proposal to repeal and amend sections of the Act that relate to expired sections	<i>Agree / Disagree</i>	<i>Agree / Disagree</i>
<b>Agree</b> to the proposal to move provisions relating to public notification of decisions from section 20B into the relevant parts of the Act	<i>Agree / Disagree</i>	<i>Agree / Disagree</i>
<b>Agree</b> that the process to revoke certain regulations pertaining to new organisms can be done in the usual way rather than when via the Bill	<i>Agree / Disagree</i>	<i>Agree / Disagree</i>



Glenn Wigley  
**General Manager – Waste & HSNO Policy**  
 Climate Change Mitigation and Resource  
 Efficiency, Ministry for the Environment

19 March 2026

Hon Penny SIMMONDS  
**Minister for the Environment**

\_\_\_ / \_\_\_ / 2026

Hon Andrew Hoggard  
**Minister for Food Safety**

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# Second briefing on delegated HSNO Act policy decisions for drafting an HSNO Amendment Bill

## Background

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1. In May 2025, Cabinet authorised the Minister for the Environment (the Minister) to make additional decisions on the levy and application matters of the Hazardous Substances and New Organisms Act 1996 (the Act). Cabinet authorised the Minister for the Environment and Minister for Food Safety (Joint Ministers) to make decisions to achieve the broad policy intent outlined in the paper and appendices under ECO-25-SUB-0075 on any issues that arise during the drafting of the Agricultural and Horticultural Products Regulatory Review Omnibus Bill (Omnibus Bill) [CAB-25-MIN-0171 refers].
2. Since then, Ministers have decided to no longer progress these amendments as an omnibus bill, but as two separate Bills: An Agricultural Compounds and Veterinary Medicines Amendment Bill and a Hazardous Substances and New Organisms Amendment Bill (**the Bill**).
3. The Parliamentary Counsel Office (PCO) has provided drafts of the Bill, and officials have provided further drafting instructions in response to PCO's queries. PCO has indicated that some policy proposals require further clarification to ensure the Bill is drafted to reflect intended policy outcomes. We seek delegated decisions on a range of amendments to enhance the workability of the Act.
4. The Ministry for Primary Industries was not consulted on this briefing as no changes to the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) are proposed by Ministry for the Environment officials.

## Policy changes to improve workability

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5. The following policy proposals require further clarification via a delegated decision to request PCO draft the Bill to reflect the intended policy outcomes.

## Issues requiring decisions from the Minister for the Environment

6. We seek delegated decisions on the following issues related to the application process under recommendation 14 [ECO-25-MIN-0075 refers]:

### Matters relating to application types and structure

*Introducing the tiered application pathway structure for hazardous substance applications via regulations*

7. On 29 June 2025, as part of the briefing on outstanding policy decisions for the Omnibus Bill (BRF-6205), you agreed to introduce a tiered application pathway

structure for hazardous substances, aligned with the EPA's current operational processes<sup>1</sup>.

8. Rather than introducing the tiered pathway structure into the Act, officials now recommend reflecting the structure in regulations for increased flexibility in the future. Regulations would provide for the Category A, B, and C application types already agreed.

*Removing the option for the Environmental Protection Authority to waive timeframes for assessing applications*

9. On 29 June 2025, as part of the briefing on outstanding policy decisions for the Omnibus Bill (BRF-6205), you agreed to retain existing powers in the Act that allow the EPA to pause, amend, or waive statutory timeframes during the assessment process, either with the agreement of the applicant or submitter, or where the EPA is satisfied that no undue prejudice would arise.
10. Officials have reconsidered these powers and now recommend removing the EPA's ability to waive timeframes, while retaining the ability to extend or reduce timeframes. This change would improve transparency by ensuring that a timeframe always applies. Requiring the EPA to set a revised timeframe in all circumstances would provide greater certainty for applicants and submitters.

