Ministry for the Environment
Manatū Mō Te Taiao

Briefing: Regulation of non-GMO new organisms

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Actions sought from Ministers		
Name and position	***Action sought***	***Response by***
To Hon Penny SIMMONDS **Minister for the Environment**	Respond to recommendations	20 June 2024

Actions for Minister's office staff

Forward this briefing to the Gene Technology Ministerial Group:

- Hon Dr Shane Reti (Health)
- Hon Judith Collins KC (Science, Innovation and Technology)
- Hon Todd McClay (Agriculture and Forestry)
- Hon Tama Potaka (Conservation, Māori Crown Relations and Māori Development)
- Hon Andrew Hoggard (Biosecurity and Food Safety)

Return the signed briefing to the Ministry for the Environment (ministerials@mfe.govt.nz).

Appendices and attachments

Appendix 1: Comparison of application type between the HSNO Act and the proposed Gene Technology Bill

Key contacts at Ministry for the Environment

Position	***Name***	***Cell phone***	***First contact***
Principal Author	Richard Souness		
Responsible Manager	Sarah Kenward	0272889374	
General Manager	Glenn Wigley	0274917806	✓

Minister's comments

Regulation of non-GM new organisms

Key messages

1. The Ministry for Business, Innovation and Employment (MBIE) is developing policy proposals for a proposed Gene Technology Bill to regulate genetically modified organisms (GMOs). Currently, GMOs are regulated under the Hazardous Substance and New Organisms Act 1996 (HSNO Act) which is administered by the Environmental Protection Authority (EPA). The Ministry for Primary Industries (MPI) is the enforcement agency for the HSNO Act in respect of new organisms.

2. While the Gene Technology Bill will remove the regulation of GMOs from the HSNO Act, the regulation of non-genetically modified (non-GM) new organisms will remain under HSNO. This includes assessing and managing the risks of viruses, bacteria, cell lines, seeds, plants, fish and animals new to New Zealand for use in containment and release.

3. The HSNO Act and the Gene Technology Bill regimes will be closely related in some situations and may interact. Ministry for the Environment (MfE) officials are working with MBIE, EPA and MPI to manage the potential interactions, and will consider:

    - regulatory contradictions or duplication of work
    - simplicity and clarity for users of the relevant systems
    - aligning compliance monitoring and enforcement
    - the relative risk profiles of non-genetically and genetically modified new organisms
    - environmental outcomes.

4. Officials will explore options for Ministerial decisions to ensure the regulation of non-GMO new organisms is in the appropriate piece of legislation and agency best matched to the intended purpose, while ensuring the regulatory system is coherent and streamlined.

5. MfE officials recommend aligning the timing of any decisions to allow for consequential changes to the HSNO Act to occur as part of the Gene Technology Bill. MfE officials will continue to work and present options on managing interactions for you to consider.

Recommendations

We recommend that you:

a. **note** that there is a need for non-GM new organisms to continue to be regulated

b. **note** if the GMOs are removed from the HSNO Act and no other changes are made, there is likely to be some closely related and overlapping requirements and processes between the HSNO Act and the Gene Technology Bill

c. **note** that MfE officials are working with MBIE, MPI and EPA officials to ensure that the two regimes align

d. **agree** to forward this briefing to the Gene Technology Ministerial Group

Yes | No

e. **agree** to the general approach applied here and the next step, which will be to provide you with additional advice on the intended outcomes of the non-GM new organism regime and options on how to best regulate this in the future in a way that best manages the interaction between the HSNO Act and the Gene Technology Bill

Yes | No

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

Yes | No

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

Yes | No

Signatures

Sarah Kenward
Manager – Hazardous Substances and Biotechnology Policy
Climate Change Mitigation and Resource Efficiency
30 May 2024

Hon Penny SIMMONDS
Minister for the Environment

Date

Regulation of non-GM new organisms

Purpose

1. This briefing describes the aspects of the new organism regulatory regime that will remain after the proposed Gene Technology Bill removes the regulation of genetically modified organisms (GMOs) from the Hazardous Substance and New Organisms Act 1996 (HSNO Act).

2. It also outlines areas where the HSNO Act and the proposed Gene Technology Bill may interact with each other with respect to applications. Ministry for the Environment (MfE) officials will provide further advice on options to manage these interactions.

