MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

COVERSHEET

Minister	Hon Dr. Shane Reti	**Portfolio**	Science, Innovation and Technology
Title of Cabinet paper		**Date to be published**	6 June 2025

List of documents that have been proactively released		
Date	**Title**	**Author**
7 February 2025	Briefing – 0008230 Gene Technology Bill Legislative and Policy Programme	MBIE
7 February 2025	Email – Background info on Gene Tech as requested	MBIE
7 February 2025	Email attachment – Background information – Overseas Field Trials and CRI Gene Tech Work	MBIE
7 February 2025	Email attachment – Draft A3 – Licence and declarations processes	MBIE
26 February 2025	Briefing – 00010210 – Gene Technology Reforms Implementation Status Report – February 2025	MBIE
26 February 2025	Briefing – 0010210 Annex One – GeneTech February 2025 A3 Programme Report	MBIE
28 February 2025	Aide Memoire – 0010160 – Materials for 05 March Health Committee meeting on Gene Technology Bill	MBIE
28 February 2025	Aide Memoire – 0010160 Annex Four – Ancedotal evidence of gene technologies in the “waiting room”	MBIE
4 March 2025	Email – Gene Tech responses for Minister (mainly for SC tomorrow)	MBIE
4 March 2025	Email attachment – Response to Minister requests 4 Mar	MBIE

Information redacted **YES**

Any information redacted in this document is redacted in accordance with MBIE’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.

Some information has been withheld for the reasons of Privacy of natural persons, Commercial Information, Confidential advice to Government, Free and frank opinions and Improper pressure or harassment.

These documents have been released as part of an Official Information Act request and therefore proactively released due to the public interest with this work

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Doc 1

Gene Technology Reform: Legislative and policy programme

Date:	7 February 2025	**Priority:**	High
Security classification:	In Confidence	**Tracking number:**	REQ-0008230

Action sought		
	Action sought	**Deadline**
Hon Dr Shane Reti **Minister of Science, Innovation and Technology**	**Note** this briefing sits alongside the Initial Briefing to the Select Committee as an overview of work underway on gene technology reform **Note** that policy development is ongoing for the Gene Technology Bill and decisions on outstanding matters will be sought from you shortly	12 February 2025

Contact for telephone discussion (if required)			
Name	**Position**	**Telephone**	**1st contact**
Tony de Jong	Manager, Biotech Policy and Regulation	Privacy of natural persons Improper pressure or harassment	✓

The following departments/agencies have been consulted

Minister's office to complete:

- ☐ Approved
- ☐ Noted
- ☐ Seen
- ☐ See Minister's Notes
- ☐ Declined
- ☐ Needs change
- ☐ Overtaken by Events
- ☐ Withdrawn

Comments

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Purpose

This briefing, alongside the previously provided draft Initial Briefing to the Select Committee (the Initial Briefing; REQ-0008293 refers), provides you an overview of the gene technology reform work underway.

- The Initial Briefing covered the Gene Technology Bill (the Bill) in an appropriate level of detail and amount of content for the Select Committee.
- This briefing covers other aspects of the regime and work underway to develop it, such as your roles and responsibilities as the Minister of Science, Innovation and Technology, ongoing policy work related to the Bill and secondary legislation, and implementation timeframes.

These two briefings together will inform the upcoming 'deep dive' into this work.

Executive summary

The Gene Technology Bill has been developed at pace and there are some policy matters requiring further development. The Initial Briefing covers these policy issues in detail, and we expect to provide a further briefing seeking decisions on these matters within the next two weeks.

Secondary legislation (for example regulations, notices, and standards) will detail how the Bill will work in practice so must be completed before the Regulator begins operation. Necessary secondary legislation is being developed in two tranches, with the first tranche covering matters necessary for the Confidential advice to Government Free and frank opinions

Implementation is a key workstream to enable the regime and is being run concurrently to other work. An interagency group with representatives from the Ministry of Business, Innovation and Employment (MBIE), the Environmental Protection Authority (EPA), the Ministry for Primary Industry (MPI), and the Ministry for the Environment (MfE) is leading this, with the work being progressed in three phases across 2025. Free and frank opinions

Finally, the briefing provides you visibility of our approach to two select committee matters that are not covered in the Initial Briefing – submissions analysis and the departmental report.

Recommended action

The Ministry of Business, Innovation and Employment recommends that you:

a **Note** that the Gene Technology Bill has been developed at pace and policy development is ongoing

Noted

b **Note** Free and frank opinions [redacted]

Noted

c **Note** that significant secondary legislation is required for the regulatory regime to be operational Free and frank opinions [redacted]

Noted

d **Note** this briefing, alongside the previous Initial Briefing to the Select Committee, will inform your requested 'deep dive' discussion of gene technology reform work with officials.

Noted

Tony de Jong
Manager, Biotech Policy and Regulation
Technology and Innovation, MBIE

07 / 02 / 2025

Hon Dr Shane Reti
Minister of Science, Innovation and Technology

..... / ..... / .....

Context

1. Your Briefing to the Incoming Science, Innovation and Technology Minister provided a high-level overview of the four workstreams underway for gene technology reform, covering:

    a. Progressing the Gene Technology Bill

    b. Secondary legislation necessary for the regime

    c. Implementation work to ensure the new regulator is established, and

    d. Confidential advice to Government

2. The previous draft Initial Briefing provided detail on the Bill appropriate for the Select Committee. This briefing provides you additional detail and context on the Bill and its ongoing development, and further detail of the other three workstreams.

Your role in Gene Technology reform

3. As Minister you are now responsible for delivering the coalition commitment to liberalise gene technology regulation. Minister Collins led the development of the Bill through to its introduction into the House and referral to the Health Select Committee in December. You are now responsible for the continued development and passage of the Bill, related secondary legislation, and establishment of the Regulator and regime.

4. After royal assent, in addition to oversight and accountability for the regime, specific ministerial responsibilities under the Gene Technology Act will be:

    a. appointing the Regulator

    b. appointing members to the Technical Advisory Committee (TAC) and the Māori Advisory Committee (MAC)

    c. issuing general policy directions to the Regulator (if required)

    d. granting emergency authorisations (if required).

Development of the Gene Technology Bill

5. We understand your office has provided relevant Cabinet papers on the reforms for background reading. This section focuses on policy decisions made during drafting of the Bill across numerous briefings following Cabinet decisions, and sets out ongoing policy work.

Decisions made under delegated authority from Cabinet

6. Minister Collins made policy decisions for the Bill under delegated authority from Cabinet (CAB-24-MIN-0294). A full list of policy decisions made is attached in Annex One, including:

    - that only the minister responsible can appoint members to the TAC and MAC, and the requirements for these appointments
    - the removal of the civil liability provisions in the Bill
    - consequential amendments to the Resource Management Act 1991, the Agricultural Compounds and Veterinary Medicines Act 1997, and the Imports and Exports (Living Modified Organisms) Prohibition Order 2005
    - the inclusion of levies in any potential cost recovery regime

- additional information sharing provisions between relevant agencies
- the offences and penalties regime for the Bill
- adding a range of regulation making powers
- the review and appeals regime for the Bill
- that the Regulator can develop, adopt, and amend standards
- that the regime will include a licence for transhipment of a regulated organism
- additional transitional provisions for the transition from the Hazardous Substances and New Organisms (HSNO) Act
- to publicly consult on the regime's secondary legislation, and
- the policy approach to the first tranche of secondary legislation.

