MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

Regulatory Impact Statement

Reform of Gene Technology Regulation

Ministry of Business, Innovation and Employment

Coversheet

Purpose of Document	
Decision sought:	Analysis produced for the purpose of informing Cabinet policy decisions on a new gene technology regulatory regime
Advising agencies:	Ministry of Business, Innovation and Employment
Proposing Ministers:	Minister of Science, Innovation and Technology
Date finalised:	31/07/2024

Problem Definition

Gene technologies offer productivity benefits, as well as potential solutions to pressing national challenges such as climate change, biodiversity loss, and improving health outcomes. Recent advances that could support better health, environmental and economic outcomes for all New Zealanders include:

- new therapies for hard-to-treat genetic diseases and cancers
- agricultural feed grasses able to reduce animal emissions, and
- better heat and drought resistant crops.

Consequently, gene technologies could prove instrumental for strengthening the resilience of the country's Four Capitals – human, social, natural, and financial/physical – as identified in the Treasury's Living Standards Framework.

New Zealand regulates the use of genetically modified organisms (GMOs) and gene technologies under the Hazardous Substances and New Organisms Act 1996 (HSNO Act), which is broad in scope and encompasses hazardous substances and new organisms (which includes GMOs). The HSNO Act regulates GMOs and gene technologies strictly and limits how they can be used in New Zealand.

To realise this missed opportunity, officials recommend the introduction of a new regulatory regime that will enable more gene technologies to be safely used in New Zealand.

Executive Summary

Why government intervention is required

The HSNO Act establishes the primary regulatory framework for authorising the importation, development, and use of GMOs in New Zealand.[1] For the purposes of this document, commentary on the HSNO Act is referencing the part of the Act that regulates gene technology and GMOs. Since the HSNO Act's commencement in 1998, there have been significant scientific advances in gene technology, increased understanding of its risks and benefits, and many gene technologies can be used safely. Although there have been amendments to the Act over time (for example to establish a more enabling approach to

[1]Other legislation further regulates use of GMOs in medicines, agricultural compounds and food.

regulating GMOs used in medicines), various reports over the past 15 years[2] have found that the HSNO Act's GMO provisions are increasingly out of date. Out-of-date provisions include:

- A purpose statement and related provisions which emphasise decision-makers should take a precautionary approach.
- A requirement for decision-makers to take into account a broad set of factors, including the economic and related benefits and costs of using a GMO, which increases the evidential burden on applicants and is difficult to assess and compare to risks the GMO may pose to the health and safety of people and the environment.
- A regulatory approach that determines risk based on the processes used to introduce or remove genetic traits, rather than assessing the risk of the resulting traits of the GMO.
- Outdated definitions which do not accommodate gene technologies that have been developed.
- An authorisations framework that requires case-by-case approvals except in limited circumstances for low-risk research, which requires a broad institutional approval.

These settings place a regulatory burden on researchers and companies that seek to develop and use gene technologies and GMOs that is not commensurate with the potential harms to society of the activity. Biotechnology is a rapidly growing sector internationally,[3]and New Zealand's biotechnology sector has identified that the current regulatory settings are a significant factor in constraining research and development in the sector. Ongoing regulatory constraint therefore represents an economic opportunity cost to New Zealand.

In addition, other sectors are also likely missing out on opportunities to benefit from gene technology applications, including the environment (targeting biodiversity, climate change), and the primary and health sectors. Potential uses include pest control, agricultural feed grasses able to reduce animal emissions, crops that are more resistant to heat/drought or are higher productivity, and new medical therapies for genetic diseases and cancers.

The Government has signalled regulatory reform as the primary priority in enabling the growth of gene technology and product development and application in New Zealand to help realise economic, environmental, and health benefits. The proposed new regulatory regime is the sole focus of this RIS and policy intervention.

Officials acknowledge that there may be a number of issues that affect the success of New Zealand's gene technology regime alongside the regulatory barrier. For example, BioTechNZ's 2020 report identified a range of barriers to innovation in the sector, including access to capital, access to experienced and qualified experts and workforce, and public perception issues.

Further analysis and advice would be necessary to understand specific issues, opportunities, and any potential role for government, should the Government and Ministers decide to consider broader options.

The options considered

MBIE considered options for a new Act to achieve the following Government objectives[4]:

- **Enabling** – the regime should enable the greater use of safe gene technologies to deliver better outcomes for New Zealand.

[2]Including by the Royal Society, the Productivity Commission, and the Prime Minister's Chief Science Advisor

[3] Having predicted annual growth rates of 10-15%.

[4] At Ministerial direction we did not consider options for reforming the HSNO Act..

- **Risk-proportionate** – restrictions on gene technology and GMOs should be proportionate to the risks that each application poses.
- **Efficient** – applications should be efficiently assessed, and the process should be easy for applicants to navigate.
- **Future focused** – the legislation should accommodate future technological developments without needing frequent amendments.
- **Internationally aligned** – the regime should be in step with our major partners to facilitate trade and improve access to new technologies.
- **Rights and interests under the Treaty of Waitangi** – the regime should appropriately consider Māori rights and interests under the Treaty of Waitangi.

We developed options in each of the following key policy areas. Unless noted, the preferred option is also reflected in the Cabinet paper:

Options (preferred in bold)	Rationale
A. Meeting Treaty of Waitangi obligations	
1. Establishing a Māori Advisory Committee Note – this option is considered further and incorporated into Section E.	The consideration of Māori rights and interests would be incorporated into the assessment process. The regulator would seek non-binding advice from a Māori Advisory Committee. **This option is informed by joint ministers' decision to adapt with modifications the process from the Plant Variety Rights Act 2022 (PVR Act), which provides for a Māori Plant Varieties Committee that has decision making powers.**
B. Regulatory approach	
1. Status quo (process based) 2. Product/Outcome based **3. Hybrid (mixture of process and product/outcome)**	Allows the regulator to determine where there is a risk to human health or the environment and to regulate accordingly (whether the outcome carries risk, or the technique does) and this option allows for gene-editing techniques that present no new risks (compared to non-GMO techniques) to be exempt.
C. Authorisations framework	
1. Status quo (activities under the HSNO Act) 2. Unmodified Australian legislative framework **3. Modified Australian legislative framework** **4. Requiring nucleic acid screening (combined with 3)**	Regulates activities using GMOs based on the risks they pose to the health and safety of people and the environment in a risk proportionate way. Very low or low risk activities will not require case-by-case approval, while activities where the risk level is medium, high or uncertain will require case-by-case approval. Allows for adjustments to risk tiers over time.

D. Decision-making factors	
1. Status Quo (considerations under the HSNO Act) **2. Assessing risks to health and the safety of people and the environment and removing local restrictions under the RMA** 3. Assessing risks to health and the safety of people and the environment, trade and market access, and removing local restrictions under the RMA	Manages risk to human health and the environment while decreasing cost, complexity, and removing assessment criteria about the benefits of an activity that the regulator is not well-placed to make.
E. Assessments, decision-making and approvals	
1. Status Quo (rapid and full assessments under the HSNO Act) 2. Modified Australian process **3. Multi-agency incorporation into assessment and decision-making process in conjunction with Option Two**	Creates processes that are tailored to each authorisation type, resulting in assessments that are proportionate to the risks associated with the activity.
F. Decision-making authority	
1. Status quo **2. Independent decision-maker** 3. Ministerial call-in power in conjunction with Option Two 4. Ministerial general policy direction power in conjunction with Option Two	Promotes confidence that the new regime is enabling and focused on decisions informed by scientific knowledge. Promotes regulatory certainty. **The Minister's preference is Options 3 and 4 and this has been reflected in the Cabinet paper.**
G. Location of the regulator	
1. EPA **2. Within an existing departmental agency (preferably MBIE)** 3. New departmental agency or Crown entity	Options 1 and 2 are both viable, with different advantages. Option 1: • Houses existing technical capability. • Established relationships with Māori and industry. • Has complementary regulatory functions. • Lower upfront cost. Option 2: • No existing related regulatory regime (e.g., HSNO) that could influence the operation of the new regime. • Experience in standing up new regulatory regimes.

	• Alignment between the location of the regulatory function and the Minister with portfolio responsibility for the regime. • Strong relationships with the science and innovation sector and opportunities for sector growth. **The Minister's preference is to present both options for Cabinet consideration.**

Annex A provides a summary of the key aspects of the proposed new regime. Together, the package of proposals will work as follows:

- The regime will focus on managing any risks to the health and safety of people and risks to the environment from the use of gene technologies.
- Gene-editing techniques producing outcomes that could have resulted from conventional breeding techniques will be exempted from regulation.
- Other gene technologies will be regulated and must be authorised to be used. Authorisation pathways and requirements will be calibrated to the level of risk of the gene technology / activity and categorised according to whether the activity is conducted in containment, is for a clinical trial or medical application, or intended to be released into the environment.
    - Notices issued by the regulator following public consultation will specify activities that are authorised without needing a case-by-case assessment because they are very low or low risk.
    - Other activities will be required to receive a licence from the regulator on a case-by-case basis.
- The regulator will be advised by a Māori Advisory Committee, a Technical Advisory Committee and relevant government agencies. The public will be consulted on licence applications that require a full assessment.
- The regime will use the expertise of comparable international counterparts to accelerate assessments and authorisations.
- Where multiple domestic regulatory approvals are required (e.g. for gene technologies or regulated organisms that are also medicines, veterinary medicines, or new organisms), information-sharing, cooperation, and delegation, where appropriate, will support streamlining application and decision-making processes.
- The Minister will have the power to call-in an application if they consider it would have nationally significant effects on the health and safety of people or the environment, and to issue general policy directions to set general parameters for the regulator such as guidance on risk tolerance (as noted above, this was not MBIE's preferred option).
- The regulator will be located at either the EPA or MBIE.

Impacts

The expected costs of the proposal are in two main areas:

- Unquantified costs to organic/non-GMO primary producers. At present this sector operates without risk of inadvertent contamination to their products from GMOs, because under the status quo there have not been any environmental releases of GMO products that could cause such contamination. Under the proposal, it is expected that eventually GMO products will be released into the environment which would require new supply chain management approaches to avoid contamination of non-GMO products. There would also be additional costs for organic and other certified non-GMO supply chains to meet assurance requirements National economy
- Additional fiscal costs. We estimate operational cost for regulatory functions over 4.25 years of Confidentia if the EPA hosts the regulator and Confidentia if MBIE hosts. This is expected to reduce to Confidenti annually in outyears. In addition, If the regulator is

MBIE, there would be a further Confidential advice to Government This also includes funding for the Ministry for Primary Industries (MPI) to undertake compliance, monitoring and enforcement activities.

The expected benefits of the proposal include:

- Reduced compliance burden for regulated parties seeking to develop and use gene technologies. This reduced burden is expected from:
    - exempting from regulation gene-editing techniques that present no new risks compared to non-GMO techniques
    - not requiring very low and low-risk activities to require prior approval
    - focusing decision-making on whether any risks to the health and safety of people and the environment can be managed, thereby reducing the evidential burden for applicants, and
    - streamlining decision-making processes.
- Increased economic activity in the biotechnology sector, including from more research and development activity, and more start-ups and commercialisation of GMO applications.
- Social, environmental, and economic benefits for New Zealand and consumers from the expected increased use of GMOs, such as in new medicines, products that contribute to mitigating climate change and biodiversity loss, and plants and animals that are more disease resistant.

We are unable to comprehensively quantify these expected benefits as technology development is uncertain, there are few "ready for market" gene technologies in New Zealand currently and the make-up of New Zealand's food and fibre industry is distinct. Realising expected benefits also relies on the biotechnology sector and industry having access to capital and skills to undertake research and development, and to commercialise innovations. A risk to achieving these benefits is that there may not be social licence for some of the potential uses. For example, research indicates that generally New Zealanders are more supportive of the use of gene technologies in healthcare and conservation than in food production and farming.

The proposals also have impacts for Māori, as use of gene technology engages Māori rights and interests under te Tiriti o Waitangi / the Treaty of Waitangi. These include rights to exercise kaitiakitanga (often translated as guardianship) for specific species and places, and for equitable access and outcomes in areas such as health and economic development.

The proposals alter the status quo by placing a duty on decision makers to manage adverse effects to Māori kaitiaki relationships with specific species, instead of requiring them to take into account Te Tiriti principles more generally. Given time and scope constraints, officials did not analyse a wide range of options on how to best protect Māori rights and interests. Nonetheless, officials consider that the Plant Variety Rights Act 2022 (PVR Act) provides an effective and transparent mechanism to take into account Māori interests in environmental risk management. The PVR Act provides for a Māori Plant Varieties Committee that has defined decision making powers. However, ministers' preferred approach is that the Māori Advisory Committee under the proposed regime will not have a decision-making role. MBIE considers that this approach is unlikely to meet Māori aspirations for partnership in decision making in this area.

Public, Stakeholder, Māori and government agencies' views

Due to the timeframes for developing the proposal, MBIE did not publicly consult on the proposed regulatory changes or engage broadly with Māori. There is some limited evidence that public opinion in respect of gene technology is becoming more favourable overtime, particularly concerning medical uses and techniques that do not involve trans-gene

modifications. However, in the absence of readily available evidence and public consultation, it is not possible to draw a broad conclusion that the public supports a more enabling approach to regulating gene technology.

That said, we carried out targeted engagement through establishing technical, industry and Māori groups to advise us and by meeting with a range of people, including iwi and Māori groups, and stakeholders across the research, biotech, and primary sectors (Annex B provides detail of who was engaged).

We also took key insights from the 2023 Ministry for the Environment (MfE) review on regulations and controls for research conducted in laboratory settings and the assessment and approval for biomedical therapies under the HSNO Act.

The research community and biotech sector strongly support the intent of the reform and are broadly supportive of the proposal.

Industry views on the proposal are mixed:

- Many primary sector stakeholders support reducing regulatory requirements for GMOs and recognise the potential of the technologies to address climate change and to improve the commercial value of products. However, they also note that commercial uptake of GMOs may be limited by social licence or export market requirements.
- Organic/GE-free primary producers are concerned at the impact for their markets of any potential environmental release of GMOs in New Zealand, and how GMO and non-GMO supply chains would coexist.

Māori whom we engaged with indicated there is a range of views about establishing a more enabling GMO regime. Key perspectives include:

- Māori should have oversight of genetic modifications made to species of importance to them (including native flora, fauna, and taonga species).
- There is interest in the opportunities gene technologies may provide in healthcare, conservation and economic development, and it was considered very important that, if restrictions on gene technologies are reduced, Māori can access and benefit from gene technologies and GMOs.
- There need to be robust processes for decisions to release GMOs into the environment and post-release monitoring to ensure there are not flow-on effects to non-modified species.
- A key interest raised in stakeholder consultation was around benefit sharing, which is not directly addressed by the proposals as it is typically considered in subsequent processes such as plant variety rights and patenting.

