



PROACTIVE RELEASE COVERSHEET

Minister	Hon Penny Simmonds	Portfolio	
Name of package	Regulation of non-GM new organisms	Date to be published	

List of documents that have been proactively released

Date	Title	Author
25 October 2024	Briefing: Regulation of non-GM new organisms	Ministry for the Environment

Information redacted **YES**

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Summary of reasons for redaction

Some information has been withheld from *[Document title]* under Section [section] of the Official Information Act [reason].



Briefing: Regulation of non-GM new organisms

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Actions sought from Ministers		
<i>Name and position</i>	<i>Action sought</i>	<i>Response by</i>
To Hon Penny SIMMONDS Minister for the Environment	Respond to recommendations	22 November 2024

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

Appendices and attachments
Nil

Key contacts at Ministry for the Environment			
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Minister's comments

Regulation of non-GM new organisms

Key messages

1. Organisms that do not have a history of presence in New Zealand, including genetically modified organisms (GMOs), are currently regulated under the Hazardous Substances and New Organisms Act 1996 (HSNO Act) as new organisms.¹ The proposed Gene Technology Act will remove regulation of GMOs from the HSNO Act, providing an opportunity to review the regulation of the remaining organisms regulated by the HSNO Act.
2. Officials are currently working on a Bill to amend the HSNO Act's hazardous substances regime. To take advantage of the opportunity of a HSNO Bill, Ministry officials have sought advice from the Ministry for Primary Industries (MPI), the Environmental Protection Authority (EPA) and the Ministry of Business, Innovation and Employment (MBIE) to identify operational challenges and inefficiencies in the new organisms regime that could be included in the HSNO Amendments Bill. The most significant issues identified were:
 - Processes to determine and change the status of species are slow and expensive.
 - Decision making is at quite a high level for some low-risk applications.
 - Laboratory and other containment applications do not have a rapid pathway.
 - Conditional release approvals have a disproportionately high administrative burden compared with the potential risk.
 - Provisions for field trials are restrictive.
 - Enforcement of the HSNO Act can limit MPI discretion in their investigation priorities.
 - MPI sometimes need to take a view on whether an organism is new with limited information that may hamper compliance.
 - Some definitions, such as 'release', require amendment.

¹ (1)Section 2A of the HSNO Act defines a new organism as:

- (a) an organism belonging to a species that was not present in New Zealand immediately before 29 July 1998;
- (b) an organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation;
- (c) an organism for which a containment approval has been given under this Act;
- (ca) an organism for which a conditional release approval has been given;
- (cb) a qualifying organism approved for release with controls;
- (d) a genetically modified organism;
- (e) an organism that belongs to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.

- The reassessment criteria and process are narrow in scope.
3. We want to test whether you want us to continue to work on these issues and to include any changes as part of the HSNO Amendments Bill officials are already working on. This work is complementary to work happening with both the Gene Technology Act and the changes to the Biosecurity Act 1993.

Recommendations

We recommend that you:

- a. **note** that the Gene Technology Bill, and consequential changes to the HSNO Act, are being led by MBIE and currently being drafted
- b. **note** that Ministry officials have been working with the Ministry of Regulation, the EPA and MPI on changes to the HSNO Act to streamline the hazardous substance regime, which will result in a HSNO Act Amendment Bill
- c. **note** that Ministry officials have worked with MPI, MBIE and the EPA to identify operational challenges and inefficiencies in the new organisms' regime
- d. **agree** to Ministry officials continuing this policy work to support proposed changes to the HNSO Act with completed proposals presented to you in early 2025

Yes | No

- e. **request** more information on any topic provided here

Yes | No

- f. **provide** any feedback on the advice provided here

Yes | No

g. **meet** with officials for further discussion.