*Clarifying that the applicant selects application pathway when applying for hazardous substances and new organisms approvals*

11. When an applicant submits an application to the EPA, there are multiple pathways under which it may be assessed. Currently, the EPA determines the appropriate pathway, which can require additional information and additional time for the EPA and may not align with the applicant's expectations.
12. The Bill proposes the EPA will have a defined timeframe to assess whether an application is complete and will be able to return incomplete applications. To support this process, officials recommend applicants select the application pathway when submitting their application.
13. This would allow the EPA to assess the application against the requirements for the selected pathway and return an incomplete application to the applicant if the requirements are not met.

*Including a list of information required for an application in regulations*

14. On 29 June 2025, as part of the briefing on outstanding policy decisions for the Omnibus Bill (BRF-6205), you decided on the content of the regulations for HSNO applications to include process steps and timeframes. We propose enabling provisions within the Bill to allow for regulations to include information requirements for applications.
15. Placing information requirements into regulations provides certainty to applicants on what their application should contain. It also improves transparency and efficiency.

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<sup>1</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [3]

## **Matters relating to the proposed Hazardous Substances levy**

16. PCO have requested further details to aid their drafting of the levy provisions. While we will undertake further analysis to complete the Cost Recovery Impact Statement part 2 (CRIS 2), and any underpinning regulations will be developed via a consultative process, we currently seek delegated decisions on the following issues related to the levy under recommendation 14 [ECO-25-MIN-0075 refers]:
17. Officials propose that the levy is introduced via regulations.

### *Waivers, exemptions and refunds:*

18. Officials seek your confirmation that the levy design in the Bill should include provisions for waivers, exemptions and refunds similar to the Financial Markets Authority levy.

### *Record-keeping and reporting requirements:*

19. Officials propose record-keeping and reporting requirements similar to the waste disposal levy.
20. Officials will update you further on the design of these provisions, along with any decisions you need to make, as work proceeds on the CRIS 2.

## **Policy issues requiring decisions from Joint Ministers**

21. Officials seek approval to ask Cabinet to make the following changes to existing Cabinet decisions [ECO-25-MIN-0075 refers].

### *Rescinding the change to the definition of “incidentally imported new organism” to include progeny<sup>2</sup>*

22. Further work with the Ministry for Primary Industries has shown that the proposed changes to the definition of “incidentally imported new organism” (IINO) would have implications for the Biosecurity Act 1993. The definition of IINO is incorporated by reference in the Biosecurity Act 1993, and any change to that definition could potentially affect MPI’s work beyond the purview of the HSNO Act. For this reason, the definition should remain unchanged. We therefore recommend asking Cabinet to rescind the relevant Cabinet decision.

### *Rescinding the change to the definition of “organism”<sup>3</sup>*

23. The proposed change to the definition of “organism” is dependent on the enactment of the Gene Technology Bill. A change prior to that Bill’s enactment would leave a regulatory gap. Officials recommend asking Cabinet to rescind the relevant Cabinet decision, so the definition remains unchanged for now.

### *Rescinding one of the two changes to the definition of “new organism”<sup>4</sup>*

24. Cabinet agreed to two changes to the definition of “new organism.” Officials recommend asking Cabinet to rescind the second change, which sought to clarify that

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<sup>2</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [27]

<sup>3</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [24]

<sup>4</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [25]

organisms that, through natural means, are no longer present in New Zealand but can be reintroduced, are not new organisms.

25. Upon further analysis, officials have identified that this change may provide a pathway for historically extinct organisms to be reintroduced without regulation (noting that there is a process for 'denewing' such an organism if appropriate).

*Rescinding the change to the determination of a new organism to include the ubiquity of an organism internationally and on the basis that the organism is otherwise new to science*<sup>5</sup>

26. The reason for this recommendation was to codify current practice for decision makers under section 26 of the Act. However, upon further analysis, this change would inadvertently allow genetically modified organisms to be determined not new organisms for the purposes of the Act. For this reason, officials recommend asking Cabinet to rescind the relevant Cabinet decision.

