Minister for Regulation

Information Release

Agricultural and Horticultural Products Regulatory Review Omnibus Bill

June 2025

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Documents in this information release

#	Reference	Title	Date	Information withheld
1	MFR2025-051	Progressing the Agricultural and Horticultural Products Regulatory Review Omnibus Bill	2 April 2025	9(2)(f)(iv): information under active consideration – pages 1, 2
2	MFR2025-088	Seeking policy decisions to progress the Agricultural and Horticultural Products Regulatory Review Omnibus Bill	24 April 2025	s 9(2)(a): personal phone numbers– pages 1. 9(2)(f)(iv): information under active consideration – pages 3, 5, 7
3	ECO-25-SUB-0075	Cabinet paper	21 May 2025	9(2)(f)(iv): information under active consideration – pages 1, 6, 12 9(2)(h): legal privilege – page 12
4	ECO-25-SUB-0075-A	Cabinet paper attachment (Appendix 1)	21 May 2025	No information withheld

#	Reference	Title	Date	Information withheld
5	ECO-25-SUB-0075-B	Cabinet paper attachment (Appendix 2)	21 May 2025	No information withheld
6	ECO-25-SUB-0075-C	Cabinet paper attachment (Appendix 3)	21 May 2025	No information withheld
7	ECO-25-SUB-0075-D	Cabinet paper attachment (Appendix 4)	21 May 2025	9(2)(f)(iv): information under active consideration – pages 4.
8	ECO-25-SUB-0075-E	Cabinet paper attachment (Appendix 5)	21 May 2025	s 9(2)(a): signatures – page 6. 9(2)(f)(iv): information under active consideration – pages 6, 10.
9	ECO-25-MIN-0075	ECO Committee Minutes	21 May 2025	9(2)(f)(iv): information under active consideration – pages 1, 4 9(2)(h): legal privilege – page 4
10	CAB-25-MIN-0171	Cabinet minute	26 May 2025	information not relevant to the Cabinet paper

Information withheld

Some parts of this information release would not be appropriate to release and, if requested, would be withheld under the Official Information Act 1982 (the Act). Where this is the case, the relevant sections of the Act that would apply have been identified. Where information has been withheld, no public interest has been identified that would outweigh the reasons for withholding it.

Sections of the Act under which information has been withheld:

s 9(2)a – to protect the privacy of natural persons

s 9(2)(f)(iv) – to maintain the constitutional conventions for the time being which protect the confidentiality of advice tendered by Ministers of the Crown and officials

s 9(2)(h) – to maintain legal professional privilege

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Aide-mémoire

Ministry for Regulation
Te Manatū Waeture

Minister and Portfolio:	**Hon David Seymour, Minister for Regulation** **Hon Andrew Hoggard, Minister for Food Safety** **Hon Penny Simmonds, Minister for the Environment**		
Title:	**Progressing the Agricultural and Horticultural Products Regulatory Review Omnibus Bill**	**Number**	**MFR2025-051**
Date:	**3 April 2025**	**Security Level:**	**IN CONFIDENCE**

Purpose

This paper provides a high-level plan of the Agricultural and Horticultural Products Regulatory Review Omnibus Bill process, including targeted engagement, roles and responsibilities and forward timeline.

Background

On 24 February 2025 Cabinet accepted all 16 recommendations of the Agricultural and Horticultural Products Regulatory Review (Review). You jointly announced the Cabinet decisions and the publication of the Review Report on 27 February.

To implement recommendations relating to primary legislation, the Ministry for Regulation (MfR), Ministry for Primary Industries (MPI) (including New Zealand Food Safety (NZFS)), Ministry for the Environment (MfE) and the Environmental Protection Authority (EPA) have been working together to support the introduction of the Review Omnibus Bill s 9(2)(f)(iv)

Joint Ministers have agreed to additional amendments being included to improve the two regulatory systems in the Review Omnibus Bill provided they did not impact the project's timeline.

Review Omnibus Bill

Contents of the Omnibus Bill

- MPI and MfE will be seeking Ministerial policy decisions for each regulatory system in early April. This includes proposals to give effect to some of Review recommendations and others to improve the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and the Hazardous Substances and New Organisms (HSNO) Act 1996.

Targeted engagement

MPI and MfE have obtained respective Minister's agreement on targeted stakeholder engagement, which occurred between 10 March and 2 April, to support policy development. Targeted engagement was desirable as the Review Omnibus Bill is likely to include other amendments to improve the two regulatory systems that may not be specifically identified in the Review's recommendations and would benefit from stakeholders' input.

The Agricultural and Horticultural Products Sector Leaders Forum, the establishment of which was a key recommendation from the Review, met for the first time on 3 April. Its agenda includes a discussion on potential legislative changes.

Ministerial roles and responsibilities

- We understand that the Minister for Regulation will lead the May Cabinet paper jointly with the Ministers for Food Safety and the Environment to seek Cabinet decisions on policy changes and report on implementation of the Review's recommendations.

- We understand that the Ministers for Food Safety and the Environment alone will jointly lead the s 9(2)(f)(iv) LEG paper to seek decisions to introduce the Review Omnibus Bill to Parliament. We also understand that it is still to be decided which of the Ministers will lead the Bill through the Parliamentary process.

Agency roles and responsibilities

- To support Ministers' introduction of the bill, MPI and MfE are leading policy development for proposed amendments to the ACVM and HSNO Acts, respectively. This includes obtaining Regulatory Impact Statements (or seeking Regulatory Impact Assessment exemption) and Cost Recovery Impact Statements for proposed changes.
- MfR is leading the drafting of the May 2025 Cabinet paper with content input from MPI (including NZFS), MfE and the EPA.
- The Review's Senior Officials Advisory Group will remain in place s 9(2)(f)(iv) to give oversight of the Review Omnibus Bill project and implementation of other Review recommendations.

After May 2025, MPI and MfE will be supporting the Ministers for Food Safety and the Environment to lead the s 9(2)(f)(iv) LEG paper and the Parliamentary process. MfR's role will be reduced to oversight, monitoring and providing second opinion advice and feedback to agencies' work, upon request.

Timeline

The next steps for the Omnibus Bill are set out in the following table.

Time	Actions
4-8 April 2025	Ministerial policy decisions for each regulatory system
3 April 2025	First Sector Leaders Forum meeting
16 April 2025	RISs/CRIS are obtained from RIA panels
22 April 2025	Draft Cabinet paper provided to Joint Ministers' offices
24-28 April 2025	Joint Ministers feedback on the draft Cabinet paper
30 April - 6 May 2025	Departmental and PCO consultation combined with Ministerial consultation (five working days)
8 May 2025	Lodgement
14 May 2025	ECO Committee
19 May 2025	Cabinet
s 9(2)(f)(iv)	
s 9(2)(f)(iv)	
s 9(2)(f)(iv)	

Next steps

- We will provide a draft Cabinet paper on 22 April 2025 for Joint Ministers to seek Cabinet policy decisions and report back to Cabinet on implementation of the Review's recommendations.

Author Vy Nguyen, Senior Advisor

Manager Peter Clark, Manager, Regulatory Reviews

Briefing Paper

2025-088

Ministry for Regulation
Te Manatū Waeture

To	**Hon David Seymour, Minister for Regulation** **Hon Andrew Hoggard, Minister for Food Safety** **Hon Penny Simmonds, Minister for the Environment**		
Title	**Seeking Cabinet policy decisions to progress the Agricultural and Horticultural Products Regulatory Review Omnibus Bill**	Number	**MFR2025-088**
Date	**24 April 2025**	Priority:	**High**
Action Sought	**Provide feedback on the draft Cabinet paper**	Due Date	**29 April 2025 (12:00pm)**
Contact Person	**Gráinne Moss, Secretary for Regulation and Chief Executive**	Phone	s 9(2)(a)
Contact	**Peter Clark, Manager Regulatory Reviews**	Phone	s 9(2)(a)
Attachments	**Appendix 1:** draft Cabinet paper – Agricultural and Horticultural Products Omnibus Bill	Security Level	**IN CONFIDENCE**
Consultation	We consulted with the Ministry for Primary Industries (MPI, including New Zealand Food Safety (NZFS)), the Ministry for the Environment (MfE), and the Environmental Protection Authority (EPA) on this briefing. We drafted the Cabinet paper with key input from MfE and MPI and additional input from NZFS and the EPA. Departmental consultation, including with the Parliamentary Counsel Office (PCO), on the draft Cabinet paper will be undertaken in parallel with Ministerial consultation from 30 April to 6 May 2025.		

Executive Summary

1. On 24 February 2025, Cabinet endorsed all 16 recommendations of the Agricultural and Horticultural Products Regulatory Review (the Review) [CAB-24-MIN-0036]. You intend to progress the Agricultural and Horticultural Products Regulatory Review Omnibus Bill (Omnibus Bill) to make necessary changes to the Hazardous Substances and New Organisms (HSNO) Act 1996 and Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 to implement the Review's recommendations relating to primary legislation. You are also due to report back to Cabinet with the implementation plan for the Review's recommendations by the end of May 2025.

2. MPI and MfE have developed proposals for legislative change, with input from targeted engagement and the first Agricultural and Horticultural Products Sector Leaders Forum meeting. The Ministers for Food Safety and the Environment have approved all these legislative proposals bar one. Cabinet approval to these policy changes is needed, and for drafting instructions to be issued.

3. In addition to seeking approval for the legislative changes, the Cabinet paper also demonstrates the positive improvements to the two regulatory systems that have been made since the Review commenced, including that application queues have reduced. A detailed implementation plan and other operational changes are also included to meet the report back requirement. This notes that all 16 recommendations have been completed or are underway.

4. We are seeking your feedback on the draft Cabinet paper by 29 April 2025 at 12:00 pm. We will provide an updated paper for you to undertake Ministerial consultation from 30 April to 6 May. We will undertake departmental and PCO consultation in parallel with this. The paper is intended to be lodged on 8 May for consideration by Cabinet Economic Policy Committee on 14 May 2025.

5. It should be noted that PCO has raised concerns about the tight timeline for the Bill drafting given the time taken for policy development and the scope of proposed changes.

Recommended Action

We recommend that you:		*Minister for Regulation*	*Minister for Food Safety*	*Minister for the Environment*
a	**note** that you intend to introduce an Omnibus Bill to give effect to the Review's recommendations relevant to primary legislation s 9(2)(f)(iv)	*Note*	*Note*	*Note*
b	**note** that you are due to report back to Cabinet with the implementation plan for the Review's recommendations by the end of May 2025.	*Note*	*Note*	*Note*
c	**note** that you agreed to additional amendments being included in the Omnibus Bill to improve the two regulatory systems provided they did not delay the Bill.	*Note*	*Note*	*Note*
d	**note** that the Cabinet paper demonstrates positive improvements for the two regulatory systems that have been made since the Review commenced, including that application queues have started improving.	*Note*	*Note*	*Note*
e	**note** that Ministers for the Environment and Food Safety have approved all legislative proposals except one relevant to the independent data assessor framework.	*Note*	*Note*	*Note*
f	**note** that officials are making further refinements to the paper, including to the wording of some recommendations and reducing the level of detail in the body of the paper.	*Note*	*Note*	*Note*
g	**provide** feedback on the draft Cabinet paper by 29 April 2025 at 12:00pm.			
h	**agree** to undertake Ministerial consultation on the draft Cabinet paper from 30 April to 6 May 2025.	*Agree / Disagree*		

		Minister for Regulation	*Minister for Food Safety*	*Minister for the Environment*
i	**note** that we plan to undertake departmental and PCO consultation in parallel with Ministerial consultation.	*Note*	*Note*	*Note*
j	**agree** that the updated Cabinet paper may be lodged following departmental and Ministerial consultation.	*Agree / Disagree*	*Agree / Disagree*	*Agree / Disagree*

Gráinne M Moss

Gráinne Moss
Secretary for Regulation and Chief Executive
Ministry for Regulation
Date: 24 April 2025

Hon David Seymour
Minister for Regulation
Date:

Hon Andrew Hoggard
Minister for Food Safety
Date:

Hon Penny Simmonds
Minister for the Environment
Date:

Purpose

1. This briefing provides a draft paper for you to seek Cabinet approval of the proposed policy changes to the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and Hazardous Substances and New Organisms (HSNO) Act 1996 for inclusion in the Agricultural and Horticultural Products Regulatory Review (Review) Omnibus Bill. The Cabinet paper also includes an update on improvements to date and a detailed implementation plan as part of a report back due by the end of May 2025.

Background

2. On 24 February 2025, Cabinet endorsed the 16 recommendations and invited the Ministers for Food Safety and the Environment to report back to Cabinet no later than May 2025 with detailed implementation plans [CAB-25-MIN-0036]. You jointly announced the Cabinet decisions and the publication of the Review Report on 27 February 2025.

3. Implementing the 16 recommendations requires both legislative and operational changes. You intend to progress legislative changes through an Omnibus Bill, which is expected to be introduced to the House of Representatives s 9(2)(f)(iv) The Bill also includes other proposals to improve the ACVM and HSNO Acts and make efficient use of House time.

Overview of the Cabinet paper

Demonstrating positive improvements

4. The paper details positive improvements in the two regulatory systems that have occurred since the Review began. This includes:

    a. The Environmental Protection Authority (EPA) has reported a 13% reduction in the queue size since 1 July 2024, and an increase in the number of applications decided.[1]

    b. The EPA has reprioritised its funding to increase the number of staff assessing new hazardous substances.

    c. New Zealand Food Safety (NZFS) has reported completed applications meeting the statutory timeframes over the last 12 months has increased from 74% to 91%.

    d. NZFS has also reported the number of applications in the queue has reduced by 20% since 25 October 2024 due to better processing times.

    e. The Minister for the Environment has set expectations for HSNO application queues and accelerating assessment times. The Minister for the Environment is also exploring options for funding the HSNO risk assessment models.

    f. The Minister for Food Safety has also directed MPI to improve the ACVM registration process, including reducing the queues and accelerate assessments.

[1] As of 14/4/2025, there were 105 release applications in the queue. This is down 13% from 121 since 1 July 2024. This is the lowest number of applications in the queue since October 2022. From 1/7/2024 to 14/4/2025, a total of 49 applications have been decided. This has surpassed the annual (three-year) average of 32.7 across all release application types.

Proposed changes to the HSNO Act

5. The proposed changes include enabling greater uses of international regulator assessments, providing a new conditional approval pathway for high-benefit novel chemicals, differentiating hazardous substances application types and timeframes to provide greater risk management and transparency, shifting HSNO statutory timeframes to be set by regulations, enabling a hazardous substances levy, allowing better data protection, and improving emergency approval provisions. There are also proposals to align New Organisms provisions with other regimes and minor and technical changes to the Act.

Proposed changes to the ACVM Act

6. The changes to the ACVM Act focus on enabling timely alterations to light-touch pathways by moving exemptions from regulations into notices, enabling flexibility for setting and reviewing statutory assessment timeframes, clarifying and streamlining processes to increase efficiency and reflect current operating practice, expanding emergency provisions and the scope of when product registration can be suspended alongside clarifying the right to be heard when this happens, and clarifying the Director-General's role in notifying prohibitions and restrictions. There are also proposals for minor and technical changes to the Act. The Minister for Food Safety is currently considering an additional proposal to strengthen the independent data assessor framework.

Operational improvements

7. In addition to legislative changes, MPI (including NZFS), MfE and the EPA have already begun operational improvements to give effect to other recommendations and improvements are already visible as listed below.

8. Specific operational improvements include the establishment of the Sector Leaders Forum. The Forum met for the first time on 3 April 2025 with constructive conversations and a future-focused approach. The Forum will be providing a joint communication to relevant Ministers to summarise the first meeting and next steps.

9. As noted previously, the EPA has reprioritised its funding to increase resource for assessing new hazardous substances. This initiative will reduce the queue of HSNO applications and assessment time once the additional staff is fully recruited and trained.

10. MPI (including NZFS), MfE and the EPA are committed to improving access to agricultural and horticultural products and demonstrating their effort in tangible changes to actual assessment process and timing. While it may take some time for all legislative changes relevant to the Review's recommendations to be developed and take effect, agencies are and will make all possible operational improvements to improve access to products. This includes improvements to achieve some of the outcomes expected through legislative changes, such as better use of international regulator assessments and decisions and light-touch pathways.

11. Agencies are reporting to responsible Ministers on implementing the Review's recommendations and ongoing improvements to the two systems, including performance reporting. Other improvements include streamlining the inhibitor registration process, increasing engagement with overseas regulators and providing better ACVM guidance for

applicants. The EPA is continuing with work on criteria and indicators for prioritisation of hazardous substances applications, which will be a useful starting point for future exploration of a broader strategic priority pathway. MfE and the EPA noted that updating HSNO risk assessment models is contingent on funding. Improving HSNO guidance is also contingent on resourcing.

12. Agencies are reporting to responsible Ministers on implementing the Review's recommendations and ongoing improvements to the two systems, including performance reporting.

13. These operational improvements are included in a detailed implementation plan attached to the Cabinet paper. This notes that all 16 recommendations have been completed or are underway.

Next Steps

14. The Minister for Food Safety will decide on the proposal relevant to strengthening the independent data assessor framework in parallel with Joint Ministers' feedback on the draft Cabinet paper.

15. Note that officials are making further refinements to the paper. This includes updating the legislation implication section based on the outcomes of the Agricultural and Horticultural Products Regulatory Review Omnibus Bill: Request for priority in the 2025 Legislation Programme. Updates are also required regarding the Regulatory Impact Statement and Cost Recovery Impact Statement, to balance the level of detail of some HSNO proposals and refine the wording of some HSNO recommendations before lodgement. We will seek to include these amendments in the next version provided to you.

16. We will address any feedback you have on the draft Cabinet paper and provide an updated version for Ministerial consultation, which needs to be undertaken between 30 April and 6 May. We will undertake departmental and Parliamentary Counsel Office (PCO) consultation in parallel with Ministerial consultation. The paper is intended to be lodged on 8 May 2025, for consideration by the Cabinet Economic Policy Committee on 14 May 2025.

17. Following Cabinet decisions on 19 May 2025, drafting instructions will be sent to PCO with a view to assess the consistency with the New Zealand Bill of Rights Act 1990 s 9(2)(f)(iv). To meet your expectations to introduce the Bill s 9(2)(f)(iv), the Bill should be considered by the Cabinet Legislation Committee on s 9(2)(f)(iv)

18. Note that PCO has raised concerns that the Bill drafting time has been significantly reduced compared to the planned timeline in the Agricultural and Horticultural Products Regulatory Review Omnibus Bill: Request for priority in the 2025 Legislation Programme. s 9(2)(f)(iv)

19. We propose you jointly announce the next steps in the progression of this Omnibus Bill by media release, once Cabinet decisions have been made.

Appendix 1: draft Cabinet paper – Agricultural and Horticultural Products Omnibus Bill

Proactive release note: Final Cabinet paper is being proactively released

Office of the Minister for Regulation

Office of the Minister for Food Safety

Office of the Minister for the Environment

Cabinet Economic Policy Committee

Agricultural and Horticultural Products Regulatory Review Omnibus Bill

Proposal

1 This paper seeks policy decisions for the Agricultural and Horticultural Products Regulatory Review Omnibus Bill (Omnibus Bill) to give effect to the Agricultural and Horticultural Products Regulatory Review (the Review) and associated changes to the relevant regulatory systems. It also seeks agreement to issue drafting instructions to the Parliamentary Counsel Office (PCO) as per policy decisions and reports back to Cabinet on the detailed implementation plan of the Review's recommendations.

Relation to government priorities

2 Implementing the Review's recommendations supports the Government's priorities of ensuring regulations are fit for purpose, reducing regulatory burden, and maximising economic growth and productivity.

Executive Summary

3 The Agricultural and Horticultural Products Regulatory Review was undertaken from August to December 2024. This focused on the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and the Hazardous Substances and New Organisms (HSNO) Act 1996. Cabinet endorsed all 16 Review recommendations on 24 February 2025 [CAB-24-MIN-0036].

4 The implementation of the Review's recommendations is expected to drive improvements in three key areas, with a range of actions underway to improve application queues and assessment times, achieve improvements in transparency and reporting, and to support greater use of international harmonisation approaches.

5 Positive operational improvements, including reductions in queues and assessment times, have already been seen since the Review commenced. Funding to upgrade the EPA's ecotoxicological risk assessment models has also been secured. The proposed changes to the HSNO and ACVM Acts will give effect to many of the Review's recommendations, including enabling greater use of international regulator assessments. We also seek agreement to other legislative changes.

6 We seek your approval to proceed with proposed changes to the HSNO and ACVM Acts and to issue drafting instructions so the Bill can be introduced s 9(2)(f)(iv) [redacted] This package of changes will make positive improvements to how these regulatory systems are operating and are expected to improve timely access to products for our farmers and growers.

7 In addition, we have also provided a detailed implementation plan to give effect to the Review's recommendations.

Background

8 The Ministry for Regulation undertook the Review in response to concerns about regulatory barriers to accessing new agricultural and horticultural products from August to December 2024.

9 The Joint Ministers agreed to all of the Review's 16 recommendations and obtained Cabinet endorsement of them on 24 February 2025. Cabinet invited a report back with detailed implementation plans no later than May 2025 [CAB-25-MIN-0036].

10 A legislative bid for the 2025 legislation programme for the Agricultural and Horticultural Products Regulatory Review Omnibus Bill to progress legislative changes from the Review was agreed to by Cabinet, with a category 5 (to proceed to select committee by the end of 2025).

Actions are already underway to deliver improvements

11 In addition to improvements across the systems, implementation of all the Review's 16 recommendations are expected to contribute to improvements in three key areas: 1) application queues and assessment times, 2) transparency and reporting; and 3) greater use of international harmonisation approaches.

12 *To improve application queues and assessment times*, specific actions that have been taken include:

12.1 The Minister for the Environment has already set a target for a 10% reduction to the HSNO queue in 2025/2026, with a more ambitious target intended once additional Environmental Protection Authority (EPA) staff are on board. The Minister for the Environment will determine a more ambitious target for queue reduction for HSNO within the next three months.

12.2 The Minister for Food Safety has directed the Ministry for Primary Industries (MPI) to improve ACVM assessment processes. The Minister will set a target of 20% queue reduction of the ACVM queues compared to the queues in October 2024, to be achieved by the end of June 2025, and a further 30% queue reduction target to be achieved by the end of June 2026.

12.3 The Minister for Food Safety and the Minister for the Environment will determine an ambitious target for reducing approval times for each of ACVM and HSNO within the next three months.

13 *To achieve improvements in transparency and reporting*, specific actions that have been taken include:

13.1 The first meeting of the Sector Leaders Forum was held in April 2025.

13.2 The EPA and New Zealand Food Safety (NZFS) have provided more detail in performance reporting, and are seeking legislative changes to statutory timeframes and updating guidance within available resources.

14 *To support greater use of international harmonisation approaches,* specific actions that have been taken include:

14.1 seeking legislative changes to improve the current HSNO international regulator rapid assessment pathway and introduce a HSNO conditional approval pathway reliant on international regulator assessments;

14.2 enabling the recognition of international regulator assessment to streamline ACVM assessments; and

14.3 more international engagement undertaken by the EPA and NZFS, including on updating HSNO risk assessment models.

Positive improvements have already been seen since the Review commenced

15 A range of positive improvements have already been seen since the Review commenced. This includes an 18% reduction in the queue size since 1 July 2024 for HSNO, and the number of applications in the queue for ACVM has reduced by 20% since October 2024. The EPA has also reprioritised funding to establish 11 new roles in a new hazardous substances application team. The Minister for the Environment and the Minister of Finance have agreed to allocate $10 million operational funding to upgrade the EPA's ecotoxicological risk assessment models from the Waste Disposal Levy.

Amendments to the HSNO Act

16 We propose changes to the HSNO Act to address the recommendations of the Review and to progress additional amendments. These changes will improve the regulatory system oversight of hazardous substances and new organisms, and ensure alignment with the Gene Technology Bill. We also propose minor and technical changes. Further detail on these amendments can be found in **Appendix 1**.