7. Further information on these decisions is available at your request.

Ongoing policy development

8. The Bill has been developed at pace and some areas of policy require further work. These areas include:

a. Free and frank opinions

b.

c.

d.

e. secondary legislation, and

f. Confidential advice to Government

9. These decisions will ideally be progressed through the Select Committee process and are likely to require some Cabinet decisions. Confidential advice to Government

We note that the submissions process may identify additional unexpected or unanticipated matters requiring policy decisions.

Secondary legislation

Secondary legislation will form the core of the gene technology regime

10. The Bill creates the framework and sets principles for the new gene technology regime, with secondary legislation providing for its operation and function.[2] Secondary legislation is essential for the public to understand the regime and for researchers and firms to adhere to it, and it is not possible for the Regulator to begin operation without most of the secondary legislation being completed.

Confidential advice to Government

[2] For example, how medical applications such as CAR T-cell therapies will be regulated, what standards and criteria must be met to carry out research in a laboratory setting, and operational requirements for the Regulator and for users of the regime.

11. Secondary legislation development for this regime is time and resource intensive because of the combination of standard process (including development, consultation, Cabinet approvals, and drafting), the technical nature of the regime, and the volume of secondary legislation required. Because of this, the secondary legislation work programme is divided into two tranches, with the first tranche focused on requirements for the regime be operational in late 2025 (as Minister Collins had originally targeted).

12. Confidential advice to Government

Exemptions

13. Cabinet agreed that some gene edited organisms should be exempt from ‘day one’. These organisms are “organisms modified by gene editing techniques that produce specific minor changes, or were modified by template(s), and do not introduce new genetic material” (CAB-24-MIN-0296). Secondary legislation is required to define the above terms in technical detail to provide certainty regarding complying with regulatory requirements.

14. Confidential advice to Government

15. While the more technical definitions are likely to be relatively short, it will be important that they are drafted to be technically correct to provide certainty to researchers. Both public and targeted consultation will be integral to getting these definitions correct.

16. Confidential advice to Government

Risk tiering criteria

17. Regulations need to be developed to set the criteria the Regulator will use to assign activities to risk tiers, including when the Regulator can determine that low and very low risk activities do not require case-by-case assessment under a licence application (i.e. suitable to be declared as a notifiable or non-notifiable activity).

Confidential advice to Government

Confidential advice to Government

Operational processes

22. This area of work includes decision-making timeframes and details relating to the Regulator's risk assessment and risk management plans.

Confidential advice to Government

Developing secondary legislation Free and frank opinions

Free and frank opinions

Confidential advice to Government

Implementation workstream

The project to establish the gene technology regime began October 2024

27. The Gene Tech Establishment Working Group (the Establishment Group) has representatives from MBIE, EPA, MPI and MFE. The Establishment Group's responsibility is to scope, plan, budget for, and implement the new regulatory function within the EPA, with the compliance, monitoring, and enforcement function delivered by MPI.

28. The Establishment Group's workstream is estimated to run for 14 months, originally aiming for the Regulator to commence operations by late December 2025. The workstream is chaired by the MBIE Gene Technology Bill Programme Manager, meets fortnightly, and reports progress back through to MBIE and the Gene Technology Steering Group.

29. Once operational, performance and monitoring will be jointly provided by MBIE and MfE's Crown Monitoring team. The implementation workstream can continue while secondary legislation is being developed. However, the regime cannot become operational until core regulations are in place (as detailed above).

30. The Establishment Group's workstream is separated into three phases:

    a. **Phase One - Planning Phase**. October 2024 to April 2025. Includes developing an initial project plan, getting project resources on board, and early operational blueprinting - designing the functional workflows and critical processes

Confidential advice to Government

Confidential advice to Government

Confidential advice to Government

Additional Select Committee matters

36. The Initial Briefing covers the background to the Bill, why it is needed, how it has been developed, what the Bill does and does not do, and the issues that are likely to be raised by submitters. This section provides an overview of how we plan to analyse the submissions, the approach to the departmental report, and the report back from the Select Committee.

The departmental report

37. Submissions on the Bill close on 17 February. The Health Committee notes there has been high interest in the Bill, and initially estimates between 5,000 – 10,000 submissions will be received. Officials have begun to analyse submissions received to date (over 2,600 so far).

38. Confidential advice to Government

39.

Next steps

40. We are preparing for a ‘gene tech deep dive’ discussion with you, tentatively scheduled for 12 February.

41. We will provide you with further advice in the next two weeks seeking your decisions on ongoing policy matters. Some of these decisions will fall within your delegated authority and some will require Cabinet approval. We will work with your office to plan this advice and timing for Cabinet.

Annexes

Annex One: Policy decisions made under delegated authority

Annex One: Policy decisions made under delegated authority

Policy	Decision	Reference
Appointments: The Bill provides for the power to appoint members to the Technical Advisory Committee (the TAC) and the Māori Advisory Committee (the MAC) that advise the Regulator.	Only the Minister can appoint members to TAC and the MAC. The Regulator can appoint members of these committees to a subcommittee. The Minister must be satisfied that a person has the appropriate technical skills or experience to be appointed to the TAC and is not required to consult the Regulator prior to appointment. The Minister must consult the Minister for Māori Development (and any other appropriate Ministers) prior to appointing a member to the MAC.	REQ-0004432, pg1.
Civil liability: Civil liability is when a person is liable for damages for any loss or damage caused while carrying out activities in breach of an Act, regardless of whether they intended to do the thing that resulted in the damage or loss or took reasonable care.	The gene technology regime will not include any provision for civil liability. Instead, the regime will rely on common law (the law of torts).	REQ-0006092, pg2.
Consequential amendments: The Resource Management Act 1991 (the RMA): To provide a nationally consistent and predictable regulatory environment for gene technology, Cabinet agreed to remove from the RMA the ability for regional councils and territorial and unitary authorities to restrict the use of GMOs. When the Gene Technology regime is live, there may be resource consents in force or applications in train. The Agricultural Compounds and Veterinary Medicines Act 1997 (the	A consequential amendment will be made to the RMA to ensure that any operative plan rules about GMO activities cease to have effect immediately.	CAB-24-MIN-0491 Appendix Three, at 6.
	The Bill will amend the ACVM to provide the necessary powers under that Act to support joint assessments and joint decision making.	REQ-0006092 pg3.

ACVM): The ACVM lacks the powers necessary to support joint assessment and decision making with the Regulator because the matters the respective regulators must consider do not overlap sufficiently. The Imports and Exports (Living Modified Organisms) Prohibition Order 2005: This Order controls importing and exporting GMOs for pharmaceutical and contained use, to be used as food or feed, and for intentional introduction into the environment. The minister responsible for this order is the same minister as HSNO.	The Bill will amend the 2005 prohibition order to make the minister responsible the same as for the Gene Technology Act.	REQ-0006531 pgg3.
Cost recovery: The Bill provides for Cost recovery to offset a proportion of the regime's costs and provides the ability to make regulations to prescribe cost, recovery, fees, and charges.	Cost recovery regulations will include the power for the Regulator to apply levies. Officials have not proposed applying levies at this time.	Briefing 2425-0880, pg2.
Information sharing: Information sharing between the Regulator and other relevant agencies is crucial to supporting the operation of the gene technology regime and must be provided for in the Bill.	Relevant agencies (e.g., MPI) can share information collected under the gene technology regime (and other listed Acts) with the Regulator to support the performance of the regime.	REQ-0006092, pg2.
Offences and penalties: The Bill creates an offences and penalties regime that includes both *mens rea* (requiring intent) and strict liability offences. Typically, the *mens rea* offences incur a higher penalty.	The Bill will include *mens rea* and strict liability offences for breaching conditions on a synthetic nucleic acid screening regime notice. The penalty for recklessly (a *mens rea* offence) giving false information to an enforcement officer will be increased to a fine exceeding $100,000 for an individual or otherwise not exceeding $500,000. The Bill will not contain a strict liability offence for obstructing an enforcement officer.	REQ-0006531 pg3.