MfE's 2023 consultation revealed that several local government bodies are opposed to regulatory change that would more lightly regulate GMOs. Other organisations, including GE Free New Zealand, the Sustainability Council, and the McGuinness Institute, share that view.

Government agencies with responsibility for domains and regulatory systems that will be impacted by the proposal, particularly MfE, MPI, and the Ministry of Health (MoH), support the intent and direction of the reform.

The Ministry of Foreign Affairs and Trade (MFAT) and Te Puni Kokiri (TPK) have both expressed concerns about aspects of the proposal, with feedback indicating:

- The regulator should be required to consider trade and market access risks in assessing organisms for environmental release. This is due to the complex assurance processes for gene technology in key export markets, and the unpredictable nature of the international trading environment where gene technology has been historically controversial. (MFAT)
- The proposal does not sufficiently provide for Māori to uphold kaitiaki relationships and directly benefit from the reforms. The regulator and Māori Advisory Committee should

be required to agree how any detrimental impacts to the kaitiaki relationship can be mitigated. (TPK)

Implementation risks noted by agencies include:

- Confidential advice to Government
- Potential regulatory difficulties in the intersection between the HSNO Act and the proposed Gene Technology Act. (MfE)

Limitations and Constraints on Analysis

The key limitation was information on the sector, and main constraints a defined, narrow scope, and a compressed timeline to undertake analysis, which also resulted in narrow, targeted consultation. These are discussed below:

Limitation – information on sector: Current understanding of the current and potential gene technology sector[5] limited our ability to outline both benefits and potential impacts (and is in part a consequence of the existing regulatory constraints on the activity). As an example, we do not have a current understanding of the number of companies in New Zealand undertaking (or who would likely undertake) activities captured by the regime and potential direct and indirect benefits that may arise from these proposed changes.

Constraint – narrow scope: Agencies were commissioned to fulfil commitments set out in the Government's two coalition agreements (informed by the National Party's 2023 pre-election manifesto), and ministerial direction:

- Both coalition agreements include a commitment to liberalise genetic engineering laws, and the National-NZ First agreement commits to this being done while ensuring strong protections for human health and the environment.
- The National Party harnessing biotechnology policy sets out three key priorities:
  - End the effective ban on Genetic Engineering (GE) and Genetic Modification (GM)
  - Create a dedicated regulator to ensure safe and ethical use of biotechnology
  - Streamline approvals for trials of use of non-GE/GM biotechnology.
- Ministers directed officials that:
  - The intention is to put in place new legislation and a new regulator to regulate the use of gene technologies in New Zealand, taking over functions currently held by the Environmental Protection Authority (EPA).
  - The reform process will encompass a wide range of genetic techniques and will also include regulation of gene therapies used in health.
  - The reform process should not consider hazardous substances regulation.
  - The scope focus solely on gene technologies because other biotechnologies are generally lower risk or are adequately regulated.

This scope limitation has meant mean that we have not considered all potential options that may have effectively addressed key issues underlying the changes sought by Government, including amending the existing HSNO Act to enable these activities. In addition, the existing HSNO Act removing GE and GM activity from the HSNO Act regime we may not have

[5]Gene technology companies are a subset of the biotechnology sector, which includes companies involved, or potentially involved in gene technology, but many that are, or will not be involved in gene technology activities.

adequately considered wider impacts and consequences on the regime (this is linked to timeframe constraints as outlined below).

Constraint – Timeframes: The policy development process has been limited by a timeline seeking to Cabinet approval of policy decisions to enable the introduction of a Bill into the House before the end of 2024, to in turn enable the regime to be operational in 2025. This has compressed the analysis able to be undertaken in a highly complex area, and may mean options, impacts, and consequences were not (or not fully) considered. Partial mitigation of this included:

- The early establishment that the Australian regulatory regime for gene technology was likely to be a model that would largely achieve the Government's objectives. As a result, policy work and engagement focused on assessing key features of the Australian regime, identifying possible adaptations for the New Zealand context, and improvements based on updated scientific views and other countries' experience with gene technologies.
- Utilisation of work undertaken and key insights of MfE's 2023 review on regulations and controls for research conducted in laboratory settings and the assessment and approval for biomedical therapies under the HSNO Act. This work included public consultation on proposals.

Timeframes – consultation: A limitation and constraint resulting from compressed timeframes was that no formal consultation or full engagement with Māori was undertaken to shape, test, inform, and refine proposals. More fulsome consultation may have:

- enhanced policy development by identifying opportunities and concerns, and introducing addition perspectives and information at key points of the process, and enabled refinement and iteration of proposals, and
- enabled increased or more comprehensive understanding and analysis of the diverse Māori interests, opportunities, and concerns on gene technology.

This was partially mitigated by:

- establishing separate Technical, Industry, and Māori Focus/Advisory Groups to shape and test proposals, and
- conducting targeted engagement with stakeholders, including universities and research institutes, iwi and Māori groups, industry associations, Crown Research Institutes, biotech companies, and primary industry and export sector groups.

The Technical Advisory Group, comprised of 15 representatives from institutes and organisations actively involved in gene technology work[6], provided officials technical advice on up-to-date gene technology regulation, including regulatory procedures and science and technical matters related to gene technology, techniques, and therapies.

These however were partial mitigations, and we recognise that it does not likely meet the level necessary for high quality regulatory analysis.

In summary, considering the limitations and constraints outlined, and the mitigations implemented, MBIE considers decision-makers can have moderate levels of confidence in using this analysis to inform decisions.

[6] See Annex B for more information on MBIE's targeted consultation process.

Responsible Manager(s) (completed by relevant manager)	
Tony de Jong Manager Biotechnology Policy and Regulation Ministry of Business Innovation and Employment  31 July 2024	
Quality Assurance (completed by QA panel)	
Reviewing Agency:	Joint MBIE, MfE and MPI panel
Panel Assessment & Comment: MBIE's Regulatory Impact Analysis Review Panel has reviewed the attached Impact Statement prepared by MBIE. The Panel considers that the information and analysis summarised in the Impact Statement partially meets the criteria necessary for Ministers to make informed decisions on the proposals in this paper.	Mark Steel, Chief Advisor Regulatory Systems, Ministry of Business, Innovation & Employment mark.steel@mbie.govt.nz

Contents

Section 1: Diagnosing the policy problem

What is the context behind the policy problem and how is the status quo expected to develop?

The New Zealand public has differing views on gene technology

1. Gene technology means any modern technique used for modifying genes.[7] Products of gene technologies can be used in areas such as human and animal health, medicines, and food production.

2. The New Zealand public has a history of being apprehensive about gene technologies. Following the Minister's direction officials have not consulted with the public on these reforms. While we do not have access to robust evidence about the current views of the public about gene technologies, there is some targeted research to suggest that consumer preferences and public perceptions in New Zealand and globally have somewhat changed over time to be more accepting of gene technologies.

3. Research carried out in 2022 by Kathlene, Munshi, Kurian and Morrison surveyed 500 Māori and non-Māori on their perspectives on genetic modification and gene editing. [8] For applications such as human medical treatments, livestock pathogen resistance, and improving the resilience of native species, they found that overall:
   - For Māori: 11% were strongly supportive, 33% leaned supportive and 13% strongly opposed.
   - For non-Māori: 12% were strongly supportive, 23% leaned supportive and 8% were opposed.

4. The research indicated that generally New Zealanders (Māori and non-Māori) are more supportive of the use of genetic modification and gene editing in healthcare and conservation scenarios compared to food production and farming scenarios.

5. 2024 research on high-level public perceptions of using gene technology from the agricultural research and advisory firm *Primary Purpose*[9] found 34% of respondents were generally supportive of gene technology, while 29% specifically wanted to keep New Zealand food production systems completely free of any gene technology.

6. Dairy Exporter also reported on research by Research First in 2024 which surveyed attitudes of farmers and growers and the public towards genetic engineering and modification.[10] This showed that after a brief description of the technology, 44% and 35% of respondents felt that gene editing and genetic modification would have benefit to their families respectively. It also reported that consumer attitude changes by application, and use in meat production is less accepted than in fruit and vegetables.

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[7] A glossary of terms used in this document is set out in Annex D.

[8] Cultures in the laboratory: mapping similarities and differences between Māori and non-Māori in engaging with gene-editing technologies in Aotearoa, New Zealand | Humanities and Social Sciences Communications (nature.com)

[9] Public perceptions of genetic technologies (squarespace.com)

[10] Dairy Exporter: Genetic Modification – What do we know? Spring 2024

7. By comparison, a 2021 survey on Australian public opinion found that 54% of respondents said GMO would improve Australia's way of life, up by 9% from a previous poll in 2019. This survey showed 44% of respondents supported GMOs in crop and food production, and 61% supported use for medical purposes.[11]

8. Some other countries have begun updating regulatory regimes to be more permissive of gene technologies, including the EU, Norway[12], and the UK. This indicates that there may be a shift in attitude internationally, but this has not been assessed in detail.

The research community, and business and industry groups are concerned about the consequences of the current regulatory regime remaining unchanged

9. The New Zealand research community, comprised by universities and research institutes, Crown Research Institutes, biotech companies, and primary industry research bodies, is particularly concerned with the current regulatory settings for laboratory research with gene technologies, and these concerns have been expressed through several avenues. Reports by the Royal Society in 2012 and 2019 concluded that our current settings were increasingly outdated and do not reflect advances in gene technology. The conclusions of both reviews were to recommend changing our regulatory system to be more future-focused and fit-for-purpose.

10. The impacts of the current regulatory settings on businesses and industry groups have also been an area of concern. In 2012, for instance, MfE commissioned a report by Rhadegund Life Sciences on the factors that influence businesses' decisions to innovate with new organisms (including GMOs). This indicated that there are issues with the whole of the HSNO Act and found that the cost of developing and introducing any new organism (GMO and non-GMO) constrained innovation and that some firms were considering going offshore.

11. In 2015, Rhadegund Life Sciences was also commissioned by Callaghan Innovation to establish what impact the New Organism provisions of the HSNO Act may have on New Zealand business. The main conclusion of this report was:

> *"New Zealand has a wide range of opportunities to increase the productivity and value of its agricultural sector and build a sustainable green manufacturing sector by innovation with new organisms. These opportunities are currently limited by New Zealand's HSNO regulations."*

12. In 2020 BioTech New Zealand issued a report on the wider New Zealand biotechnology sector. This report found that the current GMO regulations were considered by companies surveyed to be the second most significant constraint on biotechnology research and development and the third most significant constraint to biotechnology commercialisation, after access to capital.

13. More recently in 2023, Te Puna Whakaaronui, New Zealand's independent food and fibre sector think tank published an overview of modern gene technology and noted an

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11 Community attitudes towards gene technology 2021 (ogtr.gov.au)

12 Proposal for relaxation of European regulations for deliberate release of genetically modified organisms (GMO) (bioteknologiradet.no)

urgency for innovative solutions and new options to resolve food security and environmental sustainability issues.

What does the current gene technology regime look like and what are its objectives?

14. Since 1998 GMOs and gene technologies have been regulated under the HSNO Act, which is broad in scope and encompasses hazardous substances and new organisms (which includes GMOs). HSNO was amended in 2002, following the Government response to the 2001 *Report of the Royal Commission on Genetic Modification*[13], to include additional matters to be considered for certain developments and field tests, and an additional conditional release approval type.

15. 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 EPA prevents and manages adverse effects of GMOs as new organisms.

16. Applicants that wish to conduct activities that use GMOs must apply to the EPA for an approval under the HSNO Act. Under the status quo, authorised activities involving GMOs can be broadly grouped into three categories:
    - import, development or field testing in containment (i.e., research conducted in a laboratory setting)
    - environmental release, which can be further broken down into the "release" of human and veterinary medicines and general environmental releases, and
    - emergency use.

17. The HSNO Act provides for the protection of Māori rights and interests by requiring persons exercising their functions, powers, and duties to take into account the principles of the Treaty of Waitangi and the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wahi tapu, valued flora and fauna, and other taonga. Ngā Kaihautu Tikanga Taiao (NKTT), the EPA's Māori Advisory Committee established under the Environmental Protection Act 2011, provides decision-makers with a broad overview of Māori interests and perspectives. He Whetū Mārama is the EPA's framework for incorporating Māori perspectives and mātauranga into the policies, processes, and decisions of the EPA.

18. In addition to the HSNO Act, the regulation of gene technologies involves several other legislative and regulatory frameworks, including the Medicines Act 1981 the Human Assisted Reproductive Technology Act 2004, the Imports and Exports (Restrictions) Act 1988, the Biosecurity Act 1993, the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM), the Conservation Act 1987, the Animal Welfare Act 1999, and the Food Act 2014.

19. New Zealand also has obligations as a party to the Cartagena Protocol on Biosafety (the Cartagena Protocol) to the Convention on Biological Diversity.

20. MPI is vested with the compliance monitoring and enforcement function for the HSNO Act. In addition, it also assesses and approves biological imports into and exports from

[13] See Report of the Royal Commission on Genetic Modification | Ministry for the Environment

New Zealand, including the import and export of GMOs and several administrative programmes for non-GM export assurances.

There are changes on the way that impact the current system

21. The Biosecurity Act 1993 provides the legal framework to help keep harmful organisms out of New Zealand, manage those that get into the country, and manage established pests and diseases. Policy proposals for a Biosecurity Act Amendment Bill will be presented to the Minister for Biosecurity shortly, and are intended to improve, strengthen, streamline, and future-proof the biosecurity system. The proposals cover system-wide issues, funding and compensation, border and imports, readiness and response, long-term management, and interfaces with other legislation.

22. MPI has purposely excluded changes to sections which may interface with the gene technology reform. There are some proposals, however, that may interface with the proposed Gene Technology bill and regulatory system once implemented, outlined broadly below:

Theme	**Interaction**
Local knowledge in decision-making	Mātauranga and local knowledge may be considered when implementing biosecurity requirements. This is a different approach to consideration nationally consistent framework planned for the Gene Technology Act.
Changes to penalties and offences	Amendments to penalties and offences may incite additional caution for importers. The proportionality between the different penalties and offences regimes will need to be considered. Disproportionate penalty provisions may create confusion in how to treat those acting in contravention of both Acts at the same time. Additionally, there may create an inequity in how penalties and offences are applied between the two Acts for actions that have a similar level of risk.
Streamlining import requirements	Improving import requirements will likely increase the number of varieties available for import and may facilitate increased GMO import.
Improving transitional and containment facility provisions	Streamlining the provisions for transitional and containment facilities is likely to reduce compliance burden for facilities that hold GMOs. However, there is a risk of increased compliance burden if the Gene Technology Act does not align with these streamlined provisions. For example, the proposals for a Biosecurity Act Amendment Bill are considering using third-party verifiers. If the Gene Technology Act does not similarly enable this, some facilities may still need an MPI inspector for any GMO licenses requiring inspection. The interaction of Biosecurity Act amendments and the Gene Technology Act will need to be monitored to ensure that users of GMOs are not unintentionally worse off.