Proposed changes to the HSNO Act relating to hazardous substances

Enable greater use of international regulator assessments and a new conditional approval pathway to enable early access and significantly reduce assessment times

17 We propose to amend the current international regulator rapid assessment pathway to narrow the focus of the "significant effects" test under s 28A(6)(a) to limit these factors so they are New Zealand-specific. This proposal would extend the application of the rapid pathway to cover more substances and allow the EPA assessment to focus on aspects unique to New Zealand only.

18 We also propose a new conditional approval pathway to allow novel substances, which cannot proceed through the existing international regulator rapid assessment pathway, to be used in New Zealand during the time it is under assessment for full approval. International regulator assessments would be used to inform a time-limited approval with expiry conditions explained in **Appendix 1**. This proposal strikes the best balance in enabling early access to novel substances, while still appropriately managing risks to people and the environment.

Changes to hazardous substances application types and statutory timeframes

19 We propose to amend s 28 to differentiate HSNO application types based on risk and complexity, and to set appropriate timeframes that reflect different application steps and align with international best practice. We also propose to provide for public notification and hearings to be held on applications where required based on risk and public interest. This proposal would enable greater transparency and clarity in both the application process and expected timelines for assessment as well as enabling meaningful performance reporting. Changes to statutory timeframes will require replacing s 59 with an enabling provision, to set regulations specifying the process steps and relevant timeframes for all applications. A similar change is proposed for the ACVM Act that could allow for joint consultation on timeframes.

20 We also propose provisions in the HSNO Act to determine whether an application is complete, when timeframes can be paused, and when an application can be treated as lapsed and withdrawn. We propose that, for drafting purposes, further decisions relevant to these matters are delegated to the Minister for the Environment.

Enable provisions for a hazardous substances levy to enable cost recovery

21 The review found that the EPA's cost recovery levels are lower than domestic and international regulators that deliver similar regulatory functions. We propose an enabling provision to allow for a levy on the import and manufacture of hazardous substances, to be paid by importers and manufacturers, to support the costs of operating the HSNO regulatory system. It would apply to approvals to lawfully import and/or manufacture hazardous substances. Funds raised through the levy would be used towards relevant EPA's functions. Any implementation of a levy would be determined in the Stage 2 Cost Recovery Impact Statement after further analysis and consultation.

Changes to data protection to improve navigation across the two systems

22 We propose to amend the HSNO Act to allow HSNO recognition of ACVM data protection regardless of the order that applications are lodged under the HSNO and ACVM Acts. Data protection is important because it encourages companies to register innovative products in New Zealand by protecting their data for a set period of time.

Additional proposals relating to hazardous substances

23 We also propose:

23.1 extending emergency approval eligibility to allow for more approvals to be made in advance of an emergency, increasing preparedness for a wider range of biosecurity activities. Additionally, amendments will address drafting oversights and improve clarity.

23.2 three improvements to the compliance and enforcement provisions relevant to 1) extend the timeframe for filing charges, 2) providing for different infringement fees for individuals and entities, and 3) adding an "assist and intervene" enforcement power for the EPA.

23.3 amending s 63A(2) to specify that a reassessment under s 63A can also be undertaken to vary the hazard classification.

Proposed changes to the HSNO Act relating to new organisms

24 We propose to use this opportunity to make changes to the new organisms regime in the HSNO Act. The proposed changes are largely to provide clarity, enable more efficient processing of applications and to ensure that the HSNO Act aligns with the Biosecurity Act 1993 and does not conflict with the proposed Gene Technology Bill. These changes are in addition to the consequential changes under the proposed Gene Technology Bill and will only affect non genetically modified new organisms. All proposals are detailed in **Appendix 1**.

Amendments to the ACVM Act

25 We propose amendments to the ACVM Act to give effect to Review recommendations and to make additional amendments. Further detail on these amendments can be found in **Appendix 2**.

Proposed changes to the ACVM Act to implement relevant Review recommendations

26 We propose:

26.1 *empowering product registration exemptions via notices rather than regulations*. This would empower a notice issued by the Director-General for identifying substances that are exempt from registration, instead of the current approach through regulations, to ensure the regime can quickly respond to new substances.

26.2 *enabling the recognition of international regulator assessments*. This would enable the recognition of international regulators in regulations and a notice; and require the Director-General to use an appropriate, available recognised international regulator assessment when considering an application for registration or variation to an existing registration of the same (or substantially the same) product.

26.3 *strengthening the independent data assessor framework*. The proposed change would permit the recognition of data assessors to assess data packages to strengthen the data assessor framework.

26.4 *changes to the statutory timeframes*. This would empower regulations for the setting and review of statutory timeframes for application processing, to replace the specific time limits identified in the Act, providing flexibility for reviewing and amending timeframes

Additional changes to the ACVM Act for the Omnibus Bill

27 We propose amendments to improve clarity, flexibility and efficiency for the regulator and businesses, and improve transparency of communications. All proposals are detailed in **Appendix 2**, and key changes include:

27.1 clarify processes around variations to product registration controls;

27.2 clarify the Director-General's role to publicly notify a prohibition or restriction on a product or group of products;

27.3 specify in the ACVM Act the mechanism for certifying Good Manufacturing Practices for veterinary medicine manufacturers; and

27.4 streamline the regulatory interface with Medicines Act 1981 for prescription human medicines that could be registered as veterinary medicines.

28 Further complex amendments that require cost recovery or further policy analysis will be progressed in a separate ACVM Amendment Bill. That will operate on a longer timeframe for policy development and consultation to update the ACVM Act.

29 In addition to these proposed changes to the ACVM Act, the Minister for Food Safety will separately seek Cabinet approval to publicly consult on a discussion document on options to amend the ACVM regulations (Exemptions and Prohibited Substances) Regulations 2011 in the coming weeks. This also gives effect to the Review's recommendation 5 about greater uses of light-touch assessment pathways.

Joint detailed implementation plan

30 Alongside these legislative changes, MPI (including NZFS), the Ministry for the Environment (MfE) and the EPA have also been considering operational improvements to the two regulatory systems. The **Appendix 3** contains an implementation plan of the Review's recommendations.

Next steps

31 Subject to Cabinet's endorsement of the proposed amendments to the HSNO and ACVM Acts, we propose the Cabinet Legislation Committee consider the Bill [redacted]. This would allow for the Bill to be introduced to the House [redacted]

Cost-of-living Implications

32 The proposal to enable a new HSNO levy may have financial impacts on some manufacturers and importers of agricultural and horticultural products with limited flow-on effects on primary sector products later when the levy is decided. No immediate financial impacts will be realised following the introduction of this enabling provision. Other proposals are expected to reduce some compliance costs for introducing and accessing products and may improve competition.

Financial Implications

33 The proposal for an enabling provision to allow for a levy on hazardous substances would have financial implications for the hazardous substance regime. These are discussed in the Stage 1 Cost Recovery Impact Statement (CRIS) (**Appendix 4**). The $10 million funding for the EPA's ecotoxicological risk assessment models is allocated from the Waste Disposal Levy and has been agreed as part of Budget 2025.

Legislative Implications

34 Cabinet has agreed to progress the Agricultural and Horticultural Products Regulatory Review Omnibus Bill as category 5, in the 2025 Legislation Programme (to proceed to select committee by the end of 2025).

Impact Analysis

Regulatory Impact Statements

35 The Ministry for Regulation has determined that minor and technical amendments to the HSNO Act and the ACVM proposals are exempt from the requirement to provide a Regulatory Impact Statement (RIS). on the grounds that the proposals have no or only minor economic, social, or environmental impacts.

36 In addition, the Ministry has determined that the proposal to repeal ss 147 (1) (d), (e) and (f) and ss 148 (c), (d) and (e) is exempt from the requirement to provide a RIS on the grounds that it repeals or removes redundant legislative provisions.

37 A quality assurance panel with members from MfE and MPI has reviewed RIS: "Omnibus changes to the Hazardous Substances and New Organisms Act 1996" (**Appendix 5**). The Panel considers that the RIS 'partially meets' the criteria. Many of the proposals are detailed, well thought out, beneficial, and articulated in relation to the policy problem/opportunity. The current proposals were developed under significant time constraints. The authors are transparent about how this impacted their policy process, where relevant and appropriate.

38 However, given the significant breadth, depth, and complexity of the proposals, more analysis is needed on the effects of the entire package (including quantitative costs and benefits which were largely absent). Unintended consequences could not be fully explored at this stage. The Panel expects the major proposals will undergo further RIA which will require more detail.

39 A quality assurance panel with members from MfE and MPI assessed the Stage 1 CRIS. The panel considers the CRIS partially meets the quality assurance criteria for the purpose of informing Cabinet decisions. The Panel noted the CRIS was complete, clear and concise but lacked convincing detail about the setting and impact of the proposed levy, which is likely to be improved in the next stage of analysis.

Climate Implications of Policy Assessment

40 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to the policy proposals.

Population Implications

Human Rights

41 There are no New Zealand Bill of Rights Act 1990 or Human Rights Act 1993 implications.

Consultation

Targeted engagement

42 MfE undertook targeted engagement with industry stakeholders and Te Rūnanga o Ngāi Tahu HSNO Komiti. MPI also conducted targeted consultation and considered feedback. Due to timing constraints, agencies have not engaged with other stakeholders such as interest or environment groups and no Treaty of Waitangi impact assessments were undertaken.

Departmental consultation

43 MPI, MfE, the EPA and MfR jointly prepared the key contents of this paper. The following departments and agencies were consulted on this paper: the Treasury, the Ministry of Business, Innovation and Employment, the Ministry of Health, WorkSafe New Zealand, the Ministry of Foreign Affairs and Trade, the Department of Conservation, Fire and Emergency New Zealand, New Zealand Customs Service, Te Whatu Ora, and Ministry of Justice. Officials also engaged with the Parliamentary Counsel Office. The Department of Prime Minister and Cabinet has been informed.

Communications

44 We propose to publicly announce the next steps in the progression of this Bill by media release, once Cabinet decisions have been made.

Proactive Release

45 We intend to proactively release this Cabinet paper once decisions have been made subject to redactions as appropriate under the Official Information Act 1982.

Recommendations

The Ministers for Regulation, Food Safety and the Environment recommend that the Committee:

1 **Note** Cabinet endorsed all 16 recommendations by the Agricultural and Horticultural Products Regulatory Review on 24 February 2025 and invited Ministers for the Environment and Food Safety to report back on detailed implementation plans by May 2025 [CAB-24-MIN-0036].

2 **Note** that Joint Ministers intend to progress legislative changes through a joint Omnibus Bill, to be introduced to the House of Representatives [redacted]

3 **Note** that implementation of the Review's recommendations are expected to lead to improvements in application queues and assessment times, transparency and reporting, and greater use of international harmonisation approaches.

4 **Note** positive improvements have already occurred, including reduction in application queues, additional staff for HSNO assessments and allocating $10 million operational funding for the upgrade of the EPA's ecotoxicological risk assessment models.

5 **Note** the Minister for Food Safety will set a 20% queue reduction target for ACVM to be achieved by the end of June 2025, and a further 30% queue reduction target to be achieved by the end of June 2026.

6 **Note** the Minister for the Environment will determine an ambitious target within the next three months for a queue reduction target for HSNO.

7 **Note** that the Minister for Food Safety and the Minister for the Environment will determine an ambitious target within the next three months for reducing approval times for each of ACVM and HSNO.

Hazardous Substances and New Organisms (HSNO) Act recommendations

8 **Agree** to amend s 28A(6) of the HSNO Act to limit the factors in the "significant effects" test so they are New Zealand specific to allow the EPA to rely on international modelling, data, and assessments, unless there are specific New Zealand circumstances that warrant a more detailed assessment.

9 **Agree** to amend Part 5 of the HSNO Act to introduce a time-limited conditional application process and corresponding approvals as detailed in **Appendix 1**.

10 **Agree** in principle to introduce a tiered pathway structure for applications for hazardous substances based on risk.

11 **Agree** in principle to using a regulation making power, subject to legal advice and further discussion with PCO, to amend application process steps and timeframes for all applications relating to hazardous substances and new organisms made under Part 5 and Part 6A as detailed in **Appendix 1**.

12 **Agree** in principle to amend provisions in the HSNO Act associated with public notification and hearings so that public notification is required and hearings are held on applications where justified based on risk, public interest, efficiency and transparency.

13 **Agree** in principle to amend the HSNO Act to provide the EPA with powers related to application processing and timeframes for all applications made under Parts 5 and 6A as detailed in **Appendix 1**.

14 **Agree** that final decisions on the matters listed in recommendations 10 - 13 be delegated to the Minister for the Environment.

15 **Agree,** if regulations are to be developed for these matters, to provide for transitional arrangements to ensure that current timeframes and categories of applications in Part 5 and 6A remain where necessary or until relevant regulations are in place.

16 **Agree** in principle to introduce enabling provisions for regulations within the HSNO Act for a hazardous substance levy regime on the import and manufacture of hazardous substances, to be paid by importers and manufacturers to support the EPA's hazardous substances functions with criteria in the Act on relevant considerations when designing the levy regime.

17 **Agree** that final detailed decisions on the levy be delegated to the Minister for the Environment.

18 **Agree** to amend the HSNO Act to allow for the policy intent of changes to the hazardous substances regime in **Appendix 1** to be carried out on the following matters: data protection, improved emergency approval provisions, improved compliance and enforcement, and ambiguity related to scope of s 63A.

19 **Agree** to amend the HSNO Act to allow for the policy intent of changes to the new organism regime in **Appendix 1** to be carried out on the following matters: determinations, denewing and risk species, reassessments, containment, notification and extension provisions for full releases, conditional releases, delegations, EPA notices, revoking regulations, enforcement of New Organisms, information sharing, prohibition of vagrant organisms.

20 **Agree** to the changes to the definitions in the HSNO Act as in **Appendix 1** on the following definitions: Organism, New Organism, Develop, Incidentally Imported New Organism, Field Test, Release, Qualifying Organism.

21 **Agree** to the minor and technical amendments to the HSNO Act in **Appendix 1** relevant to definition of "environmental medium", interface issue with Defence Act 1990, heading of s 97, provisions of persistent organic pollutants within the HSNO Act to better align with the Stockholm convention, removing SOI and annual report provisions, clarifying agency submissions.

Agricultural Compounds and Veterinary Medicines (ACVM) Act recommendations

22 **Agree** to amend s 8A of the ACVM Act to empower substances or products to be exempted from registration by a Notice issued by the Director-General instead of in Schedule 2 of the ACVM (Exemptions and Prohibited Substances) Regulations 2011.

23 **Agree** to provide for transitional arrangements required to support the transfer of the existing exemptions to the new Notice.

24 **Agree** to amend the ACVM Act to permit the recognition of international regulators, set criteria for recognition in secondary legislation, and empower the Director-General to make a notice listing recognised international regulators.

25 **Agree** to amend the ACVM Act to require the Director-General to use an appropriate, available recognised international regulators' product assessment when considering an application for registration (or variation to an existing registration) of the same (or substantially the same) product and empower any necessary associated secondary legislation.

26 **Agree** to amend the ACVM Act to permit the recognition of data assessors to assess data packages.

27 **Agree** to remove the statutory timeframes from s 16 of the ACVM Act and empower the setting and review of statutory timeframes in regulations and supplementary notices for different application types.

28 **Agree** to provide for transitional arrangements that retain the current timeframes in s 16 while regulations are being developed.

29 **Agree** to amend s 9 of the ACVM Act to allow a registrant to apply to vary any registration controls on a product registration, rather than only conditions.

30 **Agree** to amend the ACVM Act to provide for regulations that specify the requirements and approval processes for applicants applying to vary conditions and controls for product registrations. A supplementary notice provision would be required to provide for supporting technical information to meet those regulations.

31 **Agree** to amend s 31 of the ACVM Act to require the Director-General to notify the public of a decision to prohibit or restrict the import, manufacture, sale or use of a registered product undergoing reassessment until a decision is made. The manner of notification should align with s 44ZL of the ACVM Act and proposed amendment in recommendation 40 below.

32 **Agree** to amend s 26 of the ACVM Act to change 'provisional registration' of trade name products to 'research approval' of both trade name products and unregistered products.

33 **Agree** to remove relevant references to provisional registration in the ACVM Act.

34 **Agree** to provide for transitional arrangements for applicants granted research approval under s 8C(1).

35 **Agree** to amend the ACVM Act to allow the Director-General to set standards for Good Manufacturing Practices by Notice.

36 **Agree** to amend the ACVM Act to provide for the certification of a product manufacturer's compliance with a Good Manufacturing Practices Standard and empower regulations to set out the certification process and associated requirements.

37 **Agree** to amend s 15 of the ACVM Act to allow for the Director-General to waive notification if the product is likely to be required for use in an emergency related to public health, animal welfare, trade or agricultural security.

38 **Agree** to amend s 21 of the ACVM Act to remove the mandatory requirement to obtain consent from the Director-General of Health to register veterinary medicines that are prescription human medicines. Empower regulations to specify what classes of prescription medicines require consent.

39 **Agree** to provide for transitional arrangements to continue mandatory consent from the Ministry for Health on registration related to prescription human medicines until regulations are developed.

40 **Agree** to align notification provisions in the ACVM Act with s 44ZL of the ACVM Act to provide for more flexibility for public notifications.

41 **Agree** to amend the ACVM Act to specify additional situations where registrations may be suspended. The ACVM Act should be clear that a product can be suspended

where there is a risk to public health, animal welfare, agricultural security or trade and not only for non-compliance with registration conditions.

42 **Agree** to amend s 30A of the ACVM Act to clarify that applicants have a reasonable opportunity to be heard when the Director-General is proposing to suspend a product's registration.

Report back on detailed implementation plan

43 **Note** the detailed implementation plan for all 16 Review recommendations is contained in **Appendix 3**.

Next steps

44 **Authorise** the Minister for the Environment and Food Safety to issue drafting instructions to the Parliamentary Counsel Office to amend the HSNO and ACVM Acts respectively and any relevant amendments necessary to regulations to implement the proposals described in this paper and **Appendices 1 and 2**.

45 [redacted]

46 **Authorise** responsible Ministers to make final decisions on minor and technical issues and make changes consistent with the policy intent described in this paper on any issues that arise during the drafting process.

47 **Agree** for Cabinet Legislation Committee to consider the Bill [redacted]

Authorised for lodgement

Hon David Seymour

Minister for Regulation

Hon Andrew Hoggard

Minister for Food Safety

Hon Penny Simmonds

Minister for the Environment

Appendix 1: Proposed changes to the Hazardous Substances and New Organisms (HSNO) Act 1996

Amendment title	Proposed solution
Hazardous substances	
1. Make greater use of international regulator rapid assessment pathway	Amend existing s 28A(6), to limit the factors in the "significant effects" test so they are New Zealand specific to allow the EPA to rely on international modelling, data, and assessments, unless there are specific New Zealand circumstances that warrant a more detailed assessment. This will better support the EPA to rely more on information supplied under the international regulator rapid assessment pathway. These amendments are designed to allow more substances to use this pathway but will not open the pathway to a rapid assessment of substances containing active ingredients new to New Zealand.
2. New application pathway – time-limited conditional approvals (relying on international regulator assessments)	Amend Part 5 of the HSNO Act to introduce a time-limited conditional application process and corresponding approvals that are conditional on a full application being submitted and deemed complete. These are for substances that have been approved by recognised international regulators, do not meet the criteria for assessment under the international regulator rapid pathway, and provide an identified benefit to New Zealand and can be used while the substantive assessment is conducted. The time-limited conditional approvals will have three possible expiry conditions: when a decision on the full application for the substance is made, if the applicant withdraws the application or the EPA considers it lapsed or withdrawn, or after a specified period of time has passed since the provisional approval was issued. This final condition is to ensure that both the EPA and applicant progress the assessment of the full application in as short a timeframe as possible.
3. Differentiating hazardous substance application types by risk and extent of scientific assessment required (risk tiering)	Amend existing provisions relating to hazardous substance applications (under s 28) to introduce a tiered pathway structure of applications according to differences in risk. This is consistent with the approach of other international regulators and formalises the EPA's existing operational practice. The application types (categories) will be categorised according to the potential risk to human health and/or the environment, how similar a substance is to those already approved and the extent of scientific assessment required. For example, a substance containing a new active ingredient to New Zealand has the greatest potential risk and greatest workload for the EPA, so is likely to take much longer to assess than a reformulation of a product already approved and currently on the market. The EPA has a long history of operationally splitting these applications into various categories and details of the categories will be finalised in the subsequent drafting instructions.
4. Set statutory timeframes according to application type	Redesign the process steps and timeframes for all applications relating to hazardous substances and new organisms made under Part 5 and Part 6A so as to: • provide clarity and transparency on each step required for each application type and the allocated time for each step.

Amendment title	Proposed solution
and improve process steps.	• provide timeframes that are appropriate, that align with international best practice and that include the specific provision of an assessment step by the EPA. This will include a regulation making power to be made that specifies timeframes and the requirements for applications outlined above. The EPA will also be able to: • determine whether an application is complete, and to return incomplete applications. • pause timeframes when there are delays beyond the EPA's control. • specify when an application has lapsed and can be treated as withdrawn. Drafting will specify checks and balances for these powers. Further consequential amendments to s 59 and other parts of the HSNO Act which deal with process steps and timeframes that are contingent on the regulations coming into effect will need to be made, including providing for transitional arrangements to ensure that current timeframes and categories of applications in Part 5 and 6A remain where necessary or until relevant regulations are in place. Amendments to the provisions in the HSNO Act associated with public notification and hearings so that public notification is required and hearings are held on applications where justified based on risk, public interest, efficiency and transparency, will also be made.
5. Introduce enabling provisions for a levy on hazardous substances to support the EPA's administration of its hazardous substance regulatory functions	Introduce provisions that would enable a levy regime to be developed at a later date and implemented by way of regulations. The enabling provisions would allow for a levy to be set on the import and manufacture of hazardous substances, to be paid by importers and manufacturers. The levy is intended to support the EPA's hazardous substances functions.
6. Data protection	Amend s 55(4) of the HSNO Act to remove the restriction that requires an application for an innovative Trade Name Product (TNP) to first be lodged under the ACVM Act in order for the data protection provisions in Part 6 of the ACVM Act to apply.
7. Improved emergency approval provisions	Extend and expand the eligibility threshold for ss 46-48 emergency approval provisions so that a wider range of biosecurity activities, including under National and Regional Pest Management Plans and other targeted responses, are eligible to apply for an emergency approval. In line with the intent above, make a number of consequential amendments to ss 46-48 including to address previous drafting oversights and to improve clarity (e.g. rename s 46 and 47, make amendments to s 48(2)).

Amendment title	Proposed solution
	Rename the provisions relating to emergency approvals to more accurately reflect their intent.
8. Improved compliance and enforcement: Extend the timeframe for filing charges	Amend s 109A(1) to extend the timeframe for filing charges from 6 months to 12 months.
9. Improved compliance and enforcement: Providing for different infringement fees for individuals and entities	Amend s 140 of the Act to: • provide for different infringement fees to be set for individuals and entities; and • increase the maximum infringement fee for entities from $3,000 to $12,000.
10. Improved compliance and enforcement: Adding an "assist and intervene" enforcement power for the EPA	Amend s 97(4) to enable the EPA an overarching enforcement power to provide enforcement support, where the EPA can undertake, assist, or intervene in, an enforcement action falling under another s 97 enforcement agency's jurisdiction should such action be deemed necessary or desirable to promote the purpose of the HSNO Act, with respect to hazardous substances. Model the enforcement power to be similar to Part 12A of the Resource Management Act 1991 with a scope similar to s 343 F of the Resource Management Act 1991.
11. Address ambiguity related to scope of s63A	Amend s 63A(2) to specify that a reassessment under s 63A can also be undertaken to vary the hazard classification of a hazardous substance and to ensure consistency with ss 63C and 63D.
New organisms	
12. Determinations	Amend s 26 to fulfil the following: • remove the requirement for the decision to be gazetted; • make sure that the decision can be made at various classification levels (species, family, strain type, cultivar etc) • 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; and • ensure the scope of s 26 includes the ability to provide broad decisions for taxonomic groups of organisms.
13. Denewing and risk species	Amend Part 5 to make denewing and prescribing risk species a decision made by the HSNO Committee. • possible applicants should include the Chief Executive of the EPA. • part of the process will include deciding the "newness" of an organism. • it will include a public consultation process. • outcome to be gazetted. • EPA required to maintain a public register with the status of all organisms that have been through this process. The status of new organisms subject to the regulations dealing with organisms prescribed as not new and risk species not affected.