Yes | No

Signatures



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**Climate Change Mitigation and
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25 October 2024

Hon Penny SIMMONDS
Minister for the Environment

Date

Regulation of non-GM new organisms

Purpose

1. This briefing seeks to update you on our work identifying operational challenges and inefficiencies in the new organism regime that could be addressed by amending the Hazardous Substance and New Organisms Act 1996 (HSNO Act).
2. We will provide you with proposed changes to the HSNO Act in early 2025, along with any proposed changes to the hazardous substances' regime.

Background

3. The Minister for Science, Innovation and Technology, Hon Judith Collins KC, has received Cabinet permission to draft the Gene Technology Bill which will regulate genetically modified organisms (GMOs), including their containment in laboratories and their release into the environment. A Bill is intended to be introduced to the House by the end of 2024 and is currently with the Parliamentary Counsel Office for drafting.
4. GMOs are currently regulated by the HSNO Act, the Biosecurity Act 1993 (Biosecurity Act) and the Imports and Exports (Restrictions) Act 1988:
 - i The HSNO Act regulates the importation and release of any new organism (largely this is an organism that was not present in the New Zealand environment prior to 1998), and all GMOs.
 - ii The Biosecurity Act regulates the import of risk goods to ensure unwanted pests and diseases are managed, both on arrival and within New Zealand.
 - iii The export of GMOs is regulated under the Imports and Exports (Living Modified Organisms) Prohibition Order 2005 (under the Imports and Exports (Restrictions) Act 1988).
5. The upcoming Gene Technology Bill will remove the regulation of GMOs from the HSNO Act.
6. In May we provided you with advice on what will need to be considered to ensure the regulatory systems for GMOs and new organisms are coherent and streamlined [BRF-4747 refers] after the Gene Technology Bill is enacted. Since that briefing, Hon Minister Collins KC has received Cabinet approval to begin drafting the Gene Technology Bill, which includes consequential amendments to the HSNO Act to ensure the two regimes align. We have worked with EPA and MBIE officials to develop these consequential amendments.
7. In parallel to this work, we have been working on potential improvements to the hazardous substance regime under the HSNO Act. The Ministry for Regulation (MfR) has also been undertaking a regulatory review of the processes for approving agricultural and horticultural products under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and the HSNO Act. This review flows into wider work we

are doing around improvements to the hazardous substances' functions of the HSNO Act.

8. Given this opportunity, we have been working with officials at EPA and the Ministry for Primary Industries (MPI) to discuss whether there are any areas of the new organisms' regime, outside of the scope of work for the Gene Technology Bill, that are currently not working well, that could be amended, and what those amendments would look like.

Analysis and advice

Changes that could increase the efficiency of the new organisms regime

9. The Gene Technology Bill allows an opportunity to examine potential changes to the HSNO Act that will increase the efficiency of the non-GMO new organisms' regime and better align it to the Gene Technology Bill. Additionally, some of the restrictions on new organisms were initially put into the HSNO Act to manage GMOs. With the removal of GMOs in the HSNO Act, these restrictions are no longer necessary and should be removed.
10. The following are examples of operational challenges and inefficiencies in the new organisms' regime that MfE, MPI and EPA officials think should be a priority to progress policy solutions. Some policy solutions are straightforward, while others require more consideration. We will update you on changes to the new organisms' regime in early 2025.

The processes to determine and change the status of species is slow and expensive

11. The mechanism to determine and change the 'new' status of species (denewing) is slow and expensive, and impacts applicants, particularly the research community, and enforcement agencies.
12. Denewing is the process used for organisms that are considered new by the definition in the HSNO Act but are known to be in the New Zealand environment and is designed to remove unnecessary regulation for these organisms. The reverse of this process is to prescribe that a species as a risk species, except those organisms already in New Zealand, that would be considered new and therefore regulated under the HSNO Act.
13. Both these tools allow for a change in the regulatory status of an organism, resulting in better use of time of both industry and MPI. For example, the Australian Eucalyptus variegated beetle (*Paropsisterna cloelia*) was denewed in 2021/2022. Removing the organism from the HSNO Act allowed for research to understand the effects of this pest on the New Zealand environment to progress without unnecessary red tape.
14. At present, both these processes require Cabinet approval and generally take more than a year to complete. 9(2)(f)(iv) [REDACTED]
15. The EPA can also statutorily determine whether an organism is considered new, to provide certainty about whether the HSNO Act applies to certain organisms, under s26

of the HNSO Act. Legislative improvements could speed up this process and reduce the cost. This includes clarifying how to proceed with an organism that has only recently been discovered by science, even though it may have been in present in New Zealand prior to 1998.