Improving biosecurity practices	Improving the range of risk management tools available may improve protection and reduce risk of a biosecurity incursion of a GMO.
Streamlining and improving long-term management of pests and pathways	Intended to simplify, clarify, or otherwise improve provisions pertaining to pest and pathway management. Should a released GMO become a pest or unwanted organism (i.e. have a significant negative impact) the proposed amendments may provide some benefits to the management of this GMO. There are concerns that regional pest or pathway management plans could be used by regional councils as a lever to undermine the gene technology regulator. This interaction will be closely considered by MBIE and MPI as the proposals for both pieces of legislation progress.
Improving surveillance provisions	May provide efficiencies to the processes for identifying GMO incursions.

23. Consequential amendments to the Biosecurity Act and associated secondary legislation is likely to be required to ensure the Biosecurity Act and a new Gene Technology regime work together efficiently.

24. Furthermore, on 29 July Cabinet agreed to a proposal to conduct a regulatory review into the approval path for agricultural and horticultural products, focussed on issues with regulatory approvals for agricultural products that are not genetically modified. This review is complementary to the changes proposed to gene technology regulation, and, when implemented, should ensure a streamlined pathway for the approval of both genetically modified and non-genetically modified agricultural products.

25. Of relevance is also the Organic Products and Production Act 2023, with regulations currently in development that will prohibit use of GMOs in organic production systems.

What is the opportunity?

Under the current regime New Zealand is missing out on health, economic, environmental and social benefits from safe gene technologies

26. The way the HSNO regime is designed and implemented does not enable New Zealand to fully reap the health, environmental and economic benefits stemming from gene technologies. To realise this missed opportunity, regulatory intervention in the form of a new gene technologies regime that enables more gene technologies to be safely introduced in New Zealand, is necessary.

27. The Productivity Commission's 2021 Frontier Firms Inquiry found that New Zealand's approach to regulating genetic modification techniques does not reflect technological advances since it was last reviewed in 2001. [14] It recommended that "*the Government*

[14] See New Zealand firms: reaching for the frontier (treasury.govt.nz)

should undertake a full review of the regulation of genetic modification (GM), to ensure it is fit for purpose and supports domestic innovation". [15]

28. Gene technologies could also prove instrumental for strengthening the resilience of the country's Four Capitals - human, social, natural, and financial/physical – as identified in the Treasury's Living Standards Framework. This is because, beyond the productivity benefits, gene technologies offer potential solutions to pressing national challenges such as climate change and improving health outcomes. Recent advances that could support better health, environmental and economic outcomes for all New Zealanders include:
    - new therapies for hard-to-treat genetic diseases and cancers
    - agricultural feed grasses able to reduce animal emissions, and
    - better heat and drought resistant crops.

29. Particularly when it comes to New Zealanders missing out on health benefits, the HSNO assessment pathways for medicines and medical therapies leave room for improvement around the risk proportionality. Medicines that do not meet the criteria of the faster low-risk assessment pathway under the HSNO Act, but are also not high risk, have to be subject to regulatory requirements that are disproportionate to the risk they pose for human health and safety, and the environment based on current scientific knowledge.

30. Given New Zealand's small market for medicines and therapies, which inevitably means lower profits, commercial medicines developers view New Zealand's regulatory requirements as a far greater burden compared to those of overseas regulatory regimes.

31. While low-risk medicines are technically assessed in 10 days or less under the qualifying organisms/medicines pathway, this timeframe does not take into account the time and resources spent to prepare an application. Based on feedback by the EPA this pre-application period also includes the time required to provide more information before submission, the time and resources invested in this pre-application work is likely to be a factor in commercial developers of medicines being reluctant to apply for approval under the HSNO Act.

There is evidence of gene technologies that are well understood and managed, and impacts have been positive

32. Prior to 2015, only two traits had been introduced into a few GM crops – insect and herbicide resistance. This meant that the national regulatory agencies of the 23 countries that at that time had planted GM crops had the most extensive experience with these traits and their effective management.[16]

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[15] Recommendation 10.4

[16] For example, of the of the 22 GMOs approved for commercial release in Australia eight are canola crops genetically modified for herbicide tolerance, and nine are cotton crops genetically modified for herbicide tolerance or insect resistance (so nearly 80% of approvals are for these two traits across two crops)

33. In 2016, the US National Academies of Science released a comprehensive report on genetically modified crops (GM crops).[17] It concluded that GM soybean, cotton, and maize had generally favourable economic outcomes for producers who adopted those crops through decreased yield losses and use of insecticides. Environmentally, these crops were also found to result in higher insect biodiversity. The use of herbicides was found to result in herbicide-resistance, but this risk was mitigated by following resistance-management strategies. In addition, the National Academies of Science found no effects on human health resulting from the cultivation of GM crops or the consumption of GM food.

The introduction of gene technologies has been limited in New Zealand

34. Since HSNO Act came into force for new organisms in 1998 only three unconditional releases of GMOs into the environment have been approved. All three approvals were for medical uses. Furthermore, to date the EPA (or its predecessor agency the Environmental Risk Management Authority; ERMA) has:
    - approved nine GMOs that are medicines, and a further two GMOs that are veterinary medicines or are contained in veterinary medicines.
    - recently approved CAR T-cells for the use in the treatment of cancer under its rapid assessment pathway (which provides a decision within 10 working days)
    - approved twenty field tests of GM plants, animals, and microorganisms.

This can be attributed to HSNO design, implementation, and court decisions

Blanket application of the precautionary approach

35. The HSNO Act's purpose statement signals a precautionary approach to gene technologies. It does not include provisions facilitating, enabling, or otherwise positively supporting their development and use. Instead, it focuses on protecting "…the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms."

36. That said, the precautionary approach is appropriate where there are uncertainties about risks and the risks are likely irreversible. However, to allow New Zealand to safely benefit from the advancements of gene technology, a more precise and efficient application the precautionary approach is warranted. This approach will be based on updated regulatory practices as knowledge and understanding of the risks and benefits of gene technology have accumulated.

Many broad factors to support HSNO purpose

37. The HSNO Act contains four additional provisions that support its purpose. Some of these matters are unrealistic for a regulator to assess robustly, driving unnecessary cost and complexity for applicants. Requiring at the decision-maker to take into account economic and related benefits and costs of using a new organism (a benefits assessment) increases the evidential burden on applicants and creates a practical problem, which is that benefits can be difficult to assess and challenging to compare to potential environmental or human health risks.

[17] Available at Genetically Engineered Crops: Experiences and Prospects | The National Academies Press

38. The research sector has indicated that applications often entail lengthy 'pre-engagement' with specific stakeholders (sometimes several years long) to enable the applicant to provide the decision-maker with necessary information. This pre-engagement is expected by the EPA, but it is not considered to be part of the EPAs statutory timelines and it requires a significant investment of applicants' time.

Process-based regulatory approach that may result in inconsistent regulation

39. The HSNO Act uses a process-based model to regulate products and organisms. Process based regulatory systems regulate the process or technique used to make or construct the product or organism, whereas product based regulatory systems regulate the outcome or product produced. A hybrid regulates the activity of the GMO (the product) and specifies the gene technologies and organisms that are regulated or exempt (the process).

40. The processes to create a GMO sit on a spectrum, from processes equivalent to natural mutations to creating synthetic organisms. A process-based, rather than outcome-based or a hybrid model, means that the HSNO regime determines risk based on the processes used to introduce or remove genetic traits from, rather than the resulting traits of the organism/product and their impacts.

41. The process-based regulatory approach carries an underlying assumption that products made using gene technologies are fundamentally different or more risky than similar products made using other conventional methods (such as chemical and irradiation mutagenesis).

42. Technologies that alter the genetic makeup of an organism that are not regulated under the HSNO Act are those that were in use prior to July 1998, including chemical and irradiation mutagenesis. More recent processes, such as CRISPR are regulated, even when they are used to produce the same outcomes as the less precise, unregulated techniques.

43. Since 2003, large national and international organisations have assessed the evidence on the environmental and health safety of GMOs, concluding that, to date, plants and foods produced through gene technologies are no riskier than those produced through conventional means.

Outdated definition of genetic modification

44. The HSNO Act defines new organisms, and this definition includes GMOs. Further, the HSNO Act defines a GMO as "…any organism in which any of the genes or other genetic material:
    - have been modified by in vitro techniques; or
    - are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques."

45. Even though CRISPR-Cas (developed after July 1998) is not an exempt process, the outcomes it produces are not adequately captured by the HSNO Act's definition of a GMO because CRISPR-Cas can be applied in-vivo (within the body of an organism).

46. Therefore, definitions for gene technologies should be updated to reflect a nuanced, up to date definition, that can flexibly accommodate new technologies.

Court decisions impacted EPA's ability to create a more permissive regulatory regime for advancements in gene technology

47. Historically, the EPA has sought to take a more permissive approach to regulation of GMOs, but it has lost a number of court cases when these decisions have been reviewed. It is a normal consequence of an increased perception of litigation risk for regulators to act more conservatively in decision making.

48. In 2013, the EPA sought to issue a statutory determination that deemed that products of newly developed gene editing technologies were exempt under regulations due to the products equivalence to conventional techniques listed as non-regulated technologies under the HSNO Act. However, the High Court judgement in Sustainability Council of New Zealand Trust v The Environmental Protection Authority (the Scion case) ruled that the non-regulated technology list is a closed list, and that the EPA could not expand the exemption list to include techniques similar to non-regulated technologies.

49. As a result, products of these newly developed technologies continue to be subject to full regulatory oversight as GMOs.

Regulation is still required because some GMOs can pose risks to the health and safety of people and the environment

50. Despite all the benefits that gene technologies and GMOs entail, if remained unchecked they can also pose a risk to the health and safety of people and for the environment. The risks posed by gene technologies differ and depend on the modification made, the organism subject to modification, and the intended use of the resulting product.

51. Organisms modified in a way that is not possible with conventional breeding pose may risks to ecosystems if they enter the environment without proper assessment. These risks may include, but are not limited to:
    - the modified organism outcompeting their natural counterparts, creating risk to biodiversity
    - greater weediness or resilience traits which limit the ability to control the modified organism
    - modified genes contaminating the wild gene-pool or nearby plantations, with uncertain effects on ecosystem health.

52. Similarly, some uses of gene technology pose potential risks to the health and safety of people, including:
    - uncertain effects of transgenes in food on human health
    - modified proteins having greater toxicity or allergenicity
    - unintentional gene flow creating more resilient pathogens or pests.

53. Striking the right balance between enabling the introduction of more gene technologies and products and doing so in a safe manner will allow for the benefits to be realised, while protecting New Zealand from the risks.

We have looked at both international comparators and New Zealand guidance to come up with options for a more contemporary regulatory system

54. The Government Expectations for Good Regulatory Practice makes it clear that regulatory agencies need to ensure that regulatory systems are an asset for New Zealanders, not a liability. Good regulatory systems balance protecting the safety, rights, and interests of New Zealanders while minimising the costs imposed and freedoms limited in the process.

55. As outlined, as the definitions and the core elements of the regulatory approach under the HSNO Act have not been updated in over 25 years, the regime is behind recent scientific developments. While the HSNO Act does successfully manage the risks set out in its purpose statement, as an unintended consequence it inhibits research, innovation, and commercialisation of gene technologies. Consequently, the way the HSNO Act is designed and implemented does not minimise the costs imposed, or the freedoms limited by its rules, resulting in a regulatory regime that is not an asset for New Zealand.

56. As also noted, international regulatory approaches to gene technologies have also evolved over time, with jurisdictions including Australia, England, the United States, Japan, Argentina, and the European Union either changing regulations considering new scientific understanding and advancing or proposing to do so.

57. In developing proposals, MBIE's Technical Advisory Group provided feedback on member's experiences of the current legislation and agreed that the current regulatory settings for gene technology create barriers and delays, with uncertainty about the status of organisms for medical use, challenges with pursuing biomanufacturing to pilot scale, and lengthy and costly consultation for field trials and environmental release.

58. Based on the above, effectively addressing the issues requires a comprehensive overhaul of the regulatory framework for gene technologies. New Zealand would benefit from a new regime that:
    - enables greater use of gene technologies
    - accommodates technological advances and changes in scientific practice
    - takes into account new evidence on the risks associated with gene technologies
    - is risk-proportionate, and
    - meets good regulatory practice guidelines.

Which industries have an interest in the proposed regulatory reform

59. The variety of gene technology applications means that a wide range of industries could potentially be impacted, and therefore have an interest in this regulatory reform. For the analysis presented, industry is considered to consist of users of gene technologies, including for product development, and consumers use of products of gene technology, across multiple sectors. The industries most likely to be impacted are:
    - Food and Fibre (primary sector)
    - Biotechnology
    - Health Technology

Food and Fibre

60. New Zealand's food and fibre sector consists of most primary industries with the exclusion of mining. This includes the agriculture, forestry and fishing industries, and

subsidiary industries such as horticulture and animal farming (e.g. dairy, wool, and meat). Gene technologies are most likely to be used in the horticulture, forestry and

	Actual				Forecast				
Sector	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**
Dairy	20,102	19,055	21,998	26,008	24,160	25,750	27,110	28,640	30,360
Meat and wool	10,617	10,373	12,310	12,114	11,450	11,770	12,200	12,560	12,950
Forestry	5,452	6,499	6,578	6,353	5,880	6,170	6,390	6,530	6,620
Horticulture	6,541	6,579	6,815	7,066	7,110	8,020	8,630	9,180	9,700
Seafood	1,857	1,789	1,919	2,097	2,200	2,490	2,590	2,710	2,750
Arable	289	261	252	272	310	310	310	310	320
Processed food and other products*	2,988	3,087	3,228	3,491	3,450	3,550	3,650	3,760	3,860
Total export revenue	47,846	47,642	53,100	57,402	54,560	58,050	60,890	63,690	66,560
Year-on-year % change	3%	0%	11%	8%	-5%	6%	5%	5%	5%

* Includes live animals, honey, and processed food.
Totals may not add up due to rounding.
Percentages are rounded to the nearest whole percent.
Source: Stats NZ and MPI.

dairy (via feed) sectors due to increased production requirements on animal farming and consumer preferences. The sector had a total export revenue of $57.4 billion in 2023, with expected annual growth of approximately 5% year on year. This is broken down as follows[18]:

61. The sector does not currently benefit from any approved releases of products of gene technology. New Zealand does, however, import processed food produced internationally that is derived from GMOs if they are approved by Food Safety Australia New Zealand (FSANZ) and meet other non-GMO biosecurity requirements. There are currently nine GMO crops approved by FSANZ for use as an ingredient in food sold in New Zealand, including varieties of soy, wheat, potatoes, corn, and rice.

