Ministry for the Environment
Manatū Mō Te Taiao

# PROACTIVE RELEASE COVERSHEET

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| **Minister** | Hon Penny Simmonds | **Portfolio** | Environment |
| **Name of package** | Briefing and associated appendices on Policy decisions for HSNO Act Omnibus Bill | **Date to be published** | 1 July 2025 |

| **List of documents that have been proactively released** | | |
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| ***Date*** | ***Title*** | ***Author*** |
| 3 April 2025 | Briefing Note: Policy decisions for HSNO Act Omnibus Bill | Ministry for the Environment |
| 3 April 2025 | Appendix 1: Summary of feedback received through targeted stakeholder engagement | Ministry for the Environment |
| 3 April 2025 | Appendix 2: Summary of hazardous substance policy changes to the HSNO Act | Ministry for the Environment |
| 3 April 2025 | Appendix 3: Summary of new organism's policy changes to the HSNO Act | Ministry for the Environment |
| 3 April 2025 | Appendix 4: Summary of minor and technical changes to the HSNO Act | Ministry for the Environment |
| 3 April 2025 | Appendix 5: Update on implementation of recommendations from MfR sector review | Ministry for the Environment |

**Information redacted** **YES**

Any information redacted in this document is redacted in accordance with the Ministry for the Environment's policy on proactive release and is labelled with the reason for redaction. This may include information that would be redacted if this information was requested under Official Information Act 1982. Where this is the case, the reasons for withholding information are listed below. Where information has been withheld, no public interest has been identified that would outweigh the reasons for withholding it.

**Summary of reasons for redaction**

Briefing Note: Some information withheld under s9(2)(b)(ii) as it contains commercially sensitive information, and under s(9)(2)(h) to maintain legal professional privilege.

Appendix 1: Summary of feedback received through targeted stakeholder engagement: Some information withheld under s(9)(2)(a) to protect the privacy of individuals.

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# Briefing: Policy decisions for HSNO Act Omnibus Bill

**Date submitted:** 3 April 2025
**Tracking number:** BRF-5986
**Sub Security level:** In-Confidence
**MfE priority:** Urgent

| **Actions sought from Ministers** | | |
|---|---|---|
| ***Name and position*** | ***Action sought*** | ***Response by*** |
| To Hon Penny SIMMONDS<br>**Minister for the Environment** | Respond to recommendations | 7 April 2025 |

| **Actions for Minister's office staff** |
|---|
| **Return** the signed briefing to the Ministry for the Environment (advice@mfe.govt.nz). |

| **Appendices and attachments** |
|---|
| 1. Appendix 1: Summary of feedback received through targeted stakeholder engagement<br>2. Appendix 2: Summary of hazardous substance policy changes to the HSNO Act<br>3. Appendix 3: Summary of new organisms policy changes to the HSNO Act<br>4. Appendix 4: Summary of minor and technical changes to the HSNO Act<br>5. Appendix 5: Update on implementation of recommendations from MfR sector review |

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| **Minister's comments** |
|---|
| |

# Policy decisions for HSNO Act Omnibus Bill

## Key messages

1. On 24 February 2025 Cabinet agreed to progress an Omnibus Bill to make changes to the Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) to progress the recommendations from the Ministry for Regulation sector review of the application process for agricultural and horticultural products. Cabinet also requested a report back on the progress on implementing the recommendations. The Cabinet paper to request permission to issue drafting instruction for the Omnibus Bill and to report back on the progress on the recommendations is proposed to be presented to the Economic Policy Committee on 14 May 2025 and Cabinet on 19 May 2025.

2. As part of our policy work for the Omnibus Bill, we undertook targeted stakeholder engagement from 11 to 24 March 2025. Feedback included concerns about the level of detail for some proposals, the need for greater efficiency, transparency and certainty with respect to application pathways and statutory timeframes and differing views on a levy provision. There was also a significant amount of feedback beyond the scope of the current proposals.

3. As a result of this feedback, we are seeking decisions from you on options for the following three proposals:

    i The positioning of statutory timeframes for hazardous substances in primary or secondary legislation;

    ii Whether to proceed with an enabling provision for a hazardous substance levy; and

    iii Whether to include amendments to data protection provisions.

4. We are also seeking decisions from you on the remaining proposals in the Omnibus Bill. These decisions will feed into the Ministry for Regulation-led Cabinet paper in May 2025 that will enable drafting instructions to be prepared for the Omnibus Bill.

5. The May Cabinet paper will also report back on the implementation of the full suite of recommendations from the Ministry for Regulation (MfR) sector review. Of the 16 recommendations made by MfR, five will be addressed by proposed legislative changes. The remaining recommendations are non-legislative and are progressing well. This includes the first Sector Leaders Forum meeting which takes place on the 3 April 2025.

## Recommendations

We recommend that you:

a. **note** the update on implementation of recommendations from MfR sector review

b. **note** the results of the targeted stakeholder engagement

c. **agree to:**

i **either** put application timeframes in the HSNO Act

Yes | No

ii **or** put application timeframes in regulations (recommended)

Yes | No

iii **or** put application timeframes in an EPA notice

Yes | No

d. **agree to:**

i **either** proceed with including a levy provision in this Omnibus Bill (recommended)

Yes | No

ii **or** maintain the status quo, with a plan to defer any further policy work on a levy to 2026

Yes | No

e. **agree to:**

i **either** make an amendment to the HSNO Act to allow data protection for applications prior to an application at ACVM (recommended)

Yes | No

ii **or** not proceed with any legislative changes to data protection

Yes | No

f. **approve** the remaining hazardous substance policy proposals noted in Appendix 2 (please tick/cross next to the name in the policy decision or use the Yes/No for all of them)

Yes | No

g. **approve** the new organisms policy proposals noted in Appendix 3 (please tick/cross next to the name in the policy decision or use the Yes/No for all of them)

Yes | No

h. **approve** the specific minor and technical amendments noted in Appendix 4 (please tick/cross next to the name in the policy decision or use the Yes/No for all of them)

Yes | No

i. **provide** any feedback on the advice provided here if desired

j. **meet** with officials for further discussion if desired.

Yes | No

## Signatures

s 9(2)(a)

Glenn Wigley
General Manager – Waste & HSNO Policy
**Climate Change Mitigation and Resource Efficiency**
**3 April 2025**

Hon Penny SIMMONDS
**Minister for the Environment**

**Date**

# Policy decisions for HSNO Act Omnibus Bill

## Purpose

6. This briefing is to provide you with an update on the recommendations from the Ministry for Regulation regulatory review, feedback from the targeted stakeholder engagement and the opportunity to comment on and agree final policy decisions for a Cabinet paper on an Omnibus Bill on changes to the Hazardous Substance and New Organisms Act 1996.

## Background

7. In June 2024, the Government announced that the approval process for agricultural and horticultural products would be the subject of a regulatory review by the Ministry for Regulation (MfR). This was in response to concerns from industry organisations, mainly about the time taken to get new products to market. The review formally began in August 2024.

8. The MfR review was conducted in collaboration with the Ministry for the Environment (MfE), the Environmental Protection Authority (EPA) and the Ministry for Primary Industries (MPI) and made 16 recommendations. Ministers for Regulation, Environment and Food Safety jointly took the recommendations from the review to the Economic Policy Committee on 19 February 2025 and Cabinet on 24 February 2025.

9. Cabinet agreed to progress an Omnibus Bill to make amendments to the Hazardous Substances and New Organisms Act 1996 and the Agricultural Compounds and Veterinary Medicines Act 1997. Cabinet also requested a report back on the progress of the full suite of recommendations in May 2025.

10. Final policy decisions on the Omnibus Bill will go to the Economic Policy Committee on 14 May 2025 and Cabinet on 19 May 2025, along with a report back on progress on implementing the wider MfR recommendations.

11. Meanwhile, the Gene Technology Bill is currently being progressed by the Ministry for Business, Innovation and Employment (MBIE). This Bill will remove the regulation of genetically modified organisms (GMOs) from the HSNO Act. Non-GM organisms that are new will remain under the HSNO regime. The Gene Technology Bill is currently with the Select Committee after being introduced to the House in December 2024.