	The Bill will include an offence for breaching conditions attached to a mandatory medical authorisation and that the penalty be equivalent to a breach of conditions for a notifiable activity.	REQ-0006973 pg1.
Regulation making powers: The Bill provides for the power to create regulations as required for functioning of the regime.	The Bill will provide for the power to make regulations to address any unanticipated transitional matters. This power will expire two years after commencement.	Briefing 2425-0880, pg2.
	The Bill will provide the power to create regulations for licencing, joint applications under the Gene Technology Act and HSNO, timeframes for application processes, fir and proper persons, prescribed persons with whom confidential information can be shared, and offences.	REQ-0006531 pg3.
	The Bill will provide for the power to make regulations that prescribe information to be provided for licence applications, qualifications for enforcement officers, circumstances in which the Regulator may grant an exemption, a waiver, or a refund of fees, charges or levies, and that provide for any matters contemplated by the Gene Technology Act, necessary for its administration, or necessary for giving it full effect.	REQ-0006973 pg1.
Reviews and appeals regime: Applicants and licence holders can request that the Regulator review specified decisions they've made. This is a first opportunity to identify and correct errors with the original decision, prior to any further appeals process and is therefore efficient.	Reviews process for licence decisions follows the Australian approach, appeals follows the HSNO Act. This differs from the HSNO Act, which does not have review process prior to appeal. Statutory determinations will be treated like a licence decision given they are comparable types of decision, and therefore to provide the same rights of review and appeal outlined above.	Briefing 2425-0880, pg 2. CAB-24-MIN-0491 Appendix Three, at 4.
	The right of review will be limited to licence holders and applicants only.	REQ-0004432, pg1.
Standards: The gene technology regime will include a range of different standards (for example, disposal standards) to meet its objectives.	The Regulator can, with support from the TAC, MAC, and any subcommittee or relevant agency, develop, adopt, or amend standards for activity categories, and licence and authorisation types. Minor amendments to standards to not require public consultation.	REQ-0004432, pg2.
Transhipment licence: Transhipment is the importation into New Zealand of a regulated	The gene technology regime will include an authorisation for transhipment of regulated organisms.	REQ-0004432, pg2.

organism solely to enable exportation of that organism within 20 working days to destination outside New Zealand.		
Transitional provisions: Consequential changes to the HSNO Act include transitional provisions to ensure GMO activities already approved under the HSNO Act remain approved and to preserve flexibility for applicants to determine the application pathway that best suits their circumstances.	**HSNO Act Approvals** All approvals for GMOs under the HSNO Act are approved under the Gene Technology Act and the Regulator must review these approvals as soon as practicable. **HSNO Act Applications in Progress** Applicants may choose to continue under the HSNO Act, transfer to the Gene Technology Act, withdraw, or request a reassessment of the decision by the EPA. **Minister for the Environment's power under the HSNO Act to decide application relating to a GMO with significant effects** Where the Minister for the Environment has used their power to direct that they will decide an application but it has not been decided when the Gene Technology Act commences, the application will continue to be decided under the HSNO Act.	Briefing 2425-0880, pg2.

From: Tony de Jong
To: Improper pressure or harassment
Cc: Improper pressure or harassment
Subject: Background info on Gene Tech as requested [IN-CONFIDENCE]
Date: Friday, 7 February 2025 1:28:18 pm
Attachments: Background information - Overseas Field Trials and CRI Future Gene Tech work.docx
Draft A3 - Licence and declarations processes.pptx

Kia ora Improper pressure o,

As requested, ahead of next week's gene tech discussion please find attached and below:

- Examples of gene technologies that have been developed in New Zealand that had to be trialled overseas due to the current regulatory regime
- Examples of activities CRIs may undertake if the regime changes (and some activities underway in anticipation of the change)

I've also attached a draft A3 setting out the application (or authorisation) process under the regime - this is in a form we're happy to share and discuss but flag it as draft as it may undergo some minor refinement (we expect to need a version of this for select committee so may tweak it further). I acknowledge this isn't contrasted with the existing HSNO approach but can speak to this.

I'm also going to send you a separate email with some suggested briefings for background reading if the Minister is interested.

Please let me know if you want to discuss or need anything else.

Thanks,

Tony

Offshore trials of gene technology applications or products developed in New Zealand

- **Plant and Food Research** conducted taste trials of their modified novel fruit product, red fleshed apples, in the United States of America due to regulatory barriers in New Zealand. It has now begun growing modified trees in China for further testing. Commercial Information

- **AgResearch** and its partners have developed gene edited Epichloë endophytes. Natural substances released by the endophytes deter insect pests from eating the ryegrass and improve plant growth and persistence, which collectively results in a reduced need for chemical pesticides and increases efficiencies in milk and meat production for New Zealand. Outdoor trialling of ryegrass containing these gene-edited endophytes is underway in Australia and the ryegrass seed has been sown by partners at locations in both Victoria and New South Wales.

- **AgResearch** and its partners developed a modified HME ryegrass aimed at reducing

environmental impacts while boosting animal nutrition and farm productivity, with evidence suggesting that methane reductions of 10 to 15 percent may be achievable (though animal feeding trials are still to be undertaken to definitively test this). While applying to Australia's Office of the Gene Technology Regulator (OGTR) in 2023 for permission to conduct growing trials in Australia, the team involved in the HME ryegrass programme encountered concerns about the risk from sesame as a known food allergen. The concerns were addressed by altering the modifications introduced to the ryegrass to provide certainty for external partners, including the OGTR. Field trials were also run in the United States of America. Feed trials will occur here in New Zealand, using ryegrass grown in containment facilities and collected. Further field evidence will be needed for animal use and will be likely generated through an outdoor trial in Australia.

- **AgResearch** and its and partners have also developed a High Condensed Tannin (HiCT) white clover. White clover is an important component of pastures in New Zealand and these condensed tannins offer significant promise for reducing environmental impacts from livestock farming while improving both animal health and production. With permission granted to grow the HiCT white clover outdoors under a bee exclusion tent in field trials in the Australian state of Victoria, positive results were seen in 2023 field trials. Selected plants have been chosen for seed production and seedlings have now been planted for the next field trial at the trial site in Victoria. Further Australian trials will include feeding the HiCT white clover to animals, and partners in the research programme will then be in a position to consider the potential for commercialisation.

Future Crown Research Institute activities under the new regulatory regime

- **Plant and Food Research** has partnered with Okanagan Specialty Fruits, who are responsible for developing the Arctic® range of modified apples in North America. It will utilise this collaboration to learn how to move gene edited plants from the laboratory to commercial outcomes. This will enable it to support New Zealand's horticulture sector as its partners consider introducing gene technology to domestic breeding programmes.