Biotechnology

62. Biotechnology is a multidisciplinary sector that integrates natural and engineering sciences to develop new products and services. Biotechnology is a rapidly growing sector internationally with most market estimates suggesting a total global market size between US$0.7-1 trillion and predicted annual growth rates of 10-15%. Furthermore, biotechnology is widely seen as one of a small number of critical strategic technologies that will shape the future.

63. In New Zealand, the ecosystem is made up of biotechnology companies, universities, Crown Research Institutes (CRIs), independent research institutes, accelerators, support services, and investors with growing expertise in biotechnology. New Zealand has a few firms with a significant global biotechnology presence which continue to have

[18] Situation and Outlook for Primary Industries June 2024 - Ministry for Primary Industries

a strong impact on the New Zealand ecosystem (such as LanzaTech), and has established strengths in plant genomics (such as Zespri and Fonterra).

64. In 2020, a BioTechNZ report identified 211 biotechnology companies in New Zealand (up from 108 in 2009) with a combined revenue of NZD$2.7 billion. Most are at an early stage of commercialisation, with 67 percent having fewer than 10 employees. 37 percent of biotech companies are in Auckland, 18 percent in Wellington and the remaining 45 percent located in regional New Zealand.

65. There is a strong correlation between biotechnology company locations, research institutes and universities. Biotechnology companies are by default hi-tech and knowledge intense. They are made up of highly skilled individuals who hold higher degrees and qualifications leading to high salaries. Higher education is one of the key drivers of growth. Also, New Zealand biotechnology companies predominantly conduct their research and development (R&D) in New Zealand, with only 16 percent engaging in R&D outside of New Zealand.

Health technology

66. The health technology sector focuses on the development of new devices, medicines, pharmaceuticals, and procedures to improve health outcomes. It generated an estimated $2.9b in revenue in the 21/22 financial year[19].

67. New Zealanders currently benefit from two products of gene technology in health: Car-T cell therapy to treat patients with relapsed or refractory multiple myeloma, and a modified live attenuated vaccine that protects against Japanese encephalitis. Four genetically modified health products for clinical trials were also recently approved for release.

68. Within the health technology realm, gene technologies are most likely to be used by research organisations and start-ups in the development of new medicines, such as the Malaghan Institute ($39m in 2023[20]) which is using the CAR T-cell gene therapy in its cancer research. Fisher & Paykel Healthcare, the largest organisation in the sector, is unlikely to be significantly affected due to its focus on medical devices (e.g. respirators).

Estimated benefits of a new gene technology regime to the health sector

69. To provide an estimate on the potential benefits New Zealand is missing out on under the status quo we have selected to project to the future the potential benefits for use in the New Zealand health sector.

70. Our assumption for these estimates is that under the status quo the number of applications approved and deployed would be half as much across a ten-year period compared to under the proposed new gene technology legislation. We consider this a reasonable assumption based on the rates of medical applications approved in Australia . In particular, we have assumed that under the proposed new legislation, a new health sector application would be approved and deployed every two years.

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[19] HealthTech | Callaghan Innovation

[20] Malaghan Institute of Medical Research Annual Report 2023 (malaghan.org.nz)

71. Cell and gene therapies are advanced medical treatments that modify human cells or genes to treat or prevent diseases. Cell therapy generally involves introducing modified cells into a patient's body to replace or repair damaged tissues or to threat conditions such as cancer, while gene therapy aims to correct or replace faulty genes responsible for genetic disorders. These approaches offer potential treatments for a wide range of conditions, including certain cancers, genetic diseases, and degenerative disorders.

72. Using research conducted by a range of organisations and researchers[21] including Snider et al.[22], we can estimate the potential health benefits from the approval and use of gene technologies that might result from reduced regulatory requirements under the proposed regulatory regime. We have estimated these benefits using Quality Adjusted Life Years (QALYs), a common metric for estimated health benefits from medicines and therapies. For each QALY gained, the Treasury puts the monetised value at $43,313.[23]

73. Research has estimated that the amount of QALYs gained from the use of a cell therapy (like CAR T-cell therapy) or a gene therapy ranges from 3.35 to 9.28. The medical conditions that these estimates relate to include Diffuse large B cell lymphoma, Paediatric Acute lymphoblastic leukaemia, B cell Acute lymphoblastic leukaemia, spinal muscular atrophy, and inherited retinal disease.

74. Using the range of estimated QALYs gained, the Treasury's monetised value for a QALY gained, and assuming a low patient population of 50 per annum and a high patient population of 100 per annum, the monetised benefit of a new cell or gene therapy would range between $7.25 million and $40.2 million per annum.[24] Using our assumption that the proposed new gene technology legislation would result in twice as many cell or gene therapies approved per decade compared to the status quo, and in particular a new cell or gene therapy approved and deployed every two years compared to four, the estimated increase in value to New Zealand of between $14.5 to $80.4 million every two years compared to the status quo.

Potential economic benefits of a new gene technology regime to the primary sector

75. The recent Aotearoa Circle's report on Modern Genetic Technology [25], evaluates different case study applications of genetic technology in various production systems including three specific plant case studies. Each case study is currently being explored

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[21] These include: Qi et al.'s *Cost-Effectiveness Analysis of Tisagenlecleucel for the Treatment of Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma in the United States*, the ICER's 2018 report *Chimeric Antigen Receptor T-Cell Therapy for BCell Cancers: Effectiveness and Value*, and Chambers et al.'s *Cell and gene therapies are associated with substantially larger quality-adjusted life year gains than conventional drugs and biologics*.

[22] Snider, J. T., Brauer, M., Kee, R., Batt, K., Karaca-Mandic, P., Zhang, J., & Goldman, D. P. (2019). The potential impact of CAR T-cell treatment delays on society. *Am J Manag Care*, 25(8), 379-386.

[23] The Treasury. CBAx Tool. 2024.

[24] Range of QALY's gained: 3.35 to 9.28, Treasury's value for a QALY gained: $43,313, low patient population assumption: 50, high patient population assumption: 100.

[25] Aotearoa Circle. *Modern Genetic Technology: Applications in Aotearoa Food and Fibre Production*. 2024.

by New Zealand scientists, in containment or overseas, to deliver environmental benefits to the food and fibre sector.

76. High Condensed Tannin (Hi-CT) White Clover is a genetically modified commercial White Clover which produces condensed tannins in its leaves. Implementing Hi-CT White Clover within New Zealand pasture-based farming systems, in replacement of standard White Clover, has the potential to produce a range of benefits on a dairy farm. These include increasing production, reducing methane and nitrous oxide emissions, reducing nitrogen leaching and reducing the incidence of bloating in cows.[26]

77. Aotearoa Circle's report estimated that at peak adoption Grasslanz's Hi-CT white clover would result in:
    - A reduction of greenhouse gas (GHG) emissions equivalent to between 290 kilotonnes of CO2 and 790 kilotonnes of CO2 per annum by 2050,
    - An increase in milk solids of 50 million kg per annum,
    - A decrease in the number of animal mortalities from bloat of between 4,000 to 7,500 cows per annum.

78. That said, while an enabling legislative and regulatory regime is the first step for these benefits to be realised, it is not the sole factor. Realising these benefits also depends on the outcomes of the science as well as the research and development system, and the consequent ability of industry to commercialise their innovations. Broader market attributes such as the availability of capital, the depth of our capital markets, and the acceptance of exports of GE products by key trading partners will also impact industry's ability to seize the opportunities afforded by an enabling regime.

Stakeholders in favour of changes to regulatory settings

79. Between 2022 and 2023 MfE conducted a review of the regulations and controls for research conducted in laboratory settings and the assessment and approval for biomedical therapies under the HSNO Act. To inform policy proposals developed as part of this review, in 2022 MfE undertook targeted engagement with researchers likely to be conducting research using GMOs. Twenty-four responses were received representing the views of over 32 individual researchers or laboratory managers from 11 universities, research institutes and biotechnology companies.[27]

80. The main regulatory issues highlighted were that regulations were unnecessarily stringent, not risk-proportionate, and have a high compliance burden. The responses included broad support for greater risk tiering for laboratory research similar that in place under Australia's Gene Technology Act and Regulations.

81. MfE undertook public consultation in In August 2023 on policy proposals developed as part of its review, receiving over 80 responses. Most submitters supported the proposals and the aim of reducing the stringent requirements for laboratory and

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[26] However, Hi-CT white clover has low containability and this risk needs to be appropriately managed by the regulator.

[27] Ministry for the Environment. *Interim Regulatory Impact Statement: Improving our GMO regulations for laboratory and biomedical research*. 2023. Page 10.

biomedical research. Submitters supported reduced administrative and compliance burdens, greater risk tiering, and a more permissive regime overall. While this regulatory review was narrow in scope, the views expressed in the public consultation are applicable to this broader, current regulatory proposal.

82. MBIE has held targeted engagements with sector experts and key stakeholders to seek feedback on their experiences of the current legislation (for more detail see Annex B), with feedback that:
    - Primary industry stakeholders expressed support for reducing regulatory requirements for GMOs. The sector recognises the potential benefits of the technology to contribute to future challenges of climate change and crops with increased environmental as well as commercial value, with examples including the use of new pasture grasses (e.g. HME Ryegrass, High CT White Clover) sterile Douglas fir, and improved horticulture crops.
    - Others such as the aquaculture and seafood industries have indicated they may be interested in using GMO in the future but are concerned that they do not yet have the social licence to do so.

83. When questioned about the challenges that the New Zealand biotech sector faces two problems were consistently raised by stakeholders on our targeted engagement: a lack of infrastructure and the strict regulatory environment. Under the current regulatory settings, New Zealand is missing out on the potential gains from innovation by our New Zealand biotech sector, through research either not being undertaken or being forced offshore for further development and commercialisation.

Stakeholders not in favour of changes to regulatory settings

84. MfE's 2023 public consultation found that several organisations, local government bodies, and individuals are supportive of New Zealand's current strict GMO legislation. These groups include GE Free New Zealand, the Sustainability Council, and the McGuinness Institute. These organisations are opposed to regulatory change that would more lightly regulate GMOs because, considering that GMOs must be strictly regulated to sufficiently reduce risks to human health and New Zealand's environment and economy.

85. Views that arose from MBIE's targeted engagement sessions were:
    - Some producer groups were concerned about the impacts of a more enabling system on New Zealand's brand and market access, and the coexistence of GMO and non-GMO supply chains.
    - Organic producers have signalled that losing the GM-free status could negatively impact their businesses and have supported regional and district by-laws that restricting GMO release. They have indicated that more work will need to be done to set up appropriate coexistence frameworks.

86. Some of New Zealand's trading partners will not allow import of products that include GMOs. MPI provides assurance as to GM-freedom for goods where that assurance is required by our export markets, and currently provides approximately 750 assurances annually for about 30 business who export seed and horticulture product. The regulatory reform will provide a pathway for GMOs to be released into the environment more easily, meaning New Zealand's GMO-free status will eventually change. When this happens, New Zealand will no longer be able to rely on GMO freedom to give assurance that traded goods are GMO free when they need to be. National economy

National economy

87. Proponents of New Zealand's current settings have also argued that New Zealand exporters benefit from the country's current 'GM free' status. Consumer research has not been done to determine the value of New Zealand's GM freedom on our international brand, and there are mixed views in different sector groups.

What objectives are sought in relation to the policy problem?

88. The objectives for the proposed regulatory reform have been set by the Gene Technology Ministerial Group, consisting of the Science, Innovation and Technology, Health, Agriculture and Forestry, Conservation, Māori Crown Relations, Māori Development, Environment, and Biosecurity and Food Safety Ministers. Ministers have set that the objectives are to create a regulatory framework for gene technology that is:
    - **Enabling** – the regime should enable the greater use of safe gene technologies to deliver better outcomes for New Zealand.
    - **Risk-proportionate** – restrictions on gene technology and GMOs should be proportionate to the risks that each application poses.
    - **Efficient** – applications should be efficiently assessed, and the process should be easy for applicants to navigate.
    - **Future focused** – the legislation should accommodate future technological developments without needing frequent amendments.
    - **Internationally aligned** – the regime should be in step with our major partners to facilitate trade and improve access to new technologies.
    - **Rights and Interests under the Treaty of Waitangi** – the regime should appropriately consider Māori rights and interests under the Treaty of Waitangi.

Section 2: Deciding upon an option to address the policy problem

What criteria will be used to compare options to the status quo?

89. All proposed options, except the one pertaining to the form and location of the regulator responsible for the upcoming gene technologies regime, are assessed against the following criteria:

Enabling	Will the option enable increased use of safe gene technologies to deliver better outcomes for New Zealanders?
Risk-Proportionate	Will the option proportionately manage the risks posed by the particular gene technology or GMO to the health and safety of people and the environment?
Efficient	Will the option provide: • cost-effective, and coherent application, assessment, and approval processes? • certainty and predictability of obligations and rights?
Future-focused	Will the option allow for adaptation to new technological developments and applications, knowledge, understanding, and policy changes?
Internationally aligned	Does the option bring the regime into greater alignment with New Zealand's major trading partners?
Rights and interests under the Treaty of Waitangi	Will the option allow for appropriate protection of Māori rights and interests under the Te Tiriti o Waitangi/The Treaty of Waitangi?

90. The chosen criteria are linked closely to the objectives of the proposed legislative changes. We apply these criteria using the following method.

++	Significantly better than the status quo
+	Better than the status quo
0	No better or worse than the status quo
-	Worse than the status quo
- -	Significantly worse than the status quo

91. Ministers have agreed that the new regime is expected to deliver the six distinct objectives as described above. Based on the identified problems as depicted in the intervention logic map in the next section:
    - The legislation over-regulates low-risk gene technologies
    - Application processes are slow, costly, and delay research and development
    - The legislation unduly restricts environmental releases of regulated organisms, limiting:
        - field testing of internationally developed organisms in New Zealand's unique conditions
        - field testing of domestically developed organisms

- The legislation is rigid: definitions do not encompass modern gene technologies, and it is not readily adaptable to emerging technologies and greater understanding of risks and their management
- Decision-making factors for approvals are overly complex.

92. Officials have grouped the criteria into two sets and have assigned higher importance to the following objectives:
    - Enabling – the regime should enable the greater use of safe gene technologies to deliver better outcomes for New Zealand.
    - Risk-proportionate – restrictions on gene technology and GMOs should be proportionate to the risks that each application poses.
    - Efficient – applications should be efficiently assessed, and the process should be easy for applicants to navigate.

93. Therefore, an option that scored high in promoting an enabling, efficient and risk proportionate regime will be preferred even if the comparable option/s score equally or higher but this score results from rating highly against criteria that are not part of the prioritised group.

94. The options pertaining to the location of the regulator have been assessed against a separate set of criteria as set under relevant Public Service Commission (PSC) guidance. In particular:
    - Strategic fit
    - Compatibility of functions
    - Compatibility of powers
    - Special characteristics
    - People
    - Culture
    - Reputation, relationships, and responsiveness
    - Processes and technology
    - Physical assets

What scope will options be considered within?