12. MfE officials, along with officials from the EPA, have been working on proposed changes to the HSNO Act to address the recommendations of the MfR review as well as your earlier request to consider amendments to the HSNO Act to improve regulation of hazardous substances [BRF-4349 refers]. Officials have also been working on improvements to the new organisms regime that can be included as part of this Omnibus Bill, some which will ensure alignment with the Gene Technology Bill.

13. MfE and EPA officials met with you to discuss these proposals on 4 March 2025. At this time, you gave permission to undertake targeted engagement with a selected group of stakeholders.

14. This briefing covers the result of the targeted stakeholder engagement, progress on the MfR recommendations and final policy decisions for your input prior to the Cabinet paper going to the Economic Policy Committee on 14 May 2025 and Cabinet on 19 May 2025.

# Analysis and advice

## Targeted stakeholder engagement

15. MfE officials undertook a series of meetings with targeted stakeholders from 11 to 24 March 2025. The following organisations took part in the targeted stakeholder engagement:

**Table 1: Organisations that took part in targeted engagement**

| *Hazardous substances* | *New organisms* | *Both* |
|---|---|---|
| Animal and Plant Health Association of New Zealand<br>Federated Farmers<br>Horticulture New Zealand<br>A Lighter Touch | AgResearch<br>Manaaki Whenua Landcare Research<br>Plant and Food Research<br>Scion<br>New Zealand Plant Producers Incorporated | AgriZeroNZ<br>Te Rūnanga o Ngāi Tahu |

16. Officials received a variety of feedback, both during the sessions 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 and ensuring transparency in performance reporting and the use of time waivers. There was some opposition to a potential levy, especially when the current application process efficiency was considered. However, not all organisations were opposed to the levy.

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

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

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

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

17. A summary of the targeted stakeholder engagement is presented in Appendix 1. Full written feedback can be provided on request. The feedback has enabled us to understand key stakeholders' views before submitting the proposals to Cabinet. We

have changed some of our proposals to reflect this feedback and are seeking decisions from you on the final direction of some policy proposals.

18. Officials note that some of the feedback received related to matters beyond the current proposals, which are focussed on progressing the recommendations from the MfR review. This feedback will be useful in any future amendments to the HSNO Act.

19. In light of the feedback we have received, we recommend proceeding with the proposed changes to the HSNO Act subject to your approval on specific topics.

## Proposed changes to the HSNO Act relating to hazardous substances

20. Officials have identified and finalised the proposed changes to the HSNO Act relating to hazardous substances.

### Greater use of international regulator assessments

21. We are proposing two amendments to make greater use of international regulator assessments. These involve changes to the international rapid assessment pathway and in addition the introduction of a new conditional approval pathway.

22. Targeted engagement showed a desire to expand the entry criteria for the existing international regulator rapid assessment pathway, which is consistent with Recommendation 7 of the MfR review. We are proposing to make amendments to the current rapid international pathway to clarify the “significant effects” test. The intent is to sharpen the focus of the “significant effects” test so that it only applies to effects which are New Zealand-specific, and which have not been adequately addressed by equivalent international regulator information. It will mean the EPA will be able to place greater weight on international modelling, data and decisions, unless significant effects will arise from New Zealand-specific circumstances. These amendments are designed to allow more substances to use this quicker pathway but will not open the pathway to a rapid assessment of novel substances or active ingredients new to New Zealand.

23. The proposed new time-limited conditional approval pathway will allow quicker market access for products that will not fit the criteria for the current rapid international pathway. This pathway would use international regulator assessments to allow a time limited approval for the period of time the product is under assessment for full approval. While there was concern about this pathway in targeted stakeholder engagement feedback, it was mostly centred on the pace of the consultation and uncertainty over how the proposal would be operationalised – some stakeholders indicated it could be useful if it were well designed.

24. We propose progressing with the changes to the rapid international pathway and the creation of the time-limited conditional approval pathway in legislation. This conditional approval pathway is an innovative step for chemical regulation, no other jurisdiction in the world has a comparable pathway. Officials believe it strikes the best balance in enabling novel substances to get to market quickly, which was the overarching outcome desired from the MfR review, while still appropriately managing risks to people and the environment.

25. We think this is an appropriate response to concerns raised in submissions for the following reasons:

i Unlike most regulators around the world who only approve chemicals for a certain period of time before they require reapproval, HSNO approvals do not expire and there is no scheduled review. This means that the only way to amend or revoke an approval if new information becomes available is through a resource-intensive (and costly) reassessment process.

ii The land use and farming styles in New Zealand can differ significantly from land use and farming styles in other countries. This means that chemicals can be used very differently in New Zealand from other countries and therefore risk assessments performed by other jurisdictions are often inadequate for New Zealand.

26. Officials acknowledge stakeholders' desire to understand how the time-limited conditional approval pathway will work in practice, and this work will continue through the drafting process and ongoing engagement.

**Hazardous substances application types and timeframes**

27. All hazardous substance release applications (that are not assessed under a rapid pathway) are currently considered the same under section 28 of the HSNO Act despite varying greatly in complexity and risk. Operationally, the EPA has employed a framework that tiers applications based on the likely risk of the substance and level of assessment and evaluation required.

28. We are proposing to formalise these different application pathways in the HSNO Act. By distinguishing applications of different risk and complexity, appropriate timeframes can be set that are proportional to the risk and the amount of time required to conduct the assessment. In doing so, applicants will have greater transparency and clarity on both the application process and expected timelines for assessment.

29. The application types will be based on the potential risk to human health and/or the environment, how similar a substance is to those already approved and the extent of scientific assessment required. For example, a substance containing a new active ingredient to New Zealand has the greatest potential risk and greatest workload for the EPA, so is likely to take much longer to assess than a reformulation of a product currently on the market. The EPA has a long history of operationally splitting these applications into various categories and details of the categories will be finalised in the subsequent drafting instructions.

30. We cannot yet propose specific statutory timeframes for these application types as the new overall, end-to-end timeframe will be the sum of timeframes attached to the individual process steps within the application. It is vitally important that the application process steps are sufficiently articulated before specific timeframes are considered.

31. Once the application process steps specific to application types have been refined, we can propose timeframes for each step (and the overall assessment process) by considering EPA's past performance, benchmarking against international regulators and preferably, undertaking meaningful consultation with relevant stakeholders to ensure that any timeframes we propose are reasonable. There was mixed support from industry for these new application pathways and timeframes mainly because of a perceived lack of detail and concerns about their practical implementation.

32. If unreasonable statutory timeframes are set, the risk is they will be unachievable, reducing transparency and trust in the EPA, which is the opposite of the intent and the recommendation from MfR. We are currently evaluating the timeframes used by other

international regulators including the Australian Pesticides and Veterinary Medicines Authority (APVMA), who specify timeframes within legislation. While we have not identified timeframes yet, for reference we note that the APVMA, while not directly comparable, has a timeframe of up to 22 months to complete a full application, and the European Union advises more than four years is required to assess a new active ingredient.

33. We will also need to consider use of timeframe waiver and "stop the clock" provisions that pause the statutory process and the criteria for which each can be used. If realistic process and assessment timeframes are set, the use of time waiver and stop-the-clock provisions should be less frequent. This is also contingent on there being sufficient regulatory and operational processes to elicit (more) complete applications being lodged with the EPA and to the allow the EPA to return or reject incomplete applications. However, even with these changes, there will always be the need for a regulator to be able to seek additional information or ask questions of an applicant if necessary. To provide transparency these provisions should clarify when the EPA has the responsibility to progress an application and whether there should be consequences if an application is neglected by the applicant i.e. the circumstances when the EPA can determine that an application has lapsed and can be treated as withdrawn.

34. Recommendation 4 of the MfR review recommends that the two regulatory systems (HSNO and ACVM) should be streamlined and easier to navigate. We note that as part of changes to the ACVM Act, MPI is proposing to remove statutory timeframes from the ACVM Act and place them in regulations, which they will consult on after the Omnibus Bill process. There would be benefit in also placing the HSNO statutory timeframes in regulations, one of which is that MPI and MfE could undertake a joint approach to consultation on the HSNO and ACVM timeframes. To best give effect to the MfR recommendations, there would be benefit in having as many high-level processes as possible aligned with the ACVM Act.