- **Plant and Food Research** are anticipating using its modified fast flowering apple varieties to increase the speed of developing new cultivars by over 7 times. As this would be managed environmental use, not subject to containment standards, tasking fruit would be allowed and as such they could conduct their taste trials domestically.

- Under the new regulations, **Scion** plans to expand its fermentation scale-up work, translating synthetic biology innovations to larger scales. This includes developing processes for plastic recycling, fine chemicals production, food intermediates, and biofuels, utilising waste resources. These expanded capabilities will allow demonstration of commercial viability through efficiency and yield optimisation.

Commercial Information

- In forestry research, **Scion** currently maintains New Zealand's only GM tree field trial facility. Scion last month planted CRISPR gene-edited trees (first CRISPR conifers in a field trial in the world) in anticipation of regulatory changes to enable full assessment of commercial properties, including improved tree form and processing characteristics. New regulations would enable multiple trial sites across different regions, allowing assessment of pest and disease resistance in various environments and better understanding of climate adaptation potential.

- Commercial Information

Tony de Jong
Manager, Biotech Policy and Regulation
Technlogy and Innovation Branch
Privacy of natural persons | Improper pressure or harassment

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- Commercial Information

Licence	Authorisation process							
Application	**Risk assessment**	**Draft RARMP**	**Advice**	**Public consultation**	**Finalised RARMP**	**Conditions**	**Fit and proper person test**	**Regulator's licence decision**
Licence: full assessment	Risks high or uncertain	Required	TAC and/or MAC in certain circumstance	Required	Required	Any conditions appropriate	Required	Licence issued if Regulator is satisfied that the risks can be managed and controlled, the applicant is fit and proper and will meet conditions
Licence: expedited	Risks are known	Required	TAC and/or MAC in certain circumstance	N/A	Required	Any conditions appropriate	Required	
Licence: pre-assessed activity	No higher than medium level of risk	N/A	N/A	N/A	N/A	Conditions limited to auditing, reporting, supervision and monitoring.	Required	Licence issued if Regulator is satisfied that the person is fit and proper and will meet the conditions.

Licence for regulated organism and activity

Licence can be reassessed, suspended, cancelled, surrendered, varied or transferred.

Licence Others	Authorisation process				
Application	**Risk assessment**	**Advice**	**Conditions**	**Fit and proper person test**	**Regulator's licence decision**
Transhipment activity	Contained to protect the environment	N/A	Can be adequately contained Any other conditions	Required	Authorisation issued if Regulator is satisfied that the regulated organism can be contained while transhipped, and applicant will meet conditions
Low-risk medical activity	Low risk medical activity	N/A	Any conditions Contained activities have specific conditions Applicant to notify Regulator for Notifiable	Required	Authorisation issued if Regulator is satisfied that the activity is low risk, the applicant meets the person test and will meet conditions
Mandatory medical authorisation	Would not result in imminent risk of death, serious illness or serious injury to people or serious damage to the environment	N/A	Any conditions (having regard to conditions imposed by the approved overseas authorities)	Not required Requires approval under the Medicines Act 1981	Authorisation issued if approved by 2 or more recognised overseas authorities and there is no imminent risk of death, illness, injury or damage to the environment
Emergency authorisation	Actual or imminent threat to health and safety of people or the environment	Regulator	Six-month period The Minister can impose any conditions	N/A	Authorisation issued by Minister if actual or imminent threat and the threat is likely to outweigh the risks. Reasons for authorisation must be given

Licence for regulated organism and activity

Licence can be reassessed, suspended, cancelled, surrendered, varied or transferred.

Declarations

Authorisation process

	Risk assessment	Draft RARMP	Advice	Public consultation	Finalised RARMP	Conditions	Fit and proper person test	Declaration made through secondary legislation
Licence: Pre-assessed activity (not available for contained activities)	No more than medium level of risk	Required	TAC and/or MAC in certain circumstance	Yes	Required	Any conditions	Required for licence	Required
Notified	Low risk activities requiring notification to the Regulator	N/A	TAC and/or MAC in certain circumstance	Yes	N/A	Any conditions Contained activities have specific conditions Regulator must be notified	Not required Can be carried out by any person who notifies the Regulator	Required
Non-notifiable	Very low risk activities that do not require notification	N/A	TAC and/or MAC in certain circumstance	Yes	N/A	Any conditions Contained activities have specific conditions	Not required Can be carried out by any person who notifies the Regulator	Required

Declaration

Declarations can be varied or revoked through secondary legislation

Process for exemptions and not regulated

	Risk assessment	Advice	Minister to undertake consultation	Conditions	Provided for in Regulations
Organisms exempt	Cannot be distinguished from organism created through conventional processes	Regulator	Required	Any conditions appropriate	Required
Gene technologies exempt	Creates no more than a minimal level of risk to people and/or the environment	Regulator	Required	Any conditions appropriate	Required
Not regulated	Relevant statutory determinations that are not GMOs (HSNO Act section 26) Gene technology that does not apply under the HSNO Act (HSNO (organisms Not Genetically Modified) Regulations 1998 Any of the organisms or techniques under the Australian regime (Gene Technology Regulations 2001, Schedule 1 and 1A (Aust))				Required

Regulations made by Order in Council

Regulations can be amended or revoked through secondary legislation

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

Doc 3

BRIEFING

Gene Technology Reform Implementation Status Report – February 2025

Date:	26 February 2025	**Priority:**	Medium
Security classification:	Budget - Sensitive	**Tracking number:**	BRIEFING-REQ-0010210

Action sought		
	Action sought	**Deadline**
Hon Dr Shane Reti **Minister of Science, Innovation and Technology**	**Note** the contents of the Gene Technology Reform Implementation Status Report – February 2025. **Note** that the Report will continue to be developed. **Discuss** the Report with Officials at your next weekly meeting if required	6 March 2025

Contact for telephone discussion (if required)			
Name	**Position**	**Telephone**	**1st contact**
Tony de Jong	Manager, Biotechnology Policy and Regulation	Privacy of natural persons	✓
Improper pressure or harassment			

The following departments/agencies have been consulted

Minister's office to complete:

- ☐ Approved
- ☐ Noted
- ☐ Seen
- ☐ See Minister's Notes
- ☐ Declined
- ☐ Needs change
- ☐ Overtaken by Events
- ☐ Withdrawn

Comments

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Gene Technology Reform Implementation Status Report – February 2025

Doc 3

Date:	26 February 2025	**Priority:**	Medium
Security classification:	Budget - Sensitive	**Tracking number:**	BRIEFING-REQ-0010210

Purpose

To provide you with an overview of implementation across the Gene Technology Reform programme.

Recommended action

The Ministry of Business, Innovation and Employment recommends that you:

a **Note** the contents of the Gene Technology Reform Implementation Status Report – February 2025.

Noted

b **Note** that the Report will continue to be developed as detailed implementation planning progresses and key decisions are made.

Noted

c **Agree** to discuss the Report with Officials at your next weekly meeting if required.

Agree / Disagree

Tony de Jong
Manager, Biotech Policy
Labour, Science and Enterprise, MBIE

26 / 02 / 2025

Hon Dr Shane Reti
Minister of Science, Innovation and Technology

.... / ..... / .....