95. The scope of the options considered was limited to legislative options and has been informed by the Gene Technology Ministerial Group's decisions. Officials were directed:
    - to develop an alternative option to the HSNO Act to regulate the use of gene technologies in New Zealand. that the reform process will encompass a wide range of gene techniques, and that it will also include regulation of gene therapies used in health within its scope
    - that the reform process would not consider the regulation of hazardous substances
    - to focus the scope solely on gene technologies because other biotechnologies that do not include genetic modification are generally lower risk and do not require regulation or are adequately regulated by other legislation and regulators.
    - to align the definitions of gene technologies and GMOs with the Australian Gene Technology Act 2000 with some minor changes to ensure future technological advancements are captured and definitions align with existing New Zealand legislation (such as the Biosecurity Act 1993), i.e.:
        - GMOs will include organisms modified or constructed by gene technology, and gene technology will include techniques where genes or genetic material are constructed or modified.

    - Human beings will be specifically excluded from the GMO definition to remove the possibility of humans being unnecessarily subject to regulatory oversight. However, human cells, gametes and embryos will be included.
- to maintain the regulatory status of specific techniques and organisms clarified through statutory determinations by the current regulator, for example replication defective viral vectors and non-replicating RNA and DNA, which are currently regulated in Australia.

96. Furthermore, our options were developed within the bounds of the Cartagena Protocol on Biosafety (the Cartagena Protocol) to the Convention on Biological Diversity, to which New Zealand is a party. Options were also bound by Article 8(g) of the Convention (In-situ Conservation) which prompts members, as far as possible and as appropriate to establish or maintain means to regulate, manage, or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

97. Officials considered options within that scope and given time constraints for policy development, we focused particularly on whether adapting the Australian regulatory regime for gene technology to New Zealand's context would achieve the Government's objectives. In considering the approach to regulation (whether to regulate the genetic modification process or the product), officials also assessed the regimes of other trading partners, including the EU, England, the United States, Canada, Argentina, and Australia. For more details on these regimes that have shaped our thinking when scoping our options see Annex C.

98. As previously noted, a longer process would have allowed an increased and range of views and options to be assessed in a technically and legislatively complex area. The short timeframe to undertake analysis did not provide for a complete identification of problems, causes, and solutions, or allow a full analysis of potential impacts of options considered (including any potential unintended consequences of these).

What options are being considered?

99. We have included an intervention logic map below. This map is designed to articulate the relationship between the objectives of the reform, the potential interventions (within the constraints to the scope of the analysis described above), and the expected outcomes of the interventions.

Current State: New Zealand is not realising the economic, environmental, and health benefits from the development and application of gene technologies
Shift: Gene tech regulatory environment is more enabling while remaining risk-proportionate and protecting human health and safety, and the environment

PROBLEMS

The legislation over-regulates low-risk gene technologies

Application processes are slow, costly, and delay research and development

The legislation unduly restricts environmental releases of regulated organisms, limiting:
- field testing of internationally developed organisms in New Zealand's unique conditions
- field testing of domestically developed organisms

The legislation is rigid: definitions do not encompass modern gene technologies, and it is not readily adaptable to emerging technologies and greater understanding of risks and their management

Decision-making factors for approvals are overly complex

INTERVENTIONS

Exempt use of gene-editing techniques without unique risk from regulation

Categorise gene technologies / regulated organisms into risk tiers, differentiated by contained, medical and environment uses, to enable setting regulatory requirements proportionate to risk

Remove application requirement for low-risk technologies / GMOs

Enable the regulator to update risk tiers as new evidence emerges

Require regulator take into account advice from Māori Advisory Committee about effects of proposals on kaitiaki relationships

Provide for streamlined processes for NZ regulators across different systems (e.g. GeneTech Regulator and MedSafe)

Focus decision-making on whether any risks to human health and the environment can be managed

Use comparable international regulators' assessments and approvals to speed up decision-making

Speed up and inform decision-making by using precedents from previous decisions

Increase funding to grow regulator capacity and capability

Update legislative definitions to clarify regulated organisms and activities

OUTCOMES

Decreased regulatory burden for applicants and for users of low-risk technologies / organisms

Regulator is informed and able to make decisions that provide for kaitiaki relationships to be protected

Faster decision-making on applications

Most regulatory effort is targeted to activities that are higher risk to human health or the environment and to determine and if and how risks can be managed

The regulatory system accommodates greater understanding of risks and novel or innovative gene technologies as they emerge

Regulator provides for consistent and predictable decision-making

IMPACTS

SHORT TERM

More R&D using gene technologies, including field testing

Increased and faster availability in NZ of gene technologies developed overseas

LONG TERM

Biotech sector will grow (increased activity, more start-ups, increased commercialisation of applications using gene technology) → Increased contribution to economic activity from biotechnology sector

More jobs in gene technology field and reduced emigration of skilled workers → Strengthened gene technology research skills and capacity

NZ researchers identify opportunities to research domestic application of gene technologies to address significant challenges (biodiversity, climate change) → Reduced loss of biodiversity through use of gene technologies to address issues facing species (disease, etc) or to improve predator control

NZ researchers identify opportunities to research domestic application of gene technologies to address significant challenges (biodiversity, climate change) → Improved climate change mitigation and adaptation, e.g. from genetically modified products that inhibit GHG or are more resistant to heat or drought

Increased primary sector use of exempted gene-editing techniques and regulated technologies and organisms → Improved climate change mitigation and adaptation, e.g. from genetically modified products that inhibit GHG or are more resistant to heat or drought

Increased primary sector use of exempted gene-editing techniques and regulated technologies and organisms → Productivity gains in some primary sector supply chains

Faster access to, and greater numbers of, medical gene technologies → Improved health outcomes for New Zealand's population

Accelerated R&D in medical therapies focused on benefits to NZ population → Improved health outcomes for New Zealand's population

100. We have considered options for each of the following key aspects of a new gene technology regulatory system. These options include the interventions listed in the intervention logic map, which are incorporated into the following options analyses:
    - Meeting Treaty of Waitangi obligations.
    - Regulatory approach (i.e. whether to regulate the processes used for genetic modification, or the product or outcome of the genetic modification, or a hybrid of the two).
    - Authorisations framework (i.e. how appropriate levels of authorisation will be defined for activities of differing risk levels).
    - Decision making factors (i.e. what matters are relevant for the regulation of gene technologies and GMOs).
    - Assessments, decision-making and approvals (i.e. the way the regulator makes assessments, seeks expert advice, including around Māori rights and interests, and public input, and makes decisions).
    - Decision-making authority (i.e. what level of independence or ministerial direction the regulator has).
    - Location of the regulator (i.e. where the regulator is hosted).

A. Meeting Treaty of Waitangi obligations

101. This section differs from Sections B – G in that it covers:
    - the status quo
    - constraints on the analysis
    - Māori views on the proposed reform (including concerns with the current regime and opportunities for Māori with reform)
    - Wai262 and the Waitangi Tribunal's analysis of the HSNO Act regime (regarding gene technology)
    - a high-level analysis of the option against objective six (rights and interests under the Treaty of Waitangi)
    - TPK's perspective on this option
    - the option's responsiveness to Wai262.

102. We have not included the analysis of this option against the other objectives (one to five) of the reform. Instead, the analysis against these objectives, and the multicriteria analysis, are covered in Section E – Assessments, decision-making and approvals. This is because we consider that the proposal to meet objective six is best incorporated into the decision-making process.

Māori have diverse interests regarding gene technologies.

103. Views range from opportunities for improving healthcare, conservation, and economic aspirations to concerns about the potential negative impact of gene technologies on the environment, taonga species and cultural practices.

104. Many Māori cultural practices are inextricably linked to the New Zealand environment and its flora and fauna. Traditional Māori concepts of kinship (whanaungatanga) that underpin these practices extend into the natural world, to both specific species (often referred to as taonga species) and places. These whanaungatanga relationships also create an obligation of kaitiakitanga, often translated as guardianship or stewardship. Whakapapa (genealogy) plays a critical role in obligations of kaitiakitanga, and therefore there is the potential for these relationships to be disrupted by the use and

impact of gene technologies. This relationship with taonga species has been acknowledged by the Crown across multiple Treaty settlements.

Status Quo

105. The HSNO Act provides for the protection of Māori rights and interests by requiring persons exercising their functions, powers, and duties to take into account the principles of the Treaty of Waitangi and the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wahi tapu, valued flora and fauna, and other taonga. These interests form one of five matters of consideration under HSNO and may or may not be solely determinative.

106. NKTT, the EPA's Māori Advisory Committee, provides decision-makers with a broad overview of Māori interests and perspectives and operates alongside He Whetū Mārama is the EPA's framework for incorporating Māori perspectives and mātauranga. Māori input on applications is sought on applications in three stages:
    - Expectations on applicants to conduct pre-application engagement with potentially affected parties, including Māori and industry.
    - Assessment by an internal Māori unit and advice from Ngā Kaihautu.
    - Public consultation on the application (which may involve submissions or hearings).

107. MBIE's Māori Focus Group and stakeholder interviews were generally supportive of the status quo for protecting of Māori interests. Reasons included the expectations on applicants to engage with Māori, the EPA's organisational culture for engaging with Māori, and an increased focus on Māori interests in decision making compared to the EPA's predecessor. This feedback was largely based on wider new organisms and hazardous substances assessments (which use similar processes), as the EPA has not received an application for GMO field trials or agricultural releases since 2011.

108. However, some Māori stakeholders reported to MBIE that capability constraints are a key issue with HSNO's engagement requirements, as few iwi other than Ngāi Tahu and Ngāti Porou have the time or experience to engage with the process. This has sometimes led to Ngai Tahu's HSNO Committee being the de facto representative of Māori interests during consultation. Some also expressed preference for moving to a partnership model with joint decision making between the EPA and Māori.

109. There have also been some criticisms from industry and researcher stakeholders about the EPA's requirements for pre-application engagement. There was a perception that support from iwi and industry is need for an application to be successful, which increased the time spent on this stage (in one case over two years). In addition, applicants without existing connections with iwi (such as start-ups) reported difficulties in identifying who should be consulted.

Constraints on analysis

110. As noted in Section 1 above, the compressed timeframes have constrained analysis because MBIE has not been able to test proposals beyond some key stakeholders. Public consultation would have enabled increased or more comprehensive understanding and analysis of the diverse Māori interests, opportunities, and concerns on gene technology.

111. We have partially mitigated this through conducting targeted engagement with Māori on the development of this regime. This took three forms:
    - A Māori Focus Group was established to provide advice and guidance to officials on the development of the reforms, including on:
        - matters to be considered to safeguard the interests of Māori,
        - processes a regulator should implement to ensure Māori interests are identified, understood, and considered in the decision-making process, and
        - identifying and understanding Māori rights and interests for the development of advice.
    - Interviews with individual leaders in iwi across the country (noting officials expect to meet the full Iwi Chairs Science Committee in August).
    - A hui with Māori from the research and innovation sectors.

112. There were two constraints with this process:
    - Stakeholders made clear they were providing feedback in a personal capacity and did not represent their iwis' position.
    - GMO regulation is highly technical, and several stakeholders noted they would need more time to provide feedback on some details.

Māori concerns with reforming gene technology legislation

113. GM reform is likely to have many and varied impacts on Māori rights and interests. While MBIE's engagements with Māori stakeholders were not representative of all Māori, we heard four major concerns:
    - Environmental impacts: There were unanimous concerns about the potential environmental impacts of GMOs, including flow-on effects to non-modified species. Multiple stakeholders commented on the risk of unintended consequences following an approval, particularly to taonga species, and the need for post-release monitoring to ensure risk-management conditions were effective.
    - Impact on cultural values and practices: Stakeholders raised concerns that GMOs could adversely affect the relationship between kaitiaki and their taonga species if the regime did not sufficiently provide for these interests in decision making. There were concerns this could limit their ability to use taonga species in cultural practices (e.g. through cross-contamination or adverse environmental affects). In addition, there were differing cultural perspectives on genetic modification. Some stakeholders opposed genetic modification in most or all cases due to concerns it would adversely affect an organism's mauri or whakapapa. Others reported greater comfort with such techniques from mātauranga (e.g. stories of Maui shapeshifting were seen by some as equivalent to GM), or for certain applications (such as healthcare or non-commercial uses).
    - Bioprospecting: This refers to the identification and commercialisation of biological resources, including genetic material, through activities such as genome mapping. While there are few restrictions on bioprospecting specifically, whether through gene technologies or conventional techniques, multiple stakeholders were concerned that GM reform would increase non-Māori's ability to profit from taonga and native species without benefit sharing with Māori. Stakeholders generally accepted MBIE's view that bioprospecting should be out of scope as the Government's response must be broader than GM (and is currently led by a separate work programme within TPK) but noted this work should be completed simultaneously to gene technology reform. Several recommended that the Government join the Nagoya Protocol which covers the issue.
    - Partnership and representation: Stakeholders expressed several concerns with the proposed regime's reliance on a Māori advisory group instead of a

partnership model based on Treaty principles for decision making. They noted that advisory groups do not represent all Māori and do not satisfy the need to consult with Māori and iwi. There were also concerns that an advisory group alone does not provide for partnership between Māori and the Crown, and that the group's standing would be reduced if the regulator repeatedly disregards its advice.

114. Due to the noted constraints, there may be other areas of significant concern for Māori not captured in this regulatory impact statement. We also note that, overall, researcher stakeholders were generally more conservative than other stakeholders, with a stronger focus on preventing modification of taonga species and on impacts to whakapapa (e.g. genealogy).

Opportunities identified by Māori

115. Non-researcher stakeholders (such as iwi and Māori industries) were generally more opportunity focused with a greater interest in the potential applications offered by gene technologies. In particular:
    - Healthcare: There was strong interest in GM treatments, such as Car T-Cell therapies. For example, we heard of a specific example where a hapū with a high prevalence of a type of cancer was hoping for the development of a CAR T-cell type treatment option.
    - Conservation: Applying GM to address introduced species and pathogens, such as treating Myrtle Rust and inducing possum infertility. While these conservation examples generated strong responses it was acceptable to many if a last resort option. However, there were some concerns about the risk of adverse effects if modified animals (e.g. through gene drives) escaped to their native countries.
    - Economic Opportunities for Māori: in addition to general improvements to primary sector productions, potential benefits included:
        - Using gene editing to increase the speed of Manuka breeding programmes to increase the unique manuka factor (UMF) of plants. Work had been undertaken to identify the gene that expresses UMF, and a conventional breeding programme was underway, but gene editing could be able to speed this process (noting this was proposed to use techniques equivalent to conventional breeding, which is proposed to be exempt under the regime).
        - Examples of iwi across the country working with scientists on genome mapping as a way to identify benefits from potential environmentally-derived products, or exploring doing so – the results of which could be sped up through GM.