35. We seek your decision on the legislative design for where the statutory timeframes should sit:

| Option | Benefits | Risks |
|---|---|---|
| **Option one**<br><br>Within primary legislation, such as a Schedule within the HSNO Act | • Applicants will get clarity and transparency sooner as changes will be incorporated into the Bill.<br>• Preference of some stakeholders due to high level accountability of the parliamentary process. | • No time to consult with stakeholders on the timeframes themselves outside Select Committee process.<br><br>• Risk of implementing statutory timeframes 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.<br><br>• Limited time to sufficiently consider impact of the timeframe changes on other applications under the HSNO Act (e.g. HS |

| Option | Benefits | Risks |
|---|---|---|
| | | reassessments and New Organisms applications).<br><br>• Would 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. |
| **Option two *(recommended)***<br><br>Within regulations | • It would allow time to consider the timeframes carefully and carry out meaningful consultation.<br>• Would allow applicants to take part in setting timeframes, which was their preference.<br>• 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.<br>• 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.<br>• Regulations are subject to a sufficiently high-level process which should meet stakeholders desire for accountability. They are subject to scrutiny by the Regulations Review Committee.<br>• Easier to update regulations than primary legislation.<br>• Allows time to fully consider whether changes to HS statutory timeframes would negatively impact other application types under the HSNO Act. | • This option may take another 12 – 18 months to implement but work can progress alongside the passage of the Bill. |
| **Option three**<br><br>Within EPA notices or operationally by the EPA | • EPA Notices are secondary legislation, requiring consultation and tabling in Parliament. They are also subject to scrutiny by the Regulations Review Committee.<br>• Easier and quicker to amend timeframes in future if expectations, technological or | • The process of setting the timeframes may not provide the level of accountability, or perception of accountability, expected of the EPA.<br>• Unlikely to be supported by industry stakeholders |

| Option | Benefits | Risks |
|---|---|---|
| | scientific advancements, or types of applications change.<br>• EPA Notices are issued and/or updated by the EPA Board rather than needing to go through a Cabinet process, but they are still required to be publicly consulted on which allows stakeholder to be part of the process. | |

**Enabling provisions for a hazardous substances levy**

36. We are proposing an enabling provision to allow for a levy on hazardous substances to be developed and introduced later through regulations. This would entail the completion of a Stage 2 Cost Recovery Impact Statement (CRIS). The purpose of the levy would be to allow a new revenue stream to ringfence funding for the EPA's hazardous substances functions. Any implementation of a levy, including the scope of hazardous substances it may apply to and which activities the levy may fund, would be determined in the Stage 2 CRIS after further analysis and consultation.

37. There was opposition to the levy in the targeted stakeholder engagement (s 9(2)(b)(ii) , especially if there was no opportunity for further engagement. Given the current time constraints, we may not be able to fully consider all implications of the levy. Recommendation 11 of the MfR review stated that "*MfE and the EPA review HSNO cost recovery provisions. We recommend that consideration be given to (but options should not be limited to): whether the current level of cost recovery from industry is appropriate; and* ***an annual levy to support general regulatory functions which do not provide applicant specific benefits***."

38. MfE have interpreted this recommendation to mean that:

    i any levy would need to provide a stable source of funding to support the EPA in the performance of functions and duties and exercise of powers under this Act;

    ii officials would need to ensure that the EPA's costs are generally shared among all who benefit from the potential to use their services; and

    iii the distribution of costs is equitable, so that levy payers should generally pay a levy at a level commensurate with their use of, or benefit from the potential to use, the EPA's services and with the risks associated with the activities that levy payers carry out (but without strict apportionment according to use, benefit, or risk having to be observed).

39. We seek your agreement to one of the two options below to determine how to progress this work:

    i **Option one**: proceed with a levy provision under the current timeframes noting there are some operational and levy design questions which will be answered via a Stage

2 CRIS, to support the regulatory stewardship of the hazardous substances and new organisms' regime. *(Recommended)*

ii **Option two**: maintain the current status quo, with a plan to defer any further policy work on a levy to 2026.

40. We note that the scope of hazardous substances regulated under the HSNO Act is significantly broader than agricultural and horticultural products, and the stakeholders consulted in relation to these amendments. Any future work on a potential levy would consider the whole system.

**Data protection**

41. Data protection is a provision within the ACVM Act (sections 74 – 74H), which encourages companies to register innovative products in New Zealand by not allowing anyone else to use their data for a set period of time (either five or 10 years) after registration. This effectively gives companies an exclusive period of time in the market prior to other products containing the same chemistry (or for the same crops/use profile) coming to market.

42. Industry have expressed that they would like to see similar data protection provisions in 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.

43. In their review, MfR noted that applicants who want data protection must first apply for an ACVM approval, sometimes with incomplete applications, before lodging an application under the HSNO Act. This results in:

    i 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

    ii applications to the EPA being delayed until their full application package is ready, thereby missing the opportunity for EPA to begin their assessment.

44. We note that in its review, MfR declined to make a specific recommendation on amending data protection provisions but noted that consideration could be given to providing data protection under the HSNO Act and/or that guidance be developed to help navigate the existing provisions. In addition, Recommendation 4 of the review noted “Collaboration between agencies should happen at both operational and senior levels to consider opportunities such as alignment of controls, combined guidance, and streamlining data protection processes.”

45. We are proposing two possible options for data protection at this stage. We acknowledge that there may be value in investigating a third 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. However, 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. Officials note that extending data protection beyond ACVM registrations would engage wider

economic and anti-competition issues, which require analysis beyond the scope of this Omnibus Bill.

46. Two options that are within the constraints of the Omnibus Bill process have been proposed. We seek your view on which option to progress. Note that they are not mutually exclusive, so both could be progressed. If option one is progressed, this will inherently require some degree of option two to also be undertaken during implementation.

    i **Option one**: Amend section 55(4) of the HSNO Act to remove the restriction 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. (*Recommended*)

    ii **Option two**: Implement operational changes to 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. 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.

**Additional proposals**

47. We have developed several additional proposals, including:

    i Improvements to the emergency approval provisions to allow for more assessments (and approvals) to be made in advance of an emergency, increasing preparedness for a wider range of readiness and response activities, streamlining the process and facilitating use for small-scale or localised emergencies requiring a hazardous substance or new organism. This addresses Recommendation 16 of the MfR review.

    ii A collection of proposals to improve the workability and clarity of the HSNO Act to decrease the burden on applicants, the EPA and those organisations that undertake enforcement.

48. The full list of changes, including the proposed solution and expected outcome, is in Appendix 2 for your approval. Appendix 2 includes MfE's preferred options for the proposals we are seeking your decisions on.

## Proposed changes to the HSNO Act relating to new organisms

49. Officials, working with the EPA and MPI, have finalised proposed changes to the HSNO Act relating to new organisms.

50. The proposals are largely to provide clarity and enable more efficient processing of applications and to ensure that the HSNO Act aligns with the Biosecurity Act and does not conflict with the proposed Gene Technology Bill. These changes are in addition to the genetic modification changes to the HSNO Act under the proposed Gene Technology Bill and will only affect non genetically modified new organisms. The most significant proposals are:

i Amending statutory determinations of new organisms to allow for decisions at any taxonomic level. This will allow for criteria for decision-making to be expanded and the ability for decisions to be bundled together when appropriate.

ii Changing decision-making for denewing and prescribing risk species from an Order in Council to a decision by the HSNO Committee and clarify the criteria for denewing. This will be a less burdensome process and will allow for quicker regulatory recognition of the status of organisms in New Zealand.

iii 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.

iv Changing notification and time limit provisions for both conditional and full releases of new organisms to remove administrative burden and prevent approvals lapsing before use.

v Enabling more decisions to be delegated to EPA staff. 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.

vi Changing some definitions to align better with existing legislation, clarify the intent of the HSNO Act and support greater enforcement.

51. The full list of changes, including the proposed solution and expected outcome, is in Appendix 3. We consider the proposals broadly align with the feedback we received from stakeholders and will refer back to it for more specific details.

## Proposed minor and technical changes to the HSNO Act

52. Officials have identified a variety of minor and technical changes to the HSNO Act. These changes will not materially change how the HSNO Act is implemented but will clarify the Act to ensure that its intent is preserved. Many of these changes are to correct historical issues and it is beneficial to use this opportunity to progress them through the Omnibus Bill. These minor and technical changes are in Appendix 4.