Amendment title	Proposed solution
14. Reassessments	Amend the reassessment criteria in s 62 and s 63 to give similar reassessment powers to the new organisms regime to hazardous substance regime. Include the following: • give new organisms regime the ability to revoke approvals that are no longer in use; • give new organisms regime the ability to have modified reassessments (similar to hazardous substances); and • allow for an approval to be put on hold during a reassessment (similar to s 64 or 64A for hazardous substances) but only for approvals where the organism has not yet been released.
15. Containment	Amend s 42C to change the empowering provision that enables regulations to be made to specify low risk new organisms for the purpose of containment to an empowering provision to make a corresponding EPA notice.
16. Notification and extension provisions for full releases	Amend s 38 to: • add the ability to extend a time extension multiple times as currently they can only be extended once; • include criteria that any new information will also need to be given to the EPA as part of request for extension; and • clarify notification provisions. Currently, all releases need to be notified in the first five years. Amend to mandate only the initial/first person to release to notify. Give the EPA discretion to "revive" new organisms approval that has expired due to administrative error.
17. Conditional releases	Amend ss 38A to 38H relating to conditional releases to make the pathway more useable: • give the EPA discretion to change the 5-year time limit and allow for multiple extensions; • give the EPA the discretion to require, or not, destruction of the organism, provided there will be no adverse effect on the environment; • enable, where appropriate, for a conditional release to transition to a full release based on a set of criteria.
18. Delegations	Amend s 19 of the HSNO Act to allow all non-notified Part 5 applications to be delegated to EPA staff. This will include many new organisms decisions and some hazardous substance decisions; • retain HSNO Decision Making Committee for publicly notified applications; and • make additional amendments to s 19 to clean up drafting and provide to ensure drafting consistency and address conflicting provisions.
19. EPA notices	Amend the enabling provisions for new organisms to change some regulation making powers to EPA notice making powers to allow the EPA to create notices on technical matters relating to new organisms. The topics that would be moved would be new organisms equivalence, where relevant, to hazardous substance topics have already been moved into EPA notices, including those relating to forms.
20. Revoking regulations	Revoke the following regulations: • Hazardous Substances and New Organisms (Personnel Qualifications) Regulations 2001 • Hazardous Substances and New Organisms (New Organisms Forms and Information Requirements) Regulations 1998

Amendment title	Proposed solution
21. Enforcement of New Organisms	Amend s 97A to align with wording in the Gene Technology Bill with respects to MPI's enforcement role for new organisms. MPI will remain the responsible agency for enforcement.
22. Information sharing	Change s 97C(3) to include entities referred to in s 97A, applying the information-sharing provisions to the enforcement agency for new organisms.
23. Prohibition of vagrant organisms	Amend schedule 2 to exclude native, vagrant or naturally occurring organisms. Specifically, ss 1 and 2: 1) Any snake of any species whatever. 2) Any venomous reptile, venomous amphibian, venomous fish, or venomous invertebrate. (In this item, venomous means capable of inflicting poisonous wounds harmful to human health.) And Amend s 50 to exclude not-new organisms from being prohibited.
Changes to definitions	
24. Definition of 'Organism'	Align the definition of organism with the Biosecurity Act (excluding prions)
25. Definition of 'New Organism'	Confirm that an organism that is native to New Zealand can't be a new organism. Clarify that organisms that, through natural means, are no longer present in New Zealand but can be reintroduced, are not new organisms.
26. Definition of 'Develop'	Simplify the definition of 'develop' and more broadly require permits to develop new organisms in containment. Remove the distinction between New Organisms and Incidentally Imported New Organisms, applying the same definition of 'develop' to both. Update the range of activities that are considered 'developing' a new organism to better reflect the activities that are being regulated by the Act. Proposed activities to be included in the definition include: • to carry out large-scale fermentation using a micro-organism that is a new organism; • to test, trial, or research a new organism; and • the deliberate isolation, aggregation, multiplication, breeding, propagating, growing, raising, or other use of the organism.
27. Definition of 'Incidentally Imported New Organism'	Amend definition of incidentally imported new organism to clarify that the offspring, progeny or descendant of an incidentally imported new organism that is born within New Zealand is also treated as an incidentally imported new organism.
28. Definition of 'Field Test'	Remove the requirement to "remove any heritable material" from a field trial at its end. The risk of biological material escaping from or remaining after a field trial will still be managed under s 44 - Additional matters to be considered on applications for importing and field testing of organisms.
29. Definition of 'Release'	Amend the definition of release to apply to all situations where a new organism is not contained. Specifically, a fish in an aquarium or small pond, and a plant in a pot should be considered to be released if not 'contained' as defined by the Act.

Amendment title	Proposed solution
30. Definition of 'Qualifying Organism'	Include medical devices in the definition of 'qualifying organism'. Amend s 38I to apply to assessment of applications for release of qualifying organisms contained in medical devices.
Minor and technical changes	
31. Definition of "environmental medium"	Amend the definition to replace reference to class 6 and class 9 substances (old hazard classification system) with the equivalent terms in the updated classification system adopted by the EPA in 2021.
32. Interface issue with Defence Act 1990	Amend s 3(3) to remove reference to the term "EPA controls". Amend s 3(6) to provide clarity on the auditing function.
33. Heading of s97	Amend the heading of s 97 to read "Enforcement of Act in respect of hazardous substances".
34. Provisions of persistent organic pollutants within the HSNO Act to better align with the Stockholm convention	Amend or revoke ss 19(2)(ca), 25A, 25C, 25D, 29B, 66A, 140A, and schedules 1AA and 2A of the HSNO Act, along with any consequential changes needed to align with the Stockholm convention.
35. Removing SOI and annual report provisions	Repeal ss 147 (1) (d), (e) and (f) and s148 (c), (d) and (e).
36. Clarifying agency submissions	Amend ss 58(1)(i) and (ii) to replace the word "submission" with "information".

Appendix 2: Proposed changes to the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997

Policy proposal	Proposed amendment to ACVM Act
1. Empower exemptions from registration to occur via a notice instead of through the existing regulations	Amend s 8A of the ACVM Act to empower substances or products to be exempted from registration by a Notice issued by the Director-General instead of in Schedule 2 in the ACVM (Exemptions and Prohibited Substances) Regulations 2011. Consequential amendments are required to the ACVM Exemption Regulations to provide reference to a new notice containing the exemption information currently contained in Schedule 2. Substantive obligations relating to exempt products (such as the obligation to ensure that an exempt agricultural compound must be fit for purpose when imported, manufactured or sold)[1] and ability to set conditions would remain at regulation. Provide for transitional arrangements required to support the transfer of the existing exemptions to the new Notice.
2. Ability to recognise international regulators; and to require the Director-General to use an appropriate, available recognised international regulators' product assessment when considering an application for registration	Permit recognition of international regulators, set criteria for recognition in regulations, and empower the Director-General of the Ministry for Primary Industries to make a notice listing recognised international regulators. Require the Director-General to use an appropriate, available recognised international regulators' product assessment when considering an application for registration (or variation to an existing registration) of the same (or substantially the same) product and empower any necessary associated secondary legislation.
3. Permit the recognition of data assessors to assess data packages	Amend the ACVM Act to permit the recognition of data assessors to assess data packages to strengthen the data assessor framework.
4. Provide for regulations to allow for the review of statutory timeframes	Amend s 16 of the ACVM Act to remove the statutory timeframes. Empower the setting and review of statutory timeframes in regulations and supplementary notices for different application types. Provide for transitional arrangements that retain the current timeframes in s 16 while regulations are being developed.
5. Clarify processes around variations to product registration controls	Amend the ACVM Act to allow a registrant to apply to vary any registration controls on a product registration, rather than only conditions. Amend the ACVM Act to provide for regulations that specify the requirements and approval processes for applicants applying to vary conditions and controls for product registrations. A supplementary notice provision would be required to provide for supporting technical information to meet those regulations.

[1] Regulation 7, Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011. www.legislation.govt.nz/regulation/public/2011/0327/latest/DLM3982210.html

6. Clarify that the Director-General is required to publicly notify a prohibition or restriction on a product or group of products undergoing reassessment	Amend s 31 of the ACVM Act to require the Director-General to notify the public of a decision to prohibit or restrict the import, manufacture, sale or use of a registered product undergoing reassessment until a decision is made. The manner of notification should align with s 44ZL of the ACVM Act and proposed amendment 11 below.
7. Clarify the application processes for approval to undertake research work using Agricultural Compounds and Veterinary Medicines	Amend s 26 of the ACVM Act to change 'provisional registration' of trade name products to 'research approval' of both trade name products and unregistered products. Consequential amendments to remove references to provisional registration in the ACVM Act will be required. Transitional arrangements may be required for applicants granted research approval under s 8C(1).
8. Specify in the ACVM Act the mechanism for certifying Good Manufacturing Practices for veterinary medicine manufacturers	Amend the ACVM Act to allow the Director-General to set standards for Good Manufacturing Practices by Notice. Amend the ACVM Act to provide for the certification of a product manufacturer's compliance with a Good Manufacturing Practices Standard and empower regulations to set out the certification process and associated requirements.
9. Expand emergency situations where notification waiver requirements would apply	Amend s 15 of the ACVM Act to allow for the Director-General to waive notification if the product is likely to be required for use in an emergency related to public health, animal welfare, trade or agricultural security.
10. Streamline the regulatory interface with the Medicines Act 1981 for prescription human medicines that could be registered as veterinary medicines	Amend s 21 of the ACVM Act to remove the mandatory requirement to obtain consent from the Director-General of Health to register veterinary medicines that are prescription human medicines. Empower regulations to specify what classes of prescription medicines require consent. Transitional provisions to continue mandatory consent from the Ministry for Health on registration related to prescription human medicines until regulations are developed.
11. Provide flexibility in the ACVM Act for public notifications	Align notification provisions in the ACVM Act with s 44ZL to provide for more flexibility for public notifications such as decisions on registration applications, for registration, prohibited or restricted products and other relevant situations.
12. Expand the scope of situations when product registration can be suspended	Amend the ACVM Act to specify additional situations where registrations may be suspended. The ACVM Act should be clear that a product can be suspended where there is a risk to public health, animal welfare, agricultural security or trade and not only for non-compliance with registration conditions.
13. Clarify the right to be heard when a registration is suspended	Amend s 30A of the ACVM Act to clarify that applicants have a reasonable opportunity to be heard when the Director-General is proposing to suspend a product's registration.

Appendix 3: Detailed implementation plan of 16 recommendations by the Agricultural and Horticultural Products Regulatory Review

Recommendation	Agency report-back	Key timings and milestones	Overall status progress

Recommendation 1: Recommend the formation of a Sector Leaders Forum	• The Ministry for Primary Industries (New Zealand Food Safety (NZFS)) worked with the Ministry for the Environment (MfE) and the Environmental Protection Authority (EPA) to establish the Sector Leaders Forum. The first meeting was held on 3 April 2025 with constructive conversations and a future-focused approach.
	• The Deputy Director-General of New Zealand Food Safety is proposed to chair the meetings in 2025.
	• The Forum's operation will be reviewed periodically alongside the terms of reference.
	• Forum members discussed the draft terms of reference at the meeting on 3 April, noting further consideration is needed on membership and an independent chair.
		• Report back to Ministers following each meeting with an agreed summary of the discussions, views presented, and actions or next steps that will be shared with all Forum members.
		• Schedule next Sector Leaders Forum meetings for estimated dates:
		  • End of June
		  • End of September
		  • December TBC
		• The next Forum meeting in June is expected to focus on discussing performance of the approval path across the regulatory systems, including performance reporting from agencies which will occur at every second meeting.
		• The Forum can provide input into setting ambitious targets for agencies' performance.
			Completed

Recommendation 2: Recommend that the Minister for the Environment and Minister for Food Safety ensure prompt implementation of this Review's recommendations and are required to consider issues raised by the Sector Leaders Forum	• The report back to Ministers following each Sector Leaders Forum meeting will provide an update on the implementation progress of the Review's recommendations, and will also summarise the Forum's discussions, and any matters raised for Ministerial consideration. • The Minister for the Environment has already communicated a need to reduce queue times through the most recent Letter of Expectations to the EPA and that improving hazardous substances performance is a priority. The Minister set a target of 10% reduction to the queue in	The report-back to Ministers is expected to occur promptly after each Sector Leaders Forum meeting. Ministers will then consider issues raised by the Forum and direct or set expectations for agencies to implement the Review's recommendations and improve the systems. The Minister for the Environment's Letter of Expectations to the EPA for 2025/26 is available on the EPA website (Environment-Minister-Letter-of-Expectations-to-EPA-Board-2025-2026.pdf) and has been provided to the Sector Leaders Forum.	Underway (some operational improvements already completed)

Recommendation	Agency report-back	Key timings and milestones	Overall status progress
	2025/2026 and a more ambitious target once the additional staff are on board.	The Minister for Food Safety has also directed MPI to improve the ACVM registration process, including reducing the queues and accelerate assessments.	
Recommendation 3: Recommend that the Minister for the Environment and Minister for Food Safety set expectations for targets to accelerate HSNO and ACVM processes and reduce queues	• The Minister for the Environment has set expectations for targets to accelerate HSNO processes and reduce queues (Environment-Minister-Letter-of-Expectations-to-EPA-Board-2025-2026.pdf). Minister for the Environment will determine a more ambitious target within the next three months for a queue reduction target for HSNO. • The Minister for Food Safety has also directed MPI to improve the ACVM registration process, including reducing the queues and accelerating assessments. • The Minister for Food Safety will set a 20% queue reduction target for applications for each of ACVM to be achieved by the end of June 2025, and a further 30% queue reduction target to be achieved by the end of June 2026. • The Minister for Food Safety and the Minister for the Environment will determine an ambitious target within the next three months for reducing approval times for each of ACVM and HSNO. • The EPA has carefully reprioritised its existing funding to increase resource for assessing new hazardous substances. This initiative will reduce the queue of HSNO applications and assessment times once the 11 additional staff are recruited and trained. There has already been reduction in the queue size and increase in the number of applications decided.[1]	• The Sector Leaders Forum discussed this recommendation at the April meeting. • Agencies will provide performance information on ACVM and HSNO to the Forum members at the June meeting for detailed discussion, review progress on the Omnibus Bill proposal, and discuss the statutory timeframes of each respective piece of legislation. This will be an important input for developing relevant regulations and for Ministers to set expectations. • Targets to accelerate HSNO and ACVM processes and reduce queues will be discussed every second Forum meeting.	Underway (Targets for HSNO for this financial year have been set; improvements to queues already observed).

[1] As of 8/5/2025, there were 99 release applications in the queue. This is down 18% from 121 since 1 July 2024. This is the lowest number of applications in the queue since October 2022. From 1/7/2025 to 8/5/2025, a total of 55 applications have been decided. This has well surpassed the annual (three-year) average of 32.7 across all release application types.

Recommendation	Agency report-back	Key timings and milestones	Overall status progress
	• NZFS also reports an increase in completed applications meeting the statutory timeframes[2] and a reduction in ACVM queues.[3] • While it may take some time for all legislative changes relevant to the Review's recommendations to be developed and take effect, agencies will make all possible operational improvements to improve access to products. This includes improvements to achieve some of the outcomes expected through legislative changes, such as better use of international regulators' assessments and decisions or increasing the use of light-touch pathways for low-risk products and applications. • The EPA and NZFS will provide performance information at the next Sector Leaders Forum meeting in June for discussion and to provide context on the current application numbers and queue volumes for HSNO and ACVM. The Forum will provide input and Ministers may consider setting future expectations for queue reduction and assessment time. The report back of the Forum meeting to Ministers will inform progress on this recommendation and provide visibility on queue volumes. • This recommendation is closely related to Recommendation 13 (performance reporting and statutory timeframe review), which will need to be considered together.		

[2] An increase from 74% to 91% over the last 12 months.
[3] From October 2024 to 16/4/2025, the number of applications in the ACVM queues has been reduced by 20%.

Recommendation	Agency report-back	Key timings and milestones	Overall status progress
Recommendation 4: Recommend that MPI, MfE, NZFS and the EPA make the two regulatory systems easier to navigate	• The proposal to improve data protection under the HSNO Act would address one of concerns around the interface between the two systems and improve applicants' experience with the regulators. • NZFS and the EPA will collaborate more closely and look for opportunities to increase coordination, share industry knowledge and expertise, as well as to understand the common challenges for applicants, including seeking the Sector Leaders Forum feedback and suggestions. • The Sector Leaders Forum can provide specific examples of where stakeholders have difficulty navigating the two regulatory systems and bring the regulators and the sector together to consider suitable solutions. Those would include input on ensuring the two regulators setting aligned and workable controls which allow the effective use of products, providing guidance where needed, and efficiently using available resource	• The Sector Leaders Forum and Ministers can expect this recommendation to be an ongoing action as opportunities are discussed, explored, and progressed.	Underway
Recommendation 5: Recommend that agencies increase the use and better design of group standards, rapid assessment pathways, registration exemptions, and self-assessable changes	• **ACVM:** The Omnibus Bill includes a proposal to enable more flexibility, efficiency and timely review/updates of registration exemptions by shifting the exemptions from regulations to Director-General notices. • The Minister for Food Safety will seek Cabinet approval separately from the Omnibus Bill to publicly consult on changes to the ACVM (Exemptions and Prohibited Substances) Regulations 2011. [redacted] • In anticipation of the Review's recommendation, MPI has started implementation work before the publication of the Review Report and will increase the range of self-assessable changes as appropriate.	• Joint Ministers are seeking Cabinet decision on the Omnibus Bill proposals. • Public consultation on the ACVM (Exemptions and Prohibited Substances) Regulations is proposed for six weeks [redacted]. A consultation discussion document is expected to go to Cabinet [redacted] • Increasing the use of light-touch pathways for both ACVM and HSNO is one of ongoing operational improvements the EPA and NZFS will prioritise to enable better access to products. The ability for the EPA to develop the new group standards identified is dependent on resourcing.	Underway

Recommendation	Agency report-back	Key timings and milestones	Overall status progress
	• **HSNO:** The Omnibus Bill includes a proposal that enables more new substances to be assessed under the rapid assessment pathway by specifying the criteria for using recognised international regulators' work. • The EPA has identified options for the development of new group standards under the HSNO Act for certain types of low-risk hazardous substances. The EPA notes this work will require resources. The EPA will consider the expected outcomes of this recommendation when designing these new group standards. • At an operational level, this year (FY24/25) the EPA has substantially increased the use of rapid assessments over previous years. Since July 2024, the EPA has decided 40 applications by rapid assessment (as of 14 April 2025). At this pace, the EPA estimates deciding 50-55 rapid applications by July 2025 which would be comparable to the most recent high in 2015/16 (54).		
Recommendation 6: Recommend that MPI and NZFS reduce ACVM efficacy requirements for inhibitors to the minimum required to manage risks	• In anticipation of the Review's recommendation, MPI started operational action to streamline the greenhouse gas inhibitor registration process under the ACVM Act, including: - revised operational guidelines to allow qualitative claims, as well as quantitative claims, for inhibitor products; and - changes to further emphasise minimum efficacy requirements for the qualitative claim pathway. • MPI will engage directly with stakeholders to ensure they understand the minimum efficacy information required and take feedback on any further operational improvements.	• MPI's targeted consultation of the revised methane inhibitor efficacy guidance document commenced on 26 March and closes on 9 May. Discussion on this occurred at the Inhibitor Operational Forum on 2 April 2025.	Underway

Recommendation	Agency report-back	Key timings and milestones	Overall status progress
Recommendation 7: Recommend that the EPA and NZFS maximise their use of assessments by international regulators for assessing the risks of a product while still considering aspects unique to New Zealand	• **HSNO:** The EPA already relies on assessments from international regulators in its assessments. Since 2024, international regulator information has been used to assess six applications through the rapid assessment pathway made available following previous amendments to the HSNO Act. • The Omnibus Bill includes a proposal that enables more new substances to be assessed under this rapid assessment pathway. Another proposal on a conditional approval pathway would allow some novel agrichemicals with significant benefit to New Zealand to be used while the substantive assessment is conducted. At an operational level, the EPA will continue to look for opportunities to more effectively use international information while legislative changes are underway. • **ACVM:** The Omnibus Bill includes proposals to enable international regulators to be recognised legislatively; and to require the Director-General to use available international regulators' assessments in consideration of product applications, where appropriate. • Operationally, NZFS will continue to engage with relevant overseas regulators on gaining agreement for mutual sharing of assessments, and inform the Sector Leaders Forum on key developments as these arise. NZFS will review each regulator's system to ensure they are fit for purpose and support building trust and confidence in each other's regulatory system. This is comparable to what already occurs for companion animal products with Australia through a memorandum of understanding.	• Agencies will continue to provide progress updates to the Sector Leaders Forum and Ministers on this recommendation, including any key developments in the engagement with overseas regulators and the use of international assessments for processing applications for both ACVM and HSNO.	Underway

Recommendation	Agency report-back	Key timings and milestones	Overall status progress
Recommendation 8: Recommend that the EPA and MPI (including NZFS) prioritise engagement at the international level to support harmonisation of requirements	• NZFS has regular involvement with several key international bodies, including Codex, OECD, and VICH to support harmonisation of international requirements. NZFS continues engagement with comparable international regulators to support exploration of opportunities for registration by reliance pathways. In 2025, this will involve outreach with Australia, Swiss Medic and the UK Veterinary Medicines Directorate. • The EPA actively engages in relevant international fora. This includes OECD, HEPA and SETAC as well as directly with regulators in US, UK, Canada and Australia. New Zealand benefits from this engagement in terms of: - access to combined global expertise; and - harmonisation of requirements and best practices (for example, harmonised test guidelines and mutual acceptance of data between countries).	• NZFS and the EPA has regular monthly meetings with Quins partners (Australia, USA, UK and Canada) on regulatory matters and opportunities for collaboration and will update the Sector Leaders Forum following these engagements. • The EPA is looking at how it can specifically engage with Australia's APVMA on their processes, including gaining a better understanding of their risk assessment models (related to recommendation 10).	Underway
Recommendation 9: Recommend that MPI (including NZFS), MfE and the EPA explore a strategic priority pathway, in addition to the current first come, first served queue	• There will be discussion at a future Sector Leaders Forum between agencies and stakeholder members to explore this recommendation further. The feasibility and efficacy of a separate pathway within current ACVM and HSNO settings from the current 'first come, first served' approach taken by agencies requires detailed consideration. • The EPA is developing proposals for criteria to prioritise assessment of applications and is engaging with industry on these proposals. • As noted in the review report, diverging views of applicants and industry, along with the broad scope of substances that are regulated by the HSNO Act, present challenges to developing fit-for-purpose criteria. The EPA notes that prioritisation will not reduce the size of the queue, and any move away from a "first-come, first-	• The importance of strategic prioritisation was discussed at the Sector Leaders Forum on 3 April, including the benefits and challenges of such an approach. Future discussions will likely include how the Forum can support this work going forward and how (and when) this recommendation should be progressed alongside the other recommendations. • The EPA has contracted Sapere Research Group to undertake a survey on potential indicators and criteria for prioritisation of hazardous substance applications. The survey went out to a broad group of stakeholders in early April 2025. • The EPA will share feedback on its prioritisation project with the forum which may highlight areas of	Underway

Recommendation	Agency report-back	Key timings and milestones	Overall status progress
	served" queue would inevitably mean a longer wait for some other applications.	alignment with the statutory purposes of the HSNO Act and ACVM Act.	
Recommendation 10: Recommend that the EPA update their outdated risk assessment models and consider how to keep them up to date for the future	• The Minister for the Environment and the Minister of Finance have agreed to allocate $10 million operational funding to upgrade the EPA's ecotoxicological risk assessment models from the Waste Disposal Levy, which was identified as one of the highest impact recommendations from the Review.	• Budget 25.	Underway
Recommendation 11: Recommend that MfE and the EPA review HSNO cost recovery provisions. We recommend that consideration be given to (but options should not be limited to): whether the current level of cost recovery from industry is appropriate; and an annual levy to support general regulatory functions which do not provide applicant specific benefits.	• The Omnibus Bill includes a proposal to allow a HSNO levy to be set by way of regulations. The regulations would determine the nature and scope of such a levy, and the proposals would be subject to public consultation and approval by Cabinet. • Existing HSNO application fees may be considered in the future once improvements to the queue size and assessment time are in place and the need for reviewing HSNO cost-recovery is established. Any cost recovery review will be considered in line with Treasury's Guidelines for Setting Charges in the Public Sector (2017), and the Office of the Auditor-General's guidance Setting and administering fees and levies for cost recovery: Good practice guide (2021).	• Amendment to enable the EPA to charge a levy is proposed in the Omnibus Bill. • Any work on levies and/or application fees under the HSNO Act would be consulted on before taking effect.	Underway