Background

3. The Ministry for Business, Innovation and Employment (MBIE) is currently developing policy proposals for a Gene Technology Bill. This Bill will regulate gene technologies and GMO activities, from their containment in laboratories to their release into the environment. The intention is to introduce the Bill to the House by the end of 2024.

4. Currently, GMOs are primarily regulated by the HSNO Act and the Biosecurity Act 1993 (Biosecurity Act), as they are currently defined as new organisms under the HSNO Act. The HSNO Act regulates the importation and release of any organism not present in New Zealand prior to 1998, including all GMOs. The Biosecurity Act regulates the import of risk goods to ensure unwanted pests and diseases are managed, both on arrival and within New Zealand.

5. In practice, the HSNO Act provides a mechanism for allowing new organisms into New Zealand through a dedicated application and approval process administered by the Environmental Protection Authority (EPA), which considers the risks, costs, and benefits of the proposed activity (such as importation or release of a new organism). Inspectors and enforcement officers are appointed by the Ministry for Primary Industries (MPI) under the Biosecurity Act. These officers are authorised to monitor compliance and enforce the approvals granted by the EPA under the HSNO Act.

6. Part 2 of the HSNO Act specifies the purpose of the Act and sets out the matters that any person on exercising a function, power, or duty under the Act must take into account. The purpose of the HSNO Act is to protect the environment and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms. The matters to be taken into account when exercising a function, power, or duty under the Act are:

    - the sustainability of all native and valued introduced flora and fauna
    - the intrinsic value of ecosystems
    - public health

- the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga

- the economic and related benefits and costs of using a particular hazardous substance or new organism

- New Zealand's international obligations.

7. The upcoming Gene Technology Bill will remove the regulation of GMOs from the HSNO Act. Without any further changes to the HSNO Act, all non-GMO new organisms that were not in New Zealand prior to 1998 will remain regulated by the HSNO Act. Examples of activities including organisms that will remain regulated by the HSNO Act include the following:

    - Importing into containment weed plant species from Pacific countries to allow New Zealand scientists to develop weed control strategies for Pacific countries.

    - Importing into containment animals for zoos and aquariums.

    - Importing for release animal and human vaccines, such as the Mpox vaccine or the infectious bronchitis vaccine for poultry.

    - Importing for field trials various new foraging crops, such as the forage plant kochia.

    - Keeping certain new organisms outside New Zealand, such as invasive weeds, snakes, and cane toads.

    - Importing for the release of biocontrol agents to mitigate pest populations, such as beetles to control the weeds heather and broom, and the hoverfly to control the German and common wasps.

    - Importing for the release of biocontrol agents as a biosecurity tool in case of a pest incursion, such as a parasitic wasp for the control of the brown marmorated stink bug.

8. If no further changes to the HSNO Act are made beyond the removal of the GMO provisions, there may be overlapping areas of regulation. An example of this is a recent EPA decision for a virus found in a medicine undergoing clinical trials for the treatment of Hepatitis B.[1] This virus was not in New Zealand prior to 1998 and therefore is a new organism and regulated under the HSNO Act. Additionally, the form of the virus in the medicine is genetically modified. Currently, this organism is only regulated under the HSNO Act, but in the future will also be regulated under the Gene Technology Bill. Without further changes to the HSNO Act, this medicine will be regulated under the two regimes and therefore may require two applications and additional compliance.

9. As the purpose of the proposed Gene Technology Bill, and the criteria for any decision made under this Bill, is likely to differ from that of the HSNO Act, there may be different approval criteria and process requirements, which will result in different outcomes. There may also be areas of interaction which do not directly overlap with each other between

[1] APP204509: To import for release a genetically modified GS-2829 and GS-6779 alternating 2-vector therapy for use in a Phase 1a/b clinical trial for patients with chronic Hepatitis B.

the HSNO Act and the Gene Technology Bill. The overlap and areas of interaction need to be worked through and reconciled to ensure that the overall regime is cohesive, streamlined and fit for purpose.

Analysis and advice

10. MfE has identified the type of applications and approvals that are unlikely to be regulated by the proposed Gene Technology Bill and analysed their possible interaction with aspects of the Gene Technology Bill. This analysis is shown in Appendix 1.