53. There are a number of changes to the provisions in the HSNO Act regarding persistent organic pollutants (POPs). The HSNO Act is the mechanism by which New Zealand gives effect to the Stockholm Convention, which is a global treaty to limit POPs. As new and different chemicals (e.g. from some per- and polyfluoroalkyl substances (PFAS) to additives used in the manufacture of car parts) have been added to the Convention, the provisions of the HSNO Act have been changed in a piecemeal fashion. The degree to which this has occurred means that some provisions are no longer clear or do not correctly align with the Stockholm Convention. These changes will better align the HSNO Act with our obligations under the Stockholm Convention and will provide greater clarity, including for importers of articles containing POPs.

## Update on implementation of recommendations from MfR sector review

54. Cabinet has requested a report back in May 2025 to update them on the implementation of the recommendations from the MfR review of the approval process for agricultural and horticultural products along with policy decisions to enable drafting instructions to be prepared. To do this, officials have developed a table with the 16 recommendations and the progress of each (Appendix 5). We note the following progress in particular:

    i The first meeting of the Sector Leaders Forum is on 3 April 2025 (Recommendation 1) – they will report back to you after every meeting (Recommendation 2).

    ii The proposed changes to the HSNO Act discussed above relate to recommendations 5, 7, 11, 13 and 16.

    iii The EPA are progressing operational changes and initiatives that relate to a number of recommendations.

# Te Tiriti analysis

55. Due to the short timeframes to undertake these amendments, we have not completed a Te Tiriti Impact Analysis. As part of our targeted stakeholder engagement, we have engaged with Te Rūnanga o Ngāi Tahu's HSNO Committee.

## Consultation

56. These proposals were developed collaboratively with EPA and MPI officials and have been the subject of targeted stakeholder engagement with the organisations listed in Table 1 above. Other government agencies, including the Ministry for Business, Innovation and Employment, WorkSafe, and Defence were also consulted when appropriate.

## Risks and mitigations

57. In addition to the risks outlined in specific sections above, an additional risk includes decreased quality of analysis and outcomes due to the short timeframes for introducing the Omnibus Bill. We have mitigated this by undertaking targeted stakeholder engagement in the limited timeframe that we have.

58. There may be a risk some stakeholders will not be satisfied with the scope of the proposals, including stakeholders who were not part of the targeted stakeholder engagement that we undertook. Given the limited timeframes, the scope of the proposals is limited.

## Legal issues

59. s 9(2)(h) [redacted]

60. s 9(2)(h) [redacted]

## Financial, regulatory and legislative implications

62. These policy proposals will have financial, regulatory, or legislative implications for the hazardous substance and new organism regime. These implications will be further discussed in the upcoming Regulatory Impact Statement and Cost Recovery Impact Statement that will accompany the Cabinet paper.

# Next steps

63. Officials are working with MfR to provide policy proposals and content for the Cabinet paper expected to be presented to the Economic Policy Committee on 14 May 2025, and Cabinet on 19 May 2025.

# **Appendix 1:** Summary of feedback received through targeted stakeholder engagement

Written feedback was provided by stakeholders. The feedback received on proposals has been summarised below:

| **Proposal** |
| --- |
| • *New application pathway - time limited conditional approvals (relying on international regulator assessments)*<br>• *Make greater use of international regulator assessments* |

Feedback received

- The proposal for time-limited conditional approvals was seen as having a high level of uncertainty in the absence of more detail.
- There was desire for this to align with the criteria under ACVM.
- Concern was also raised about time-limited conditional approvals replacing the current enduring approvals.
- A suggestion was made to lower the thresholds for using the s28A(2)(ab) international regulator rapid assessment pathway and making it mandatory if requested by the applicant.
- A request was made to use only one international regulator instead of two.
- There was suggestion that this pathway was not needed as the legislation was already available for rapid applications using international data.
- It was noted that ACVM registration does not address the Crown's obligations under Te Tiriti o Waitangi and any new pathway or modifications to existing pathways should meet the obligations the EPA has to uphold Te Tiriti o Waitangi and Settlements undertaken under Te Tiriti o Waitangi.

| **Proposal** |
| --- |
| • *Identifying application types and timeframes in legislation* |

Feedback received

- The need for clear and enforceable statutory timeframes was highlighted. Suggestions included implementing a tracking system and conducting independent reviews to address delays.
- It was suggested that timeframe waivers should only be used when necessary; in a transparent manner; and for a limited period of time only.

- There was an emphasis on statutory timeframes remaining in primary legislation for greater scrutiny. Another suggestion was to use the EPA's past performance as a benchmark for setting timeframes rather than comparing with overseas regulators.
- There was a strong desire for consultation regarding timeframes – to insure there was confidence in the resulting timeframes.
- A request to ensure that any public consultation was of a reasonable length and allowed for the EPA staff report to be made available prior to consultation.

| **Proposal** |
| --- |
| • *Improved emergency approval provisions* |

Feedback received

- There was support for clarifying operational policies for emergency approvals and conducting risk assessments during non-urgent periods.
- There was also support for the rapid approval of substances when necessary.
- There was some concern that there would be less consultation using these processes.
- There was a suggestion to include tools to mitigate climate change.

| **Proposal** |
| --- |
| • *Introduce enabling provisions for a levy on hazardous substances to support the EPA's regulatory administration of its HS functions* |

Feedback received

- There was opposition from some stakeholders to the proposed levy until the EPA was able to demonstrate a measurable improvement in its core work. Concerns about the impact of additional costs on the horticulture sector are raised.
- There was also some support for the levy from those who adhered to a user pays model.

| **Proposal** |
| --- |
| • *Data protection* |

Feedback received

- Stakeholders wanted data protection provisions, including enforcement, added to HSNO Act.

| **Proposal** |
| --- |

*Improved compliance and enforcement:*

- *Extending the timeframe for filing charges*
- *Adding "assist and intervene" enforcement power for the EPA*
- *Providing for different infringement fees for individuals and entities*

Feedback received

- No significant feedback

| **Proposal** |
| --- |
| • *New organisms proposed amendments* |

Feedback received

- One stakeholder cautioned aligning with Gene Technology Bill, as it is yet to be approved.
- There was general support for the new organisms proposals with the denewing proposal and the and relaxing of timeframes for approvals before lapsing being the most popular.
- There was a strong desire for ongoing engagement.
- There were some suggestions for how denewing could be used in practice and suggested criteria.
- We were encouraged to align changes in organism status under HSNO Act and the Biosecurity Act, either through legislative change or operationally.
- There was a suggestion that the expanded use of the conditional release pathway should only be if the organism posed no risk, and the suggestion that a condition could be sterility of the organism.
- There was a concern that care was needed to ensure that organisms that were extinct in New Zealand long ago (such as the Moa) were still seen as new organisms, as their native ecosystem had long changed.
- There were calls to ensure that any change to the field test regime still prevented organisms escaping and forming pest species.
- Removing clause 35(2)(b)(i) of the HSNO Act was initially proposed by MfE, but upon further discussion it was suggested this would change the risk profile too much and be out of scope for this suite of changes.

Feedback received out of scope of the proposals

- There was a request for clarification of the scope of the "assist and intervene" powers. We have now decided not to propose these powers for new organisms.

- There was a request to change the requirements for "significant" in s36 minimum standards.
- There were suggestions on how to best manage containment facilities for genetically modified organisms.
- There were also recommendations to improve the pathway for approving microbial pesticides and address high regulatory barriers.

**Other feedback**

We received a significant amount of feedback that was not in the scope of the Omnibus Bill proposals. For the feedback related to regulatory efficiency and transparency, the Sector Leaders Forum will be a good platform to discuss and consider these issues. For the other feedback, officials will only be able to investigate possible non-legislative improvements that may address these after the omnibus bill process.

Timeframe of consultation and amount of detail in proposals

- While being grateful to be included in consultation, stakeholders wanted the opportunity to consider more detail than available over a longer period of time.