Recommendation	Agency report-back	Key timings and milestones	Overall status progress
Recommendation 12: Recommend that MPI strengthen the framework overseeing independent data assessors	• NZFS currently holds ad hoc workshops with data assessors to calibrate on such matters as consistency. It also provides feedback on the quality of data assessment reports. • In the short-term NZFS can undertake actions to administratively strengthen the data assessor framework, including calibration of data assessor skills and education via published guidance. Subject to agency resourcing and funding, NZFS could develop dedicated training frameworks for data assessors, such as ACVM calibration and training workshops for data assessors on a periodic basis. NZFS will receive feedback from the Sector Leaders Forum to help inform the most efficient path forward. The Omnibus Bill includes a proposal to strengthen the independent data assessor framework, following consultation with industry and the Forum.	• The recommendation was discussed at the Sector Leaders Forum in April, resulting in an additional proposal in the Omnibus Bill. • While legislative change is underway, NZFS will explore short-term administrative actions to strengthen the framework for data assessors within existing resources and advise the Sector Leaders Forum in June. The update will detail additional options for a potential work programme for strengthening the data assessor framework further for ACVM.	Underway
Recommendation 13: Recommend the EPA and NZFS improve their performance reporting and MfE and MPI review statutory timeframes in their respective legislation	• **ACVM:** The Omnibus Bill proposal seeks to amend the ACVM Act to provide regulations or Notice-level settings that will enable a review of application statutory timeframes. The reviewed timeframes would enable meaningful performance reporting in the future. • As per Recommendation 3, NZFS will present performance information to the Sector Leaders Forum for discussion at the June meeting for ACVM applications and welcome feedback, which will also be provided to Ministers through the report back. ACVM regular reporting is currently provided to the ACVM Advisory Council (AVMAC) and provided via monthly stakeholder publications.	• Cabinet is considering the Omnibus Bill proposals that will seek to amend the HSNO Act and ACVM Act to give effect to the recommendation for reviewing the statutory timeframes for respective legislation. • Proposed HSNO Act amendments will include differentiation of applications by type/complexity, and clarification of process steps so that specific statutory timeframes can be assigned (and reported against). • The EPA will continue to refine operational reporting, incorporating feedback from the Minister, EPA Board and the Sector Leaders Forum where applicable, and will retain the granularity of timeframe reporting.	Underway

Recommendation	Agency report-back	Key timings and milestones	Overall status progress
	• **HSNO:** In responding to the sector's early feedback to the Review and in anticipation of the Review recommendation, the Minister for the Environment has requested more detail in the EPA's performance reporting. Since September 2024, the EPA's quarterly reports to the Minister have been improved, including reporting across the end-to-end assessment process. The EPA will also begin releasing a specific quarterly hazardous substances performance report. • MfE and the EPA have developed proposals to amend the HSNO Act in the Omnibus Bill to allow the setting of new statutory timeframes and to improve application processes by way of regulations. Fit-for-purpose timeframes will provide greater clarity to applicants and clear performance measures for the EPA.	• For the ACVM Act, while legislative change is underway, MPI will commence work in parallel to review the ACVM statutory timeframes in line with policy decisions agreed to, and seek to consult with agencies, industry stakeholders, and the Sector Leaders Forum members on the appropriate timeframes for ACVM applications processing. MPI anticipates then seeking Ministerial approval on the revised statutory timeframes to be established for ACVM applications. • Performance reporting will be discussed at every second Sector Leaders Forum meeting.	
Recommendation 14: Recommend that the EPA and NZFS prioritise the provision of up-to-date guidance, pre-application support, and transparency on application processing	• Agencies acknowledge that improving the quality of applications is essential to making assessment processes more efficient and will be mutually beneficial to applicants and the agencies. Developing additional guidance, and then keeping it up to date, requires significant time and resources. • Agencies will continue to progress this recommendation as resourcing permits and look for opportunities to align on HSNO-ACVM interface areas as part of ongoing work under Recommendation 4 (making the two regulatory systems easier to navigate). • Agencies will invite feedback from the Sector Leaders Forum on specific examples or areas where updated guidance would be most impactful and beneficial for applicants.	• The recommendation can be discussed as part of the Sector Leaders Forum to identify additional opportunities for satisfying the recommendation. • MPI (NZFS) continues to make efforts to ensuring ACVM guidance is updated and developed in line with trusted international sources and guidance and supports applicants early where appropriate at the pre-application stage. • The EPA is currently preparing guidance relating to inhibitors to help streamline understanding of requirements across both regulatory systems. Other guidance will be updated as resourcing allows. The work will need to be aligned with actions taken with Recommendation 4.	Underway

Recommendation	Agency report-back	Key timings and milestones	Overall status progress
Recommendation 15: Recommend that NZFS and the EPA extend existing stakeholder engagement forums to operate across both regulatory systems	• The Sector Leaders Forum will discuss possible options and ensure appropriate representation and engagement at the leadership level (strategic), as compared to existing stakeholder engagements at the operational and technical level, such as the ACVM Advisory Council (AVMAC) and the Inhibitors Operational Forum. • MPI may expand the scope of AVMAC if required to include MfE officials and additional EPA representation to broaden focus. • Agencies can work closely to implement this recommendation in a mutually beneficial manner for regulators and stakeholders.	• Discuss at Sector Leaders Forum and action any changes to agency stakeholder engagement approaches at the earliest convenience and for the Forum to track the progress (preferably once agency resourcing permits as the Omnibus Bill progresses). Agencies will work in collaboration with stakeholders and focus on practical outcomes of this recommendation.	Underway (scheduled for discussion at the Sector Leaders Forum).
Recommendation 16: Recommend that MfE review the emergency approval provisions under the HSNO Act, including better enabling products to be approved for biosecurity responses	• The existing emergency and special emergency provisions under the HSNO Act are not being utilised as was envisaged. • MfE has developed legislative amendments to improve these provisions, which will better support biosecurity responses. • MPI is supporting MfE and the EPA on their consideration of the emergency approval provisions relevant to biosecurity responses.	• The proposed legislative amendments to the HSNO Act are part of the Omnibus Bill.	Underway

Stage 1 Cost Recovery Impact Statement

Proposal for a Hazardous Substances and New Organisms Levy

Status quo

1. Since 2017, the Environmental Protection Authority (EPA) has struggled to fund its approval processes under the Hazardous Substances and New Organisms Act 1996 (HSNO). Currently, the EPA receives approximately 90% of its funding from the Crown. From this funding, about 18% is allocated to the HSNO system overall. This includes resourcing, retention and recruitment. Currently the regulatory system is under significant strain, as highlighted by reports from Sapere, MartinJenkins, and the Ministry for the Environment. A recent review has also been undertaken by the Ministry for Regulation.

2. The strain on the regulatory HSNO system is based on the discrepancy between the fees recovery undertaken by the EPA, and the amount of effort, expertise and time needed to undertake day-to-day functions while also conducting application assessments, emergency responses, and managing risk from non-compliance.

3. In August 2024, the Ministry for Regulation commenced the Agricultural and Horticultural Products Regulatory Review[1] (MfR review). The review was triggered by concerns raised about access to new horticultural and agricultural products and New Zealand's international competitiveness. The MfR review was completed in November 2024, with the approval of joint Ministers for the Environment, Food Safety and Regulation sought in December 2024. Further information on the MfR review, including its recommendations can be found on the MfR website. The regulatory impact statement associated with the attendant Cabinet paper outlines MfE's view and response to these recommendations.

4. This cost recovery impact statement (CRIS) responds to both the need outlined by previously commissioned reports, and recommendation 11 in the MfR review: ***We recommend that consideration be given to (but options should not be limited to): whether the current level of cost recovery from industry is appropriate; and an annual levy to support general regulatory functions which do not provide applicant specific benefits.***

5. MfR concluded that an annual levy as part of an overall cost recovery assessment could "*…improve proportionality and transparency. Investing cost recovered funds in improved tools like risk assessment models could improve efficiency and effectiveness…*" (Agricultural and Horticultural products regulatory review – February 2025, page 88).

[1] https://www.regulation.govt.nz/regulatory-reviews/agricultural-and-horticultural-products-regulatory-review/

6. Currently, importers and manufacturers who benefit from hazardous substances and new organisms have their applications assessed by the EPA. The cost for the EPA to provide these services is far greater (around five times higher) than the fees paid by these importers and/or manufacturers.

7. Importers and manufacturers are the direct recipients of the services provided by the EPA in assessing their application, but there are also indirect benefits which accrue to farmers, growers, the New Zealand public, and biosecurity. As the lead policy agency, the Ministry for the Environment (MfE) believes the introduction of the Omnibus Bill following from MfR's review provides an opportunity to address the need for how the EPA's costs are recovered.

8. This is the first time in 29 years that MfE have been able to undertake substantive changes to the HSNO Act. MfE proposes to ensure that the risk of adverse effects from the use of hazardous substances and new organisms is managed and mitigated. This level of risk is influenced by both the intrinsic properties of chemical substances and how and where they are used. The HSNO regime is not about simply setting controls – it is concerned with regulating and monitoring how and where hazardous substances are used i.e., in workplaces, homes, gardens and everyday locations, and managing the effect on human health and the environment.

9. Most of the EPA's services are considered 'club goods,' meaning they provide public benefits without being rivalrous. For instance, mitigating the effects of hazardous substances and new organisms benefits the environment and human health without excluding others from enjoying these benefits. Similarly, the EPA's efforts in educating and providing information to importers and suppliers of HSNO substances are non-rivalrous.

10. There is a 'private good' component, particularly in the application of Group Standards. Approximately 30,000 chemicals, contained in over 150,000 hazardous substances, are approved for use in New Zealand, with around 3,700 having individual approvals. Most domestic and workplace chemicals are covered by about 210 group standards, which the EPA is responsible for. Many of these approvals date back to the 1960s, leading to a free rider effect where a significant part of the chemical industry does not pay for regulation costs, creating an asymmetry between those who pay and those who do not.
    The EPA faces challenges in adequately funding its hazardous substances regulatory functions. This has been documented over the past few years in a variety of reports. The key indicators of this include:
    - **Resource limitations**: The EPA has fewer resources dedicated to hazardous substances assessments compared to similar regulators in other countries. This under-resourcing impacts its ability to process applications and reassess the safety of in-use chemicals.
    - **Comparative spending**: New Zealand spends considerably less on hazardous substances functions than benchmarked countries such as Australia, Canada, the United Kingdom, the United States, and the European Union.
    - **Impacts of past underfunding**: The lack of adequate funding previously has led to significant wait times for processing applications. This limits the EPA's capacity to reassess chemicals, as noted in the concerns raised by industry, this has both environmental and economic impacts.

- **Outdated tools**: The EPA relies on outdated ecotoxicological modelling tools, (some of which are more than 20 years old) which hampers its ability to effectively assess and manage hazardous substances.

11. One indicator of the strain on the system is the current backlog of applications being processed by the EPA. While this queue has reduced by 13% as a direct consequence of funding allocated to the EPA in the last budget, industry bodies have raised concerns about the time taken to get products approved in New Zealand, particularly focused on those products with new active chemical ingredients.

What are the policy outcomes charging a levy will achieve?

12. The proposed levy would create funding specific to the EPA's hazardous substances and new organisms' function and contribute to transparency and accountability for levy payers within the HSNO system.

13. Currently the funding for the HSNO area forms part of the EPA's overall funding envelope. This means there is no prioritisation for HSNO funding. Ministerial directives, public feedback and the MfR review have all pointed to a need to change this. Providing a specific funding stream would ensure both prioritisation of HSNO funding and transparency of funding allocation as this would be ringfenced to the HSNO system.

14. Fees alone will never fully recover the cost of processing HSNO applications, or the other costs – such as assessment, and the recruitment of specific technical expertise related to the ongoing maintenance of the HSNO regulatory system.

15. Fees for hazardous substance approvals are currently set at between 20% and 26% cost recovery. This reflects the need to ensure charges or fees are not a barrier to other outcomes such as economic growth, innovation, and environmental protection. We have made the assumption that fees will continue to rise in recognition of ongoing costs for the EPA, subject to fee reviews. We will need to work through the criteria needed for exemptions under the levy.

16. We have used the following policy principles to determine the need for a levy:
    - universal, so that the EPA's costs are generally shared among all who benefit from the potential to use their services;
    - 'polluter pays' to ensure alignment with the principles already applied in the Waste Levy, and the ACVM levy;
    - equitable, so that policyholders should generally pay a levy at a level commensurate with their use of the EPA's services;
    - set at a level that recognises the risks associated with the activities that applicants to the EPA carry out;
    - and to provide predictability for both the EPA and levy payers.

This proposal is for a new levy

17. This proposal is for a new levy to support the HSNO system overall. Our broad proposal is to ensure a stable source of funding to support the EPA in the performance of functions and duties and exercise of powers under the HSNO Act.

18. Currently the EPA relies solely on Crown funding and fees. Given the growing distance between the fees charged and the cost of the service, the HSNO system's responsiveness and resilience will continue to degrade. Creating enabling provisions for a levy in the HSNO Act will allow surety for the EPA to continue to develop resources and tools. Referring to both the MartinJenkins and Sapere reports, a levy is the most effective approach to addressing the ongoing funding issue. Fees were reviewed in 2018 and 2023 in line with the above.

19. Applications for new active ingredients are becoming increasingly complex and time consuming as scientific data improves. Some applications involve reviewing hundreds of pieces of scientific literature by highly technical staff, with specialist knowledge. The cost of processing these applications is a major challenge for the EPA and international equivalent bodies.

20. It is clear that there is an ongoing risk to the overall regulatory system's ability to deliver on expectations and requirements. For these reasons, and given this is the first opportunity in nearly 30 years to undertake substantive changes to the HSNO Act, MfE do not believe there is a case for deferring the levy.

21. During targeted engagement, some parties supported the levy, while others, such as Animal and Plant Health NZ (APHANZ), opposed it, particularly if there was no opportunity for further engagement. In our next steps work we have some significant questions to work through including how long the levy will run before review, the specifics of how the levy will be applied to ensure the polluter pays principle and its alignment with the Waste Levy and the ACVM levy.

22. The HSNO Act does not include provisions for the regulatory administration of its functions through any levy funding.

23. In contrast, the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM) imposes a levy on the sale of agricultural compounds and veterinary medicines to help fund MPI's regulatory activities and ensure that those who benefit from the use of these products contribute to the costs of their regulation. The HSNO Act and ACVM are cross-over regulatory systems, with inter-linked application processes through 'joint' approvals for chemicals and biological controls.

24. While the EPA's remit within the HSNO Act is broader with respect to hazardous substances than the ACVM's focus on risks associated with the use of agricultural compounds and veterinary medicines, the common objectives of both systems are to ensure effective regulatory requirements of their respective Acts are met.

The MartinJenkins reports 2020 and 2022[2]:

25. In 2020[3], MartinJenkins conducted a review of the EPA's cost recovery arrangements and evaluated an EPA proposal to introduce a levy on importers and manufacturers of hazardous substances to cover the costs of reassessment and monitoring activities. Although practical issues prevented the immediate implementation of the levy, the review recommended that the EPA and MfE collaborate to improve the regulatory system including how to enable a levy in future.

26. The EPA commissioned a further MartinJenkins report in 2022 to assess the efficiency and effectiveness of its systems in the HSNO area. The report noted that the EPA, as a Crown entity, has its own cash reserves from an initial cash injection when it was formed, and some surpluses in its early years. Since 2017/18, the combination of additional functions and associated staff, as well as inflationary pressures, has resulted in costs exceeding revenues for operational activities.

27. The 2022 MartinJenkins report made the overall assessment that the EPA is making good use of its available resources, but funding constraints pose risks of not delivering on required outcomes. The report also noted "*Over time, it also risks inefficiency if systems and processes are not upgraded and more automated…*" (Martin Jenkins executive summary, page 3).

The Sapere report[4] 2023:

28. MfE and the Treasury provided funding for further examination of the EPA's funding and performance, and a further independent report was completed in 2023. The paper benchmarked the funding and performance of the EPA against regulators in Australia, Canada, the United Kingdom, the United States and the European Union.

29. One of the findings of the report was that New Zealand spends considerably less on hazardous substances functions than benchmarked countries. In 2022/23, New Zealand invested approximately $3.9m to assess applications to manufacture or import hazardous substances and to reassess the safety of already approved chemicals. This level of funding is considerably less than the countries benchmarked against, even after adjusting for population, GDP, and key sectors.

30. Lengthening assessment times has been a key focus of both chemical Industry groups and the Minister for the Environment.

31. MfE agrees with the conclusions of the Sapere report that resourcing, models and tools are key to addressing both the costs of service and the level of private benefits through the approval of hazardous substances and new organisms.

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[2] https://www.epa.govt.nz/resources-and-publications/our-2022-independent-functional-and-funding-reviewnew-page/

[3] https://environment.govt.nz/publications/the-epas-cost-recovery-arrangements/

[4] https://srgexpert.com/resource/the-epas-role-and-performance-in-assessing-hazardous-substances/

32. In 2022/23 New Zealand invested approximately $3.9m to assess applications to manufacture or import hazardous substances and to reassess the safety of already approved chemicals.

33. **Relevant Policy decisions:** Cabinet Minute, Ministry for Regulation: CAB-25-MIN-0036, showing the decisions from Joint Ministers, and MfE Briefing #5986 which sought policy decisions from the Minister for the Environment on the introduction of a levy. The Minister confirmed these decisions on 8 April 2025.

Policy Rationale: Why a user charge? And what type is most appropriate?

34. The policy rationale for a HSNO levy is multifaceted and aims to support the regulatory framework for the hazardous substances regime under the HSNO Act. The rationale includes:
    i. The need to fund Regulatory Activities: the levy is intended to provide essential funding for the EPA to carry out its regulatory functions, including the assessment, approval, and compliance of hazardous substances.
    ii. Equitable Cost Distribution: A tiered levy structure will ensure the cost of regulation is distributed equitably among companies based on their import volumes. This means that larger companies with larger volumes will contribute more, reflecting their greater impact on the market and the environment.
    iii. Encouraging Compliance: The imposition of a levy will incentivise companies to comply with regulatory requirements. The levy will likely be based on import volumes and will encourage companies to maintain and report accurate records.
    iv. Risk Management: The levy will help the EPA to manage potential risks associated with the use of hazardous substances. By funding compliance and enforcement activities, the EPA can act against non-compliant products, thereby protecting public health and the environment.

A partial cost recovery levy is proposed

35. The levy is currently proposed to recover a percentage of the EPA's operating and capital costs over an initial levy period, after which a funding review will be undertaken. MfE believe that a levy is necessary due to the declining capacity of the EPA to deliver its functions in the HSNO area. The decline in capacity and functionality has been documented by the MartinJenkins reports, the Sapere report, MfE's internal reports and the MfR review.

36. Currently the EPA has costs of around 20% ($8.6m) of its total operating budget for the HSNO regime. Fees recovered are around 10% of the total amount, ($887,000). It is important to note that costs vary year on year depending on the number of applications received and how complex these applications are. Some applications may have around 800 separate pieces of scientific literature and case studies to be reviewed. We are assuming that the levy would partially recover fees to recognise the public good component undertaken by the EPA's work in protecting the environment and human health, as well as their role in emergency responses and biosecurity emergencies.

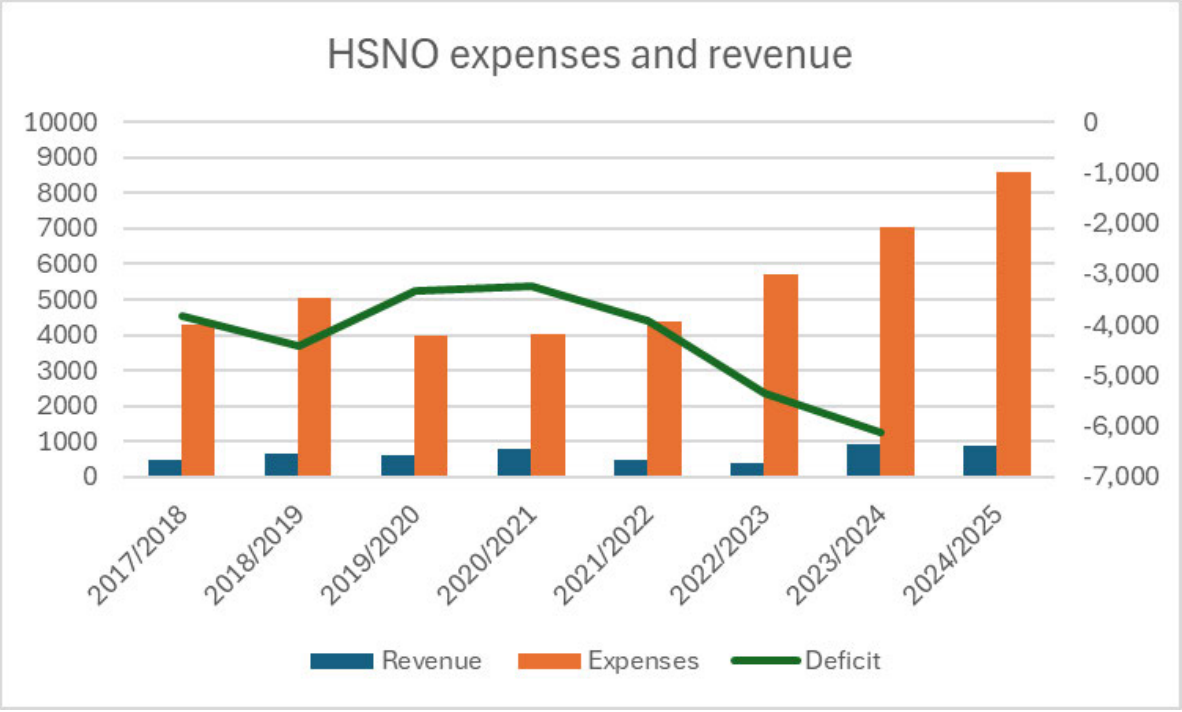
37. We reviewed the fees of internationally comparable jurisdictions. We used this comparison to inform our proposed percentage recovery through the levy. For further information see the table of international comparison countries at **appendix one**. While we have done our best to do a 'direct' comparison, this is difficult as some countries have one combined authority for ACVM and HSNO functions, while others focus on very different outcomes to the HSNO Act.

38. MfE propose, subject to further analysis and consultation, the levy should provide for 65% of the EPAs hazardous substances costs, while the final 35% of the EPA's HSNO costs would remain government funded to recognise the public good component of the services. We anticipate this will equate to costs of approximately $5.6m per year recovered through the levy and this will be ring-fenced to functions and duties under the HSNO system. MfE anticipate that the breakdowns proposed here will be further researched during consultation.

39. The table below details the rounded figures for EPA outgoings and cost recovery from 2017. The figures focus on the operational component as overall system figures are not available. This is because HSNO finances are included within the EPA's overall financial totals. Note: the fees recovered below covered the period of two fee increases, in 2020 and 2023.

HSNO revenue and expenses (deficit figures not yet available for 2025)								
$000	2017/2018	2018/2019	2019/2020	2020/2021	2021/2022	2022/2023	2023/2024	2024/2025
Revenue	480	645	629	784	476	370	928	887
Expenses	4,292	5,047	3,967	4,031	4,389	5,709	7,039	8,600
Deficit	(3,812)	(4,403)	(3,337)	(3,246)	(3,912)	(5,339)	(6,111)	---

The graph below shows that despite the EPA's fee increases, revenue continues trending down against expenses.