*Rescinding the changes to section 97A, which change the wording regarding the enforcement role in respect of new organisms*<sup>6</sup>

27. The proposed change to s97A would align the wording between the Act and the Gene Technology Bill with respect to Ministry of Primary Industries' new organisms enforcement role. With the Gene Technology Bill not proceeding at the moment, we recommend not making this change at this time. This change was a modernisation of wording only and would not change Ministry for Primary Industries' enforcement role. We therefore recommend asking Cabinet to rescind the Cabinet decision to change the wording of s97A.

*Rescinding the removal of Statement of Intent (SOI) and annual report provisions (minor and technical changes)*<sup>7</sup>

28. This change was recommended to Cabinet as it appeared that these provisions (sections 147 and 148 of the Act) were redundant<sup>8</sup>. However further analysis has shown that the provisions are not redundant and therefore should be retained. Officials recommend asking Cabinet to rescind the relevant Cabinet decision.

### **Designing the temporary hazardous substances approvals**

29. Cabinet agreed to introduce a time-limited conditional application process and corresponding approvals that are conditional on a full application being submitted and deemed complete.<sup>9</sup> This will reduce the time users must wait before using a particular hazardous substance. Officials, with PCO, have further developed the temporary conditional approvals pathway to better reflect the policy intent. Officials request your approval of the following:

- The name of the approval changed from "time-limited conditional approval" to "**temporary hazardous substances approval**" to fit best naming practice.
- The EPA may consult with relevant government departments or Crown entities.

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<sup>5</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [12]

<sup>6</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [21]

<sup>7</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [35]

<sup>8</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [35]

<sup>9</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [2]

- These approvals can be reassessed if, for example, significant new information relating to the effects of the substance becomes available.
- Reassessment of a hazardous substance that is the subject of a temporary hazardous substances approval does not affect the status of the related substantive application, but any information related to the reassessment can be considered by the Authority when determining the related substantive application.
- A temporary hazardous substances approval can be suspended, modified or revoked.
- Compensation is not available to any person for loss resulting from any changes to a temporary hazardous substances approval.

### **Clarifying the criteria of the international regulator rapid assessment pathway**

30. Cabinet agreed to amend the criteria for the international regulator rapid assessment pathway to ensure that only New Zealand-specific effects can exclude the use of the pathway<sup>10</sup>. Officials recommend an additional change to further clarify when this pathway can be used.
31. The recommended change will specify that the information available from the international regulator must be 'sufficient' and 'relevant' to assess the effects of the substance in New Zealand. This will provide clarity to both applicants and the EPA regarding the required information content of international regulator assessments.

### **Changing modified reassessments process to match other applications and reassessments**

32. Cabinet agreed to changes to application pathways and processes for hazardous substances and new organisms, however it is unclear if Cabinet's approval extends to modified reassessments, which are deemed applications in the Act.
33. Officials recommend allowing people to apply for a modified reassessment (instead of deeming every reassessment to be an application) so the application can be treated like any other under the Act.

### **Changing the definition of "new organism" to clarify migratory species are not new organisms**

34. Cabinet agreed to amend the definition of "new organism" to confirm that an organism that is native to New Zealand can't be a new organism. To give effect to the policy intent of this change, officials want to amend the new organism definition to exclude migratory species that have been coming to New Zealand prior to 29 July 1998 (the key date for which an organism is a new organism or not). Examples include migratory sea birds, such as the wandering albatross.<sup>11</sup>
35. Officials consider it necessary to provide clarity in respect of migratory species where the available evidence does not support either a time to time, or immediate presence, before 29 July 1998.