11. Aspects of the Gene Technology Bill are still being worked through, so areas of overlap between the HSNO Act and the Gene Technology Bill cannot be confirmed at this stage. However, possible interaction between the HSNO Act and the Gene Technology Bill has been identified in the following areas so far:

    - Some facilities may need to meet requirements under both the HSNO Act and the Gene Technology Bill for containment activities, such as a laboratory that holds both GM and non-GM microorganisms.

    - Zoo and aquarium facilities may wish to display organisms that are genetically modified. An example is that aquarium facilities may wish to introduce glow in the dark fish, which are commercially available overseas and are genetically modified to fluoresce in the dark or glow under ultraviolet light.

    - Human and animal medicines may require different approval processes depending on whether they are or contain GMOs or non-GM new organisms and one process may be quicker, easier and more likely to gain approval than the other.

    - There may be applications for the environmental release of a GMO of an organism that was not in New Zealand prior to 1998.

    - Certain organisms are already prohibited from New Zealand. No decision has yet been made about whether GMOs of these organisms should also be prohibited under the new Gene Technology Bill. An example of this would be a genetically modified non-venomous snake.

12. There may also be overlap between the Gene Technology Bill regime and the Biosecurity Act that will need to be considered, such as in containment facilities. Many of these facilities need to meet requirements under the Biosecurity Act because the GMOs and new organisms they are holding may also be regulated under the Biosecurity Act as unwanted organisms, a type of risk goods.

13. MfE officials are working with MBIE, MPI and EPA officials to ensure all the related regimes line up and will provide options to assist in Ministerial decision-making as other policy options develop and decisions are made.

14. Options will include whether the intended outcomes of the regulation of non-GMO new organisms and the matters to consider for decisions still match the purpose of the HSNO Act; and the consequences of that decision for legislation and regulator.

15. When identifying issues and proposing options, officials will consider:

- Whether the two systems contradict or replicate work. Officials understand that there is already a desire to streamline the regulatory system across different Acts when possible.

- Simplicity for users of the system, from understanding who to approach for applications to compliance requirements.

- Aligning the compliance approach of both new organisms and GMOs.

- The relative risk profile and risk assessment approach of a new organism compared with the relative risk profile and risk assessment approach of a GMO.

- Environmental and human health outcomes.

16. It is worth noting that some of those who work on biocontrol pest agents consider the current new organism regime for biocontrol agents to be one of the most fit for purpose regimes in the world.

Outcomes

17. A key outcome of this work is an analysis of the potential overlaps and interactions between the HSNO Act and the Gene Technology Bill. This will include options for how best to manage these overlaps and interactions to ensure that the legislation is streamlined and coherent, easily navigable and takes a logical approach to assessing relative risks in accordance with the purpose of each regulatory system.

18. Other possible outcomes, including possible solutions, could include:

    - Ensuring that the remaining functions of the new organism aspects of the HSNO Act are in the right piece of legislation, under the most appropriate regulating agency and do not contradict other regimes.

    - Ensuring that functions with significant overlap are managed by one regulating agency and the respective legislation enables cross agency consultation where appropriate.

    - Exploring whether changes to the HSNO Act could provide for new pathways or processes to facilitate alignment with those proposed under the Gene Technology Bill.

    - Ensuring that references to the HSNO Act and the Gene Technology Bill are cross-referenced in the respective legislation to further establish clear pathways for use.

Other changes to the New Organisms regulatory regime

19. Development of the Gene Technology Bill provides an opportunity to make other changes to the new organisms regulatory regime to streamline the application process outside of the interaction with the Gene Technology Bill.

20. MfE officials are discussing possible changes with EPA officials. If the scope of these changes is beyond what can be done in relation to the Gene Technology Bill, these changes may be better placed to occur with any changes to the hazardous substances regime in the HSNO Act being worked on by officials.

Timeframe

21. The Gene Technology Bill will require significant consequential changes to be made to the HSNO Act. We recommend making the decisions on the alignment between the two regimes at the same time.

22. Secondary legislation and any other changes can then be made at the same time as secondary legislation is made for the Gene Technology Bill. We are working with all relevant parties to identify the best way to introduce the changes.

Consultation on GMOs used in laboratory settings and for biomedical therapies in 2023

23. In 2023, MfE consulted on changes to the HSNO Act and regulations for GMOs used in laboratory settings and for biomedical therapies. We received a number of high-quality submissions, which we have analysed and shared with MBIE officials to help shape policy for the Gene Technology Bill. This work will be incorporated into the Gene Technology Bill.