Regulatory efficiency and transparency

- There was some emphasis on the need for improved efficiency in the EPA's processing of applications. Transparency in performance reporting and the use of time waivers is crucial to build trust and accountability.
- There was also a request to collaborate with MPI to enable a single set of regulations for setting and reviewing statutory timeframes

Precautionary approach

- The current precautionary approach was seen by some as overly stringent, making crop protection tools inaccessible to growers.
- There was a call to align the HSNO Act's risk appetite to that of the upcoming Gene Technology Bill.

Enabling more flexible implementation and amendment to group standards

- There was a desire for more flexibility for what is allowed in group standards, especially around methane inhibitors.

Biopesticide Application Pathway

- There was a call for an improved approval pathway for biopesticides, including joint reviews with international regulatory agencies.

**Individuals who submitted on behalf of targeted stakeholder groups**

| Name | Organisation | Job title |
|---|---|---|
| s 9(2)(a) | Animal and Plant Health Association of New Zealand | s 9(2)(a) |
| s 9(2)(a) | Federated Farmers | s 9(2)(a) |
| s 9(2)(a) | Horticulture New Zealand | s 9(2)(a) |

| | | |
|---|---|---|
| s 9(2)(a) | A Lighter Touch<br>Note: They provided their feedback through Horticulture New Zealand | s 9(2)(a) |
| s 9(2)(a) | AgResearch | s 9(2)(a) |
| s 9(2)(a) | Manaaki Whenua Landcare Research | s 9(2)(a) |
| s 9(2)(a) | Plant and Food Research | s 9(2)(a) |
| s 9(2)(a) | New Zealand Plant Producers Incorporated | s 9(2)(a) |
| s 9(2)(a) | AgriZeroNZ | s 9(2)(a) |
| s 9(2)(a) | Te Rūnanga o Ngāi Tahu | s 9(2)(a) |
| N/A | Scion<br>Note: Scion was a stakeholder we engaged with the others above, but did not submit written feedback | N/A |

# **Appendix 2:** Summary of hazardous substance policy changes to the HSNO Act

| Amendment title | Proposed solution | Outcome |
|---|---|---|
| New application pathway - time limited conditional approvals (relying on international regulator assessments) | Amend the Act to provide for time limited conditional approvals where certain substances that have already been approved by international regulators, but do not meet the criteria for the international rapid pathway (s28A (2)(ab)), can be used while the substantive assessment is conducted. | A new approval pathway will widen the scope of applications where international assessments are relied upon, while maintaining a balance to protect people and the environment.<br><br>This will enable novel substances with the greatest benefit to be used sooner while not undermining the strength of the regulatory system that supports exporters of agricultural and horticultural products and allows them access to international markets.<br><br>It will also make greater use of information from the EPA's already recognised international regulators.<br><br>**MfR review Recommendation 7** |
| Make greater use of international regulator rapid assessment pathway | Amend existing s 28A(6), to clarify the significant effects test so as to better support the EPA to rely more on information supplied under the international regulator rapid assessment pathway. | This would potentially allow more substances, but likely not those containing new active ingredients, to be assessed under the rapid pathway and for new and beneficial products to come on the market more quickly.<br><br>Substances with new active ingredients (and meeting other criteria) would be eligible to apply for a time limited conditional approval, which is complementary to the existing international regulator rapid pathway |

| Amendment title | Proposed solution | Outcome |
|---|---|---|
| | | and will increase use of information from international regulators.<br><br>**MfR review Recommendations 5 and 7** |
| Differentiating hazardous substance application types by risk and extent of scientific assessment required (risk tiering) | Amending existing provisions relating to hazardous substance applications (under section 28) to introduce different types (categories) of applications according to differences in risk. This is consistent with the approach of other international regulators and formalises EPA's existing operational practice. | Currently all individual hazardous substance applications not assessed under a rapid pathway, are considered the same under the HSNO Act despite varying greatly in complexity and risk. Operationally, the EPA has employed a framework that tiers applications into different categories (pathways) depending on the likely risk and level of assessment required. By formalising these pathways in the HSNO Act, appropriate timeframes can be attached to each that are proportional to the risk and the amount of time required to assess applications. In doing so, applicants will have greater transparency and clarity on the application process and timelines. The pathways are expected to be supplemented with operational guidance relevant to the information requirements for each application type. |
| Set statutory timeframes according to application type and improve process steps. | Propose to replace the current time limits in section 59 with an enabling provision to set regulations. These regulations will set out appropriate timeframes that are proportional to the degree of complexity and risk of application type and that are in line with comparable international regulators. These regulations will also make a number of other improvements to the process steps in section 59 to streamline the application processes. | Setting appropriate process timelines according to application type will provide greater certainty to applicants and clearer performance targets for the EPA. We are proposing that the time limits be set in regulations to align with the changes to the timeframes being proposed by MPI under the ACVM Act. The improvements to the process steps are intended to streamline the assessment process, these include the following main changes: |

| Amendment title | Proposed solution | Outcome |
|---|---|---|
| | | - introducing an application completeness step under each pathway, with the ability to return incomplete applications<br>- improving and clarifying the time waiver and stop the clock provisions<br>- including a clear process step for EPA to undertake the substantive assessment, and for this to be before an application is notified (those requiring notification)<br>- streamlining the notification requirements according to application type<br>- reducing the requirement for hearings for certain application types<br>- clarifying when an application lapses and can be treated as withdrawn<br><br>**MfR review Recommendation 13** |
| Improved emergency approval provisions | Rename the provisions to more accurately reflect their intent.<br><br>Extend and expand the eligibility threshold for s46 emergency approval provisions so that biosecurity readiness and response activities, including under National and Regional Pest and Pathway Management Plans, during Biosecurity Emergencies, the detection of pests through surveillance activities, and border responses are eligible to apply for an emergency approval.<br><br>Amend s48(2)(a) to only require an emergency declaration when relevant. | Emergency approvals will be a tool available for the range of the range of biosecurity emergencies that require responses. Pre-approval can be given for the use of substances and organisms when pests are detected, promoting a proactive biosecurity system and ensuring appropriate treatments and tools are available when emergencies arise. This will also encourage the use of emergency approvals over special emergency approvals, improving regulatory oversight.<br><br>There will be a more defined distinction between use cases for emergency approvals and special emergency approvals. Emergency approvals will be used to access tools for responses with appropriate |

| Amendment title | Proposed solution | Outcome |
|---|---|---|
| | | assessment, engagement and oversight, while special emergency provisions will be used for unanticipated or larger-scale emergencies which involve more limited assessment and a Minister-level declaration of special emergency.<br><br>This will potentially require consequential amendment to the ACVM Act to align with any changes.<br><br>**MfR review Recommendation 16** |
| Introduce enabling provisions for a levy on hazardous substances to support the EPA's administration of its HS regulatory functions | Introduce provisions that would enable a levy regime to be developed at a later date and implemented by way of regulations. | The EPA's funding model relies primarily on government appropriations and a low level of cost recovery through fees and charges. It faces challenges in adequately funding its hazardous substances regulatory functions. Levy funding support would help address those challenges akin to other "user pays" levies.<br><br>The amendment would be enabling only. Any levy scheme would need to be developed, consulted on, before implementation.<br><br>**MfR review Recommendation 11** |
| Data protection | Amend section 55(4) of the HSNO Act to remove the restriction that requires an application for an innovative Trade Name Product (TNP) to first be lodged under the ACVM Act in order for the data protection provisions in Part 6 of the ACVM Act to apply. | This will give applicants clarity that the data protection provisions will apply regardless of the sequence in which the applications are lodged.<br><br>Whilst not a recommendation, was suggested in the MfR review. |

| Amendment title | Proposed solution | Outcome |
|---|---|---|
| Improved compliance and enforcement: Extend the timeframe for filing charges | Amend section 109A(1) to increase the time for filing charges from 6 months to 12 months. | A 12-month timeframe finds a better balance between providing the enforcement agency with enough time to carry out and complete a thorough investigation, and the need for prompt enforcement action. It would also align with the timeframes in HSWA and RMA. . |
| Improved compliance and enforcement: Adding an "assist and intervene" enforcement power for the EPA | Amend section 97(4) to give the EPA an overarching enforcement power, where the EPA can undertake, assist, or intervene in, an enforcement action falling under another s97 enforcement agency's jurisdiction should such action be deemed necessary or desirable to promote the purpose of the HSNO Act, with respect to hazardous substances. | The proposed amendment to s97(4) will provide the EPA with the authority to act directly, and without delay, to enforce the provisions of the HSNO Act (with respect to hazardous substances) following consultation with the primary responsible agency. |
| Improved compliance and enforcement: Providing for different infringement fees for individuals and entities | Amend section 140 of the Act to:<br>• provide for different infringement fees to be set for individuals and entities, and<br>• increase the maximum infringement fee for entities from $3,000 to $12,000. | These proposed amendments align with HSW legislation, which also deals with non-compliances around hazardous substances, with a similar regulated community.<br><br>The ability to set higher infringement fees for entities would be more effective at achieving deterrence, especially with repeat offenders. Setting lower fees carries a risk that repeat offender more profitable entities may consider them the cost of doing business. |
| Address ambiguity related to scope of section 63A | Amend section 63A(2) to specify that a reassessment under section 63A can also be undertaken to vary the hazard classification of a hazardous substance and to ensure consistency with sections 63C and 63D. | The addition of sections 63C and 63D to the HSNO Act has created unintended ambiguity with the wording of section 63A. |