Gene Technology Reform Implementation Status Report

1. This Gene Technology Reform Implementation Status Report – February 2025 is designed to provide you with an overview of progress on this reform based on your preferences for reporting. It provides an overview of the programme as a whole, and more detailed information on each workstream. Information includes programme-level risks and issues, critical path activities, and key project milestones and their status.

2. Please note that the milestones in this report are provisional as they are subject to key future decisions and processes outside of our control (such as Confidential advice to Government and the Select Committee process). We have also noted in previous advice that the current indicative timeframe work for secondary legislation is ambitious.

3. We would be happy to discuss the contents of this Report with you at your convenience. We are also happy to make any further amendments to the Report format to ensure it meets your needs.

Next steps

4. Officials will be available to discuss this Report at your next weekly Officials meeting.

5. We will provide you an updated Report in early March, and the first week of each month thereafter.

Annexes

Annex One: Gene Technology Reform Implementation Status Report – February 2025.

Annex One: Gene Technology Reform Implementation Status Report – February 2025.

[Please see attached Report].

Gene Technology Reform

Doc 3b

CP	The Gene Technology Bill is passed and the Office of the Gene Technology Regulator is operational in late 2025 (**CRITICAL PATH**) *This project establishes a new regulatory regime and regulatory function (within EPA)*	Confidential advice to Government	
CP1	Introduction of the Gene Technology Bill and referral to Select Committee	Dec 2024	C
CP2	Select Committee process (six months)	Dec 2024 - 17 Jun 2025	→
CP3	Oral Submissions to Committee	05 & 12 Mar	→
CP4	Departmental Report	Confidential advice to Government	
CP5	Further policy decision from Cabinet (if required)		
CP6	MBU / Budget 25 Submission		
CP7	Select Committee Report to House		
CP8	PCO redrafting and refinement of the Bill		
CP9	Second Reading of the Bill (TBC)		
CP10	Third Reading/Bill Assent (TBC)		
CP11	Bill in effect (TBC)		
CP12	Necessary Secondary Legislation in place (see Workstream 2)		
CP13	Office of the GeneTech Regulator established and operational		

W1	Workstream 1: Supporting the Select Committee *Providing robust and transparent advice to effectively support the Committee's consideration of the Bill*	17 June 2025	↓
W1.1	Initial briefing to the Select Committee	12 Feb	C
W1.2	Submissions analysis	28 Jan - 7 Mar	↓
W1.3	Oral Submissions	05 - 17 Mar	→
W1.4	Departmental Report	Confidential advice to Government	
W1.5	Committee Report	17 Jun	→

W4	Workstream 4 : Establishing the Regulator Ensuring the new Regulator is in place to enable the regime to begin.	**End Dec 2025**	↓
W4.1	Planning Phase	Mar	→
W4.2	Pre-Establishment Phase	Confidential advice to Government	
W4.3	Formal Establishment Phase		

W2	Workstream 2: Developing Secondary Legislation *Developing the necessary secondary legislation required for the effective regulation of gene technologies*	Confidential advice to Government
W2.1	Policy and discussion document development	
W2.2	RIA Panel decision expected	
W2.3	Minister's review of discussion document	
W2.4	Ministerial and political consultation on discussion document	
W2.5	EXP Committee gives approval to consult Confidential advice to Government	
W2.6	Public consultation	
W2.7	Cabinet makes final policy decisions on regulations	
W2.8	MBIE develops drafting instructions	
W2.9	PCO drafts the regulations + MBIE drafts notices / declarations	
W2.10	Cabinet agreement to final regulations + Regulations submitted to Executive Council	
W2.11	Gazette notification	
W2.12	Regulator begins operation	

W3	Workstream 3: Refining and progressing the Bill through the House *To refine the Bill further (if required) and support its progression through the House*	Confidential advice to Government
W3.1	Further refining / revising the Bill following Select Committee consideration (if required)	
W3.2	Cabinet paper for any further substantive policy revisions (if required)	
W3.3	Remaining House stages and Royal Assent (TBC)	

Free and frank opinions

Issues:

Decisions required:
Programme Steering Group – None at this time

Minister - None at this time

↑	→	↓	C	🔴	🟠	🟢
Improvement since previous report	No change since previous report	Decline since previous report	Completed since previous report	Off track / Major issue	Off track / minor issue	On track

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

AIDE MEMOIRE

Doc 4

Materials for 05 March Health Committee meeting on Gene Technology Bill

Date:	28 February 2025	**Priority:**	High
Security classification:	In Confidence	**Tracking number:**	BRIEFING-REQ-0010160

Information for Minister
Hon Dr Shane Reti **Minister of Science, Innovation and Technology**

Contact for telephone discussion (if required)

Name	Position	Telephone	1st contact
Tony de Jong	Manager, Biotech Policy & Regulation	Privacy of natural persons	ü

Improper pressure or harassment

The following departments/agencies have been consulted
Ministry for Primary Industries (MPI), Ministry of Foreign Affairs and Trade (MFAT), Ministry of Health (MoH), Ministry for the Environment (MfE), Environmental Protection Authority (EPA).

Minister's office to complete:

- ☐ Approved
- ☐ Noted
- ☐ Seen
- ☐ See Minister's Notes
- ☐ Declined
- ☐ Needs change
- ☐ Overtaken by Events
- ☐ Withdrawn

Comments

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

AIDE MEMOIRE

Gene Technology Bill – Initial Briefing for Select Committee

Doc 4

Date:	28 February 2025	**Priority:**	High
Security classification:	In Confidence	**Tracking number:**	BRIEFING-REQ-0010160

Purpose

To provide you with talking points and answers to possible questions for your appearance before the Health Committee on Wednesday 5 March 2025 on the Gene Technology Bill. We also provide for visibility a set of draft responses to Committee questions following its initial briefing with officials.

Tony de Jong
Manager, Biotech Policy and Regulation
Technology and Innovation Branch, MBIE

28 /02 / 2025

Background

1. You are the Minister responsible for the Gene Technology Bill, which is currently being considered by the Health Committee (the Committee). The Committee has received nearly 15,000 submissions on the Bill. It has scheduled 45 hours of hearings from submitters, via the full committee on Wednesday 5 and Wednesday 12 March, and via subcommittees on Friday 10 March, Monday 14 March, and Friday 17 March.

2. The Bill is a Government omnibus Bill. It creates a standalone regime to regulate genetically modified organisms, making consequential amendments to other Acts, including replacing parts of the Hazardous Substances and New Organisms Act 1996 (the HSNO Act) which currently regulates genetically modified organisms.

Your appearance at the Committee

3. The Committee has invited you to appear at 10am on Wednesday 5 March for 30 minutes.

4. We have drafted proposed talking points (**Annex One**) for approximately 5 minutes, after which the Committee may ask questions. We have included answers to possible questions the Committee may ask (**Annex Two**), and MBIE's internal Q&As developed for our recent initial briefing to the Committee (**Annex Three**) – these may provide additional context and background for matters that may be raised by the Committee.

5. We have also provided you with some anecdotal evidence on gene technologies in the "waiting room" for the new regulatory regime (**Annex Four**). This is based on officials' engagement with the sector over the past year as well as from submissions received.