116. In considering benefits, emphasis was given that under a potential new regime Māori should be able to access genetic modification and benefit from it. There was a view conveyed that colonialism has caused significant harm both culturally and economically, and that access to new technologies (including genetic modification) could help contribute to easing the impact of this legacy if Māori have sufficient control and access to benefits.

117. Officials are aware of more recent research suggesting that Māori attitudes to gene technologies, using more modern techniques such as gene editing, are becoming more open.[28] Catalysts driving more flexible attitudes include climate change, protection of te

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[28] Clark, A., Wilcox, P., Morrison, S., Munshi, D., Kurian, P., Mika, J., Chagne, D., Allan, A. and Hudson, M., 2024. Identifying Māori perspectives on gene editing in Aotearoa New Zealand. *Communications Biology*, *7*(1), p.221.

taiao, threats to taonga species, and more Māori working in the field of genetic science and research. Māori are also interested in exploring how new technologies can provide economic opportunities and improve health outcomes.

Wai262 – Ko Aotearoa Tēnei review of the HSNO regime

118. The Waitangi Tribunal reviewed HSNO's approach to GMOs as part of its response to the Wai262 claim, Ko Aotearoa Tēnei. This focused on the HSNO Act and ERMA, as it was published in 2011 when the EPA was being established. It focused its analysis on kaitiaki relationships in its simultaneous review of GMOs, bioprospecting and intellectual property (e.g. plant variety rights):

> *"While the Treaty does not provide for Māori ownership of either the genetic or biological resources of taonga species, or their associated mātauranga Māori, kaitiaki unquestionably have a right to protect their relationships with taonga species and a right to a reasonable level of control over their mātauranga Māori…the level of protection can only be decided after a proper balancing of all competing interests and on a case-by-case basis."*[29]

119. While the Tribunal recognised that the HSNO regime had greater protections for Māori interests than other areas such as bioprospecting, it found that the HSNO regime still did not sufficiently protect Māori interests regarding GMOs. Its primary concern was that Māori values appeared to be subordinate to scientific considerations in decision making because there had been no applications to its knowledge where Māori values alone had determined the outcome. It stated there should be circumstances in which this should occur for Māori interests to be accorded appropriate weight.[30]

120. It therefore made three recommendations to increase this weighting in decision making:
    - Introduce a new provision into HSNO requiring all those exercising powers and functions to recognise and provide for the kaitiaki relationship between kaitiaki and their taonga species.
    - Ngā Kaihautū could remain as an advisory body but should be able to proactively give advice on applications of interest to Māori, instead of requiring a referral from ERMA.
    - Ngā Kaihautu should appoint at least two members to the ERMA board to increase its proximity to decision making.

Options for protecting Māori rights and interests are based on the Plant Variety Rights Act 2022

121. If we were not operating within the constraints outlined, we would have completed a full options analysis and considered a range of options to best enable the proposed regime to meet obligations under the Treaty of Waitangi. However, the options for protecting Māori rights and interests in this RIS are informed by joint ministers' decision to adapt the process from the PVR Act. The option itself is discussed below in Section E.

122. The main difference from the PVR Act is that joint ministers have decided that the Māori Committee should be an advisory body, whereas the PVR Māori Committee has the power to require conditions or decline applications outright. Free and frank opinions In practice, we consider that the regulator has only limited discretion to ignore advice from the committee, because the legislation requires the regulator to address these risks. This

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29 Ko Aotearoa Tēnei, page 85.

30 Ko Aotearoa Tēnei, page 86.

differs from legislation which envisages a balancing of interests where Māori rights and interests are weighed against the interests of others.

123. Further, the risk management plan mechanism provides broad scope to identify practical solutions to risks raised by the committee.

124. The PVR model is considered because it covers related issues (i.e. intellectual property of new plant species), was informed by similar feedback in Ko Aotearoa Tēnei, and the relevant provisions are based around a similar risk mitigation approach (unlike the cost benefit model in HSNO). The regime establishes a Māori committee to determine whether any kaitiaki relationships exist with species of significance that would be adversely affected by an application. If so, the committee can require the imposition of mitigations or decline the application. As with the HSNO regime, consultation is expected with relevant Māori interests.

125. A key advantage of the PVR model is it clearly identifies a body that can identify risks to Māori interests. A particular complaint of applicants under the current HSNO process is that they are required to undertake extensive efforts prior to application to identify potential risks, and this is a substantial hidden cost. Under the adapted process, the applicant would still be incentivised to establish relationships and identify risks in advance, with the aim of having greater certainty about the regulatory process, but risk assessment and mitigation steps would be formally the responsibility of the regulator.

Te Puni Kokiri considers the proposed model does not sufficiently provide for Māori interests

126. TPK has advised that changing the Māori committee to an advisory body limits the scope for Māori to uphold kaitiaki relationships and directly benefit from these reforms. TPK's advice is that Māori interests would be better provided for through strengthening the Māori Advisory Committee proposal to include a provision that, at minimum, requires the Committee and the regulator to agree to a way forward regarding any detrimental impacts to the kaitiaki relationship and whether these can be mitigated. MBIE has some sympathy for this view, but on balance considers this concern is overstated in practice, given that the regulator will still have to take decisions consistent with its regulatory framework, and because a well-performing regulator will seek agreed solutions as a matter of course.

127. Māori stakeholders have also noted that including the concept of kaitiaki relationships in the proposed regime's narrower scope requires a broader definition of environmental risks to include risks to how the environment is used (e.g. in cultural practices).

Responsiveness to Wai262 recommendations

128. While the options to protect rights and interests under the Treaty of Waitangi are constrained by ministerial decisions, the proposed regime responds to the Waitangi Tribunal's recommendations in Ko Aotearoa Tēnei in the following ways:
    - Provide for kaitiaki relationships: Fully implemented as the proposed regime is based around this consideration.
    - Māori committee should proactively provide advice: Partially implemented as the regulator must refer all applications for full assessments to the Māori Advisory Committee. The regulator is not required to refer expedited and pre-assessed activities licence applications (but may choose to) as these are reserved for activities where the regulator has experience, which will include experience with relevant Māori interests.
    - Māori committee should be represented on decision-making board: Not implemented with the preferred option for a single decision maker model. The proximity of Māori interests to decision making could be partially provided through employing Māori experts in the regulator's internal assessment team.

Further, the regulatory model moves from a paradigm based on a balancing of interests to a direct assessment of risk, and therefore the case for an advocate for certain interests in decision-making is reduced.

B. Regulatory Approach

129. To regulate gene technology, broadly there are three regulatory approaches: to regulate the process only, the product or outcome of a gene technology only, or a hybrid approach that is mixture of the first two.

Option One – Status Quo – Process based regulatory approach[31]

130. New Zealand currently has a process-based regulatory approach under the HSNO Act. This means that regulation is triggered by the gene technology processes involved in the development of an organism rather than the risk presented by the modification or resulting trait. All organisms with genes or genetic material modified using in vitro techniques are defined as GMOs and are therefore in scope of regulation, regardless of what the specific genetic changes are, or the traits these changes encode, or risk posed.

131. Organisms that are developed using specified non-regulated techniques that modify the genetic makeup of an organism, including conventional techniques such as selective breeding or chemical mutagenesis, are not subject to regulation as GMOs.

132. Under the status quo, existing regulations can only be updated by Order in Council to list techniques that are not gene technology and organisms that are not GMOs for the purposes of the HSNO Act under secondary legislation. However, any changes like this, such as deregulating low risk organisms from containment regulations, would be inconsistent with the current definition GMOs under the HSNO Act.

Would this option deliver the identified policy objectives?

Enabling

133. Maintaining the status quo would only partially enable the safe use of gene technologies to deliver better health, environmental, societal, cultural, and economic outcomes for New Zealanders. Under continued use of the current process-based approach, all products of gene technologies would remain subject to stringent pre-market assessment and approval for release by the Regulator on a case-by-case basis, keeping regulatory and administrative barriers high.

134. This approach may result in the continued over-regulation of gene technologies where a process is captured by the regime even when the resulting GMO is very low-risk or indistinguishable from a product made through conventional processes. Continued over-regulation may also mean that no non-medical gene technology products are released in full in New Zealand, as is the case to date, and no applications for an environmental release of a GMO, as has been the case for the past 14 years.

135. Maintaining the status quo would not address the problems identified by stakeholders that regulatory settings are out date and do not reflect advances in gene technology. This has held back the adoption of gene technology and long-term will disadvantage New Zealand and New Zealanders health, environmental, societal, and economic outcomes.

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[31] The process-based approach is described in detail at the problem definition section of this document.

Risk-proportionate

136. Maintaining a process-based approach would mean that the risks that gene technology poses risk to human health and the environment will not be proportionally managed.

137. A process-based approach carries the underlying assumption that products of gene technologies are fundamentally different from or present more risk to human health and the environment, than products developed through conventional methods. This assumption is not based on any evidence that gene technologies fundamentally pose more risk to human health and the environment than conventional methods, which can produce a range of unguided changes to the genetic makeup of an organism. Unguided changes can be untargeted large-scale modifications resulting in a new trait and off target effects of a similar magnitude.

138. Under this option all products in scope of regulation would continue to be subject to the same regulatory scrutiny regardless of modification made or the risk posed to human health or the environment by the organism produced. This option would maintain the same level of pre-application and pre-approval risk assessment required of applicants, including for applications of technologies known to be low risk.

Efficient

139. The current approach does not promote the efficient assessment and approval of safe and ethical technologies using processes that are easy for applicants to navigate. Under the current regime all organisms developed using gene technologies are in scope of regulation. Maintaining the status quo would perpetuate the high administrative costs for users of gene technologies by requiring all activities to be regulated, either on a case-by-case basis or through broad approvals, regardless of risk.

140. Organisms developed using new gene technologies can be indistinguishable in genetic makeup and traits from naturally occurring or organisms produced with conventional techniques. As such, current scientific understanding suggests organisms developed using new techniques do not pose any greater risks to health or the environment. Under this option, indistinguishable products are regulated differently based on the technique used to achieve a modification which may result in regulatory uncertainty for users of gene technologies.

141. This option also means it will progressively become more difficult to enforce requirements for imports and exports of organisms when there is no way of distinguishing regulated organisms from unregulated ones.

Future focused

142. Continuation of the status quo also does not anticipate or flexibly accommodate future technological developments to benefit New Zealanders. Under this option all advancements in gene technologies would be subject to regulation regardless of the type of modification or the resulting trait.

143. Regulations would need to be regularly updated regularly in line with advancing scientific knowledge regarding new gene technologies but would still be required to regulate based on the process used rather than the resulting modification or trait produced. However, under this option, the EPA is unable to update the list of exemptions under the HSNO Act itself, because a High Court ruling in 2012 that found

that the HSNO Act does not implicitly giving the EPA discretionary power to add to the exemption list and that adding to the exemption list was a political decision, not an administrative decision.[32] Any changes to the regime to align it with new scientific advances would need to be made via an Order in Council, which can be a much slower process than a regulator's own administrative process.

Internationally aligned

144. If we choose to maintain the current process-based approach, we would be consistent with our international obligations and commitments. However, New Zealand is one of the only remaining jurisdictions operating a process based regulatory regime. If we maintained the status quo, New Zealand would remain out of step with our major trading partners and other comparable jurisdictions.

Rights and interests under the Treaty of Waitangi

145. This option would partially protect Māori rights and interests under te Tiriti o Waitangi/the Treaty of Waitangi because the approach used does not impact on the legislated responsibility of the regulator to seek Māori advisory input for all gene technology activities covered by regulations.

146. Maintaining the status quo of a process based regulatory approach with regulation being triggered by the use of gene technology would be consistent with the Māori concept of whakapapa, relating to the genealogy of an organism.

147. However, the over-regulation of gene technologies under this option may limit options for gene technologies to support Māori to exercise their responsibilities with their kaitiaki relationships where gene technologies may be beneficial or required to deal with threats to biodiversity and taonga species, such as introduced pests, genetic diseases, and fertility issues.[33]

148. This option would continue to allow for active protection of Māori rights and interests under te Tiriti o Waitangi/the Treaty of Waitangi as a process based regulatory approach provides opportunity for the regulator to seek Māori advisory input for all gene technology activities covered by regulations.

Level of stakeholder support

149. Through MBIEs targeted engagement, stakeholder feedback from both researchers and industry generally does not support maintaining the current regulatory regime, as it is considered to be overly burdensome for users of the technology and not risk proportionate.

150. Organics sector representatives do not support moving to a more permissive regulatory approach and would prefer maintaining the status quo with no releases of GMOs to market.

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[32] Gene Editing in Aotearoa – Legal Considerations for Policy Makers. Everett-Hincks, J., and Henaghan, M. (2019) Page 525. Accessed at https://doi.org/10.26686/vuwlr.v50i3.5990

[33] Hudson M, Mead ATP, Chagné D, Roskruge N, Morrison S, Wilcox PL, Allan AC. Indigenous Perspectives and Gene Editing in Aotearoa New Zealand. Frontiers in Bioengineering and Biotechnology. 2019. Accessed at https://doi.org/10.3389%2Ffbioe.2019.00070

Impacts

151. Maintaining the process-based approach would mean:
    - For firms and researchers:
        - Products developed using gene technologies would continue to be subject to pre-market risk assessment and approval requirements entailing high administrative cost regardless of the risk associated with the GM product itself. This creates a restrictive operating environment for firms and researchers involved in all areas utilising gene technology, including emerging fields such as industrial biotechnology.
        - These high administrative costs have been cited as reasons for firms moving activities involving gene technologies overseas to operate under a more enabling regulatory regime, including for full release of products. High administrative cost could be one of the main factors hindering the development of a flourishing gene technology or biotechnology sector in New Zealand.
        - There has been strong support for moving away from the status quo from both researchers and cross sector industry representatives, particularly for changing the regulatory approach for low-risk applications of gene technologies.

    - For all government agencies involved in administering the current regime:
        - There would be no additional administrative cost to amend legislation, regulations, and processes.
        - As gene technologies advance and verification of genetic modification becomes more difficult, there could be issues with enforcing the Act as there would be no way of verifying what process was used to introduce a genetic change that could have occurred through conventional techniques.
        - As international jurisdictions update their regulatory approach to enable the use of low-risk modifications, there is a risk of increased costs for verification of imports to New Zealand due to potential unintentional presence of genetically modified material.

    - For Māori:
        - Over-regulation may restrict options for Māori to exercise their kaitiaki role for taonga species where gene technologies cannot be explored or used to remedy threats to taonga species.
        - Over-regulation, the current process-based approach and the lengthy engagement EPA requires with communities at the pre-application stage may be perceived by certain members of the Māori community as appropriately protecting Māori rights and interests.

    - For the organics sector:
        - There would be no additional costs to what they currently bear to comply with national and international requirements for organic production.

    - For society as a whole:
        - New Zealand is potentially missing out on positive flow effects because the current regulatory regime does not enable the domestic development or release of gene technology products which could be utilised to promote health and advance the economy.

