MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

Gene Technology Bill

Presentation of Departmental Report to the Health Committee

21 May 2025

Te Kāwanatanga o Aotearoa
New Zealand Government

Recap on policy objectives for the Bill

The purpose of the new regulatory regime is to enable the safe use of gene technologies and regulated organisms by managing their risks to the health and safety of people and the environment.

The Bill seeks to provide for:

- Risk-proportionate regulation,
- Efficient application and decision-making processes,
- A flexible legislative framework able to accommodate future technological and policy developments without requiring frequent amendments to primary legislation,
- International alignment, including with key trading partners, to facilitate trade and improve access to new technologies and products; and
- Ways to recognise and give effect to the Crown's obligations under the Treaty of Waitangi.

Overview of submitters

Submitter Category	Count
Agriculture (non-dairy)	72
Agritech	5
Apiary	10
Biotech	16
Dairy	29
Environmental Non-Governmental Organisation (E-NGO)	32
Fisheries	2
Forestry	3
Horticulture	41
Iwi/hapū	25
Legal	6
Māori Non-Governmental Organisation (Māori NGO)	12
Māori sector	2
Officers of Parliament	1
Organics	99
Other	56
Research institute	17
Researcher (Individual)	43
Sector group	22
Seeds	12
Think tank	4
University	6
Individual	14,230
TOTAL	**14,745**

Key themes across submissions

	Key themes
Submissions in **support**	• Helping to address environmental challenges • Supporting innovation • Providing flexible and modern regulatory settings • Implementing a risk proportionate approach • Supporting potential benefits to human and/or animal health
Submissions in **opposition**	• Gene technologies not being safe • Damage to New Zealand's reputation, trading relationships or the economy • Negative impacts on non-GMO or organic producers • Inadequate consultation • Insufficient liability and compensation provisions

Overview of recommendations

- 100+ recommendations to improve workability of the regulatory regime

- Three areas with interdependent recommendations:
    1. Clarifying provisions on non-regulated organisms and technologies, and exemptions
    2. Extending kaitiaki relationships to include specified non-indigenous species of significance
    3. Clarifying appointment and accountability arrangements relating to the Regulator

- Other key recommendations include:
    - Adding criteria and requirements for the Māori Advisory Committee, based on the Plant Varieties Rights Act 2022
    - Adding a review of the Act after 4 years
    - Using “recognised” medical authorisations (instead of “mandatory”)
    - Making it explicit that the Regulator can require verification of genetic changes made

1. Non-regulated technologies and organisms, and exemptions

Many submissions raised concerns with clause 163, including how provisions for non-regulated organisms and technologies, and exemptions, are described.

- The recommendations we have made work together to provide clarity, regulatory certainty, and prevent automatic adoption of potential future Australian regulatory changes. Our recommendations include:
    - Replacing reference to the HSNO regulations and Australian regulations (that set out non-regulated technologies and organisms) with a **prescriptive list** (e.g. as a schedule) of items that are **not regulated** by the Act to clearly define the scope of the regime.
    - Amending the **criteria for exempting organisms**, to refer to organisms **indistinguishable** from those either:
        - not regulated by the Act [as set out in the recommended prescriptive list], or
        - could be produced using a technology not regulated by the Act.
    - Removing references in the Bill to ‘conventional processes’ as it was ambiguous and is redundant with the recommended changes.

2. Kaitiaki relationships with non-indigenous species

Currently, the Bill requires that the Regulator must in its decisions have regard to advice from the Māori Advisory Committee (MAC), on whether authorising the activity would have a material adverse effect on kaitiaki relationships with the indigenous species used as a host organism.

Submitters noted that Māori have kaitiaki relationships with non-indigenous species as well.

- The Plant Variety Rights (PVR) Act 2022, on which Government agreed to model the MAC and consideration of kaitiaki relationships with native species, considers non-indigenous plant species of significance that are listed in regulations (10 species)
- We have recommended that kaitiaki relationships in the gene technology regime also include specified non-indigenous species of significance, with particular changes to the Bill being:
  - Amending the definition of kaitiaki relationships to include non-indigenous species of significance
  - Adding a definition of non-indigenous species of significance based on the PVR Act's definition
  - Adding a power to make regulations to list non-indigenous species of significance

3. Regulator accountability arrangements

Some submissions raised concerns about the perceived or actual independence of the Regulator, given the Bill provides for the Minister to appoint the Regulator, and issue general policy directions to the Regulator. The Public Service Commission also raised some functional difficulties with direct ministerial appointment of the Regulator.

- We have recommended changes to the Bill that we consider would make ministerial appointment of the Regulator workable, in particular:
  - providing for the EPA to recruit the Regulator, in consultation with the Minister
  - clarifying that the Regulator is accountable to the EPA in respect of their obligations as an employee (distinct from accountability to the Minister for performance of statutory functions)
- We are working to finalise policy proposals to clarify provisions on liability insurance and the EPA's powers and functions

- On the Minister's general policy direction power, we consider the changes you have already approved to align provisions in the Bill with the relevant provisions in the Crown Entities Act 2004 will address submitters' concerns and ensure appropriate constraints.

Other issues raised in submissions

Some submitters thought that…	No change recommended because…
Additional factors should be included in the purpose of the Bill – primarily trade and market access risks, but also ethics, and benefits	• Keeping the purpose (and therefore the focus of the Regulator's decision making) on managing risks to the health and safety of people and the environment, has worked well in Australia for 20+ years, and supports the policy objective of efficiency and evidence-based decision making • Trade and market access risks can be addressed in a combination of ways, including non-regulatory approaches, rather than adding complexity and subjectivity to the Regulator's decision making
Detail of risk tiers should be in the Bill, not secondary legislation	• Having detail in secondary legislation supports the policy objective of flexible regulatory settings, and is consistent with LDAC guidance that secondary legislation is more appropriate for technical detail • Secondary legislation development will include consultation
The Bill should include a civil liability regime like the HSNO Act	• The regime provides a comprehensive offences and penalties regime including pecuniary penalties • A statutory civil liability regime could reduce overall activity, prohibitively discouraging entrants to the regime • The common law (law of torts) is available for compensation for damages
Local authorities should remain able to make decisions on GMOs (i.e. do not amend the RMA)	• A nationally consistent approach is needed to deliver on the policy objectives • The Regulator will provide a consistent approach to risk management of gene technologies, making expert, science-based, risk-proportionate decisions

Thank you.

Questions?

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