# **Appendix 3:** Summary of new organisms policy changes to the HSNO Act

| Amendment | Proposed solution | Outcome |
|---|---|---|
| Determinations | • Remove the requirement for the decision to be gazetted<br>• Make sure that the decision can be made at various classification levels (species, family, strain type, cultivar etc)<br>• Include a provision that allows for a decision to be made on the basis of the ubiquity of an organism internationally and on the basis that the organism is otherwise new to science.<br>• 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. | Allow for criteria for decision making to be expanded and the ability for decisions to be bundled together when appropriate. |
| Denewing and risk species | Make denewing and prescribing risk species a decision made by the HSNO Committee. Use s26 of the Act as a starting point for drafting.<br><br>• Possible applicants should include the CE of the EPA<br>• Part of the process will include deciding the "newness" of an organism<br>• Should always include a public consultation process<br>• Outcome should be gazetted<br>• EPA required to maintain a public register with the status of all organisms that have been through this process<br>The status of new organisms subject to the regulations dealing with organisms prescribed as not new and risk species not affected. | Remove MfE, Minister and Cabinet from process.<br><br>Process is quicker and more efficient and allows for a level of decision making in line with other decisions on new organisms. |

| Amendment | Proposed solution | Outcome |
|---|---|---|
| Reassessments | • Amend the reassessment criteria in s62 and s63 to give similar reassessment powers to the NO regime to HS regime. This would provide a more fit for purpose reassessment regime for new organisms, which takes account of new information and a changing environment.<br>• Give NO the ability to revoke approvals that are no longer in use<br>• Give NO the ability to have modified reassessments (similar to HS)<br>• Allow for an approval to be put on hold during a reassessment (similar to s64A for HS) but only for approvals where the organism has not yet been released | Allow for changes to existing approvals more easily.<br><br>To revoke approvals – the ability to 'tidy-up' redundant or replaced approvals is needed. Currently they are not timebound, and there is no reassessment pathway to remove redundant approvals. ly undertake a 'full' reassessment, rather than looking at a particular aspect of an approval. This would make the system consistent between HS and NO.<br><br>It is acknowledged that once an organism is released under a full release, it may be too late for reassessment to have any meaningful effect. |
| 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. |
| Conditional releases | Review the provisions relating to conditional releases to make the pathway more useable.<br><br>• Give EPA discretion to change the 5-year time limit and allow for multiple extensions<br>• Give EPA the ability to waive the condition for the organism to be destroyed at the end of the approval provided there will be no adverse effect on the environment.<br>• Enable, where appropriate, for a conditional release to transition to a full release. This would involve an assessment based on a set of criteria. | Less administrative burden for conditional releases, especially those obtained for emergency purposes. |

| Amendment | Proposed solution | Outcome |
|---|---|---|
| Notification and extension provisions for full releases | • Add the ability to extend time extension multiple times as currently you can extend them only once<br>• Include criteria that any new information will also need to be given to the EPA as part of request for extension<br>• 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.<br>• Give EPA discretion to "revive" new organisms approval that has expired due to administrative error. | Time limits allow for any new or unforeseen risks to be managed, however relaxing the notification provisions will decrease administration on releases. |
| Regulations | Allow for EPA notices in relation to new organisms. This would allow EPA to create secondary legislation on technical matters relating to NO. The topics that would be moved would be comparable to those that HS have moved into EPA notices, including those relating to forms.<br><br>Revoke the following regulations:<br><br>• Hazardous Substances and New Organisms (Personnel Qualifications) Regulations 2001<br>• Hazardous Substances and New Organisms (New Organisms Forms and Information Requirements) Regulations 1998 | More efficient creation of secondary legislation for NO for technical matters.<br><br>Revoked regulations are not used. |
| Delegations | • Amend s19 to enable NO decisions to be delegated to EPA staff in line with HS delegations<br>• Retain HSNO DMC for publicly notified applications.<br>• Make additional amendments to s 19 to clean up drafting and provide clarity. ' | Improve efficiency by reducing administrative burden on EPA to stand up committees of the board for low risk, non-GMO new organisms.<br>Align delegations for new organisms with those for hazardous substances.<br><br>Changes to HS modified reassessment delegations will also occur as part of this proposal |

| Amendment | Proposed solution | Outcome |
|---|---|---|
| Information sharing | Change s97C(3) to include entities referred to in section 97A, applying the information-sharing provisions to the enforcement agency for new organisms. | Better access to EPA specific information (e.g. previous applications) would help MPI make non-statutory determinations that are likely to align with the eventual statutory determination. |
| Enforcement of New Organisms | Ensure that wording of s97A specifies that MPI is the responsible agency for enforcement of the HSNO new organisms regime.<br><br>The policy intent is for MPI to be the responsible agency for the enforcement of the new organisms regime.<br><br>How they may choose to operationalise this, including decisions to use discretion and prioritise, is their responsibility and their operational choices may come with risks. | MPI's resource allocation is more efficient and appropriately prioritised within the new organism portfolio and between new organisms and biosecurity. |
| Changes to definitions | | |
| Definition of 'Organism' | Align the definition of organism with the Biosecurity Act (excluding prions)<br><br>Amend the definition of organism to be applied at any taxonomic level. | Alignment will aid application between Acts and is good regulatory practice.<br><br>Clarifying taxonomic level of application will make applications more flexible and targeted, improving operational efficiency |
| Definition of 'New Organism' | Confirm that an organism that is native to New Zealand can't be a new organism.<br><br>Clarify that organisms that, through natural means, are no longer present in New Zealand but can be reintroduced, are not new organisms. | Native species and reintroduction efforts for species that became extinct on or after 29 July 1998 will not be regulated by the HSNO Act<br><br>Clarifying taxonomic level of application will make applications more flexible and targeted, improving operational efficiency |

| Amendment | Proposed solution | Outcome |
|---|---|---|
| | Amend the definition of new organism to be applied at any taxonomic level | |
| Prohibition of vagrant organisms | Amend schedule 2 to exclude native, vagrant or naturally occurring organisms.<br><br>Specifically, sections 1 and 2:<br><br>1) Any snake of any species whatever.<br>2) Any venomous reptile, venomous amphibian, venomous fish, or venomous invertebrate. (In this item, venomous means capable of inflicting poisonous wounds harmful to human health.)<br>And<br><br>Amend s50 to exclude not-new organisms from being prohibited | Naturally occurring vagrant sea snakes and marine organisms would be eligible for importation, release and development in New Zealand. The most likely impact of this would be that sea snakes could be added to zoos and aquariums.<br><br>These species are unlikely to establish permanent populations in New Zealand, and if they were determined to have an adverse impact, they could be managed as Unwanted Organisms under the Biosecurity Act. |
| Definition of 'Develop' | To streamline applications to import and develop, expand and aggregate the range of activities that are considered 'developing' a new organism to better reflect the activities that are being regulated by the Act.<br><br>Also, remove the distinction between New Organisms and Incidentally Imported New Organisms, applying the same definition of develop to both.<br><br>Proposed activities to be included in the definition include:<br><br>• to carry out large-scale fermentation using a micro-organism that is a new organism:<br>• to test, trial, or research a new organism. | The EPA will be able to more comprehensively regulate new organisms in New Zealand, regardless of how they arrive.<br><br>New Organisms will not be able to be bred or multiplied without a permit.<br><br>To avoid doubt, an approval will still be required to import, develop, field test or release a new organism.<br><br>The activities that develop includes will be clearer and easier to apply operationally.<br><br>Changes to other parts of the Act may be required to align with changes to the definition of develop. |