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<sup>10</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [1]

<sup>11</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [25]

## **Introducing a new application containment pathway to develop vagrant prohibited new organisms in containment**

36. Cabinet agreed to amend Schedule 2 to exclude native, vagrant, or naturally occurring prohibited organisms in New Zealand, and to amend section 50 to exclude not-new organisms from being prohibited. The policy intent was to ensure that prohibited new organisms that arrive in New Zealand naturally, such as sea snakes, can be contained for observation, study, or care if unwell<sup>12</sup>.
37. Further analysis indicates the agreed legislative approach is not the most effective method to allow for development of these organisms in containment. We now propose inserting a new application pathway into the Act to allow prohibited new organisms that have naturally arrived in New Zealand to be developed in containment.
38. An application will only be approved if the EPA is satisfied that the organism (and any offspring, progeny or descendants) will not escape from containment. The approval must also include controls to ensure that any organisms are placed in and contained in a containment facility indefinitely (unless disposed of). This pathway will not be available to import prohibited new organisms into New Zealand. Only vagrant prohibited new organisms already in New Zealand can be developed in containment. We recommend approving this change, as it is consistent with the policy intent of the Cabinet decision.

## **Matters relating to emergency provisions**

39. Officials propose that an “emergency” is renamed an “adverse event” for the purposes of sections 46 to 49. This aligns with the intent of Cabinet approval to extend and expand the eligibility threshold for emergency approvals so that a wider range of biosecurity activities are eligible.<sup>13</sup>

### *Increasing the scope of containment approvals for all types of emergencies*

40. The Act has provisions to allow for the import of hazardous substances into containment for a variety of uses, including for emergencies (section 30). While Cabinet agreed to make a number of consequential amendments in respect of emergency approvals, it is unclear if this approval extends to section 30<sup>14</sup>. Officials recommend changing the provisions for importing hazardous substances into containment to cover adverse events and special emergencies under the Act, along with emergencies declared in any other Act.

### *Updating special emergency approvals to include medical devices as well as medicines*

41. Special emergency approvals, requiring an emergency declared by a Minister, can include approval for medicines but are silent on medical devices. Officials recommend expanding special emergency approvals to include medical devices as well as medicines. This extension will align with the Cabinet decision to allow qualifying organisms for the intended purpose of medical devices.

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<sup>12</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [23]

<sup>13</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [7]

<sup>14</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [7]

### **Clarifying data protection for confidential information**

42. Cabinet agreed to remove the restriction that requires an application for an innovative Trade Name Product to first be lodged under the ACVM Act for the data protection provisions under Part 6 of that Act to apply.<sup>15</sup>
43. Officials consider there should be a requirement on the applicant to confirm, in writing, that they intend to make an innovative Trade Name Product application within 6 months after they have made an application under the HSNO Act. This is consistent with the policy intent of the proposed changes to the Act, as it will reduce the administrative burden on both the EPA and applicants seeking data protection.

### **Incorporating the ability to delegate decisions for new powers and pathways**

44. Section 19 of the Act allows a range of decisions and powers to be delegated for different application types. Cabinet has already agreed to amend section 19 to align new organism decisions and powers with those for hazardous substances, however it is not clear if this covers new application types introduced by this Bill and their associated decisions, functions, duties, or powers<sup>16</sup>.
45. Officials recommend allowing proposed new application types, such as temporary hazardous substance approvals, and new powers relating to applications, such as the EPA's ability to return incomplete applications, to be delegated as appropriate. Allowing delegation for new application types and to align these processes with existing delegation arrangements will ensure timely decisions. This will improve efficiency and promote consistency across the Act.
46. This approach provides for risk proportionate regulation and is consistent with the policy intent of the proposed changes to the Act.