6. Officials from MBIE, as well as agencies contributing to the Bill's development (MPI, MFAT and the EPA), will be in attendance at your appearance.

Written supplementary advice from officials to the Committee

7. At the Initial Briefing session with officials on 12 February, Free and frank opinions [redacted]

8. The Committee asked for written responses to a series of questions following the initial briefing. Draft responses to the Committee's questions are at **Annex Five** for your information – these are near final but may have editorial changes as we continue to receive comment from other agencies. Responses are due to the Committee at 10am Monday 3 February.

9. Free and frank opinions [redacted] These matters are likely to continue to be of interest to the Committee. Draft responses are factual and explanatory, and consistent with Government policy decisions to date.

Annexes

Annex One: Suggested talking points

Annex Two: Q&As to potential questions

Annex Three: MBIE's internal Q&As for Select Committee initial briefing

Annex Four: Anecdotal evidence on gene technologies in the "waiting room"

Annex Five: Draft responses to Committee questions (due 3 March)

Annex Four: Anecdotal evidence of gene technologies in the "waiting room"

- We provide the below information sourced from technical advisory networks, examples we're already aware of, and submissions analysed to date.
- We note these are speculative, and will be heavily dependent on innovation, investment, adoption, and subject to assessment and approval under the new regulatory regime.
- These new technologies would likely provide a cumulative benefit over time rather than a 'silver bullet' big shift.

Sustainable Agriculture

AgResearch and GrassLanz have developed High Metabolisable Energy Ryegrass with increased levels of plant oils, which increases the amount of energy available to livestock. AgResearch and GrassLanz have demonstrated these changes reduce methane and nitrous oxide emissions from livestock.

Late-stage research is still needed, and enabling this to be done in New Zealand allows our researchers to ensure these products would work for our animals and our farmers. Under the new regime, with an existing clear pathway to market, HME Ryegrass can contribute to more sustainable and efficient agricultural practices, benefiting the environment and the economy.

Improved Pasture for Animal Welfare

GrassLanz and AgResearch have also developed ryegrass endophytes with a number of beneficial properties. As some of you may know, endophytes are a type of fungus that forms a symbiotic relationship with ryegrass, but they typically produce harmful compounds which impact animal health and wellbeing.

Researchers from Grasslanz and AgResearch have succeeded in using simple gene edits to prevent the production of these harmful compounds, protecting plants from insect pests, and improving pasture yields and animal wellbeing.

Field trials are ongoing in Australia due to their more enabling regulatory regime. New Zealand scientists are awaiting the opportunity to test these new, improved ryegrasses at home with a clear pathway to market under the new regime.

Protecting our Biodiversity from Wilding Pines

CRI Scion has developed new pine trees that do not spread, eliminating the threat wilding pines pose to our native species and bush. It cannot currently test these outside, meaning Scion cannot complete the late-stage research needed to support New Zealand's $6.6 billion dollar forestry industry.

These trees do not have any new DNA, they do not produce pollen, and they do not produce seeds. Under the new regime these trees could be used to expand planting for timber building materials, erosion control, and carbon capture, without risking Aotearoa's unique biodiversity.

Precision Fermentation for the Bioeconomy

LanzaTech, a world leading precision fermentation biotech company, started here in New Zealand. Our restrictive regulatory regime was a primary reason the company moved overseas. Humble Bee Bio, Daisy Labs, and Jooules are innovative New Zealand companies, creating jobs, intellectual property, and high-value exports, who are currently stifled under the existing regime.

Scion is now using precision fermentation involving yeast and bacteria to take our primary industry waste streams and create high-value biochemicals, but under current settings it is also stuck in the laboratory-scale and is unable to scale-up.

Under the new regime the innovative New Zealand precision fermentation will be enabled, allowing them to scale up and commercialise these sustainable, high value products.

Precision Fermentation for the Export Industry

A start-up company that spun out from Fonterra and DSM has recently secured over 32 million euros in funding to turn its non-animal milk protein precision fermentation technology into commercial reality. Currently, precision fermentation activities at this commercial scale can only be conducted offshore, due to regulatory barriers.

Under the new regime New Zealand could become a leader in this innovative technology, boosting the economy through job creation, scientific advancements, and increased exports.

Accelerating Plant Breeding

Competing horticultural industries in China, America, and England can perform faster breeding programmes programs with less barriers, potentially beating us to market with better cultivars.

Plant and Food Research have developed breeding programs that can generate new cultivars 10 times faster than the competition, which could keep them ahead of the market and allow them to address critical industry needs, such as warming

temperatures. Our current regime limits them to just a few hundred plants in high level of containment, which is not enough to deliver the potential value of these programmes.

Under the new regime this breeding would be regulated in a risk-proportionate manner, enabling them to support our 4 billion dollar kiwifruit , 1 billion dollar pipfruit, and 4 billion dollar grape industries in the face of superior competition in export markets.

Animal Health

Proving the efficacy and benefits of veterinary medicines for the New Zealand market is fundamental to improving animal welfare and health outcomes. AgriHealth New Zealand primarily operates at home, but they have had to establish an Australian entity to conduct medicine and vaccine trials overseas because the current regime makes it too difficult for them.

This Bill would allow them to support local innovation conducting research locally, anchor IP, retain talent, and ensure that New Zealand remains competitive in the animal health sector.

Wine Industry Innovation

New Zealand has the world's youngest grapevine improvement programme. Traditional breeding is too slow to effectively and competitively address emerging disease threats and adapt to a changing climate.

Gene technology can rapidly address emerging diseases and climate pressures by producing improved clones of existing wine varieties. Traditional breeding can provide disease resilience, for example to Pierce's disease, but these vines are illegal to import. Using gene technology, New Zealand's wine industry could introduce this disease resistance at home, preserving the traits of our premium varieties.

Local application of modern breeding technologies, including to reduce fungicide use, would benefit growers economically and support the $2.1 billion dollar export industry and national sustainability goals.

From: Tony de Jong
To: Improper pressure or harassment
Cc:
Subject: Gene Tech responses for Minister (mainly for SC tomorrow)
Date: Tuesday, 4 March 2025 4:48:00 pm
Attachments: Examples of activities in each risk tier.docx
Submitters list for Wednesday 5th March 2025.docx
Response to Minister requests 4 Mar.docx

Kia ora Improper pressure o

Good to hear the Minister found the session yesterday useful. Please find below and attached answers to the Minister's questions.

Officials in attendance tomorrow:

- **MBIE**, proposed on front bench beside Minister (but happy to be guided by office if he'd like for them to be behind him)
  - Emily Parker (LSE) (Departmental science advisor and Professor of Chemical Biology at Vic Uni) – for questions on the science, exemptions, types of activities in risk tiers
  - Improper pressure or harassment – for questions on trade and market access, organics sector and industry assurance processes, and policy history of Māori Advisory Committee / kaitiaki decisions by Cabinet
- **MBIE**, behind Minister/front row:
  - Improper pressure or harassment and myself from the MBIE policy team – any other questions (e.g. ethics, compliance monitoring and enforcement, secondary legislation, mandatory medical authorisations, emergency authorisations, Cartagena Protocol and international obligations, use of international regulators, school kits
  - Improper pressure or harassment (all round Bill guru) will also be in attendance
- **MFAT** - Improper pressure or harassment from MFAT's Trade Policy Negotiations team will be in the room for trade and market matters
- **EPA** - Improper pressure or harassment will be there in person, with Improper pressure or harassment online.