| Amendment | Proposed solution | Outcome |
|---|---|---|
| | • the deliberate isolation, aggregation, multiplication, breeding, propagating, growing, raising, or other use of the organism | A transition plan with operational changes will be needed to ensure existing import approvals will be able to continue their current activities even if they now fall within the new definition of develop. |
| Definition of 'Incidentally Imported New Organism" | Amend definition of incidentally imported new organism to clarify that the offspring, progeny or descendant of an incidentally imported new organism that is born within New Zealand is also treated as an incidentally imported new organism. | 'Incidentally imported new organisms' and their progeny will be regulated as intended. |
| Definition of 'field test' | Remove the requirement to "remove any heritable material" from a field trial at its end.<br><br>The risk of biological material escaping from or remaining after a field trial will still be managed under s44 - Additional matters to be considered on applications for importing and field testing of organisms. | Field testing of new organisms will be easier to approve. The risk of new organisms escaping the trial, establishing new populations, and being difficult to eradicate will still be managed or applications declined if appropriate |
| Definition of 'release' | Amend the definition of release to apply to all situations where a new organism is not contained.<br><br>Specifically, a fish in an aquarium or small pond, and a plant in a pot should be considered to be released if not 'contained' as defined by the Act.<br><br>The intent is that an organism can be considered 'released' even if it is still subject to legal restrictions, as it primarily relates to physical status. The existing caveat for the Biosecurity and Conservation Acts will be retained: "other than those imposed in accordance with the Biosecurity Act 1993 or the Conservation Act 1987" should be clarified separately to avoid confusion of the intent of this definition. | Release will apply to situations where a new organism is unsecured, which more appropriately manages the risk of a new organism spreading on its own, from adverse events or through human intervention.<br><br>This would also better enable enforcement and compliance action to be taken.<br><br>This would clarify that a new organism in an enclosed pond can still be considered released is it is outside of containment, as it could still be physically accessed and moved. Just because it may be still subject to legal restrictions on movement, doesn't mean it isn't released. |

| Amendment | Proposed solution | Outcome |
|---|---|---|
| Definition of 'qualifying organism' | Include medical devices in the definition of 'qualifying organism'.<br><br>Amend s38I to apply to assessment of applications for release of qualifying organisms contained in medical devices. | Qualified organisms contained in medical devices could be assessed through the pathway in sections 38I-38L |

## **Appendix 4:** Summary of minor and technical changes to the HSNO Act

| Amendment title | Section | Change | Reason for the change |
|---|---|---|---|
| Updating definition to refer to updated classification system. | 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 | Sections 3(3), 3(6) | Amend s3(3) to remove reference to the term "EPA controls"<br><br>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.<br><br>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. |

| Amendment title | Section | Change | Reason for the change |
|---|---|---|---|
| Provisions of persistent organic pollutants within the HSNO Act to better align with the Stockholm convention | Section 25A, 25C, 25D, 29B, 66A, 140A, and schedules 1AA and 2A all need to either be amended or revoked to align with the Stockholm convention. | Many deletions and changes within those sections | 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 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 |
| Reviewing 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. |
| Reviewing annual reporting provisions | Section 148 | Specify that only those agencies with HSNO responsibilities need to report on it on the annual reports | According to s148, all agencies are required to report on the HSNO Act – this clarifies that only those agencies with responsibilities under the HSNO Act need to report on it.<br><br>This will not need to proceed if you agree to proceed to the amendment directly above (Reviewing SOI and annual report provisions). |
| Redefining agency submissions | Section 58(1)(i) and (ii) | Change “submission” to “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 |

| Amendment title | Section | Change | Reason for the change |
|---|---|---|---|
| | | | application should be considered, not just formal submissions. |

# **Appendix 5:** Update on implementation of recommendations from MfR sector review

Table 1 summarises the update on the implementation of recommendations from the MfR sector review. As some of the recommendations relate to operational improvements, officials worked with the EPA to prepare the content in the table for updates that are apply to MfE and EPA. The table does not include updates from MPI and New Zealand Food Safety (NZFS) on their progress. The content was also shared with members of the Sector Leaders Forum and was discussed at their first meeting on 3 April 2025.

**Table 1: Progress update on the implementation of MfR's recommendations**

| Recommendation | Progress update | Key timings and milestones | Status |
|---|---|---|---|
| Recommendation 1: Recommend the formation of a Sector Leaders Forum | • NZFS has worked with the EPA and MfE to establish the Sector Leaders Forum and invited stakeholder members for the first meeting on 3 April 2025. The Deputy Director-General of NZFS is proposed to chair the first year of meetings in 2025 in the draft terms of reference. | • Forum members will discuss and approve a terms of reference at the first forum meeting on 3 April 2025.<br>• There will be a report back to Ministers following each meeting with an agreed summary of the discussions, views presented, and actions or next steps. This will be shared with forum members as well.<br>• The next forum meetings will be scheduled for:<br>o End of June<br>o End of September<br>o December<br>• The next forum meeting in June 2025 is expected to focus on discussing performance of the approval path across the regulatory systems, and this discussion will occur at every second meeting thereafter. | Ongoing |

| Recommendation | Progress update | Key timings and milestones | Status |
|---|---|---|---|
| Recommendation 2:<br>Recommend that the Minister for the Environment and Minister for Food Safety ensure prompt implementation of this Review's recommendations and are required to consider issues raised by the Sector Leaders Forum | • The report back to Ministers following each forum meeting will provide an update on the implementation progress of the review's recommendations, summarise the forum's discussions, and any matters raised for Ministerial consideration.<br>• The EPA's ability to undertake a work programme to implement many of the recommendations is limited by current funding and capacity. The MfR report also acknowledges some of the recommendations will require additional funding, particularly updating their risk assessment models (recommendation 10). | • The report back to Ministers is expected to occur promptly after each forum meeting. This will be shared with forum members as well. | Ongoing |
| Recommendation 3:<br>Recommend that the Minister for the Environment and Minister for Food Safety set expectations for targets to accelerate HSNO and ACVM processes and reduce queues | • To inform the forum's discussion on this recommendation, operational agencies (EPA and NZFS) propose to provide performance information at the next forum meeting in June 2025 for the forum to discuss and provide context on the current application numbers and queue volumes for HSNO and ACVM. The report back of the forum meeting to Ministers will inform progress on this recommendation and provide visibility on the queue volumes.<br>• This recommendation is closely related to recommendation 13 (performance reporting and statutory timeframe review), which will need to be considered together.<br>• The Minister for the Environment sets expectations and targets for the EPA through an annual Letter of Expectation. The Minister for the Environment may also provide feedback on progress via the EPA Board. | • Forum to discuss initially at the April 2025 forum meeting.<br>• Agencies to provide performance information on HSNO and ACVM to the forum members at the June 2025 meeting for discussion, review progress on the omnibus bill, and discuss the review of statutory timeframes (recommendation 13) of each legislation to determine what the next steps are for these recommendations.<br>• The Minister's Letter of Expectations to the EPA for 2025/26 is now available on the EPA website and has been provided to the forum. | In progress |

