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.