Option Two – Product / Outcome based regulatory approach

152. Under this option products would be regulated based on the novelty of the introduced trait, regardless of the process used to develop it (including conventional techniques and gene technologies). Regulation would be triggered by the presence of a novel trait that may pose a risk to human health or the environment in the same manner it does in the Canadian regime.

153. The regulator would have the power to produce a set of criteria in secondary legislation that would define limits for allowable levels of 'novelty' based on equivalence to products developed through conventional methods, with products deemed novel being subject to regulation as 'novel products'.

Would this option deliver the identified policy objectives?

Enabling

154. This option may enable the safe use of gene technologies to deliver better health, environmental, societal, cultural, and economic outcomes for New Zealanders through enabling the domestic development and release of products of gene technology that are not considered novel through a faster route to market due to lack of regulatory hurdles. However, to date there is no evidence that an outcome based regulatory approach alone results in more approvals for products entering the market.

155. Regulating based on novelty of an introduced trait regardless of the techniques used in development risks conventional breeding practices being subject to regulation for activities that have been unregulated to date. Conventional techniques have been used historically to introduce new traits to organisms, and regulating based on outcome alone may have the unintended effect of inhibiting established innovative research and development.

Risk-proportionate

156. The risks that gene technology poses to human health and the environment would be proportionally managed. However, removing the use of gene technologies from regulatory oversight and regulating based on the presence or absence of an introduced novel trait, risks New Zealand being unable to regulate any high-risk gene technology processes that may develop in the future.

157. While an outcome based regulatory approach based on novelty of introduced trait may regulate certain products with extensive history of gene technology application in a risk proportionate manner, such as plants, it is unclear if this would remain the case for other classes of organisms.

Efficient

158. By regulating based on the presence or absence of a novel trait, removing the use of gene technologies from regulatory oversight would remove the high administrative cost of developing an organism using gene technology under the current regulatory regime.

159. All pre-assessment data about an organism's introduced trait would need to be collected in laboratory conditions. This data may not accurately reflect the organism's trait or behaviour when released into the environment. If an organism does not display novel traits in the lab but does when in the environment, this may lead to unanticipated risks and create enforcement issues.

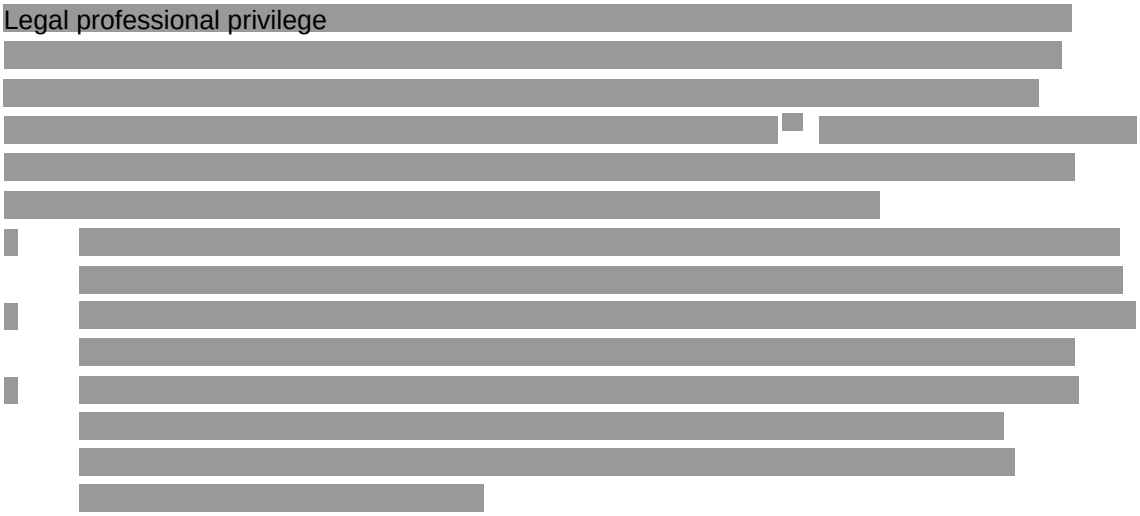
Future focused

160. This option would provide flexibility for advancements in gene technologies because regulation is based on the trait introduced rather than the process used in development, meaning that the regime does not need to account for new processes.

161. However, the criteria for what is considered a 'novel' trait will need to be updated over time to ensure that it reflects the reality of the New Zealand's environment.

Internationally aligned

162. Legal professional privilege



163. This option would bring New Zealand into regulatory alignment with Canada, who operate an outcome based regulatory regime.

Rights and interests under the Treaty of Waitangi

164. An outcomes-based approach to regulation would remove regulatory oversight of any modification that does not confer a novel trait made to species potentially important to Māori. This approach poses the risk that the whakapapa of an organism may be impacted by a change that may not be regulated. Therefore, further protections for Māori rights and interests under Te Tiriti o Waitangi/The Treaty of Waitangi would be required to ensure obligations are not breached. It therefore does not provide for protection of rights and interests as well as the status quo.

Level of stakeholder support

165. There has been stakeholder support from both research and industry representatives for adopting an outcome based regulatory approach, with particular emphasis on low-risk gene editing techniques.

166. Representatives from the organics sector oppose introducing an outcome based regulatory approach, as regulating based on novelty of trait would allow the release of products developed using gene technologies to the market with no tracing requirements. Organic certification explicitly excludes the use of certain processes,

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34 Legal professional privilege

irrespective of their environmental outcomes, and outcome based regulatory regime would be at odds with this approach. There are concerns regarding contamination of organic crops with neighbouring organisms that may be a product of gene technologies, and traceability of products that do not contain a novel trait, and therefore are not captured by regulation, under an outcome-based regime.

167. The concerns of the organic sector relate to the release of modified organisms into the environment, and any unintended crossing events that may occur with the potential to contaminate organic crop. Confidential advice to Government [redacted] For products of gene technology that are not captured by regulatory scope, existing organic certification processes and sector specific behavioural rules, such as distance boundaries between organic and GM farming adequate to prevent cross pollination, are intended to maintain the organic sector.

168. Engagement with Māori representatives has indicated that there may not be widespread agreement to a regulatory approach that removes oversight of modifications made to species of importance to Māori, including native flora, fauna, and taonga species as this may not uphold te Tiriti o Waitangi/the Treaty of Waitangi obligations.

169. The EPA notes the importance of the new system enabling compliance with New Zealand's obligations under the Cartagena protocol.

Impacts

170. Using a regulatory approach based on the novelty of traits developed, including by gene technologies, would mean that:
    - For firms and researchers:
        - The burden of proof regarding the novelty of an introduced trait would fall on the users of the technology. Data regarding the novelty of trait introduced would need to be collected through functional studies under laboratory conditions. This may risk large corporations who have the capital to fund large scale molecular and functional studies setting the burden of proof at a scale out of reach for small innovative companies. This change may form a regulatory barrier to entry that inhibits competition in the nascent gene technology and biotechnology sector in New Zealand.
        - The regulatory burden of any new trait, regardless of novelty, would fall predominantly on the first mover as discussed above. This burden risks inhibiting research and development due to the perceived barrier of proving a trait is not novel or would not pose risk to human health or the environment.
        - There may be unintended impacts on ongoing domestic research and development because there is a possibility that a lack of clear rules for research conducted within laboratories (i.e., the process of developing a product that may carry a novel trait) would have an inhibitory effect due to the complexity of navigating the regulatory environment.

- For Māori:
  - Removing processes from regulation (when the outcome is not novel) could result in unregulated changes to taonga organisms that would alter their whakapapa.

- For government departments/agencies involved in administering the current regime:
  - There would be additional administrative cost to amend legislation, regulations and processes, detection and assurance capability and capacity particularly for products that would not have been regulated previously.
  - The regulator's risk assessment will need to meet the risk assessment requirements pertaining to the activity, as prescribed in the Cartagena Protocol. The EPA and MFAT note the importance of the new system enabling compliance with New Zealand's obligations under the Protocol.

- For the organics sector:
  - There would be a cost associated with implementing coexistence measures and additional assurance costs due to increased products of gene technology not being subject to regulatory oversight.

- For society as a whole:
  - Regulating based on novelty of trait would increase the availability of products developed using gene technologies, regulating those that may pose a risk to human health and the environment. These products could promote health and economic outcomes for all New Zealanders.

Option Three – Hybrid (preferred option)

171. Under this option, the regulatory approach is a mixture of process- and outcome-based regulation, where the trigger for regulation is the risk to human health and the environment, whether that risk stems from the process itself or the outcome. This option would:
    - remove from regulatory oversight certain gene-editing techniques that are indistinguishable from conventional development techniques and as such do not present a unique risk.
    - require authorisation under the Act for all other gene editing techniques or processes. (The options for the authorisations framework are discussed in detail in Section B.)

172. The Act will enable regulations to exempt specified techniques and products of those techniques from the scope of the Act. In addition to the criterion noted above about being indistinguishable from conventional development (breeding) techniques, a further criterion will include that the technique does not involve the insertion of genetic material. Human beings would be explicitly excluded from regulation.

Would this option deliver the identified policy objectives?

Enabling

173. Exempting certain gene editing techniques would reduce regulatory barriers, such as the high administrative burden of applying for a licence, for users of low-risk gene technology. This would allow greater applications of safe technologies and provide a faster route to market, thereby enabling the delivery of products that may confer benefits for New Zealanders and the economy.

Risk-proportionate

174. This option would remove low risk gene-editing techniques that are indistinguishable from what could be achieved through natural cell repair processes or conventional techniques from regulatory oversight. This would reflect current scientific understanding that these modifications do not present unique risk to human health or the environment when compared to conventionally developed products.

175. Regulatory oversight would be maintained for gene technology activities that may present a known or unknown risk, allowing proportionate risk management through the proposed risk tiering system. This will allow risk management effort to be focused on the areas of highest risk or greatest uncertainty.

Efficient

176. Removing low risk-gene editing techniques from regulatory oversight would reduce regulatory barriers, such as the high administrative burden of applying for a licence, for users of low-risk gene technology.

177. This option would also increase regulatory certainty for users of gene technology as it would provide clarity and assurance of the regulatory status of indistinguishable organisms, regardless of development process used. Therefore, this approach promotes the efficient assessment and approval of safe and ethical technologies using processes that are easy for applicants to navigate.

Future focused

178. Exempting of low-risk gene editing techniques from regulation based on the modification made (i.e., achievable through conventional techniques) would provide durability as future technologies would be regulated based on the extend of genetic change introduced to an organism rather than the process itself.

179. Different gene technologies can introduce the same trait, so exemptions based on modification made to an organism would maintain deregulation of low-risk applications while higher risk applications of the same technology would be regulated in a risk proportionate manner.

180. Additionally, the ability to exempt organisms that are low risk while maintaining a graduated risk management approach for activities within regulatory scope would provide opportunity to reclassify any technique considering emerging scientific evidence. This would allow the regulator to exempt any demonstrably low-risk applications, provides the ability to reclassify, and bring back into regulatory scope, any technique that may have unforeseen risk to human health and the environment.

Internationally aligned

181. This option would be consistent with our international obligations and commitments and would align New Zealand's regulatory approach with our major trading partners and other comparable jurisdictions such as Australia, England, and the EU.

Rights and interests under the Treaty of Waitangi

182. Under this option the regulator will be required to seek Māori advisory input, and to take this into account, for most gene technologies and activities. This will provide

necessary information for the regulator to actively protect Māori rights and interests under te Tiriti o Waitangi/the Treaty of Waitangi.

183. However, removing low risk gene editing techniques from regulatory oversight would also remove the ability for Māori advisory input for these activities and, as under Option Two, could result in unregulated changes to taonga organisms that would alter their whakapapa.

Level of stakeholder support

184. There is generally strong stakeholder support from both research and industry representatives for removing modifications that are indistinguishable from natural breeding or conventional methods from regulation.

185. Organics sector representatives do not support moving to a more permissive regulatory approach which includes exempting certain gene editing technique from regulation.

186. Industry representatives highlighted the importance of New Zealand reaching regulatory alignment with major trading partners, as they anticipate the EUs proposal to introduce a hybrid regime for plants being influential on global regulatory approaches.

187. Engagement with the Māori research community and industry representatives also emphasised the importance for international alignment in playing a role in delivering benefits for New Zealand, including Māori.

Impacts

188. Introducing a hybrid approach would mean:
    - For firms and researchers:
        - Exempting certain gene editing techniques would reduce the administrative burden on users of gene technologies in both research settings and in industry. The lack of pre-market assessment and approval for these products would provide developers with a quicker route to market, enabling domestic development of products.
    - For Māori:
        - The impacts under this option are the same as under Option Two.
    - For all government agencies involved in administering the current regime:
        - There would be additional administrative cost to amend legislation, regulations and processes, detection and assurance capability and capacity. This cost is discussed in detail in the cost and benefits section of this document.
        - The regulator's risk assessment will need to meet the risk assessment requirements pertaining to the activity, as prescribed in the Cartagena Protocol. The EPA and MFAT note the importance of the new system enabling compliance with these obligations.
    - For the organics sector:
        - There would be costs in the form of more stringent coexistence measures and assurance requirements in response to both exempt products of gene technology being present in the environment and licensed environmental releases of regulated products.

- For society as a whole:
  - A hybrid regulatory approach would reduce regulatory barriers for products of low-risk gene editing techniques entering the market, which would enable the development and release of products that could promote health and economic outcomes for all New Zealanders.
  - Maintaining regulatory oversight of higher risk applications would maintain a risk proportionate regulation of gene technology products, with risk assessment and approvals needed before allowing environmental release.