### **Defining "large-scale fermentation" as a consequence of the Cabinet decision to amend the definition of "develop"**

47. We propose defining "large-scale fermentation" in the Act. Cabinet decided to change the definition of "develop" with respect to new organisms to clarify the activities that can occur in containment. One development activity is "large-scale fermentation:" however, this was not in the Cabinet paper<sup>17</sup>.
48. We recommend using a definition similar to that included as a consequential amendment to the Act in the Gene Technology Bill, which specifies that large-scale fermentation is fermentation by a microorganism with a total vessel volume greater than 10 litres. This refers to the vessel capacity and not volume produced. By defining "large-scale fermentation," we clarify the scope of "develop" and when approvals are required.

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<sup>15</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [6]

<sup>16</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [18]

<sup>17</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [26]

### **Clarifying medical devices and expanding the situations where new organisms in medical devices can be approved**

49. Cabinet agreed to include medical devices in the definition of “qualifying organisms” and to update the Act to allow provisions to apply to the assessment of applications for release of qualifying organisms contained in medical devices.<sup>18</sup>
50. To achieve this, the Act requires a definition of “qualifying medical device.” We propose to use a similar definition to “qualifying medicine”, so that a qualifying medical device will be a medical device (as defined in section 3A of the Medicines Act 1981) that is or contains a new organism and meets the criteria set out in section 38I(3) of the Act.
51. Medicines can be approved under multiple pathways in the Act, and we request you agree to allow medical devices to be eligible for all the same application pathways as medicines.

### **Technical corrections to the Act we require decisions from Joint Ministers on:**

52. Officials have identified some technical corrections needed in the Act. We recommend making the following changes under recommendation 46 [ECO-25-MIN-0075 refers]:

### **Repealing and amending sections of the Act that relate to expired sections**

53. Officials propose technical changes to the part of the Act regarding group standards and enforcement (Parts 6A and 7 respectively) to remove reference to transitional provisions from the enactment of the Act that have now expired (Parts 11 to 15 of the Act).<sup>19</sup>
54. There is no material change to the Act with this change. Additional minor changes on top of those listed here may also be needed.

### **Streamlining sections relating to public notification of decisions**

55. Officials recommend some technical amendments to streamline and bring together provisions relating to public notification of decisions. These amendments bring related sections together for ease of reading.
56. There is no material change to the Act with this change. Additional minor changes on top of those listed here may also be needed.

### **Repealing existing regulations:**

57. Cabinet agreed to repeal the Hazardous Substances and New Organisms (Personnel Qualifications) Regulations 2001 and the Hazardous Substances and New Organisms

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<sup>18</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [30]

<sup>19</sup> These changes would include:

- Repeal section 96B(2)(b);
- Rewrite section 96B(2)(c) to omit reference to Part 11;
- Repeal section 96F;
- Rewrite section 114(2) to remove the reference to section 156(1).

(New Organisms Forms and Information Requirements) Regulations 1998 on advice of officials as they were no longer used.<sup>20</sup>

58. It is not usual practice to repeal regulations when amending primary legislation. Given timeframe regulations are being developed, officials recommend bundling up this revocation process with the introduction of new regulations to support the Bill.
59. In addition to this, further analysis of these regulations suggests that, while not directly used, their existence provides a framework that underpins some application and enforcement functions and there may be some risk if their content is not present somewhere. To mitigate this risk, we propose the following approach:
  - Identify whether aspects of the regulations could be represented in EPA notices and work with EPA to implement these notices prior to the revocation of the regulations.
  - If there are necessary aspects that remain, reconsider the decision to revoke some or all of the regulations. This could be made to Cabinet as part of the current process to introduce the new timeframe regulations.
60. We recommend you authorise any changes to the Bill that may need to occur to allow this approach. Any changes would be minor and in line with Recommendation 46 [ECO-25-MIN-0075 refers].

## **Next steps**

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61. A draft of the Bill will be provided to your Office for Ministerial consultation, after which the Bill is planned to progress to the Cabinet Legislation Committee and Cabinet on 30 April and 4 May respectively for approval to introduce.

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<sup>20</sup> ECO-25-SUB-0075 Appendix 1 Paragraph [20]