High level cost recovery model (the level of the proposed fee and its cost components)

40. The current fee for a statutory determination is $1,000 excluding GST ($1,150 including GST). The Sapere report shows costs to the EPA are about $6,000 to progress an application. This means that applicants are paying around 16% of the cost to process their application, and government funding pays the remaining 84% of the cost. We are not proposing that a levy would replace the current statutory fees charged.

41. In determining who should bear the costs, the activities required to deliver on the HSNO functions were assessed against the Treasury framework, considering whether the activities are excludable and rivalrous. The assessment aligns with approaches taken by other agencies such as the Ministry for Primary Industries (MPI), the Ministry of Business, Innovation and Employment (MBIE), transport Crown entities, and the New Zealand Customs Service.

42. For the purposes of this CRIS, and without prejudice to any future consultation, an example of how such a levy could be set and who would pay it could be along the following lines The charges for the hazardous substances levy could be primarily determined based on the risk posed by the substances to human health and the environment. The method involves prescribing a leviable rate based on the hazard class of each substance. This approach would result in substances with higher hazard classifications and those applied directly to the environment being charged higher rates. The levy rates would be set on a per volume or weight basis, allowing for a proportional relationship between the amount of substance and the levy charged.

43. In addition to the changes currently being enacted through the Omnibus bill, we believe a levy would benefit those subject to the levy. This is because it would create a dedicated resource within the EPA which would be accountable to the Minister for the use and outcomes arising from the levy.

44. Depending on the duration approved for the levy e.g. one or three or five years, we expect the EPA will focus more on engagement and education as the administrative demands of the HSNO system reduce. This assumption forms part of the underpinning for our policy rationale within the regulatory impact statement (RIS). The RIS supports clearer and more direct application pathways and the levy would form a component of this. The funding from the levy would enable better automation, updates to the ecotoxicological models used to ensure up-to-date information to inform the assessment of new active ingredients, which would lead to better and faster outcomes for low-risk new active ingredients, and clearer timeframes for more complex active ingredients. For these reasons, we believe the levy would be a net benefit for levy payers.

45. Regulations would specify which hazardous substances are subject to the levy and the corresponding rates. This process would involve assessing the hazard class, environmental fate, and other relevant criteria to prevent unintended consequences. Data from approvals, hazard classifications, and controls would be used to help determine the appropriate levy amounts. Additionally, information collected from the EPA's Importers and Manufacturers

Notice would likely help estimate potential revenue and ensure accurate levy payments.

46. A threshold system, which charges a flat fee per volume or weight, could also be considered, but might prove less practical due to the need for bespoke leviable amounts for each substance. Targeting all hazardous substances is also likely to be impractical due to the sheer number of substances approved under group standards or individual approvals.

47. The levy will likely be primarily targeted at importers and manufacturers of hazardous substances. This approach aligns with the HSNO Act, which issues approvals to import and manufacture these substances. Data on these parties would be provided under the Importers and Manufacturers Notice, ensuring that the levy is imposed on those directly responsible for bringing hazardous substances into New Zealand.

48. It is expected that importers and manufacturers will pass the costs down the supply chain to suppliers and end users, effectively distributing the financial burden across all parties involved in generating risks associated with hazardous substances.

49. Targeting parties further down the supply chain, such as retailers or end users, could be considered but would increase complexity due to the larger number of organisations that would need to be managed. By focusing on importers and manufacturers, the levy system would remain more straightforward and manageable, ensuring that those who introduce hazardous substances into the market bear the primary responsibility for the associated risks.

Next steps

50. We propose that further work be undertaken in the stage 2 CRIS to determine the circumstances for levy exemptions, including where and under which circumstances. We will also explore the exact proportions of the levy relating to fees.

51. We will undertake further consultation including the need to engage more widely and with different types of users of the HSNO system. During the consultation we will test how and where the levy revenue will be targeted within the HSNO system.

52. Given the issues identified within the current regulatory system, our design for the levy will be informed by working through a detailed model of the current application, emergency response and risk pathways with the EPA. Our key aim is to ensure this is tied to outcomes and ringfenced to HSNO regulatory system functions.

Previous consultation

53. From the 11 to 24 March 2025, MfE officials undertook a series of meetings with targeted stakeholders, with meetings geared towards either hazardous substances, new organisms or both. The participating stakeholders received a slide deck outlining the proposals amendments and these were discussed at each meeting. The following organisations took part in the targeted stakeholder engagement:

Table 1: Organisations taking part in targeted engagement		
Hazardous substances	New organisms	Both
Animal and Plant Health NZ (APHANZ) Federated Farmers Horticulture New Zealand A Lighter Touch	Manaaki Whenua Landcare Research Plant and Food Research AgResearch Scion New Zealand Plant Producers Incorporated	AgriZeroNZ Te Rūnanga o Ngāi Tahu (HSNO Kōmiti)

54. Many of the stakeholders consulted were part of the MfR Reference Group and were supportive of the recommendations from the review. MfE intend further consultation in the development of the Stage 2 CRIS to ensure all parties who may be affected by the levy will have the chance to provide their views.

55. Officials received a variety of feedback, both during the meetings and through written feedback following this. The major themes of the feedback were:
    i. **Regulatory efficiency, cost and transparency**: There was an emphasis on improving the EPA's application processing efficiency and ensuring transparency in performance reporting and the use of time waivers. There was some opposition to a potential levy, especially when the current application process efficiency was considered. However, not all organisations were opposed to the levy.
    ii. **Use of the international regulator assessments:** There was a desire for increased use of the current rapid international pathway. There was also concern that the conditional approval proposal lacked clear criteria.
    iii. **Statutory timeframes**: There was a desire for clear statutory timeframes in primary legislation. These should be of a reasonable timeframe and many stakeholders were interested in being involved through consultation.
    iv. **New organisms proposals**: There was generally positive feedback regarding these proposals, with some suggestions and concerns given around certain proposals.
    v. **Out of scope of the proposals: Precautionary approach and biopesticide pathway**: There were calls to review the precautionary approach, along with a call for joint reviews with international regulatory agencies. There was also a request for a specific biopesticide pathway.

56. Where possible we amended proposals to include the feedback received in the targeted consultation. This is noted in the companion regulatory impact statement to this CRIS. While some of the targeted stakeholders were supportive of the introduction of a levy, the

submission from Animal and Plant Health NZ (APHANZ) indicated their opposition to the introduction of a levy at the current time, especially if there was no opportunity for further engagement. Officials note it has not been determined whether the stakeholders represented by APHANZ would be subject to such a levy. Future work on the scope of a levy and the activities it may fund would be subject to further consultation with all parties regulated under the HSNO Act.

57. Officials note that some of the feedback received related to matters beyond the current proposals within the remit of the Omnibus Bill. As part of our next steps phase to develop the specifics of the levy, we will engage with industry and the public for feedback on the detailed design of the levy.

APPENDIX ONE: COMPARISION OF INTERNATIONAL EPA EXAMPLES

Country	Regulatory Body	Legislation/Framework	Levy/Fee Structure
Australia	Australian Industrial Chemicals Introduction Scheme (AICIS)	Industrial Chemicals Act	Annual levy based on the value of chemicals imported or manufactured. Registration charges vary by revenue levels.
	Australian Pesticides and Veterinary Medicines Authority (APVMA)	Agricultural and Veterinary Chemicals Code Act	Annual levy based on sales of registered products. Fees for registering new products and active constituents.
United States	Environmental Protection Agency (EPA)	Toxic Substances Control Act (TSCA)	Fees to cover up to 25% of the costs associated with TSCA activities. Examples include $16,000 for PMN, SNUN, and MCAN, and $1,350,000 for risk evaluation.
		Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	Fees for registering pesticides and annual maintenance fees. Examples include $830,274 for new active ingredient with food use and $4,875 for annual maintenance fee.
		Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)	Tax on the chemical and petroleum industries to fund the cleanup of hazardous waste sites.
European Union	European Chemicals Agency (ECHA)	REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals)	Fees based on the size of the company and the volume of the substance. Examples include 33,699 EUR for large company new registration (over 1,000 tonnes) and 54,100 EUR for authorisation application for a large company.
		Biocidal Products Regulation (BPR)	Fees for authorisation vary depending on the member state and the type of authorisation.
South Korea	Ministry of Environment	K-REACH (Korea REACH)	Registration fees for chemicals based on tonnage bands and hazard characteristics.
Canada	Environment and Climate Change Canada (ECCC)	Canadian Environmental Protection Act (CEPA)	Fees for new substance assessments, with a maximum fee of $4,021 CAD.
	Pest Management Regulatory Agency (PMRA)	Pest Control Products Act	Fees for pesticide registration and other regulatory activities, with a maximum fee of $258,867 CAD for complex applications.
United Kingdom	Health and Safety Executive (HSE)	REACH and Biocidal Products Regulation	Charges bespoke fees for chemical regulation services, including biocides and REACH authorisation. Examples include £25,000 for a single product authorisation and £160,000 for active substance approval.

Regulatory Impact Statement: Omnibus changes to the Hazardous Substances and New Organisms Act 1996

Decision sought	Agreement on the updates to the Hazardous Substances and New Organisms Act 1996. These changes will modernise the Act and align it with the recommendations from the Ministry for Regulation which were finalised in February 2025.
Agency responsible	Ministry for the Environment
Proposing Ministers	Minister for the Environment
Date finalised	6 May, 2025

BACKGROUND

In 2024, the Ministry for Regulation (MfR) reviewed the approval processes for agricultural and horticultural products under the ACVM and HSNO Acts due to sector concerns about limited access, lengthy and uncertain approval pathways, and regulatory complexity. The review found that while the systems manage risks well, they do not ensure timely access to products. It recommended 16 changes to improve efficiency, transparency, and certainty. The Government accepted these recommendations in March 2025 and plans to implement legislative amendments via an Omnibus Bill. If no changes are made, inefficiencies and delays will persist, harming competitiveness and innovation.

Executive Summary: Problem definition and options

What is the policy problem or opportunity?

The core policy issue is to make the existing two-system regulatory approval path for agricultural and horticultural products in New Zealand more efficient, timely, transparent, and certain, while maintaining effective risk management, supporting the primary industry sector's competitiveness and growth, and sustaining New Zealand's unique environment.

What is the policy objective?

The overall objective is to create a regulatory system for new organism and chemical substance approvals that balances fostering innovation, productivity, and competitiveness with effective risk management. The intended outcome is a modern and functional HSNO Act that supports regulatory stewardship. Success indicators include a transparent understanding of costs for applicants and the enforcement agency, fair cost distribution, reduced application timeframes, and encouraged competition, ensuring environmental protection while New Zealand consumers benefit from better prices and choices.

What policy options have been considered, including any alternatives to regulation?

The core policy issue is to improve the regulatory approval path for agricultural and horticultural products in New Zealand, while maintaining effective risk management. To address these challenges, several policy opportunities have been identified:

- Options for improving application processes
- Options to ensure the HSNO Act is clear and fit for purpose now and into the future
- Options for improved regulatory frameworks for compliance and enforcement

Improving application processes

Improving the efficiency and timeliness of the approval pathways is vital. Increasing efficiency and proportionality is another key area, which involves maximising the use of 'light-touch' pathways such as rapid pathways and group standards. Better using international regulators' assessments also provides an opportunity to improve efficiency.

Ensuring the HSNO Act is clear and fit for purpose now and into the future

Addressing regulator capacity and tools is important, and this includes reviewing HSNO cost recovery provisions and levy funding options. The proposals also incorporate changes required to ensure consistency with the treatment of non-genetically modified (GM) new organisms under the proposed new Gene Technology regime, legislative amendments to improve clarity relating to general functions and processes under HSNO, and minor and technical changes to streamline the Act.

Improved regulatory frameworks for compliance and enforcement

These proposed changes aim to strengthen the compliance and enforcement framework of the HSNO Act. By extending the timeframe for filing charges, granting the EPA assist and intervene powers, differentiating infringement fees, and clarifying the scope of reassessments, the amendments will enhance the regulatory system's ability to manage risks and ensure compliance. Reviewing emergency provisions under the HSNO Act will better enable the approval of products needed for biosecurity responses.

The substantial evidence presented through the MfR review, along with earlier reports such as the 2022 MartinJenkins report commissioned by the EPA and the 2023 Sapere report commissioned by MfE and the Treasury, indicates that regulatory intervention is necessary. While non-regulatory operational improvements can also contribute, they alone are insufficient to achieve the required improvements.

What consultation has been undertaken?

From the 11 to 24 March 2025, MfE officials undertook a series of meetings with targeted stakeholders, with meetings geared towards either hazardous substances, new organisms or both. The participating stakeholders received a slide deck outlining the proposals amendments and these were discussed at each meeting. The following organisations took part in the targeted stakeholder engagement:

Table 1: Organisations that took part in targeted engagement		
Hazardous substances	***New organisms***	***Both***
APHANZ Federated Farmers Horticulture New Zealand A Lighter Touch	Manaaki Whenua Landcare Research Plant and Food Research AgResearch Scion New Zealand Plant Producers Incorporated	AgriZeroNZ Te Runanga o Ngāi Tahu (HSNO Komiti)

Many of the stakeholders engaged were part of the MfR Reference Group which supported the MfR review. This meant they had prior knowledge and were generally supportive of the recommendations arising from the MfR review.

Officials received a variety of feedback, both during the meetings and afterwards via written feedback. The major themes of the feedback were:

i **Regulatory efficiency, cost and transparency**: There was an emphasis on improving the EPA's application processing efficiency, ensuring transparency in performance reporting and the use of time waivers. There was some opposition to a potential levy, especially when the current application process efficiency was considered. However, not all organisations were opposed to the levy.

i. **Use of the international regulator assessments:** There was a desire for increased use of the current rapid international pathway. There was also concern that the conditional approval proposal lacked clear criteria.

ii. **Statutory timeframes**: There was a desire for clear statutory timeframes in primary legislation. These should be of a reasonable timeframe and many stakeholders were interested in being involved through consultation.

iii. **New organisms proposals**: There was generally positive feedback regarding these proposals, with some suggestions and concerns given around certain proposals.

iv. **Out of scope of the proposals: Precautionary approach and biopesticide pathway**: There were calls to review the precautionary approach, along with a call for joint reviews with international regulatory agencies. There was also a request for a specific biopesticide pathway.

The feedback has allowed officials to understand the perspectives of key stakeholders, leading to adjustments in some proposals before finalisation to incorporate this input. Officials also acknowledge that some feedback addressed issues beyond the current proposals, which are focused on advancing the recommendations from the MfR review. This additional feedback will be valuable for any future amendments to the HSNO Act.

Is the preferred option in the Cabinet paper the same as preferred option in the RIS?

The preferred policy options outlined in the Cabinet paper align with those in this RIS, reflecting the outcomes and recommendations of the MfR review.

Summary: Minister's preferred option in the Cabinet paper

Costs (Core information)

The Environmental Protection Authority (EPA) will continue to undertake regulatory and compliance activities. The implementation costs of the proposed changes to the HSNO Act are primarily related to these activities, sourcing expertise, and managing application processing. The addition of enabling levy provisions will eventually allow the EPA to recover some costs from applicants, addressing the funding shortfall that has persisted since the 2017/18 year. The funding shortfall has posed risks to the delivery of regulatory services, which the levy aims to mitigate. The EPA needs to source the right expertise, particularly for complex scientific analysis. There is a global deficit in qualified ecotoxicologists, and New Zealand will be competing in this market. Mitigation strategies include partnering with agencies like the Tertiary Education Commission and Immigration New Zealand to train and recruit suitable candidates. These costs are necessary to address the EPA's funding challenges, improve regulatory efficiency, and ensure the EPA can continue to fulfil its responsibilities effectively.

Benefits (Core information)

The proposed changes to the HSNO Act are expected to provide substantial benefits for both the environment and industry. Environmentally, the changes will improve risk management, enhance biosecurity, ensure proactive environmental protection, increase transparency and accountability, align with international standards, use resources efficiently, and support sustainable practices. These improvements will help safeguard New Zealand's unique environment and promote sustainable development. For industry, the changes will improve efficiency, transparency, and predictability in the regulatory process, ensure financial stability for the EPA, support innovation and competitiveness, enhance strategic engagement, leverage international assessments, provide data protection for agrichemicals, and strengthen compliance and enforcement. These improvements will help the industry maintain its competitiveness and support sustainable growth.

Balance of benefits and costs (Core information)

Does the RIS indicate that the benefits of the Minister's preferred option are likely to outweigh the costs?

While there are costs associated with implementing the proposed changes, the long-term benefits to both the environment and industry are expected to be substantial. The improvements in regulatory efficiency, transparency, and effectiveness will support sustainable development and enhance New Zealand's competitiveness, making the investment worthwhile.

Implementation

How will the proposal be implemented, who will implement it, and what are the risks?

The proposed changes to the HSNO Act come with several implementation risks that need to be managed for successful implementation. One significant risk is sourcing the necessary expertise, particularly for complex scientific analysis, due to a global shortage of qualified

ecotoxicologists. To mitigate this, the EPA plans to partner with agencies like the Tertiary Education Commission and Immigration New Zealand to train and recruit suitable candidates and also consider active recruitment through international agencies.

Another risk is the potential backlog of applications. The introduction of a levy and fee increases may not immediately reduce the current backlog, as many applications will still be processed under the old fee schedules. To address this, the levy will be designed with clear and consistent goals and outcomes linked to the funding, and further engagement with stakeholders will be held as the Omnibus Bill progresses.

Stakeholder relationships could also be impacted by the levy, potentially leading to dissatisfaction and resistance. Engaging with stakeholders throughout the implementation process will be crucial to ensure transparency and address concerns. The levy will be designed to align with stakeholder expectations and regulatory goals.

Operational adjustments pose another risk, as the EPA and other regulatory bodies will need to adapt to new procedures and requirements, which may involve initial disruptions and learning curves. Providing training and support to staff will be essential to ensure a smooth transition to the new processes. The EPA board will monitor the implementation closely, with regular reports to the responsible Minister.

Financial stability is another concern. Ensuring the levy provides sufficient and stable funding for the EPA's regulatory functions without placing undue financial burden on the industry is critical. A thorough Cost Recovery Impact Statement (CRIS) will determine the specifics of the levy, including whether it will be full or partial, and regular reviews will ensure it meets the funding needs.

Public perception and acceptance of the changes are also important. Clear communication about the benefits and rationale behind the changes will help gain public and industry support. Highlighting the long-term benefits for both the environment and industry will be key.

Limitations and Constraints on Analysis

The analysis in this Regulatory Impact Statement (RIS) is constrained by several factors:

1. Previous Cabinet and ministerial decisions:
The recommendations from the MfR review have been a driving force behind this work. The Government accepted and agreed to implement all the recommendations of that review. The HSNO Act, however, covers a broader scope of hazardous substances than those just related to agriculture and horticulture. Without a comprehensive understanding, changes could lead to unintended consequences.

2. Pace of reform:
The Government aims to introduce these policy changes via an Omnibus Bill [redacted] This tight timeframe has limited the identification of options, the depth of analysis, the collation and review of evidence and data, and engagement with stakeholders. The urgency meant only targeted engagement with stakeholders was possible, and public consultation was not conducted. It also limited the ability to test final options with stakeholders.

Despite these limitations, officials believe that the Cabinet has sufficient information to make decisions. This confidence is based on the substantial amount of work undertaken for the MfR review and within MfE prior to the decision to proceed with changes via the Omnibus Bill. The groundwork laid by these efforts provides a foundation for informed decision-making, even within the constraints outlined.

I have read the Regulatory Impact Statement and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the preferred option.

Responsible Manager(s) signature: s 9(2)(a)

pp [redacted]

Glenn Wigley
General Manager, Waste and HSNO Policy, Ministry for the Environment
[Insert date]

Quality Assurance Statement	***[Note this isn't included in the four-page limit]***
Reviewing Agency:	**QA rating:** partially meets

Panel Comment: A quality assurance panel with members from the Ministry for the Environment, and the Ministry for Primary Industries have reviewed the Regulatory Impact Statement (RIS): 'Omnibus changes to the Hazardous Substances and New Organisms Act 1996'.

The Panel consider that the RIS 'partially meets' the criteria. Many of the proposals are detailed, well thought out, beneficial, and articulated in relation to the policy problem/opportunity. The current proposals were developed under significant time constraints. The authors are transparent about how this impacted their policy process, where relevant and appropriate.

However, given the significant breadth, depth, and complexity of the proposals, more analysis is needed on the effects of the entire package (including quantitative costs and benefits which were largely absent). Unintended consequences could not be fully explored at this stage. The Panel expects the major proposals will undergo further RIA which will require more detail.

Section 1: Diagnosing the policy problem

What is the context behind the policy problem and how is the status quo expected to develop?

1. In 2024 the Ministry for Regulation (MfR) conducted a regulatory review into the approval processes and pathways for agricultural and horticultural products under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM) and the Hazardous Substances and New Organisms Act 1996 (HSNO).
2. The review was prompted by significant concerns from the industry association representing chemical companies about the existing regulatory approval path for products such as feeds, fertilisers, veterinary medicines, pesticides, and environmental inhibitors. These concerns related to but were not limited to:
    - Limited and delayed access to essential products: New products are not being prioritised and facilitated within the current system, resulting in limited access to necessary tools for farmers and growers, impacting their export potential.
    - Uncertainty and time-consuming approval pathways: The approval process is often uncertain and lengthy, particularly within the EPA queue, making business planning challenging and exacerbating New Zealand's competitive disadvantage.
    - Delayed access to products that could support improved outcomes: This includes products that enhance biosecurity, animal welfare, productivity, and environmental performance.
    - Complexity of navigating the approval path across two regulatory systems (ACVM and HSNO): The split between these systems creates additional regulatory burdens for the industry.
    - Efficiency issues in the approval pathway: Including a perception there is insufficient use of international assessment information.
3. The approval pathways are complex as they are split across two distinct regulatory systems operating under the HSNO Act and the ACVM Act. The Ministry for the Environment (MfE) is responsible for the administration of the HSNO Act and the Ministry for Primary Industries (MPI) is responsible for the administration of the ACVM Act. The operational responsibilities lie with the Environmental Protection Authority (EPA) and New Zealand Food Safety (NZFS) respectively.
4. The MfR review concluded that while the regulatory systems are effective in managing risks to human, animal, and plant health, trade, agricultural security, and the environment, they do not consistently allow for efficient and timely access to these products.
5. The MfR review recommended 16 changes to improve the proportionality, efficiency, transparency, and certainty of the approval path. Two key suggestions were to establish a Sector Leaders Forum and to update the EPA's risk assessment models to enhance proportionate decision-making.
6. The Government accepted all 16 recommendations in March 2025 and agreed to implement legislative amendments via an Omnibus Bill.
7. The proposals set out in this paper relate solely to amendments to the HSNO Act.
8. If no changes are implemented, the current inefficiencies, complexities, and delays in the regulatory system are likely to persist, leading to continued competitive disadvantages,

limited innovation, potential environmental and biosecurity risks, and strained relationships between regulators and the regulated community.

What is the policy problem or opportunity?

9. The core policy issue is to make the existing two-system regulatory approval path for agricultural and horticultural products in New Zealand more efficient, timely, transparent, and certain, while maintaining effective risk management, thereby supporting the primary industry sector's competitiveness and growth.
10. The policy opportunities to address these problems and aim to improve the system, include:
    - Improving Efficiency and Timelines: Opportunities exist to improve the speed and certainty of the approval pathways.
    - Streamlining the Interface: Better coordination between the two regulators can make the system easier to navigate. Opportunities include combined guidance, sharing industry knowledge, technical expertise, aligning controls, and exploring options for joint pre-application meetings.
    - Increasing Efficiency and Proportionality: This involves maximising the use of 'light-touch' pathways like rapid pathways and group standards. Greater use of international regulators' assessments also presents an opportunity for efficiency.
    - Addressing Regulator Capacity and Tools: Opportunities include reviewing HSNO cost recovery provisions to ensure appropriate funding levels and considering options like annual levies. Investing in modern, fit-for-purpose risk assessment tools is also an opportunity.
    - Enhancing Strategic Direction and Engagement: Establishing a senior Sector Leaders Forum involving policy agencies, regulators, and stakeholders can improve transparency and facilitate strategic discussions. Opportunities also exist to improve more operational engagement and communication between regulators and regulated parties.
    - Reviewing Emergency Provisions: The emergency approval provisions under the HSNO Act could be reviewed to better enable the approval of products needed for biosecurity responses, as this pathway has not been effectively utilised.