9(2)(f)(iv)

17. Finally, statutory determination decisions need to be Gazetted. 9(2)(f)(iv)

9(2)(g)(i)

18. Decisions on applications under the HSNO Act can be delegated to the Chief Executive or another EPA staff member. Currently, the delegations for hazardous substance applications are broader than for applications for new organisms. This is because delegations were restricted in line with constraints related to GMOs, which will no longer be relevant. 9(2)(f)(iv)

Laboratory and other containment applications have no expedited processing pathway

19. 18(d)

9(2)(f)(iv)

20. Given there are very few of these applications (there has only been one in 2024) and they are generally for similar areas of work (biocontrol agents), any solution would need to be light touch to ensure we do not spend more time and resources on the solution than the status quo. 9(2)(f)(iv)

Conditional release approvals are not fit for purpose

21. Conditional release approvals have a time limit to them, after which they lapse. They can also lapse when all the conditions are met. When they lapse, all of the organisms covered by the approval are required to be destroyed and the applicant required to apply again. 9(2)(f)(iv)

22. An example of a conditional release approval is for the pre-approval to release the Samurai Wasp as a biocontrol agent for brown marmorated stink bug should it arrive in New Zealand. 9(2)(f)(iv)
23. Furthermore, there are minimum standards that apply to all new organism applications, which may not always fit the purpose of conditional release approvals. More work will be needed to identify whether these should be relaxed and to what extent.

Field trials are restrictive

24. As noted in briefings relating to the gene technology regime, the current definition of field trials in the HSNO Act requires no heritable material to leave the site, which is a significant barrier for field trials for all new organisms, not just GMOs. In short, the current strict outdoor containment for field tests prevents the proper evaluation of crops and forestry species. 9(2)(f)(iv)

Enforcement of the HSNO Act

25. Section 97A of the HSNO Act specifies that MPI, as the enforcement agency “must ensure that the provisions of the HSNO Act are enforced in respect of new organisms.” This wording can limit the amount of discretion MPI can take when responding to breaches of the HSNO Act. 9(2)(g)(i)
26. There may be some other changes that would also allow for more alignment of enforcement between the HSNO Act, Biosecurity Act and Gene Technology Act.

MPI sometimes need to form a view on whether an organism is new

27. For the purpose of compliance and incursion responses, MPI may need to quickly form a view on whether an organism is new. The EPA’s statutory determination on whether an organism is new gives legal status to any decision, however this takes a full assessment of all relevant information, which takes time to collate and consider. If there is not the time, MPI can form a non-statutory view on whether an organism is new, but they must ensure it can withstand scrutiny if it decides to proceed with compliance activity.
28. Officials are investigating potential ways for MPI to make high quality and more efficient decisions on an organism.

9(2)(f)(iv)

Some definitions do not currently work

30. Some of the definitions under the HSNO Act are not fit for purpose. Below are three examples:

- If an exotic plant (new organism) is imported into New Zealand and separated into cuttings and new plants, MPI are unable to proceed with compliance under the HSNO Act as the definition of 'release' does not include a cutting of a plant being planted in a pot, even though it is a new organism.
- Sea snakes are considered native species under the Wildlife Act 1953, but also considered a new organism and a prohibited and unwanted organism under the HSNO Act. This means that a zoo or aquarium is limited as to what native species it can exhibit. Working through the definitions in the HSNO Act will allow for this to be addressed.
- The definition of 'organism' under the HSNO Act could be better aligned with the Biosecurity Act and upcoming Gene Technology Act. 9(2)(f)(iv)

[REDACTED]

31. The three definitions are examples only and other definitions also have challenges associated with them. Officials need to do more work to ensure that these definitions and others in the HSNO Act are clear and don't result in contradictory or inefficient outcomes. There may also be a requirement for additional definitions. Officials may need to identify if it would be better to make other changes to the HSNO Act instead of the definitions.