MPI officials covering trade, market, and industry matters will be online for support will also be online **(**but more likely that we'd take questions away to respond to).

The Office should note that Officials have a hearing with the Committee 940-10am immediately prior to the Minister's session so we'll have a limited ability to answer questions from ~910am onwards.

List of submissions:
We don't have a list of submissions – it's not available from the Clerk yet as it is still

processing subs. I have attached a list of tomorrow's oral submitters and a summary of their written submissions – please note this was for our internal use and is pretty rough and ready.

Examples of activities in each risk tier
In yesterday's session the Minister sought examples of activities in tiers – we've provided the attached as a more detailed but indicative overview, noting these are all TBC (subject to decisions on Bill and regulations).

Page 1 questions:
These are addressed in the attached document. The latter two points re "potential values" and "Inventory of gene tech projects from Universities" are something we'll look into, but have attempted to indicatively provide some of this through the regions response to the first bullet.

Page 2 commissioning:
Thanks for the discussion before, we'll pull together some pro/cons tables as requested ahead of more formal development through the departmental report process (will let you know re timing)

Page 3 – related to Malaghan
Improper pressure or harassment

Specific responses to the questions are provided by Improper pressure or **in bold** are:

> ***[For the release of] WZTL-002 CAR T-cells for the ENABLE phase 1 CAR T-cell trial, and the subsequent 2024 EPA approval for 'unconditional release' of WZTL-002 CAR T-cells:***
>
> - How many hours and at what cost for each under current HSNO provisions
>
> ***Including initial application, consultation and subsequent responses to the EPA, we estimate:***
>
> - ***For the initial approval to generate the CAR T-cells within containment, around 160 person-hours were spent between various individuals.***
> - ***For the second approval, to release CAR T-cells for patient treatment in the phase 1 ENABLE trial, around 120 person-hours were spent, over many months.***
> - ***For the third approval, to approve unconditional release of our CAR T-cell product, around 60 person-hours were spent (including consultations).***
> - ***For the approval required to run our first clinical trial- the entire timeline took about 1 year and included a 3 month delay to the start of our trial. Costs difficult to estimate but at least $250K delay-related costs, not including all the time to write and follow-up on the applications.***

- What category would they be considered if the Bill was enabled? Medical non-notifiable?
  - Confidential advice to Government
  -
- In which 5 eyes countries would this have been unregulated or low regulation?
  For all other 5 eyes countries, no specific GMO release approval is required. Instead, CAR T-cells are regulated by medical regulatory agencies (as for other medicines). Clinical trials have their own review and ethical approval processes, as for other medical product.
  - *In **Australia**, CAR T-cells would be considered a 'low risk dealing' for notification to the Office for the Gene Technology Regulator, not requiring specific GMO release approval. The TGA is the regulator, as for other medicines.*
  - *In the **USA** no specific GMO release approval is required. Under a co-ordinated framework for regulation of biotechnology, regulation of CAR T-cells is a responsibility of the Food and Drug Administration (which regulates other medicines)*
  - *In **Canada** no specific GMO release approval required. CAR T-cells are regulated similarly to other drug products.*
  - *In the **UK** no specific GMO release approval is required. CAR T-cells are classified as ATMPs (advanced therapy medicinal products) and are regulated by the MHRA (Medicines and Healthcare products Regulatory Agency), which regulates all other medicines .*

In addition, MBIE also note that Malaghan's submission on the Bill highlights the impact of the current regime on it's RNA technology work and on liver cancer vaccines:

RNA technology
As part of the government funded national RNA development platform, the Malaghan is wanting to advance capability and expertise in saRNA technology – the next generation of RNA technology which offers a leap forward in the technology's ability to fight disease. Among other things it is planning to explore its potential in the development of a vaccine for malaria.

Currently under the HSNO Act, saRNA is defined as a new organism/living thing because it has 'replicative potential' meaning an application was needed to the EPA. This took a year to be approved, despite there being no environmental risk. Commercial Information

Liver cancer vaccines
In an international collaboration with researchers in New York, the Malaghan is contributing to research into liver cancer to find better treatment options for this genetically diverse disease.

As part of this research, the Malaghan sought to perform key experiments on a genetically modified mouse model to provide novel insights into the project with the potential for new IP. Despite there being no risk in these modifications being passed on (they were not in the germline) this required EPA approval under the current regime, which took more than six months to be approved. Commercial Information [redacted]

Hope this helps, please let me know if you need anything further.

Thanks,

Tony

Responses to Ministerial requests 4 March

#	Request	Response
1	Which regions are "GE free" and which of the 'waiting room' projects might benefit these regions and by how much (approx.)?	Please refer response below this table.
2	Examples from yesterday's discussion about school education that would be enabled by the Bill	Commercially available kits are used in Australian schools to help science students learn about genetics. For example, there are kits for adding fluorescent colours to bacteria. Under our current rules any genetic modification of organisms requires the use of an MPI-approved containment facility, which would be impossible for a school to achieve from both a financial and feasibility standpoint. This would be the case even for organisms that present essentially no risk to human health or the environment. In contrast, Australia, the USA and Canada have all allowed the use of GM kits in schools for over twenty years. As noted in the attached fact sheet produced by the Australian regulator (the OGTR), GM kits generally use bacteria that have a long history of safe use in schools and university teaching laboratories and as such only require schools to follow good laboratory practice. The activities likely to be proposed for New Zealand's non-notifiable risk tier will present at most a very low risk to human health and the environment (and most activities will present even less risk than that). Confidential advice to Government [redacted]
3	Are ethics and trade implications in HSNO or the Australian legislation? Are trade and ethics considered as part of costs and benefits consideration?	*Ethics* The HSNO Act does not require an ethics assessment. The Australian Gene Technology Act 2000 enables the Ministerial Council to issue policy principles about ethical issues relating to dealings with GMOs. The regulator must not issue a licence if to do so would be inconsistent with a policy principle. Our

#	Request	Response
		understanding is that to date the Ministerial Council has not issued any such policy principles. The Act also establishes the Gene Technology Ethics and Community Consultative Committee to provide requested advice to the regulator and ministers across a range of areas including ethics, community consultation, and risk communication. The committee does not advise on application decisions as the regulator does not consider ethics during assessments. The committee has issued the following documents, which do not have legal standing: • a framework of ethical principles which Australian scientists and researchers are expected to abide by when dealing with gene technology and genetically modified organisms.[1] • a paper on environmental ethics, which examines those currently applicable to the Act and its implementation.[2] The Gene Tech Bill does not have a requirement for the Regulator to consider ethics. This continues the policy under the HSNO Act. The ethics of gene technologies are addressed by other legislation, in particular, the Human Assisted Reproductive Tissues Act 2004 and the Animal Welfare Act1999. Accordingly, a supporting committee equivalent to the Australian Ethics and Community Consultative Committee was not considered necessary. Commercial Information [redacted]

[1] Gene Technology Ethics and Community Consultative Committee (Australia), *National Framework of Ethical Principles in Gene Technology 2012*.
[2] Gene Technology Ethics and Community Consultative Committee (Australia), *Gene Environmental ethics as it relates to gene technology in Australia*.