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| Recommendation 4:<br>Recommend that MPI, MfE, NZFS and the EPA make the two regulatory systems easier to navigate | • Agencies will continue to collaborate closely and look for opportunities to increase coordination, and to understand the common challenges for applicants, including seeking forum feedback and suggestions.<br>• Agencies will welcome any suggestions made through the forum for specific examples of where stakeholders have difficulty navigating the two regulatory systems, so that most effective use of resource can be considered (alongside existing work programs). | • Forum and Ministers can expect this recommendation to be an ongoing action as opportunities are discussed, explored, and progressed. | Ongoing |
| Recommendation 5:<br>Recommend that agencies increase the use and better design of group standards, rapid assessment pathways, registration exemptions, and self-assessable changes | • The EPA have identified options for the development of new group standards for certain types of low-risk hazardous substances, but this development will require resources. EPA will consider this recommendation when designing these new group standards.<br>• The EPA are also working with MfE on amendments to the HSNO Act and are considering options to improve the legislative processes for issuing and amending group standards.<br>• This year (FY24/25), the EPA have substantially increased their use of rapid assessments over previous years. Since July 2024, EPA have decided 37 applications by rapid assessment (as of 26 March 2025). At this pace, EPA estimate deciding 50-55 rapid applications by July 2025, which would be comparable to the most recent high in 2015/16 (54) and not bettered since 2011/12. | • The ability for the EPA to develop the new group standards identified is dependent on resourcing.<br>• Any legislative amendments will be incorporated in the omnibus bill. | In progress |
| Recommendation 6:<br>Recommend that MPI and NZFS | • N/A – this recommendation relates to ACVM and is for MPI and NZFS to action | • N/A | N/A |

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| reduce ACVM efficacy requirements for inhibitors to the minimum required to manage risks | | | |
| Recommendation 7:<br>Recommend that the EPA and NZFS maximise their use of assessments by international regulators for assessing the risks of a product while still considering aspects unique to New Zealand | • The EPA have always relied on assessments from international regulators in their assessments. EPA have also used international regulator information to assess six applications through a specific rapid pathway made available following amendments to the HSNO Act in 2022.<br>• The EPA will continue to look for opportunities to more effectively use this information. EPA and MfE are working together on legislative amendments in the omnibus bill to include a proposed conditional approval scheme to allow some novel agrichemicals with significant benefit to New Zealand to be used while the substantive assessment is conducted. | • Agencies will provide progress updates to the forum and Ministers on this recommendation, key developments in the engagement with overseas regulators, and the use of international assessments for processing applications for both HSNO and ACVM.<br>• Any legislative amendments will be incorporated in the omnibus bill. | Ongoing |
| Recommendation 8:<br>Recommend that the EPA and MPI (including NZFS) prioritise engagement at the international level to support harmonisation of requirements | • The EPA actively engage in relevant international fora (within current resourcing). This includes OECD, HEPA and SETAC as well as directly with regulators in US, UK, Canada and Australia. New Zealand benefits from this engagement in terms of:<br>- access to combined global expertise<br>- harmonisation of requirements and best practices (for example, harmonised test guidelines and mutual acceptance of data between countries). | • The EPA and NZFS have regular monthly meetings with Quins partners (Australia, USA, UK, and Canada) on regulatory matters and opportunities for collaboration, and can update the forum following these engagements as part of normal reporting.<br>• The EPA are looking at how they can specifically engage with the Australian Pesticides and Veterinary Medicines Authority on their processes, including gaining a better understanding of their risk assessment models (related to recommendation 10). | Ongoing |

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| Recommendation 9:<br>Recommend that MPI (including NZFS), MfE and the EPA explore a strategic priority pathway, in addition to the current first come, first served queue | • This is recommended to be discussed at forum meetings between agencies and forum members to explore this recommendation further. The feasibility and efficacy of a separate pathway within current HSNO and ACVM settings from the current "first-come, first-served" approach taken by agencies requires detailed consideration.<br>• The EPA are developing proposals for criteria to prioritise assessment of applications, and they are engaging with industry on these proposals.<br>• As noted in the MfR report, diverging views of applicants and industry, along with the broad scope of substances that are regulated by the HSNO Act, present challenges to developing fit-for-purpose criteria. The EPA note that prioritisation will not reduce the size of the queue, and any move away from a "first-come, first-served" queue would inevitably mean a longer wait for some applications. | • Discuss initially at the forum meeting on 3 April 2025 and propose any actions, including for agencies and forum members to explore appropriate criteria or framework for developing a possible strategic priority pathway that aligns with the statutory purpose of the HSNO and ACVM Acts, and report back to subsequent forum meetings for consideration.<br>• The EPA have contracted Sapere Research Group to undertake a survey on potential indicators and criteria for prioritisation of hazardous substances applications. The survey is planned to go out to a broad group of stakeholders in April 2025. | In progress |
| Recommendation 10:<br>Recommend that the EPA update their outdated risk assessment models and consider how to keep them up to date for the future | • Specific funding/appropriation is required before risk assessment models can be modernised. | • Contingent on funding. | Not started |
| Recommendation 11:<br>Recommend that MfE and the EPA review HSNO cost recovery provisions. We recommend that consideration be given to (but options should not be limited to): whether the current level of cost | • The EPA and MfE are working to explore amendments to the HSNO Act to allow the setting of levies. A legislative provision to enable the setting of the levy is only the first step, and further work will be required to determine the scope of such a levy. | • Any legislative amendments will be incorporated in the omnibus bill.<br>• Any work on levies and/or application fees would be consulted on. | In progress |

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| recovery from industry is appropriate; and an annual levy to support general regulatory functions which do not provide applicant specific benefits. | • No work is currently underway to review existing HSNO application fees but will be considered in future in relation to overall cost-recovery. | | |
| Recommendation 12: Recommend that MPI strengthen the framework overseeing independent data assessors | • N/A – this recommendation relates to ACVM and is for MPI and NZFS to action | • N/A | N/A |
| Recommendation 13: Recommend the EPA and NZFS improve their performance reporting and MfE and MPI review statutory timeframes in their respective legislation | • The EPA have already improved their performance reporting at the request of the Minister for the Environment, including reporting across the end-to-end assessment process. EPA will also begin releasing a specific quarterly hazardous substances performance report.<br>• MfE and the EPA are developing proposals regarding the statutory timeframes in the HSNO Act and to improve application processes. The intention is to provide fit-for-purpose timeframes that will provide greater clarity to applicants and clear performance measures for the EPA. | • The EPA will continue to refine their operational reporting, incorporating feedback from the Minister and EPA Board where applicable, and will retain the granularity of timeframe reporting.<br>• Any legislative amendments will be incorporated in the omnibus bill. Proposed HSNO Act amendments will include differentiation of applications by type/complexity, and clarification of process steps so that specific statutory timeframes can be assigned (and reported against). | In progress |
| Recommendation 14: Recommend that the EPA and NZFS prioritise the provision of up-to-date guidance, pre-application support, and transparency on application processing | • The EPA acknowledge that improving the quality of applications is essential to making assessment processes more efficient and will be mutually beneficial to applicants and the EPA. However, developing additional guidance, and then keeping it up to date, requires significant time and resources.<br>• Agencies will continue to progress this recommendation as resourcing permits and look for opportunities to align on HSNO-ACVM | • The EPA has not yet begun this work as resourcing is currently being prioritised for work on amendments to be included in the omnibus bill.<br>• The work will need to be aligned with actions taken with recommendation 4.<br>• To be discussed as part of the forum to identify additional opportunities for achieving the recommendation. | Ongoing |

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| | interface areas as part of ongoing work under recommendation 4 (making the two regulatory systems easier to navigate).<br>• Agencies will invite feedback from the forum on specific examples or areas where updated guidance would be most impactful and beneficial for applicants. | | |
| Recommendation 15: Recommend that NZFS and the EPA extend existing stakeholder engagement forums to operate across both regulatory systems | • The forum to discuss possible options and ensure appropriate level of representation and engagement at the leadership level (strategic), as compared to existing stakeholder engagements at the operational and technical level.<br>• Agencies will work closely to implement this recommendation in a mutually beneficial manner for regulators and stakeholders. | • This will be discussed at a forum meeting and any changes to agency stakeholder engagement will be actioned, once agency resourcing permits, for the forum to track the progress. Agencies look forward to a constructive dialogue with forum members, focused on practical outcomes on this recommendation. | Not started |
| Recommendation 16: Recommend that MfE review the emergency approval provisions under the HSNO Act, including better enabling products to be approved for biosecurity responses | • The EPA agrees that the existing emergency and special emergency provisions under the HSNO Act are not being utilised as was envisaged. MfE are developing legislative amendments to improve these provisions, which are intended to also better support biosecurity responses. | • Any legislative amendments will be incorporated in the omnibus bill. | In progress |