The reassessment criteria and process are narrow in scope

32. There are opportunities for efficiencies to be made by updating the existing approvals for new organisms. This could include removing approvals no longer active or changing approvals to reflect current practice.
33. Currently, under the HSNO Act grounds for reassessment must be found before an approval can be reassessed. While there are many criteria for grounds 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. 9(2)(f)(iv)

[REDACTED]

9(2)(f)(iv)

[REDACTED]

Other changes required due to the Gene Technology Act and Biosecurity Act

35. This briefing has considered current policy decisions regarding the Gene Technology Act. Officials from MBIE, MfE and EPA have also been working together to develop processes and empowering provisions 9(2)(f)(iv) in situations involving a new organism that is genetically modified, further to Cabinet decisions.
36. As the Gene Technology Act is progressed, further changes to the HSNO Act to better align the two regimes may become necessary. We will keep across this work and inform you of any updates if needed.

37. MPI is currently consulting on amendments to the Biosecurity Act, with consultation closing on 29 November 2024. This process may show other areas of concern that we can address. We will continue to work with our MPI colleagues on this and inform you of any updates if needed.

Regulations sitting under the HSNO Act regarding the new organisms' regime

38. There are many sets of regulations under the HSNO Act regarding new organisms. Most can be revoked as they focus on GMOs. The remainder will need to be reviewed to ensure they are still fit for purpose or whether they would better fit as either operational decisions or changes to primary legislation. 9(2)(f)(iv)

Way forward

39. We consider changes to address the operational challenges and inefficiencies mentioned above will increase the efficiency of the new organisms' regime. EPA and MPI have highlighted other changes to the HSNO Act. MfE officials are working through these additional changes to identify which ones to progress. This includes proposals made as part of the consultation performed last year on changing the biotechnology containment system.
40. If you agree for officials to continue work on improvements to the new organisms' regime, these will continue and feed into the proposed HSNO Amendments Bill currently underway. We intend to provide completed solutions to these issues, as well as other changes for your approval in early 2025. This will be timed to line up with the hazardous substance work already underway, at which point, the work streams will be amalgamated to ensure there is one HSNO Bill that covers both hazardous substances and new organism changes.

Te Tiriti analysis

41. There are Te Tiriti issues being worked through associated with the Gene Technology Bill. This work is being led by MBIE.

Other considerations

Consultation and engagement

42. This briefing was shared with EPA, MBIE and MPI officials for feedback and that feedback has been incorporated into the paper. While EPA and MBIE are supportive of this work, MPI wanted us to express their strong support, especially due to the timing of their work in considering changes to the Biosecurity Act. We will continue to work with all relevant parties, including the Department of Conservation, who were not consulted for this briefing, to progress this work.

Risks and mitigations

43. There will be risks associated with the review of the HSNO Act which may impact the delivery of fit for purpose legislation, including limited Ministry resourcing and the timeframe and quality of consultation for any changes.

Legal issues

9(2)(h)

Financial, regulatory and legislative implications

45. The review of the HSNO Act will have financial, regulatory and legislative implications. However, there are no financial, regulatory or legislative implications from consulting on the proposals. If these proposals were carried through to legislation, regulation and then implementation, there may be financial implications for Government to enact these changes.
46. The implications on the review of the legislation will be discussed more fully in a Regulatory Impact Assessment.

Next steps

47. MfE officials will continue to work on improvements to the new organisms regime and will give you progress updates and requests for decisions as appropriate.