What objectives are sought in relation to the policy problem?

11. The overall objective is for a regulatory system for new organism and chemical substance approvals that strikes the right balance between fostering innovation, productivity, and competitiveness on the one hand, and effectively managing the risks to people and the environment on the other.
12. The intended outcome from this work is to ensure a modern and functional HSNO Act which has reference to the broader legislative system and is an effective vehicle for regulatory stewardship.
13. Indicators of the success of this policy would be a transparent and clear understanding of relative costs for applicants and the enforcement agency, a fairer distribution of costs, reduced timeframes for some application types, and encouraging competition within the

means available to ensure the New Zealand consumer is not penalised by higher prices and limited choices.

What consultation has been undertaken?

14. Following approval from the Minister for the Environment, officials conducted targeted stakeholder engagement through a series of meetings over a two-week period in March 2025. Officials received feedback both during the meetings and afterwards through written feedback.
15. The following organisations took part in the targeted stakeholder engagement. Many of them had previously been engaged during the MfR review.
    i. Animal and Plant Health Association of New Zealand
    ii. Federated Farmers
    iii. Horticulture New Zealand
    iv. A Lighter Touch
    v. AgResearch
    vi. Manaaki Whenua Landcare Research
    vii. Plant and Food Research
    viii. Scion
    ix. New Zealand Plant Producers Incorporated
    x. AgriZeroNZ
    xi. Te Rūnanga o Ngāi Tahu HSNO Komiti

Section 2: Assessing options to address the policy problem

The criteria used to compare options to the status quo

16. The following four criteria will be used to assess the options: effectiveness, efficiency, alignment, implementation.
    i. **Effectiveness**: The extent to which the option achieves the objectives and provides a solution to the identified problem.
    ii. **Efficiency**: The extent to which the option is cost effective, and to which the proposal achieves the intended outcomes and objectives for the lowest cost burden to regulated parties, the regulator; and, where appropriate, the courts. The regulatory burden cost is proportionate to the anticipated benefits.
    iii. **Alignment**: The extent to which the option integrates well with other proposals and the wider statutory framework, is reducing complexity in the system and providing clarity for stakeholders and regulators.
    iv. **Implementation**: The extent to which the option is clear about implementation requirements by regulators and others and the ease of implementation. The extent to which the proposal results in implementation risks. The extent to which the proposal is implementable within reasonable timeframes.

What scope will options be considered within?

17. The scope of feasible options has been limited by several factors, including the commissioning and scope of the MfR review recommendations, and the agreement to introduce a Bill with these changes [redacted] Given the ongoing work to address other issues with the HSNO Act, this has resulted in legislative changes that implement the MfR review recommendations as well as other legislative and regulatory changes outside the review's scope but beneficial to the HSNO regulatory system. While the MfR review was the catalyst for these changes, MfE has adopted a broader approach, incorporating technical considerations, risk management through concurrent changes (including the Gene Technology regime changes), and closing compliance and enforcement loopholes that have emerged due to the age of the HSNO Act and its original context.

What options are being considered?

18. Several options were considered for each issue and assessed with both inter-agency considerations on the HSNO regime and the views of external stakeholders.

Policy issues to be addressed

19. We propose changes to address the following issues:
    1. Improving application processes
        1.1 Making greater use of the data and information from approved international regulators.
        1.2 Improving the application assessment pathways to better take account of risk and the extent of scientific assessment required.
        1.3 Enabling the establishment of a hazardous substances levy regime to assist with the regulatory administration of the hazardous substance system.
        1.4 Improving access to data protection for agrichemicals under the HSNO Act.
    2. Clarifying the Act to ensure intent is clear and fit for purpose now and into the future
        2.1 Improving access to emergency provisions.

2.2 Better aligning the new organisms regime under HSNO to work with the proposed new gene technology regime and other Acts.

3. Adopting improved regulatory frameworks for compliance and enforcement
   3.1 Making improvements to HSNO's compliance and enforcement regime
4. Addressing some minor and technical changes, which do not result in changes to the regulatory system but correct prior errors and update wording.

1 Improving application processes

(1.1) Making greater use of the data and information from approved international regulators

20. In New Zealand, approvals for hazardous substances, including agrichemicals, are granted in perpetuity, subject to an EPA reassessment. The EPA conducts comprehensive assessments to ensure that these substances are safe for use in the New Zealand environment. However, this process can be time-consuming, potentially delaying the introduction of beneficial new agrichemicals and creating a backlog of assessments.
21. The Rapid International Regulator Pathway was introduced in 2022 under section 28A(2)(ab) of the HSNO Act. This pathway was designed to streamline the assessment process for hazardous substances by allowing the EPA to rapidly assess the adverse effects of substances that have already been approved by international regulators.
22. The pathway includes specific restrictions to ensure that the rapid assessment process does not compromise the safety and wellbeing of New Zealand's unique environment and cultural heritage. While the use of the new pathway is still bedding in, there is a sense that its restrictions are overly cautious and that more use could be made of the new pathway without compromising our environment and cultural heritage.
23. Some applicants have suggested that the EPA's interpretation of the rapid pathway's 'significant effects test' is too stringent and that more substances could be assessed through the Rapid International Regulator Pathway.
24. The issue as we see it, however, is that it is unreasonable to expect that an application for a new active ingredient to New Zealand or a novel substance that has not been assessed here before, can be considered as not meeting the threshold for 'significance' and being processed via rapid pathway, which has a 10-day assessment period.
25. We have canvassed amendments aimed at addressing this issue, facilitating quicker access to novel, less hazardous agrichemicals in New Zealand, while ensuring that the EPA can still conduct thorough, New Zealand-specific assessments.
26. We have assessed two possible amendments against the status quo below that will work in tandem to provide the outcome to use more data from international regulators, which will in turn reduce the backlog of assessments and decrease processing time.

Options to Address the Issue

Option One – Status Quo – Continue to rely on existing approval pathways

27. Without changes, the backlog of applications for new substances is unlikely to decline and the time to process applications is unlikely to reduce. This does not meet the objective of the reforms.

Option Two – Clarify the significant effects test to make greater use of the existing international regulator rapid assessment pathway (recommended)

28. This option involves amending the wording of section 28A(6) to provide greater clarity and focus on New Zealand-specific considerations. The amendment would specify that the significant effects test applies only to effects that are unique to New Zealand and

have not been adequately addressed by equivalent international information. This would provide clearer direction for EPA decision-makers and support greater reliance on international data and assessments.

1. By clarifying the significant effects test, the EPA would be better positioned to rely on international modelling, data, and assessments, unless there are specific New Zealand circumstances that warrant a more detailed assessment. This approach aims to reduce application wait times and allow innovative products to enter the market more quickly.

29. The advantage is legislative intervention will provide the EPA with a firmer operating basis to rely more on international regulator information. This would in turn reduce the level of quantitative assessment required for some applications, freeing up resources for higher-risk assessments.
30. The main disadvantage is that some may consider it a "watering down" of the current provisions.

Option Three – Operational Changes

31. Clarify the Rapid Assessment Process: The EPA would develop and publish guidance to clarify the rapid assessment process under section 28A(2)(ab). This guidance would outline how the EPA will evaluate applications using international data and assessments, and how it will determine whether an application is suitable for the rapid pathway.
32. Adjust Approach to Significant Effects: The EPA would adjust its approach to how it currently considers ‘significant effects’ under section 28A(6).
33. Develop Guidance for Applicants: The EPA would provide detailed guidance for applicants on the requirements for using the rapid pathway. This guidance would explain how applicants can demonstrate that their substance has been authorised by an international regulator and how they can provide the necessary information to support their application. It would also clarify the specific assessments needed to address New Zealand-specific risks.
34. The key advantage of this approach is that legislative change is not required. The disadvantages are the potential for push-back and legal risks from a less expansive interpretation of ‘significant effects’ and that operational changes alone may not clear the current backlog of applications for processing.

Option Four – A new approval pathway - time limited conditional approvals for agrichemicals (recommended)

35. This amendment would allow for conditional approvals of certain agrichemicals that have been approved by at least two recognised international regulators. This conditional approval would enable these substances to enter the New Zealand market more quickly, provided they meet specific criteria, and the EPA can manage the associated risks.
36. As noted above, it is not reasonable to expect that a new active ingredient or novel substance can be assessed under the rapid approval pathway, in 10 days, and be given a permanent and enduring approval. This new pathway would allow for qualifying substances to be approved for use, with conditions, for a limited time while the full assessment is being completed.

37. The conditional approval process would be limited to agrichemicals, as these are most applications involving new active ingredients. Agrichemicals are also the subset of hazardous substances where international assessments cover most of the necessary risk compartments.
38. The EPA would issue guidance on the implementation of the conditional approval scheme. Applicants would need to submit a complete application for the agrichemical, including a statutory declaration and evidence of approval by international regulators. The EPA would have the discretion to grant conditional approvals based on the criteria set out in the Act.
39. The proposed amendment aims to balance the need for thorough risk assessments with the benefits of quicker access to innovative agrichemicals. This could lead to economic benefits for farmers and growers, encourage the use of less hazardous substances, and make better use of information from international regulators.
40. There are inherent risks in allowing substances into New Zealand without a full assessment. The proposal could be criticised for potentially insufficient risk management and the perception of double-handling with two separate approval processes. Additionally, conditional approval does not guarantee full approval, which may create uncertainty for applicants.

How do the options compare to the status quo/counterfactual?

	Option One – Status quo (no changes to HSNO Act)	Option Two – Amending section 28A(6) to make greater use of existing international regulator rapid assessment pathway	Option Three – Operational Changes	Option Four – A new approval pathway - time limited conditional approvals for agrichemicals
Effective	0	+	+	++
Efficiency	0	+	0	+
Alignment	0	+	0	+
Implementation	0	+	+	0
Overall assessment	0	++	+	++

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

41. Both Option 2 (Clarify the significant effects test) and Option 4 (A new approval pathway - time limited conditional approvals for agrichemicals) are our preferred options. Both options are designed to work together to achieve a balance between efficiency and thorough risk assessment for hazardous substance applications while ensuring that New Zealand-specific risks are adequately managed.
42. They will achieve the objectives of allowing the EPA to better utilise international data and assessments and streamline the existing approval process. Option 4 will enable qualified innovative products to be brought to the New Zealand market more quickly but still provide the rigor of a full assessment.

(1.2) Improving the application assessment pathways to better take account of risk and the extent of scientific assessment required.

43. The current statutory timeframes set out in section 59 of the HSNO Act present several significant issues that impact the efficiency and effectiveness of the application assessment process. These issues include:
    - Inadequate Time for Complex Applications: The statutory time limits do not provide the Environmental Protection Authority (EPA) with sufficient time to appropriately assess applications, particularly those that are complex and require quantitative risk assessment.
    - Uniform Application of Time Limits: The time limits apply uniformly to all application types, without accounting for differences in complexity or risk. This one-size-fits-all approach fails to recognise that some applications are more complex and require more time for a comprehensive assessment.
    - Outdated and Incomplete Process Steps: Section 59 prescribes certain process steps for assessing applications, but these steps do not cover the entire assessment process. Additionally, the prescribed steps do not reflect best practices or align with the processes of other international regulators. This misalignment can lead to inefficiencies and inconsistencies in the assessment process.
    - Unrealistic Expectations and Operational Challenges: The current time limits create unrealistic expectations for applicants, who may anticipate quicker decisions than what is feasible given the complexity of their applications. This discrepancy can lead to dissatisfaction and frustration among applicants. These unrealistic timeframes create operational challenges for the EPA.
    - Lack of Specific Timeframes for All Processes: Not all processes within the application assessment are assigned specific timeframes. For instance, there is no statutory completeness step to determine if an application is administratively complete before the assessment begins. This omission can lead to delays and ambiguities in the process.
    - International Comparisons: When compared to international regulators, the statutory timeframes under the HSNO Act are significantly shorter and less flexible. For example, the Australian Pesticides and Veterinary Medicines Authority (APVMA) has 18-25 months to complete its evaluation of a product with a new active ingredient, whereas the EPA has only 100 working days for a similar application. This discrepancy highlights the need for more realistic and internationally aligned timeframes.
    - Reliance on Time Waivers: To manage the unrealistic statutory timeframes, the EPA often relies on time waivers issued under section 59(4) of the HSNO Act. While these waivers provide some flexibility, they also create uncertainty for applicants regarding the timing of decisions. This reliance on waivers indicates that the current timeframes are not workable and need to be revised.

Options to Address the Issue

44. To address the identified issues, several options have been proposed. These options aim to improve the process steps for assessing applications, introduce additional application types to account for differences in complexity, set more appropriate statutory time limits, and ensure alignment with international best practices. The key options are:
    - Formalise the existing non-statutory categories into the HSNO Act to provide separate pathways for each type of application based on complexity and risk.
    - Improve the process steps to include:
        - A completeness check: Introduce a statutory step for determining the administrative completeness of an application.
        - An assessment step: Clearly define a statutory step for the EPA to undertake its assessment of an application.
    - Set Statutory Time Limits for Each Application Type
        - The options being either Step-by-Step timeframes with prescribed statutory time limits for the completion of each process step, or End-to-End timeframes, with a single end-to-end statutory time limit for the entire process from application lodgement to decision notification. Or to use a combination of step-by-step and end-to-end timeframes, with specific time limits for certain steps and an overall timeframe for others.
    - The legislative options are to:
        - Amend section 59 of the HSNO Act to include the new time limits and process steps.
        - Create a schedule within the HSNO Act that can be amended via an Order in Council process.
        - Set the time limits and process steps in regulations, which can be amended more easily than the Act itself.
        - Allow the EPA to issue and amend the time limits and process steps via an EPA notice.

<u>Option One – Status Quo</u>

45. No changes. Applications for the full assessment pathway continue to use non-statutory operational categories.

<u>Option Two – Formalise existing non-statutory processing categories</u>

46. Formalise the EPA's current non-statutory processing categories in legislation, as a risk-tiering framework consistent with comparable international regulators, including having timeframes that vary with the degree of complexity and risk.
47. Applications will be categorised based on potential risk to human health and the environment, similarity to already approved substances, and the extent of scientific assessment required. For example, a substance with a new active ingredient to New Zealand poses the greatest risk and workload for the EPA, taking longer to assess than a reformulation of an already approved product.
48. To ensure clarity and transparency in processing times, we propose amending s 59 of the HSNO Act to include an enabling provision for setting regulations that specify the process steps and overall timeframes for each application type. Regulations offer the

right balance of oversight, accountability, and flexibility for adjusting timeframes. Aligning these timeframes with proposed changes to the ACVM Act could allow for joint consultation, enabling stakeholders to comment on the end-to-end timeframe of both regulatory regimes.

49. The regulations will include provisions for:
    - Determining application completeness and returning incomplete applications.
    - Time waivers and stop-the-clock provisions.
    - Process steps for applications, including substantive assessment before public notification.
    - Public notification and hearing requirements for certain application types.
    - Clarifying when an application lapses and can be treated as withdrawn.
    - These new application categories and associated timeframes will take effect once the regulations are enacted. Until then, transitional provisions may be needed to maintain the status quo. Consequential changes to existing HSNO Act provisions related to process steps and timeframes contingent on the proposed regulations will also be required
50. We have assessed two possible amendments against the status quo below that will work in tandem to increase transparency and trust in this process.

Option Three – Set Statutory Time Limits for Each Application Type

51. When considering the statutory timeframes for the assessment of applications under the HSNO Act, two primary approaches can be taken: step-by-step timeframes and end-to-end timeframes. Each approach has its own set of advantages and disadvantages.
52. Step-by-step timeframes provide maximum visibility to applicants regarding the progress of their application. Each step in the process has a clear deadline, allowing applicants to track their application's status and understand where it stands at any given time.
53. By setting clear deadlines for each step, step-by-step timeframes increase accountability for the EPA. The agency must meet multiple milestones throughout the application process, ensuring that each part of the assessment is completed in a timely manner.
54. This predictability allows applicants to plan accordingly and have realistic expectations about when they will receive a decision.
55. The disadvantage of the step-by-step timeframe, however, is that its rigidity could be challenging when dealing with particularly complex or unique applications. It provides less flexibility for the EPA to manage the application process.
56. Managing multiple deadlines for each step of the process can be administratively complex. It requires tools and systems to monitor progress and ensure compliance with the various deadlines. Setting appropriate timeframes for each step could also be challenging, as it requires a deep understanding of the time needed for different types of applications.
57. End-to-end timeframes provide greater flexibility for the EPA to manage the application process within a single overall time limit. This would allow the agency to allocate time

as needed across different steps, accommodating unexpected complexities or additional information requirements, and would be particularly useful for complex applications that may require more time for certain parts of the assessment.

58. Having a single end-to-end timeframe simplifies the administrative process. There is no need to monitor multiple deadlines, reducing the administrative burden on the EPA. This streamlined approach would make it easier to manage the overall process and ensure that applications are assessed efficiently.
59. Without clear milestones, however, there is less accountability for the EPA to meet specific deadlines throughout the application process. End-to-end timeframes provide less visibility to applicants regarding the progress of their application. Without clear milestones, it can be harder for applicants to track the status of their application and understand where delays may occur.
60. A combination approach of step by step and end to end balances the need for clear expectations with the flexibility for the EPA to manage the process. It allows for statutory time limits for certain critical steps while providing an overall end-to-end timeframe for other parts of the process.
61. This approach can also accommodate different types of applications and their varying complexities. It enables a tailored approach that can be adjusted based on the unique requirements of each application.
62. Implementing a combination approach will require careful design and clear guidance. It may still require significant administrative effort to monitor and manage both step-by-step and end-to-end timeframes.

Option Four – Legislative options

63. Implementing new pathways and statutory time limits by amendments to the HSNO Act would provide clarity and transparency sooner than other options as changes will be incorporated into the Bill. Proceeding like this was also the preferred option of some stakeholders as it provides the high level of accountability of the parliamentary process.
64. However, this option would provide no time to consider all the aspects needed to identify appropriate timeframes and consult with stakeholders on the timeframes themselves, outside the Select Committee process. There is also a risk that statutory timeframes might be implemented that are not reasonable or achievable as there would be insufficient time to benchmark against comparable regulators or current and historical performance. This would undermine the intent of the amendment.
65. Additionally, there would only be limited time to sufficiently consider the impact of the timeframe changes on other applications under the HSNO Act (e.g. hazardous substances reassessments and new organism applications). It would also not align with proposed changes to the ACVM Act (to have statutory timeframes in regulations) and could be seen as undermining the intent of the MfR recommendations to make the two regulatory systems easier to navigate.
66. Implementation by way of secondary legislation would not only allow time to consider the timeframes carefully and carry out meaningful consultation but also allow stakeholders to take part in setting timeframes, which was their preference.

67. This option is also consistent with MPI's proposal to remove statutory timeframes from the ACVM Act and place them in regulations. If that proposal is maintained, a joint consultation with MPI could be undertaken, covering the timeframes across the two regimes.
68. It also aligns with multiple recommendations from the MfR review in making the two regulatory regimes (HSNO and ACVM) more aligned, more transparent and easier to navigate.
69. Regulations are subject to sufficiently high-level decision making which should meet stakeholders' desire for accountability. The regulations are subject to scrutiny by the Regulations Review Committee[1].
70. Additionally, it is easier to update regulations than primary legislation and allows time to fully consider whether changes to hazardous substances statutory timeframes would negatively impact other application types under the HSNO Act.
71. However, this option may take another 12 – 18 months to implement, but work can progress alongside the passage of the Bill.
72. EPA Notices are secondary legislation, requiring consultation and tabling in Parliament. They are also subject to scrutiny by the Regulations Review Committee.
73. While EPA Notices are issued and/or updated by the EPA Board rather than needing to go through a Cabinet process, they are still required to be publicly consulted on, which allows stakeholders to be part of the process.
74. This option would make it easier and quicker to amend timeframes in future if expectations, technological or scientific advancements, or types of applications change.
75. One disadvantage of this option is that the process of setting the timeframes may not provide the level of accountability, or perception of accountability, expected of the EPA, as noted by the lack of support of this approach by industry stakeholders.

(1.3) Enabling the establishment of a hazardous substances levy regime to assist with the regulatory administration of the hazardous substance system

76. Since 2017, the hazardous substances and new organisms (HSNO) area of the Environmental Protection Authority (EPA) has struggled to fully recover its costs. Currently, the EPA is approximately 90% funded by the Crown, with around 18% of its total budget allocated to the HSNO area. Despite this funding, the regulatory system is under significant strain, as evidenced by reports from Sapere, MartinJenkins, and the Ministry for the Environment (MfE).
77. One clear indicator of this strain is the backlog of applications being processed by the EPA. Although the EPA is recognised internationally for its efficiency, industry bodies have raised concerns, particularly in light of fee increases in 2018 and 2023. These bodies expect that the increased fees should correlate with material improvements in the application process.
78. Training new staff to accurately assess HSNO applications takes approximately four months, not including the time needed to acquire specialist knowledge or advice. The cost of processing these applications is a major driver of the current challenges. Some

[1] https://www.parliament.nz/en/pb/sc/scl/regulations-review/

applications involve reviewing up to 800 separate pieces of scientific literature, yet the fees charged by the EPA only cover about 10-15% of the actual costs.

79. To address the financial shortfall, the EPA has increased its fees. However, these increases have not kept pace with the rising costs of processing applications. The scope of the EPA's regulatory responsibilities is also set to expand with the proposed introduction of functions under the Gene Technology Bill, which, although separately funded, will add to the overall burden on the EPA.
80. This issue is particularly pressing given the Minister's expectations for faster and more efficient processing of applications, recommendations around risk appetite within the EPA, and current gaps in the regulatory system regarding tools, efficiency development, and resourcing. To address these financial discrepancies, the MfE, with the agreement of the EPA, is considering the introduction of a levy.
81. The proposed levy would create a new revenue stream specifically for the EPA's hazardous substances and new organisms functions. During targeted engagement, some parties supported the levy, while others, such as Animal and Plant Health NZ (APHANZ), opposed it, particularly if there was no opportunity for further engagement.
82. In determining who should bear the costs, the activities required to deliver on the HSNO functions were assessed against the Treasury framework, considering whether the activities are excludable and rivalrous. The assessment aligns with approaches taken by other agencies such as the Ministry for Primary Industries (MPI), the Ministry of Business, Innovation and Employment (MBIE), transport Crown entities, and the New Zealand Customs Service.
83. Most of the EPA's services are considered 'club goods,' meaning they provide public benefits without being rivalrous. For example, mitigating the effects of hazardous substances and new organisms benefits the environment and human health without excluding others from enjoying these benefits. Similarly, the EPA's engagement in educating and providing information to importers and suppliers of HSNO substances is non-rivalrous.
84. However, there is a 'private good' component, particularly in the application of Group Standards. Approximately 30,000 chemicals, contained in over 150,000 hazardous substances, are approved for use in New Zealand, with around 3,700 having individual approvals. Most domestic and workplace chemicals are covered by about 210 group standards, which the EPA is responsible for. Many of these approvals date back to the 1960s, leading to a free rider effect where a significant part of the chemical industry does not pay for regulation costs, creating an asymmetry between those who pay and those who do not.
85. In summary, the EPA faces significant financial and operational challenges in the HSNO area. The proposed levy regime aims to address these challenges by providing a dedicated revenue stream, ensuring that the EPA can continue to fulfil its regulatory responsibilities effectively and efficiently.

<u>Option One – Status Quo – EPA remains reliant on Crown Funding and Fees</u>

86. Currently there is no levy in place and there are no provisions within the HSNO Act to provide for a levy. It is likely that the fees will be increased to attempt to meet this shortfall; however, given the discrepancy between the fees charged and the cost of the

service, this is unlikely. The consequence of this is that the HSNO system's responsiveness and resilience will continue to downgrade. Given New Zealand's small market size there is also a realistic limit to how much the fee can be increased.

Option Two – Create enabling provisions for a levy in the HSNO (recommended)

87. In creating these provisions which will be ringfenced to HSNO functions within the EPA, this will allow surety for the EPA to develop resources and tools. In referring to both the MartinJenkins and Sapere reports we believe a levy is the most likely and appropriate approach to addressing the ongoing funding issue. Our Stage 2 CRIS will address whether this is a full or partial levy.