Confidential advice to Government [redacted]

#	Request	Response
		Confidential advice to Government *Trade* The HSNO Act requires that decision makers under the Act take into account the economic and related benefits and costs of using a particular new organism and New Zealand's international obligations (s 6). This could – if relevant to the application – include an assessment of the effects on trade. The Australian Gene Technology Act does not require an assessment of impacts for trade or marketing in decision making. However, the ability of States and Territories to enact their own laws to address these issues is preserved. For example, Tasmania has put a moratorium on the release of GMOs into the Tasmanian environment in place until November 2029.
4	Potential value of the waiting room projects for CRIs. [Did indicated this might be difficult to get and it would all be based on assumptions, he said he didn't mind but just wanted to have a value in mind (not something to hold anyone to)	Based on analysis conducted by the Aotearoa Circle, the adoption of white clover with increased levels of condensed tannins could be expected to result in an 8-10% increase in milk production on farm. While speculative, based on common re-grassing rates, we expect that even if only 25% of dairy farms adopt white clover (or alternatively, HME ryegrass) - a conservative estimate given the estimated benefits - after 10 years the increase in milk solids per annum would be at least 12.5 million kilograms of milk solids. At current farmgate prices this would translate into a financial benefit of at least $100 million per annum for the New Zealand dairy industry.
5	Inventory of gene tech projects from Universities – he has talked to the VC at University of Auckland who indicated she will get him a list of these. He mentioned that Emily might be able to do something similar for Victoria (& might be able to reach out to others to do the same).	See email body.
6	Malaghan two GMO releases 2022/2024	See email body.

#	Request	Response
	• How many hours and at what cost for each under current HSNO provisions • What category would they be considered if the Bill was enabled? Medical non-notifiable? • In which 5 eyes countries would this have been unregulated or low regulation?	

Request 1: *Which regions are "GE free" and which of the 'waiting room' projects might benefit these regions and by how much (approx.)?*

Response

Regions which are "GE free"

MBIE is aware that the following unitary, regional and district plans contain rules setting out prohibitions for activities with GMOs. We have not, however, read through all regional and district plans so there may be additional regions or districts that include prohibitions.

- Northland Regional Plan
- Far North District Plan
- Whangarei District Plan
- Kaipara District Plan
- Auckland Unitary Plan
- Hastings District Plan

Each plan has different activity status settings for various activities with GMOs. Northland's and Auckland's plans have effectively the same settings (albeit expressed slightly differently):

- It is prohibited to release GMOs on land and within the coastal and marine area and any structure intended to house or otherwise contain plants and animals which are associated with outdoor GMO releases, except as specifically provided for (ie as a permitted or discretionary activity).
- Field trials are a discretionary activity, ie require a resource consent.
- Research and trials within contained laboratories, and medical applications including viable and/or non-viable GMOs are permitted activities.
- The use of GMOs in veterinary applications is split across permitted and discretionary activities depending on whether the GMO is viable and the activity is supervised by a veterinarian.

Northland's district councils each have slightly different plan rules. For example, the Whangarei District Council and Far North District Council plans do not specify as permitted the use of viable GM products in medical applications. Those plans prohibit activities involving the non

food-related release of GMOs meaning that a vaccine or other medical treatment with a viable GM component could not lawfully be administered in the district. This would include the three approvals to date under HSNO[7].

Hastings District Plan is more both more restrictive and more permissive – it prohibits outdoor field trials of GMOs (as well as outdoor releases of GMOs) – there is no possibility of obtaining a consent. On the other hand, it permits activities with GMOs which involve research within contained laboratories or in medical and veterinary applications (ie there are no stipulations about whether the GMO is viable or the activity is supervised by a veterinarian).

As an aside, the Waikato District Council recently rejected including specific provisions in its district plan, concluding that: *"Overall, we are satisfied that the development, release and use of GMO can be appropriately managed through the EPA approval process and it is unnecessary to include provision for them in the [Proposed Waikato District Plan]."*

Benefits to the regions from 'waiting room' examples

Considering the 'waiting room' examples we sourced from stakeholders, we assess that there could be significant benefits to the regions and districts. We are not able to quantify this in a meaningful way, but where possible we provide proxy figures to give a sense of potential scale:

Northland

- Forestry is a significant industry in Northland. About 11% of Northland is plantation forestry – and logs make up 15% of the region's exports.[8] Use of Scion's sterile pines could cut the costs of wilding pine management. In 2020, the government announced a $100 m boost to the National Wilding Conifer Control Programme over four years and Northland Regional Council received funding to carry out projects in the region. The region's wilding control status is identified as "stopped spread but significant wilding seed sources remain".[9] In addition to combatting the wilding pine problem, Scion's sterile pines may also enable the greater use of conifer fir, a more profitable pine species when compared to pinus radiata.

- Dairy is the second-largest contributor to economic activity in Northland. Improved pastures – such as High Metabolisable Energy Ryegrass with increased levels of plant oils and those using ryegrass endophytes protecting plants from insect pests[10] – could increase the amount of energy available to livestock, improve pasture yields and animal wellbeing, and reduce livestock emissions.

- Northland (and Auckland) have around 3.5% - 5% each of New Zealand's kiwifruit growing area. The national industry is worth $4 billion. Accelerated plant breeding

[7] **IMOJEV®***:* A genetically modified live-attenuated vaccine to protect humans against Japanese encephalitis – this is a modification of the yellow fever vaccine, where two genes have been replaced with similar genes (encoding envelope and premembrane proteins) from the Japanese encephalitis virus. **CARVYKTI***:* A genetically modified, chimeric antigen receptor T (CAR-T) cell therapy to treat patients with *relapsed* or refractory multiple myeloma – this is viable in culture under very defined conditions. **WZTL-002 cells***: G*enetically modified live CAR-T cells for use in the treatment of patients with relapsed or refractory large B-cell non-Hodgkin lymphoma – these are also considered viable but the cells only proliferate under certain conditions.

[8] Plantation forestry is big in Northland

[9] Wilding Control Progress: North Island | Wilding Pines

[10] Both developed by AgResearch and GrassLanz.

developed by Plant and Food Research can generate new cultivars 10 times faster than the competition, which could keep them ahead of the market and allow them to address critical industry needs, such as warming temperatures.

Auckland

- As above, Auckland's kiwifruit industry could benefit.
- As our largest commercial centre, and a key potential location for biotech companies, Auckland could benefit economically if chosen by investors as the region where they want to establish precision fermentation activities at commercial scale. The types of investment that could occur in Auckland under the new regime – and if Auckland's plan rules were not in place – include non-animal milk protein precision fermentation and precision fermentation involving yeast and bacteria to take our primary industry waste streams and create high-value biochemicals.

Hastings District

- Hawke's Bay is one of New Zealand's main pipfruit-growing areas (worth $1 billion nationally) and is the second largest grape-producing region with 12% (worth $4 billion nationally). Benefits would be available for these industries from the accelerated plant breeding programmes to produce fast-flowering apples and other fruit varieties.
- Additionally, in respect of grapes for existing wine varieties, this district could benefit the use of gene technology to rapidly address emerging diseases and climate pressures by producing improved clones. Traditional breeding can provide disease resilience, for example to Pierce's disease, but these vines are illegal to import. Using gene technology, New Zealand's wine industry could introduce this disease resistance at home, preserving the traits of our premium varieties.
- Local application of modern breeding technologies could reduce fungicide use which would benefit growers economically.