Te Tiriti analysis

24. 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

25. This briefing was shared with EPA, MPI and MBIE officials for feedback and that feedback has been incorporated into the paper. Information about the proposed Gene Technology Bill has been supplied by MBIE.

Risks and mitigations

26. Due to the speed of policy formulation for the Gene Technology Bill, there are risks that:

    - the analysis takes longer than the current timeframe;
    - meeting the current timeframe results in proposed options that may not fulfil all the criteria noted in paragraph 18, or create unintended consequences;
    - the proposed options potentially create regulatory difficulties and implications with other legislation, especially the Biosecurity Act. The Biosecurity Act is currently under review but the timeline does not align with that of the Gene Technology Bill.

27. This will be worked through and officials will keep you informed in upcoming briefings. There may be other risks associated with the Gene Technology Bill, which is being led by MBIE. Officials will keep you informed in upcoming briefings.

Legal issues

28. This briefing contains a high-level presentation of the policies and a general assessment of potential overlaps, potential outcomes and potential solutions. Further legal analysis will be undertaken when details and options have been further identified.

Financial, regulatory and legislative implications

29. Future briefings will further consider the financial, regulatory and legislative implications associated with this work.

Next steps

30. MfE officials will continue to work with MBIE, MPI and EPA officials to identify options to align the remaining new organism regime with that proposed under the new Gene Technology Bill and will provide these to you.

31. MfE officials will identify options on the best way to proceed with the changes to the HSNO Act and will provide these to you.

Appendix 1: Comparison of application type between the HSNO Act and the proposed Gene Technology Bill

Table 1: High level comparison of application types of new organisms under the HSNO Act and likely equivalences under the Gene Technology Bill. It does not show specific application types or whether something is a full or rapid application.

Application type	Examples of non-GM use	Equivalence in the Gene Technology Bill	Possible interaction with the Gene Technology Bill
Import into containment			
Laboratory	Import microorganisms including cell lines for research and diagnostic work Exotic plants to test biocontrol research	Containment of GMOs in laboratories	It is possible that some facilities will require both GM approval and NO approval Possibility that a NO may be genetically modified in the laboratory
Large scale fermentation containment	Fermentation of mushrooms for health care products	Large scale fermentation containment of GMOs	
Field trials	Field test plants for potential forage crops	GMO field trials	
Import into containments at zoos and aquariums			
Zoos and aquariums	Snow leopards in Wellington zoo		It is possible that GM animals may be displayed in zoos in future
Release of human and animal medicines			
No controls	Mpox vaccine	Release of GM medicines	Dependent on policy decisions made, it is possible that a medicine may be a NO and a GMO This is already an interaction with MedSafe for human vaccines
Some controls	Infectious bronchitis vaccine for poultry	Release of GM medicines	
Release into the environment			
No controls	Biocontrol agents, houseplants	Release of a GMO into the environment	Dependent on policy decisions made, there may be an application for a new organism that is also genetically modified as well as an application for a GMO
Release with controls	Biocontrol agents for use in case of an incursion.	Release of GMO into the environment	

	Single specimen of plant in botanical gardens	(including field trials of GMOs)	
Transhipment[2]			
	Moving marine organisms from Antarctica to Italy via NZ		
Determining the new organism status of an organism			
Statutory determination	Determined the new organism status of Atlantic salmon or soil bacteria. This pathway determines if an organism is regulated under the HSNO Act	The Gene Technology Bill is likely to have its own statutory determination function	These powers will need to be changed to clarify whether it is relevant to take account of status under Gene Technology Bill
Regulations to change status of an organism			
"Denewing" and prescribing risk species.	Denewing species that have established populations in New Zealand after 1998. Prescribing strains of a risk species after other strains were approved for release	The Gene Technology Bill is likely to have its own ability to change the status	These powers will need to be changed to take account of status under Gene Technology Bill
Changing approvals			
Amendments, reassessments and grounds for reassessments	Allowing various zoo approvals to be grouped under the same approval with the same controls	The Gene Technology Bill is likely to have its own provisions for amendments and reassessments	Different scope from Gene Technology Bill

Note: GM = genetically modified, NO = new organism

[2] Transhipment means the importation into New Zealand of a hazardous substance or new organism solely for the purpose of export within 20 working days to another destination outside New Zealand.