Option Three – Defer creating a levy until further evidence is gathered

88. The body of evidence created indicates that a levy is necessary to the effective ongoing resourcing, tools and functions. Both the reports about the need for a levy have been clear there is an ongoing risk to the overall regulatory system's ability to deliver on expectations and requirements. For these reasons we do not believe there is a case for deferring the levy, however we have yet to determine the period over which the levy will run before review, the specifics of how the levy will be applied to ensure the polluter pays principle, and whether this will be a full or partial levy.

How do the options compare to the status quo/counterfactual?

	Option One – Status quo (no changes to HSNO Act)	Option Two – Enabling provisions for the levy	Option Three – Defer creating a levy
Effective	-	++	-
Efficiency	-	+	+
Alignment	+	0	-
Implementation	+	+	-
Overall assessment	--	++	-

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

89. Option two: Based on the current available evidence MfE believe that introducing enabling provisions for a levy is the best and most efficient way to address the opportunity presented via the proposed Omnibus bill.

(1.4) Improving access to data protection for agrichemicals under the HSNO Act

90. Data protection is a provision within the ACVM Act (sections 74 – 74H), which encourages companies to register innovative products in New Zealand by granting companies an exclusive period of time in the market (either 5 or 10 years) prior to other products containing the same chemistry (or for the same crops or use profile) being allowed.
91. Industry have expressed that they would like to see similar data protection provisions in the HSNO Act. The HSNO Act currently contains a provision (section 55) that any data

protection afforded under the ACVM Act will be recognised under the HSNO Act. However, this provision only applies to substances that are regulated under both the ACVM and HSNO Acts, which means that some types of substances, such as home use pesticides and those used in forestry are not eligible for stand-alone data protection.

92. Some stakeholders are concerned that the current time limits on data protection are not sufficiently long, and that HSNO leaves substances which are not covered by ACVM and the Medicines Acts unprotected.
93. In its review, MfR noted that applicants who want data protection must first apply for an ACVM approval, before lodging an application under the HSNO Act. This results in:
94. incomplete applications being delivered to ACVM so data protection through HSNO can be obtained and a place in the EPA queue can be secured; or
95. applications to the EPA being delayed until their full application package is ready, thereby missing the opportunity for the EPA to begin their assessment.
96. We are proposing two possible options for data protection, in addition to the status quo. While there may be value in investigating another option at a later date, to include stand-alone data protection provisions under the HSNO Act, including for substances that do not require approval under the ACVM Act, the lack of a sufficient problem definition and the uncertain scope of the issue precludes broader amendments being proposed at this time. There are also significant international implications with using the HSNO Act to enact data protection provisions. Extending data protection beyond ACVM registrations would engage wider economic and anti-competition issues, which require analysis beyond the scope of this Omnibus Bill.
97. The options are not mutually exclusive, so both could be progressed. If Option two is progressed, this will inherently require some degree of Option three to also be undertaken during implementation.

Option One – Status Quo

98. Retaining the status quo would mean that no changes to data protection provisions are made. The risk here is that some industry representatives would not be supportive of this continued state.

Option Two – Amend HSNO Act to grant access to data protection regardless of prior application to ACVM (recommended)

99. This option would remove the restriction in section 55(4) of the HSNO Act that requires an application for an innovative Trade Name Product to first be lodged under the ACVM Act in order for the data protection provisions in Part 6 of the ACVM Act to apply. This will give applicants clarity that the data protection provisions will apply regardless of the sequence in which the applications are lodged. Officials believe that going further under the provisions of the HSNO Act is out of scope.

Option Three – Operational changes

100. This option would make the ACVM and HSNO regulatory systems easier to navigate, including providing guidance on how to obtain data protection through both regulators under the existing provisions, by implementing operational changes.

101. This option would be consistent with Recommendation 4 of the MfR review to provide more guidance on data protection through both the HSNO and ACVM Acts.

How do the options compare to the status quo/counterfactual?

	Option One – Status quo (no changes to HSNO Act)	Option Two – Amend HSNO Act	Option Three – Operational changes
Effective	0	++	+
Efficiency	0	++	+
Alignment	0	+	+
Implementation	0	+	++
Overall assessment	0	++	+

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

102. Option two would not only address the problem and meet the policy objectives by improving ease of access to data protection but would also provide the most clarity for all stakeholders.

2 Clarifying the HSNO Act to ensure the intent is clear and fit for purpose now and into the future

(2.1) Improving access to emergency provisions

103. The Ministry for Regulation's regulatory review of the approval processes for agricultural and horticultural products noted emergency approval provisions under the HSNO Act have not been utilised since 2013, indicating there may be barriers to their use. Between 2006 and 2013 there had been 10 section 49B special emergency applications approved, and no section 47 emergency approvals.
104. The HSNO Act has two kinds of approvals that can be used to access hazardous substances and new organisms in emergency situations – S47 Emergency Approvals and S49B Special Emergency Approvals. Emergency approvals are used to get pre-approval to import and use a hazardous substance or new organism when an emergency situation arises. Special emergency approvals are used to respond to adverse events when other options are not available, with a declaration of emergency from the relevant Minister.
105. Emergency approvals can facilitate access to products that would otherwise not be approved for a full release approval, managing this risk by being more targeted in the scope of use, and justifying any residual risk through the emergency nature of the situation it is being used in.
106. While investigating the potential legislative barriers to utilising emergency provisions the following issues were identified:

107. Existing provisions are unclear in their use and intent, leading to difficulties applying them in emergency situations. The terms 'emergency' and 'special emergency' do not accurately reflect their intended use. There is also limited guidance for their use.
108. Section 47 emergency approvals for biosecurity responses are very narrow in scope and do not enable their use for the variety of emergency situations that can occur in the biosecurity system. The only situations eligible for emergency approval are those involving the release of a new organism subject to a National Pest Management Plan. National Pest Management Plans are not well adopted and are not used throughout the biosecurity system, leading to 49B special emergency approvals being used instead, which have less regulatory oversight and lower requirements for consultation.
109. Section 47 and 49B emergency approvals require an emergency to be declared before they can be used. This can be a disproportionate requirement that limits their use in situations that are not emergencies yet but have the potential to become one if not addressed quickly. There is also an issue with the existing provision where a declaration of emergency is required to use an emergency approval, but some of the situations eligible for an emergency approval have no statutory mechanism for an emergency to be declared.

Option One – Status Quo

110. No changes. Emergencies and biosecurity responses that would justify the use of a niche product may not have access.

Option Two – Legislative and operational improvements to promote clarity and ease of use (recommended)

111. Operational policy providing detail and guidance on the role and process for different emergency provisions would empower Ministers and government organisations in utilising these provisions when needed and appropriate.
112. Section 47 and section 49B emergency provisions would be renamed to more accurately reflect their intent and use.
113. S48(2)(a) would be amended to only require an emergency declaration when relevant.
114. These actions would facilitate the use of emergency provisions by improving clarity around procedure and risk and ensure the intent and purpose of the provisions is communicated clearly.

Option Three – Legislative amendments to facilitate use of s47 emergency provisions (recommended)

115. This option would extend and expand section 47 emergency approval provisions to apply to biosecurity response activities, including National and Regional Pest and Pathway Management Plans, Biosecurity Emergencies, detections of pests through surveillance activities, and border activities.
116. This would enable MPI to include pre-approval of agricultural and horticultural products as part of their response planning. Pre-approval can be given for the use of hazardous substances and new organisms when pests are detected, promoting a proactive biosecurity system and ensuring appropriate treatments and tools are available when emergencies arise.

Option Four – Legislative amendments to facilitate use of s49B special emergency provisions

117. This option would reduce the level of decision-making of special emergency provisions to the head of the relevant authority, for instance the Director-General of MPI. Currently the requirement to have the Minister declare a special emergency is seen as a barrier to its use, making a technical decision into more of a political one. A Ministerial decision also takes longer, which can be critical in an emergency situation. By reducing the level of decision making to the head of the relevant authority, decisions could be made faster and with responsibility held by the technical decision makers.

Option Five – Remove the requirement to publicly notify s47 emergency approvals and rely on the public interest test

118. This would involve amending the requirement to publicly notify only when there is likely to be significant public interest (move from section 53(1) to section 53(2)). This is to enable approvals for minor foreseeable situations as public notification and hearings can significantly delay application processing. Some emergency applications could be very narrow in scope and public notification would apply a disproportionate cost.

How do the options compare to the status quo/counterfactual?

	Option One – Status quo	Option Two – Legislative and operational improvements	Option Three – Amendments to s47 provisions	Option Four – Amendments to s49B provisions	Option Five – Reduce requirement to publicly notify
Effective	0	+	+	0	+
Efficiency	0	++	+	+	+
Alignment	0	+	+	-	-
Implementation	0	-	+	-	--
Overall assessment	0	+	+	-	-

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

119. A combination of both options two and three would most likely address the issues identified and meet the policy objectives of improving clarity and usability of emergency provisions in the HSNO Act, improving access to emergency provisions for agricultural and horticultural products, and maintaining appropriate levels of decision-making and consultation.
120. Option two would provide cost-effective benefits with minimal intervention required. The development of operational policy and guidance would also potentially support future amendments after non-legislative options have been pursued.
121. Option three would provide quality of life improvements and appropriate expansion of access to emergency provisions for biosecurity that are proportionate to the scope of

the issue identified. Issues such as the requirement to declare an emergency to use the provisions are an oversight with the original design and a barrier to their use, while an expansion of the eligibility of biosecurity responses would allow pre-approval of substances as part of wider readiness and response programme which identifies and plans for incoming biosecurity threats.

122. Option four is discarded because Special Emergency approvals are very broad and enabling, intended to address the range of emergency situations that cannot be anticipated. This breadth of application is balanced by the requirement for a Minister to declare a special emergency, making it suited to only being used in situations that warrant an emergency response.

123. Option five is discarded because the evidence of a need for change is not strong and does not justify changes to both expand the scope of eligibility for emergency applications and reduce the public's ability to participate in the application process. Additionally, the ability of the public to provide additional information for consideration is more important for emergency approvals, as they have a lower bar for information required and cannot be declined based on a lack of information.

(2.2) Better aligning the new organisms regime under HSNO to work with the new gene technology regime and other Acts

2.2.1 Making the enforcement of New Organisms easier

124. MPI is the enforcement agency of the new organisms regime and will be the enforcement agency of the Gene Technology Bill. The current wording of the HSNO Act with regards to the responsible enforcement agency is different from the proposed wording in the Gene Technology Bill, which could put a perceived expectation on MPI for different enforcement between the two regimes.
125. There is no specific provision in the Act for information sharing between MPI and the EPA like there is for hazardous substances and its relevant authorities. This can be an issue when MPI needs to make a non-statutory determination as to whether an organism is a new organism and therefore warrant compliance action.
126. Finally, there are currently regulations in force regarding how MPI must conduct their enforcement actions, including forms, that are no longer required or fit for purpose.

Option One – Status Quo (No changes to the HSNO Act)

127. No action taken. MPI's enforcement activities will not be prioritised efficiently between portfolios, and information will be shared between EPA and MPI on an ad hoc basis with little guidance or support.

Option Two – Operational improvements

128. Agreements and guidance are developed to facilitate information sharing but with no legislative foundation. Guidance would clarify the relationship between MPI's different enforcement responsibilities but there would be legal risk when prioritising as the different legislation is not aligned. Regulations would still exist and would likely remain unused.

Option Three – Legislative amendment

129. MPI will be provided with the information sharing provisions that exist for hazardous substances, supporting collaboration and robust decision making when undertaking enforcement activities.
130. MPI will remain the responsible agency for enforcement, but modern legislative wording to align with wording in the Gene Technology Bill will clarify their role and expectations. Regulations that are no longer necessary or useful will be removed.

How do the options compare to the status quo/counterfactual?

	Option One – Status quo (no changes to HSNO Act)	Option Two – Operational improvements	Option Three – Legislative amendment
Effective	0	+	++
Efficiency	0	-	++
Alignment	0	+	++
Implementation	0	+	+
Overall assessment	0	+	++

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

131. Options one and two are unlikely to achieve the policy objectives. While better guidance and operational processes could help clarify the issues, there will still be legal uncertainty when sharing information or prioritising activities to avoid this risk.
132. Option three is most likely to reduce legislative barriers to the enforcement of new organisms and ensure the enforcement resources can be allocated appropriately. Information sharing provisions will reduce barriers to cooperation between EPA and MPI and enable more robust decision-making. Improved clarity and alignment of enforcement responsibilities will aid allocation of resources between enforcement portfolios and reduce legislative barriers and legal risk when doing so.

2.2.2 Making it easier to determine whether an organism is new and to change the status of organisms

133. The decision-making criteria in the Act do not enable a new organism determination to be made based how common an organism is i.e. the presence of the same organism in similar environments across the world, or that the organism is otherwise 'new to science'. For example, newly discovered geothermal microbes or fish species discovered within New Zealand's Exclusive Economic Zone. Only those that are new are regulated but even 'not-new' organisms may need a determination to establish that they are not regulated. The new organism regime in New Zealand relies on identifying whether an organism is a new organism. Currently there are administrative burdens making it difficult to identify which taxonomic level of organisms a decision should be made for.
134. Currently there is a significant cost and administrative barrier to changing the status of an organism, requiring an Order in Council. EPA only run the process for this on an ad hoc basis with no clear criteria or timeframe. This creates a delay for users who need a determination before they can import, develop or research an organism. It is often important to ensure that organisms are being regulated appropriately but currently the cost of changing an organism's status limits this.
135. Under the HSNO Act grounds for reassessment must be found before an approval can be reassessed. While there are criteria to reassess a hazardous substance approval, the only criteria available to reassess a new organism approval is if there is significant new information relating to the effects of the organism.

136. Much of the design decisions that resulted in these issues were due to the regulation of GMOs by the Act. A lower level of decision making was restricted in line with constraints related to GMOs, which is no longer relevant. With the removal of GMO's, decision on applications can be delegated to the Chief Executive or an EPA Staff member. Extending the delegation provisions will reduce time and cost for applicants without affecting risk to people or the environment.

Option One – Status Quo

137. No changes made to legislation. Applications are for denewing[2], prescribing risk species [3] and, determinations continue to use existing regulations and will require a high level of decision making. Current provisions do not allow for determination criteria to be bundled together when required. This makes it harder to remove unnecessary legal restrictions on an organism already established in New Zealand.

Option Two – Reducing the decision making to the Minister

138. This option requires that we keep Section 26 (determination of a new organism) the same but make denewing and prescribing risk species a Minister decision. This would remove Cabinet approval and an Order in Council from the decision-making process, making it more time efficient and lowering the cost. Minister decision will still take longer compared to an application processed under Part 5 of the Act with the decision maker being the HSNO Committee.

Option Three – Make denewing and prescribing risk species an EPA notice

139. Revoke two existing regulations (one for organisms prescribed as Not New Organisms and the other for Risk species) and create an EPA notice instead. Creating an EPA notice would be a faster process and less administrative. However, to denew an organism is a technical decision more suited to a HSNO decision making committee. The regulations would remain as they do not interfere with the proposed changes to denewing.

Option Four – Amend s26 and lower decision making for denewing

140. Changing the denewing and prescribing risk species from a decision under Order in Council to HSNO decision making committee. This improvement will make the process quicker and more efficient and allows for a level of decision making in line with other decisions on new organisms.
141. The Minister would still have the option of exercising their call-in powers for applications that have high public interest or potential significant effects under Section 68 of the HSNO Act. Call-in is a power that is only expected to be used in exceptional circumstances if the Minister decides a more expert panel is required.
142. Removing the requirement for denewed organisms to be gazetted was considered. However, to ensure that there is an official govt record above and beyond that of the

[2] Denewing is the process of prescribing an organism as 'not new', so that it will no longer be regulated by the HSNO Act.
[3] Risk species is the process of prescribing a not new organism as 'new', so that it will be regulated as a new organism under the HSNO Act.

EPA register the requirement to be gazetted should remain. This would also provide a record of changes to the new-ness status of a new organism.

143. Amending statutory determinations of new organisms to allow for decisions at any taxonomic level will allow for criteria for decision-making to be expanded and the ability for decisions to be bundled together when appropriate. Four main legislative improvements are proposed below:
    i. Decisions can be made at various classification levels (species, family, strain type, cultivar etc). This allows for applicants and the EPA to apply for and make decisions on a wider range of organisms quickly and more efficiently.
    ii. Include a provision that allows for a decision to be made on the basis of how widespread an organism is internationally and on the basis that the organism is otherwise new to science.
    iii. Ensure the scope of s26 includes the ability to provide broad decisions (perhaps at a species level) to allow for multiple different organisms made through classical techniques, such as hybridisation, are available in one decision.
    iv. Remove the requirement for the decision to be gazetted as the EPA already maintains a public register of organisms that have been deregulated. Removing this requirement and replacing it with a requirement of a register held and published by the EPA (which already exists) would decrease costs and administrative burden.

How do the options compare to the status quo/counterfactual?

	Option One – Status quo (no changes to HSNO Act)	Option Two – Reduce the decision making to Minister	Option Three – Make denewing and prescribing risk species an EPA notice	Option Four – Amend s26 and lower decision making for denewing
Effective	0	0	+	++
Efficiency	0	+	+	++
Alignment	0	+	++	+
Implementation	0	+	+	+
Overall assessment	0	+	+	++

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

144. Option four best addresses the problem and is most likely to meet the policy objectives. The proposals broadly align with the feedback we received from stakeholders and the EPA, who administer the Act. This option allows for quicker regulatory recognition of the status of organisms in New Zealand and will speed up the denewing and prescribing risk species process significantly. Changes to section 26 will allow for the EPA to make decisions on a wide range of organisms quickly and more efficiently. This will benefit the users of these system particularly researchers and

enforcement agencies. This is crucial for users determining if an approval is required before importing, developing, field-testing, or releasing the organism.

2.2.3 Making EPA functions and applications easier to use and more fit for purpose, with shorter wait times

145. The provisions for new organisms in the HSNO Act are not aligned with the Hazardous Substances provisions of the Act, because of this, new organism applications have a number of barriers we are addressing. These include individual parts of the application are difficult to amend; it is hard to navigate the approval process with unnecessary duplicated steps; and they sometimes stop being active due to administrative oversight. Hazardous substance decision making has been modified to allow for faster decisions, and we now intend to create the same provisions for new organisms. Specific issues being addressed include:
    i. Reassessment criteria and pathways for new organisms are not aligned with hazardous substances provisions. Only full assessments can be undertaken (not modified) and provisions to revoke approvals under new organisms do not exist. This makes the system inconsistent between hazardous substances and new organisms.
    ii. Regulations and EPA notice making powers do not exist for new organisms.
    iii. Delegations for new organisms were previously restricted in line with constraints related to genetically modified organisms, which are no longer required.
    iv. Conditional releases have a time limit to them and lapse when all the conditions are met.
    v. Laboratory and other containment applications have no expedited processing pathway.

<u>Option One – Status Quo</u>

146. The current Act would apply as it is currently. With the removal of genetically modified organisms from the HSNO Act, some of the administration for non-genetically modified new organisms is unnecessary.

<u>Option Two – Legislative amendment</u>

147. A suite of legislative amendments to improve processes for new organisms and align the new organisms provisions with those existing for hazardous substances. The paragraphs below outline the changes for each relevant sub-section.
148. Conditional Releases – Amending conditional releases to allow them to be less administratively burdensome and more useful for applicants. This includes automatically rolling over expired approvals, removing the requirement to destroy organisms at the expiry of the approval, giving EPA discretion to change the 5-year time limit, allow for multiple extensions as well as facilitating a simpler pathway to full release of a new organism.
149. Notification extensions – Add the ability to extend time extension multiple times as currently you can extend them only once. Include criteria that any new information will also need to be given to the EPA as part of request for extension. Clarify notification

provisions. Currently, all releases need to be notified in the first five years. Amend to mandate only the initial/first applicant to notify.

150. Give EPA discretion to 'revive' new organisms approval that has expired due to administrative error.
151. Regulations – Allowing for the creation of EPA notices in relation to new organisms. This would enable the creation of efficient secondary legislation for new organisms for technical matters comparable to those that exists for hazardous substances.
152. Delegations – The option for decisions on applications under the HSNO Act to be delegated to the Chief Executive or another EPA staff member as appropriate is best suited. This will reduce the administrative burden on the EPA to stand up decision-making committees for low-risk decision making. This proposal is for efficiency and is considered appropriate given that genetically modified organisms will no longer be regulated by the HSNO Act.
153. Reassessments – The option of amending the reassessment provisions to give similar reassessment powers to the new organisms' regime as those available in the hazardous substances' regime, including giving the EPA the ability to perform modified reassessments for new organisms. This will provide a more fit for purpose regime for new organisms that takes account of new information and a changing environment.
154. Containment – Change the empowering provision that enables regulations to be made to specify low risk new organisms for the purpose of containment to an empowering provision to make a corresponding EPA notice. Once the EPA has created the EPA notice, the EPA will be able to decide containment applications for qualifying low risk new organisms under a rapid pathway.

How do the options compare to the status quo/counterfactual?

	Option One – Status quo (no changes to HSNO Act)	Option Two – Legislative amendment
Effective	0	++
Efficiency	0	++
Alignment	0	++
Implementation	0	+
Overall assessment	0	++

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

155. Option Two will directly address the need to align the new organisms regime with the hazardous substances regime. Most of the changes proposed are a result of ensuring the new organism amendments are consistent with the provisions for hazardous substances. As well as addressing resourcing, amending these provisions would streamline the process for applicants and give them more flexibility in their application.

2.2.4 Clarifying the Act to ensure the intent is clear and fit for purpose

156. Since 1996 ongoing issues have been identified with the definitions used within the Act. In some cases, the definitions are ambiguous in their intent, in others there have been unintended consequences from definitions which have created enforcement and compliance loopholes.
157. The Gene Technology Bill will also make consequential changes to the Act which present an opportunity to align and modernise the following technical aspects:
    - The definition of 'organism' does not specify the taxonomic level it can be applied to and also could be aligned with the Biosecurity Act with the changes made from the Gene Technology bill.
    - Definition of 'new organism' does not specify the taxonomic level it can be applied to and refers to 'species' which can be difficult to apply. The definition is also unclear about whether a native organism or an organism that has been reintroduced is considered a new organism.
    - Some vagrant organisms are on the prohibited organisms list even though they arrive naturally in New Zealand.
    - The definition of 'develop' is unnecessarily complex and results in some loopholes where new organisms are not regulated differently depending on how they enter the country. The consequential changes from the Gene Technology bill present an opportunity to modernize and align the import and development in containment approvals pathway.
    - The progeny of an 'incidentally imported new organism' is not considered an 'incidentally imported new organism' under the current definition. All of the risks of 'incidentally imported new organisms' are still present for their progeny, but they are instead regulated as new organisms.
    - The current definition of 'field test' requires the removal of 'any heritable material'. This is burdensome and was intended to manage the risks associated with genetically modified material escaping a trial, which are now regulated by the Gene Technology Bill.
    - The definition of 'release' does not adequately cover the range of situations it was intended to. This has led to situations where new organisms could be kept and moved without enforcement action being taken.
    - 'Qualifying organisms' in the HSNO Act do not include those contained in medical devices which should be regulated under those provisions.

<u>Option One – Status Quo</u>

158. The Act would continue to be applied as it is currently. Some loopholes will not be addressed. The definitions will not align with legislation or terms in the Gene Technology regime.

<u>Option Two – Operational changes – including guidance on how to approach</u>

159. In some cases, operational guidance and legal advice would aid in applying the existing definitions and legislation. This would not be suitable for all issues raised and loopholes will continue to be an issue.

Option Three – Amend definitions to address issues (recommended)

160. Make changes to the definitions with issues to address loopholes, improve clarity, and modernise and align the legislation[4].

How do the options compare to the status quo/counterfactual?

	Option One – Status quo (no changes to HSNO Act)	Option Two – Operational changes	Option Three – Amend definitions
Effective	0	+	++
Efficiency	0	0	+
Alignment	0	0	++
Implementation	0	+	+
Overall assessment	0	+	++

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

161. Option three is most likely to deliver on the policy objectives of clarity to applicants and those using new organisms, and more efficient use of time for EPA and MPI. The status quo would continue to present issues with ambiguous definitions and greater operational inefficiencies as they are applied. Operational changes would help, but would only partially help alleviate the issues identified, without addressing the underlying issues.

162. Option three is a cost-effective way to provide substantial benefits in terms of providing clarity and improving efficiency for the EPA and MPI. As the issues are discrete and well identified, with only small changes to the legislation required to address them.

[4] This includes:

i. Clarifying that the definition of organism can be applied at all taxonomic levels.
ii. Clarifying that the definition of new organism can be applied at all taxonomic levels and does not include native or reintroduced organisms.
iii. Excluding vagrant organisms form schedule 2.
iv. Simplifying the definition of develop and more broadly apply it to activities undertaken in containment.
v. Clarifying the progeny of incidentally imported new organisms are also considered incidentally imported new organisms.
vi. Removing the requirement to "remove any heritable material" from a field trial at its end. The risk of biological material escaping from or remaining after a field trial will still be managed under s44.
vii. Amending the definition of release to apply to all situations where a new organism is not contained.
viii. Including medical devices in the definition of 'qualifying organism'.

3 Adopting improved regulatory frameworks for compliance and enforcement

(3.1) Making improvements to HSNO's compliance and enforcement regime

3.1.1 Improved compliance and enforcement: extend the timeframe for filing charges

163. Section 109A(1) of the HSNO Act limits the timeframe for filing charges for offences under the Act to 6 months from the date the enforcement agency became aware of the non-compliance. This timeframe is half of those that are provided in three related acts, all of which allow 12 months for the relevant enforcement agencies to file charges:
    i. Resource Management Act (RMA).
    ii. Health and Safety at Work Act (HSWA).
    iii. Exclusive Economic Zone and Continental Shelf (Environmental Effects) Act 2012 (EEZ).
164. The 6-month abridged timeframe presents practical challenges for HSNO Act enforcement agencies. In many cases, and in particular in complex cases, 6 months is insufficient time to complete an investigation and file charging documents. This is because investigations can require applications for search warrants, specialist analysis and testing of evidence before determining the appropriate compliance action to take – all in accordance with the Crown Law Prosecution Guidelines.

Option One – Status Quo

165. Enforcement opportunities are missed. If the enforcement agency does not have enough time to carry out and complete a thorough investigation, enforcement action may not be taken and someone who has committed an unlawful act will escape punishment. Alternatively, the enforcement agency may lay changes when they are not ready to keep within the timeframe. This may mean the evidence isn't as comprehensive and the prosecution may not be successful.

Option Two – 12-month timeframe (recommended)

166. A 12-month timeframe balances the public interests of ensuring that an offender does not escape punishment because the investigating agency does not have sufficient time to complete its investigation, and the need for prompt enforcement action. As this is the timeframe for other pieces of legislation where there have been successful prosecutions, we can be confident that this is an appropriate timeframe.

How do the options compare to the status quo/counterfactual?

	Option One – Status quo (no changes to HSNO Act)	Option Two – 12-month timeframe
Effective	0	+
Efficiency	0	++
Alignment	0	+
Implementation	0	+
Overall assessment	0	+

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

167. Option two would address the issue and not be limited by funding and backlog. It would strike a balance between ensuring that an offender does not escape punishment because the investigating agency does not have sufficient time to complete its investigation, and the need for prompt enforcement action.

3.1.2 Improved compliance and enforcement: adding an 'assist and intervene' enforcement power for the EPA

168. Enforcement of the HSNO Act for hazardous substances is spread over many central and local government agencies (section 97).
169. MfE understands there some areas where risks are potentially going unmanaged. The areas of most concern are:
170. Enforcement of ecotoxic and disposal controls in workplaces (WorkSafe).
171. Enforcement of hazardous substances in non-workplaces (territorial authorities).
172. Both these enforcement entities carry out a range of functions under legislation other than HSNO. As such, they need to balance their HSNO enforcement responsibilities with responsibilities under that other legislation (e.g. Health & Safety at Work Act (WorkSafe) and Resource Management Act (TAs)) and prioritise where to place their limited resources for the most impact.
173. MfE officials considered investigating options for other agencies to undertake the enforcement responsibilities currently assigned to WorkSafe and territorial authorities. However, the work required to understand the impacts of any further proposals would be significant, involve multiple agencies and the need to consider impacts on funding and resourcing, and impacts on other associated Acts, should there be changes to their current enforcement responsibilities.
174. As a current measure, amending section 97(4) to give the EPA an overarching enforcement power, similar to Part 12 A of the Resource Management Act, where the EPA could undertake, assist, or intervene in, an enforcement action falling under another section 97 enforcement agency's jurisdiction should it be deemed necessary under the purpose of the HSNO Act.
175. This will enable the EPA to better fulfil its responsibility under section 99 to ensure the provisions of the Act, reduce potential harm, and ensure the system objectives of the HSNO Act are met.

Option One – Status Quo

176. There will continue to be some areas where risks are potentially going unmanaged due to a lack of enforcement by some section 97 enforcement agencies.
177. Low levels of enforcement activity will likely lead to continued non-compliant behaviour as there is no disincentive to stop non-compliant behaviour. Continued non-compliance increase the risk of harms to people and the environment.
178. Non-compliant parties will not be held to account for breaching their HSNO obligations.

Option Two – Assist and intervene enforcement powers (recommended)

179. It will enable the EPA to act without delay where a non-compliance has occurred and the 'first line' responsible enforcement agency has chosen not to / failed to act.
180. More non-compliant parties will be held to account for breaching their HSNO obligations.
181. Increased enforcement activity should help compliance, which in turn, should lead to less harm to people and the environment.

Option Three – Operational changes

182. This would include operational changes to both the EPA and other enforcement agencies to allow for EPA staff to provide assistance and advice on investigations and enforcement situations. As the EPA staff would not have any enforcement powers, they would have to rely on the enforcement agency to perform all the appropriate functions. It would also not allow the EPA to step in when there is a failure to act.

How do the options compare to the status quo/counterfactual?

	Option One – Status quo (no changes to HSNO Act)	Option Two – Assist and intervene powers	Option Three – Operational changes
Effective	0	++	+
Efficiency	0	+	-
Alignment	0	+	+
Implementation	0	-	-
Overall assessment	0	+	0

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

183. Option 2 (the assist and intervene powers) is the best options, as it would allow EPA to act without delay where a non-compliance has occurred and the 'first line' responsible enforcement agency has not acted. It would also allow easier collaboration between EPA and the enforcement agency for large or complex cases. This in turn will increase enforcement actions and therefore compliance.

3.1.3 Improved compliance and enforcement: providing for different infringement fees for individuals and entities

184. MfE consider the HSNO Act should provide for different infringement fees to be set for individuals and entities, especially for offences where there is the potential for significant adverse effects. Section 140(1)(i) of the HSNO Act sets a maximum infringement fee level of $3,000 for each infringement offence, noting that the different fee may be set for different offences. The Act does not currently provide for different infringement fees to be set for different parties (e.g. individuals vs entities) that commit the same offence.
185. In contrast, the HSWA does provide for different infringement fees for different parties. The maximum infringement fee that can be set under HSWA is $12,000 (refer section 211(1)(u)).
186. We also consider that the maximum infringement fee (for entities) provided for in the HSNO Act should be increased from $3,000 to $12,000. This would align with the maximum fee provided for in HSWA which also deals with non-compliances around hazardous substances and has a similar regulated community.

Option One – Status Quo

187. Not having the ability to set different infringement fees for individuals and entities limits the maximum recommended infringement fee for many infringement offences to $1,000. This is the case even for offences where there is the potential for significant adverse effects.

Option Two – Targeted infringement (recommended)

188. Option two will mean that more targeted infringement fees can be set depending on who the non-compliant party is, with higher fees being set for entities. Entities typically have more resources than individuals so should be more aware of their compliance requirements and have the resources to ensure compliance. Regulators should be able to impose a higher penalty on an entity who stands to gain financially from non-compliance as compared with an individual. Entities should also have better financial capacity to pay higher infringement fees than an individual, and arguably, should be held to a higher level of culpability. There may also be issues of scale involved. Increasing the max infringement fee for entities will assist in having an infringement regime that is as effective as possible. This proposal will provide consistency with the HSWA legislation that also deals with non-compliances around hazardous substances, with a similar regulated community.

How do the options compare to the status quo/counterfactual?

	Option one – Status quo	Option 2 – Targeted infringement
Effective	0	+
Efficiency	0	+
Alignment	0	+
Implementation	0	+
Overall assessment	0	+

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

189. Option two will increase infringement fees ability to have a deterrent effect. The ability to impose higher infringement fees for entities would be more effective at achieving deterrence, especially with repeat offenders. Entities typically have more resources than individuals so should be more aware of their compliance requirements and have the resources to ensure compliance.

3.1.4 Address ambiguity related to scope of section 63A

190. The issue here is the ability to use section 63A to change the hazard classification of a substance. Section 63A allows a modified reassessment to vary the EPA controls and/or description of the hazardous substance, which was previously interpreted as including the hazard classification, but the addition of sections 63C and 63D to the HSNO Act has created unintended ambiguity with the wording of section 63A. The drafting of section 63C and 63D has separated out the description of a hazardous substance from hazard classification. Section 63C relates to the reassessment of a hazardous substance because of changes or amendments, while section 63D duplicates some of the reasons for reassessment and adds others.

Option One – Status Quo

191. Currently modified reassessments are being used to change hazard classifications but under the current provisions this runs the risk of decisions outside of scope of application type.

Option Two – clarify s63A modified reassessments can change hazard classifications

192. Change the wording of modified reassessments in section 63A(2) to be consistent with the wording of section 63C(2) and 63D(2), clarifying their ability to change hazard classifications.
193. Operationally no change but removes legal risk of decisions outside of scope of application type.

How do the options compare to the status quo/counterfactual?

	Option One – Status quo (no changes to HSNO Act)	Option Two – Clarify s63A modified reassessment can change hazard classifications
Effective	0	++
Efficiency	0	++
Alignment	0	+
Implementation	0	++
Overall assessment	0	++

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

194. Option two is a relatively straightforward fix that will reduce legal risk with no regulatory cost. It will clarify modified reassessments can change hazard classifications and give certainty to industry about which application pathway to take.

Section 3: Delivering an option

How will the proposal be implemented?

195. The regulator responsible for implementation of the changes will be the EPA. This remains the same as the arrangements in place under the current Act. The proposed changes proposed don't change the fundamental settings of the Act, but streamlining and aligning to ensure regulatory stewardship, efficiency, and transparency.
196. The implementation actions we propose are to be funded through the levy enabling provisions included in the CRIS attached to this RIS. We anticipate no additional resource burden to the EPA from most of the changes to the Act but note some unknown variables around the introduction of the time-limited conditional approvals.
197. Arrangements will come into effect at a time to be agreed following the introduction of the Omnibus bill to Cabinet.
198. Under the Act, the EPA board is the primary monitor, with the responsible Minister expecting regular board reports on entity performance, risks, and opportunities. Delivery and prioritisation expectations are currently provided to the EPA through a letter of expectations from the Minister for the Environment. This is used to develop the EPA's annual Statement of Performance Expectations and Statement of Intent every 3 years. MfE then monitors based on this process, and we believe that this is robust and effective in regard to changes arising from these legislative amendments.
199. For the outcomes sought via the introduction of the levy provisions we are currently working through how often the levy will be reviewed and the outcomes sought from any review. In the stage two Cost Recovery Impact Statement on the levy we will determine both the outcomes sought and what the additional trigger points may be for a review of the levy provisions.
200. MfE officials believe the actions detailed above will enable clear accountability mechanisms to both the public and regulated bodies; continue to ensure the Act can deliver effective risk management and mitigation to ensure human and environmental health; remain active in monitoring emerging risks from up-to-date international data; maintain effective systems to ensure compliance and monitoring; and continue to create transparency via reporting against this monitoring.

Appendix 1: Summary of proposed minor and technical changes to the HSNO Act

Amendment title	Section	Change	Reason for the change
Definition of "environmental medium"	Section 2: definition of 'environmental medium'	Amend the definition to replace reference to class 6 and class 9 substances (old hazard classification system) with the equivalent terms in the updated classification system adopted by the EPA in 2021.	The definition of 'environmental medium' in the interpretation section refers to the old alpha-numeric hazard classification system that was replaced on 30 April 2021.
Interface issue with Defence Act 1990	Sections 3(3), 3(6)	Amend s3(3) to remove reference to the term "EPA controls". Amend s3(6) to provide clarity on the auditing function.	When section 3 was amended on 1 December 2017 to take account of the Health and Safety legislative reforms, the amended wording lacked clarity particularly relating to use of the term 'EPA controls' in s3(3) and s3(6). This lack of clarity is causing problems for the NZ Defence Force, particularly the auditing requirement in s3(6) as it is unclear from the current wording exactly what needs to be audited. Amending s3(3) and 3(6) will clarify the original intent of these sections.
Heading of s97	Section 97	Amend the heading of s97 to read "Enforcement of Act in respect of hazardous substances".	S 97A reads "Enforcement of Act in respect of new organisms". This change will align the two headings.
Provisions of persistent organic pollutants within the HSNO Act to	Section 25A, 25C, 25D, 29B, 66A, 140A, and schedules 1AA and 2A all need to either be amended or	Amend or revoke sections 25A, 25C, 25D, 29B, 66A, 140A, and schedules 1AA and 2A of the	The Stockholm convention has included additional chemicals since it was first included in the HSNO Act in 2003. However, not all the provisions in the HSNO Act were changed to incorporate these new

Amendment title	Section	Change	Reason for the change
better align with the Stockholm convention	revoked to align with the Stockholm convention.	HSNO Act to align with the Stockholm convention.	chemicals. This means that some aspects of the HSNO Act are either no longer clear or aligned with the Stockholm convention. This change clarifies this.
Removing SOI and annual report provisions	Section 147 and 148	Repeal section 147 (1) (d), (e) and (f) and section 148 (c), (d) and (e).	Sections 147 and 148 include matters that the EPA should include in the statement of intent and annual report. However, information required by these sections is either already published on the EPA website or would be addressed as a matter of course in the SOI, SPE, or annual report. Therefore, there is no need for these provisions.
Clarifying agency submissions	Section 58(1)(i) and (ii)	Amend sections 58(1)(i) and (ii) to replace the word "submission" with "information".	The EPA notifies certain government departments or entities of all applications, even those not publicly notified and then often get emails as a response from WorkSafe and/or DOC, which are not necessarily formal submissions. This change clarifies that any information regarding the application should be considered, not just formal submissions.

ECO-25-MIN-0075

Cabinet Economic Policy Committee

Minute of Decision

Agricultural and Horticultural Products Regulatory Review Omnibus Bill

Portfolios **Regulation / Environment / Food Safety**

On 21 May 2025, the Cabinet Economic Policy Committee (ECO):

1 **noted** that, in February 2025, ECO endorsed all 16 recommendations by the Agricultural and Horticultural Products Regulatory Review (the Review), and invited the Minister for the Environment and the Minister for Food Safety (joint Ministers) to report back on detailed implementation plans by May 2025 [ECO-25-MIN-0006];

2 **noted** that joint Ministers intend to progress legislative changes through a joint omnibus Bill (the Bill), to be introduced to the House of Representatives s 9(2)(f)(iv) ;

3 **noted** that implementation of the Review's recommendations is expected to lead to improvements in application queues and assessment times, transparency and reporting, and greater use of international harmonisation approaches;

4 **noted** that positive improvements have already occurred, including reduction in application queues, additional staff for Hazardous Substances and New Organisms Act 1986 (HSNO) assessments and allocating $10 million operational funding for the upgrade of the Environmental Protection Authority's (EPA) ecotoxicological risk assessment models;

5 **noted** that the Minister for Food Safety will set a 20 percent queue reduction target for Agricultural Compounds and Veterinary Medicines Act 1997 (ACMV) applications to be achieved by the end of June 2025, and a further 30 percent queue reduction target to be achieved by the end of June 2026;

6 **noted** that the Minister for the Environment will determine an ambitious target within the next three months for a queue reduction target for HSNO applications;

7 **noted** that the Minister for Food Safety and the Minister for the Environment will determine an ambitious target within the next three months for reducing approval times for each of ACVM and HSNO applications;

HSNO recommendations

8 **agreed** to amend section 28A(6) of HSNO to limit the factors in the "significant effects" test so they are New Zealand specific to allow the EPA to rely on international modelling, data, and assessments, unless there are specific New Zealand circumstances that warrant a more detailed assessment;

9 **agreed** to amend Part 5 of HSNO to introduce a time-limited conditional application process and corresponding approvals, as detailed in Appendix 1 to the submission under ECO-25-SUB-0075 (Appendix 1);

10 **agreed in principle** to introduce a tiered pathway structure for applications for hazardous substances based on risk;

11 **agreed in principle** to using a regulation making power, subject to legal advice and further discussion with the Parliamentary Counsel Office, to amend application process steps and timeframes for all applications relating to hazardous substances and new organisms made under Part 5 and Part 6A as detailed in Appendix 1;

12 **agreed in principle** to amend provisions in HSNO associated with public notification and hearings so that public notification is required, and hearings are held on applications where justified based on risk, public interest, efficiency and transparency;

13 **agreed in principle** to amend HSNO to provide the EPA with powers related to application processing and timeframes for all applications made under Parts 5 and 6A as detailed in Appendix 1;

14 **authorised** the Minister for the Environment to take final decisions on the matters listed in paragraphs 10 to 13 above;

15 **agreed**, if regulations are to be developed for these matters, to provide for transitional arrangements to ensure that current timeframes and categories of applications in Part 5 and 6A remain where necessary or until relevant regulations are in place;

16 **agreed in principle**, subject to paragraph 17 below, to introduce enabling provisions for regulations within HSNO for a hazardous substance levy regime on the import and manufacture of hazardous substances, to be paid by importers and manufacturers to support the EPA's hazardous substances functions with criteria in HSNO on relevant considerations when designing the levy regime;

17 **authorised** the Minister for the Environment to take final detailed decisions on the above levy;

18 **agreed** to amend HSNO to allow for the policy intent of changes to the hazardous substances regime in Appendix 1 to be carried out on the following matters: data protection, improved emergency approval provisions, improved compliance and enforcement, and ambiguity related to scope of section 63A of HSNO;

19 **agreed** to amend HSNO to allow for the policy intent of changes to the new organism regime in Appendix 1 to be carried out on the following matters: determinations, denewing and risk species, reassessments, containment, notification and extension provisions for full releases, conditional releases, delegations, EPA notices, revoking regulations, enforcement of New Organisms, information sharing, prohibition of vagrant organisms;

20 **agreed** to the changes to the definitions in HSNO in Appendix 1 on the following definitions: Organism, New Organism, Develop, Incidentally Imported New Organism, Field Test, Release, Qualifying Organism;

21 **agreed** to the minor and technical amendments to HSNO in Appendix 1 relevant to definition of "environmental medium", interface issue with Defence Act 1990, heading of HSNO section 97, provisions of persistent organic pollutants within HSNO to better align with the Stockholm convention, removing statement of intent and annual report provisions, clarifying agency submissions;

ACVM recommendations

22 **agreed** to amend section 8A of ACVM to empower substances or products to be exempted from registration by a Notice issued by the Director-General instead of in Schedule 2 of the ACVM (Exemptions and Prohibited Substances) Regulations 2011;

23 **agreed** to provide for transitional arrangements required to support the transfer of the existing exemptions to the new Notice;

24 **agreed** to amend ACVM to permit the recognition of international regulators, set criteria for recognition in secondary legislation, and empower the Director-General to make a notice listing recognised international regulators;

25 **agreed** to amend ACVM to require the Director-General to use an appropriate, available recognised international regulators' product assessment when considering an application for registration (or variation to an existing registration) of the same (or substantially the same) product and empower any necessary associated secondary legislation;

26 **agreed** to amend ACVM to permit the recognition of data assessors to assess data packages;

27 **agreed** to remove the statutory timeframes from section 16 of ACVM and empower the setting and review of statutory timeframes in regulations and supplementary notices for different application types;

28 **agreed** to provide for transitional arrangements that retain the current timeframes in section 16 of ACVM while regulations are being developed;

29 **agreed** to amend section 9 of ACVM to allow a registrant to apply to vary any registration controls on a product registration, rather than only conditions;

30 **agreed** to amend ACVM to provide for regulations that specify the requirements and approval processes for applicants applying to vary conditions and controls for product registrations, noting that a supplementary notice provision would be required to provide for supporting technical information to meet those regulations;

31 **agreed** to amend section 31 of ACVM to require the Director-General to notify the public of a decision to prohibit or restrict the import, manufacture, sale or use of a registered product undergoing reassessment until a decision is made, and that the manner of notification should align with section 44ZL of ACVM and the proposed amendment in paragraph 40 below;

32 **agreed** to amend section 26 of ACVM to change 'provisional registration' of trade name products to 'research approval' of both trade name products and unregistered products;

33 **agreed** to remove relevant references to provisional registration in ACVM;

34 **agreed** to provide for transitional arrangements for applicants granted research approval under section 8C(1) of ACVM;

35 **agreed** to amend ACVM to allow the Director-General to set standards for Good Manufacturing Practices by Notice;

36 **agreed** to amend ACVM to provide for the certification of a product manufacturer's compliance with a Good Manufacturing Practices Standard and empower regulations to set out the certification process and associated requirements;

37 **agreed** to amend section 15 of ACVM to allow for the Director-General to waive notification if the product is likely to be required for use in an emergency related to public health, animal welfare, trade or agricultural security;

38 **agreed** to amend section 21 of ACVM to remove the mandatory requirement to obtain consent from the Director-General of Health to register veterinary medicines that are prescription human medicines, and to empower regulations to specify what classes of prescription medicines require consent;

39 **agreed** to provide for transitional arrangements to continue mandatory consent from the Ministry for Health on registration related to prescription human medicines until regulations are developed;

40 **agreed** to align notification provisions in ACVM with section 44ZL to provide for more flexibility for public notifications;

41 **agreed** to amend ACVM to specify additional situations where registrations may be suspended, noting that ACVM should be clear that a product can be suspended where there is a risk to public health, animal welfare, agricultural security or trade and not only for non-compliance with registration conditions;

42 **agreed** to amend section 30A of ACVM to clarify that applicants have a reasonable opportunity to be heard when the Director-General is proposing to suspend a product's registration;

Report back on detailed implementation plan

43 **noted** the detailed implementation plan for all 16 Review recommendations contained in Appendix 3 to the submission under ECO-25-SUB-0075;

Next steps

44 **invited** joint Ministers to issue drafting instructions to the Parliamentary Counsel Office to amend HSNO and ACVM respectively and any relevant amendments necessary to regulations to implement the proposals described in the paper and Appendices 1 and 2 under the submission ECO-25-SUB-0075;

45 s 9(2)(f)(iv) [redacted]

46 **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;

47 **noted** that the Cabinet Legislation Committee is expected to consider the Bill by s 9(2)(f)(iv) [redacted]

Rachel Clarke
Committee Secretary

Present: (see over)

Present:
Rt Hon Winston Peters
Hon David Seymour
Hon Chris Bishop (Chair)
Hon Simeon Brown
Hon Brooke van Velden
Hon Shane Jones
Hon Erica Stanford
Hon Louise Upston
Hon Dr Shane Reti
Hon Simon Watts
Hon Penny Simmonds
Hon Andrew Hoggard
Hon Nicola Grigg
Hon James Meager
Hon Scott Simpson
Simon Court MP

Officials present from:
Office of the Prime Minister
Office of Hon Simon Watts
Officials Committee for ECO

CAB-25-MIN-0171

Cabinet

Minute of Decision

Report of the Cabinet Economic Policy Committee: Period Ended 23 May 2025

On 26 May 2025, Cabinet made the following decisions on the work of the Cabinet Economic Policy Committee for the period ended 23 May 2025:

ECO-25-MIN-0075	**Agricultural and Horticultural Products Regulatory Review Omnibus Bill** Portfolios: Regulation / Environment / Food Safety	CONFIRMED

[redacted]

Diana Hawker
for Secretary of the Cabinet