How do the options compare to the status quo/counterfactual?

neutral = no change; + = improvement; - = less than status quo

	Option One – Process [*Status Quo*]	Option Two – Product	Option Three - Hybrid
Enabling	**0** This option would maintain all products in scope of regulation being subject to stringent premarket assessment and approval, limiting the ability to deliver beneficial outcomes for New Zealanders.	+ This option would enable greater domestic development and release of products that are not considered novel through a faster route to market due to lack of regulatory hurdles.	+ This option would remove low risk gene editing techniques from regulatory oversight, enabling domestic development and release of products through a faster route to market due to lack of regulatory hurdles.
Risk-proportionate	**0** This option would regulate all products in scope of regulation on a case-by-case basis or through broad approvals regardless of the risk posed by the organism produced.	+ This option would regulate based on risk posed by introduced traits, regardless of the method used in development, in a risk proportionate manner. However, this option would remove the application of gene technologies from regulatory oversight, which may risk New Zealand being unable to regulate any high-risk gene technologies that may develop in the future.	++ This option would regulate products of gene technologies in a risk proportionate manner, removing low risk gene editing techniques from regulatory oversight. This option would maintain regulation of modifications that may pose risks to human health and the environment through the proposed risk tiering system.
Efficient	**0** This option would maintain high administrative cost for pre-market risk assessment and approval.	+ Removing gene technologies (when the traits are not novel) from regulation remove regulatory barriers for	+ This option would reduce regulatory barriers for users of low-risk gene technology such as the high administrative burden of applying for approval by removing

	This option would result in inconsistent regulation of products that are indistinguishable based on the technology used in development.	developers and users of those technologies. By regulating based on the novelty of trait produced, there is a possibility that a lack of clear rules for research conducted within laboratories would have an inhibitory effect due to the complexity of navigating the regulatory environment.	low risk gene editing techniques from regulatory oversight.
Future-focused	**0** This option would be inflexible for technological advancements as all advancements in gene technologies would be subject to regulation.	+ This option would provide flexibility for advancements in technologies as regulation is based on the trait introduced rather than the process used to develop it. However, criteria for what is considered 'novel' will need to be updated to remain relevant over time.	++ This option would improve flexibility for future technological advancements compared to the status quo due to exempting certain gene editing techniques from regulatory oversight based on the modification made rather than the technology used. This option would provide flexibility through a graduated risk management approach, allowing reclassification of current and future techniques as further scientific understanding and associated risks is established.
Internationally - aligned	**0** This option would mean New Zealand remains out of line with international jurisdictions and would fall further behind as international approaches develop. New Zealand is the only remaining jurisdiction to regulate with a process-based approach, in comparison to our major trade partners and comparable jurisdictions.	+ This option would provide regulatory alignment with Canada.	++ This option would provide improved regulatory alignment with most major trading partners including Australia, England, Norway, Japan, and the EU once its proposal is brought into force.

Rights and Interests under the Treaty of Waitangi	**0** This option would retain a process based regulatory trigger, which allows the regulator to seek Māori advisory input for all activities covered by regulations.	-- This option would remove regulatory oversight of some modifications made to species potentially important to Māori, which risks breaching obligations te Tiriti / the Treaty. Further protections for Māori rights and interests under would be required to ensure obligations are not breached.	-- The regulator will be required to seek Māori advisory input, and to take this into account, for most gene technologies and activities. This option would exempt low-risk gene editing techniques from regulation, removing the ability for the regulator to seek Māori advisory input.
Overall assessment	**0**	+	++

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

189. Our preferred option is Option Three, where the regulatory approach is a mixture of process- and outcome-based. This approach will allow for techniques that present no new risks, compared to conventional breeding techniques, to be exempt from regulatory oversight. This sets the focus of regulation on techniques that may present a greater risk to the health and safety of people and the environment.

190. Our preferred option will change the regulatory approach for GMOs from strictly process-based to a mixture of a process trigger with outcome-based exemptions. Legislation will enable regulations to determine which techniques produce organisms that are not subject to regulation for the purposes of the new Act. Changing the approach in this way makes the legislation more flexible, so that as gene editing techniques advance, the regulations may be updated to include those which do not create a risk to human health and/or the environment greater than that of conventional breeding.

191. Furthermore, our preferred option will reduce regulatory barriers to technologies which have low public health and/or environmental risks, such as certain gene editing techniques. This will unlock the benefits gene technologies can bring to New Zealanders without unnecessary regulatory burden. This option would clarify the scope of regulation and improve certainty of what is regulated or not for users of gene technologies.

192. Lastly, a hybrid approach allows for implementing risk-proportionate regulation which can be adapted as technology develops.

C. Authorisations framework

Option One – Status Quo

193. Parties wanting to undertake activities involving GMOs must first obtain authorisation from the EPA within a framework related to the proposed use of the GMO.

Authorisations may be accompanied by conditions set by the EPA, e.g. which standards of containment must be met for an activity to be carried out in a laboratory.

194. Setting aside authorisations for emergency use[35], there are two broad categories of authorisation:
    - Contained import, development, or field testing, and
    - Environmental release: either for use as or in human and veterinary medicines, or for general environmental release, which includes conditional releases and full releases.

195. There are two main approval pathways the regulator may utilise:
    - A rapid assessment is available for:
        - contained importation or development if the activity is considered low risk[36], and
        - human or veterinary medicines if criteria are met related to improbability of significant adverse effects[37].
    - Full assessments are required for all other proposed uses of GMOs.

196. Three New Zealand universities (Auckland, Otago, and Massey) have institutional low-risk approvals that cover a broad range of research and GMOs. These approvals have significantly reduced the number of low-risk laboratory research applications that must be sent to the EPA.

197. The conditions imposed in legislation on the conduct of field tests also means that this pathway is not enabling of research and development. The conditions prevent most users from testing the organisms for their key agronomic traits. This is because they must be run under strict containment conditions where nothing heritable can escape.

Would this option deliver the identified policy objectives?

Enabling

198. The status quo enables contained laboratory research into GMOs and use of medicines that are or contain GMOs, provided they are considered low risk / highly improbable to cause adverse effects. However, approval of any routine low-risk laboratory uses that fall outside existing institutional low-risk approvals still requires an application to the EPA and case-by-case consideration.

Risk-proportionate

199. The status quo provides in a minimal way for proportionate management of risks to the environment and the health and safety of people, through the rapid assessment pathway for laboratory research and medicines. However, outside of these uses, applications must go through a full assessment process, even if the risks and appropriate management conditions are well understood.

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35 Emergency use is not addressed further in this section as an emergency use specific authorisation continues to be required and it is not a main factor in achieving the policy objectives.

36 HSNO Act, Sections 42 and 42B

37 HSNO Act, Section 38I

Efficient

200. The status quo imposes greater administrative cost and regulatory oversight than is necessary because case-by-case assessments are always required for research that is not already covered by existing approvals (institutional low-risk). It provides only limited certainty/predictability for applicants of their obligations and the level of information they are required to provide to the EPA, given only two approval pathways for the varied spectrum of risk levels for different uses.

Future focused

201. The status quo does provide a small degree of flexibility in respect of advancements that lead to low-risk laboratory and medical uses – these can be assessed under the rapid assessment pathway. However, it has no flexibility in respect of environmental releases, which may not be assessed under an alternative pathway, even if there is greater knowledge of risks and technologies which suggests a less onerous authorisation approach would be proportionate.

Internationally aligned

202. The HSNO Act's GMO provisions are regarded as some of the most stringent within the members of the Organisation for Economic Co-operation and Development (OECD). It is not aligned with several countries comparable to New Zealand, including Canada, the United States and Australia, which have legislation that provide for the regulator in question to not undertake case-by-case assessments of low-risk activities.

Rights and interests under the Treaty of Waitangi

203. It is not clear how well the current authorisations framework protects Māori rights and interests. The rapid assessment approval pathway provides faster access to new medicines, which would benefit Māori (who experience inequitable health outcomes) as well as non-Māori. However, the authorisations framework's overall lack of efficiency, proportionality and enabling of benefits likely means that Māori (as well as non-Māori) miss out on other benefits from gene technology.

204. Māori are able to provide input to decision-makers on how their rights and interests may be affected on a case-by-case basis, except under the rapid assessment pathway for low risk uses. On the one hand, this enables the EPA to ask for information in respect of most application processes so it can understand the effects of the activities on Māori rights and interests. On the other hand, it potentially places a burden on Māori to submit information for applications which are not novel and to repeat previously provided views.

Level of stakeholder support

205. During our targeted consultation, key stakeholders, including researchers and companies across a range of sectors, told us that authorisations available for GMOs do not appropriately address the differences in risk that individual applications may pose. This is because, aside from the limited low-risk pathways available, all other GMO activities are assessed under a largely similar authorisation framework as if they pose uniform levels of risk. Stakeholders have also said that interacting with the current authorisation system can be confusing, costly and time consuming as it can be difficult at times to understand which type of approval is required for activities that use GMOs.

Impacts

206. Maintaining the status quo approach to authorisations would mean:
    - For firms and researchers:
        - Ongoing high administrative costs from a lack of proportionality to risk in the types of authorisations available.
    - For all government agencies involved in administering the regime:
        - Ongoing high administrative costs for the regulator to authorise use of GMOs.
    - For the organics sector:
        - Approvals for non-medicine GMOs to be released into the environment will remain unlikely, enabling the organics sector to continue to benefit from there being no risk of inadvertent contamination to their products from GMOs. The benefit is in the form of avoiding the cost of having to establish and implement frameworks to coexist with GM products and additional assurance processes.
    - For society as a whole:
        - People who are concerned about any use of GMOs may feel more reassured that a case-by-case assessment is required for activities not already covered by an existing approval. However, society as a whole misses out on the benefits of a more risk-proportionate and efficient system which enables the greater use of safe gene technologies.

Option Two – Unmodified Australian legislative framework

207. This option is to adopt Australia's current framework for the authorisation of activities involving GMOs. The main difference between this option and Option One above is an increased ability to tailor the authorisation type to the risk level of the GMO or its use. A key feature is that there are several types of authorisation within this framework that do not require the regulator to undertake a case-by-case assessment before a regulated party may undertake the activity, because the activity is known to pose a very low or low risk to the environment and the health and safety of people. Secondary legislation is used to specify the activities that meet the criteria for these types of authorisation. Other types of authorisations, for activities with GMOs that are higher risk, do require case-by-case assessment by the regulator.

208. The authorisation types are as follows:

Authorisation	**Types of activity / Indicative risk**	**Involvement of the regulator and conditions**
Exempt activity	Lowest-risk activities	No regulator involvement beyond specifying which activities meet the criteria for exempt. Must not release the GMO into the environment – i.e., must be undertaken in containment.
Activity included on GMO Register	Specific GMOs with minimal risk	Regulator approves entry onto the GMO Register. Once an activity has been entered on the GMO Register anyone can conduct the

Authorisation	Types of activity / Indicative risk	Involvement of the regulator and conditions
		activity, provided any specified conditions are met. The GMO could be released into the environment.[38]
Notifiable activity	Low-risk activities if risk management requirements are met.	Regulator notified annually. Regulator may require particular types of activities are verified by a compliance body run by the research institution[39] as meeting notifiable activity criteria. Must not release the GMO into the environment. Must be undertaken in an approved containment facility and related standards concerning transport, storage and disposal would apply. Activity must be carried out by people with appropriate training and/or experience.
Licensed: non-release	Higher-risk laboratory work not eligible for the notifiable risk tier, e.g., with pathogenic (disease-causing) organisms. Clinical trials and medical applications with GMOs unlikely to be released into the environment.	Must not release the GMO into the environment. Must comply with any licence conditions.
Licensed: intentional release	Field trials (limited and controlled releases) or full environmental releases of GMOs, including for some medical applications.	Regulator undertakes case-by-case assessment, including preparing a risk assessment and risk management plan. Must comply with any licence conditions.

38 As an example, the one activity that has been listed to date on Australia's GMO Register is the commercial release of four lines of colour-modified GM carnations.

39 Institutional Biosafety Committees in the Australian regime.

Authorisation	Types of activity / Indicative risk	Involvement of the regulator and conditions
Licensed: inadvertent activity	Authorises people who have inadvertently come into possession of a GMO to dispose of it in a safe manner.	Temporary licence for up to 12 months. Must comply with any licence conditions concerning safe disposal.

Would this option deliver the identified policy objectives?

Enabling

209. This option would enable a greater amount of research using GMOs to be undertaken, but it is likely comparable to Option One for low-risk medical uses as there is no distinct authorisation pathway. Would likely increase research and development, leading to better outcomes for New Zealanders.

Risk-proportionate

210. This option provides for a more risk-proportionate approach than Option One to authorise very-low and low-risk GMO research activities which may be safely carried out with a reduced number of requirements. However, it only provides a minimum proportionate approach for low-risk medical uses because these must still be licensed case-by-case.

Efficient

211. For authorisations not involving case-by-case assessments, there would be reduced administrative and regulatory costs. However, compared to the status quo, this option is more inefficient in relation to the inadvertent possession of a GMO. That is because the HSNO Act does not require an approval/licence for inadvertent possession, it includes offences for knowingly importing or releasing a GMO in contravention of the Act, and for knowingly, recklessly, or negligently possessing or disposing of a GMO imported, manufactured, developed, or released in contravention of the Act.

212. This option would increase the certainty and predictability of obligations and rights for applicants by providing more clearly delineated authorisation pathways for activities with different categories of use (non-release, intentional release) and risk levels than the status quo.

Future focused

213. The ability to readily amend secondary legislation to specify the types of activities with GMOs that meet criteria for exempt and non-notifiable authorisations, which can then be undertaken by researchers without requiring an application, enables the regulatory system to better accommodate future technological developments that are low risk.

Internationally aligned

214. This approach would align with the regulatory regimes of several countries comparable to New Zealand including Canada, the United States and Australia, which more proportionately regulate very low and low-risk GMO activities. It would not take account of recommended changes following the most recent review of the Australian regime.

Rights and interests under the Treaty of Waitangi

215. This option is likely to result in greater research outcomes leading to beneficial applications in both the medical and non-medical space, which would support improved health outcomes for Māori (as well as non-Māori) and other opportunities, e.g. in agribusiness and to address biodiversity loss.

216. However, by establishing an authorisations framework where low-risk laboratory activities may be exempted or simply notified annually, this would change the opportunities for Māori to provide input to decision-makers on how their rights and interests may be affected by the activities. It would change from predominantly case-by-case input under the status quo to providing input on the class of activities that qualify for those types of authorisations, while still having the opportunity to input on activities that require a licence and case-by-case assessment. This will support a more efficient approach for the regulator to ensure it is informed about how Māori rights and interests are affected, and for Māori to provide input. However, this trades off the ability for Māori to provide input for most individual low-risk activities (excepting those qualifying for the rapid assessment pathway).

217. Establishing an authorisations framework where low-risk laboratory activities may be exempted or simply notified annually, would also change the opportunities for Māori to provide input to decision-makers on how their rights and interests may be affected by the activities. It would mean that from predominantly case-by-case input under the status quo, Māori would have the opportunity to provide input on the class of activities that qualify for those types of authorisations. Māori would still have the opportunity to input on activities that require a licence and case-by-case assessment i.e. high-risk activities.

Level of stakeholder support

218. Stakeholders involved in health and medicines research are concerned about regulatory processes that may be costly or slow for gene technology therapeutics and vaccines. This option would not address their concerns.

219. Other industry stakeholders indicated support for basing authorisations on the current Australian framework but noted the necessity of introducing modifications in line with the recent review of the Australian regime, and to adjust for the New Zealand context.

Impacts

220. Adopting this approach to authorisations would mean:
    - For firms and researchers:
        - Reduced administrative costs from not having to obtain a case-by-case assessment for each proposed research activity that is very low-risk or low-risk.
    - For all government agencies involved in administering the regime:
        - Lower administrative costs for the regulator than Option One for lower-risk research activities, but comparable costs to assess medicines to authorise use of GMOs.
        - Confidential advice to Government

- Because this option would result in some gene technologies not being assessed on a case-by-case basis, the same risk assessment mitigations described above (Section A – Option Two) would be required to ensure that New Zealand can meet its obligations under the Cartagena Protocol.

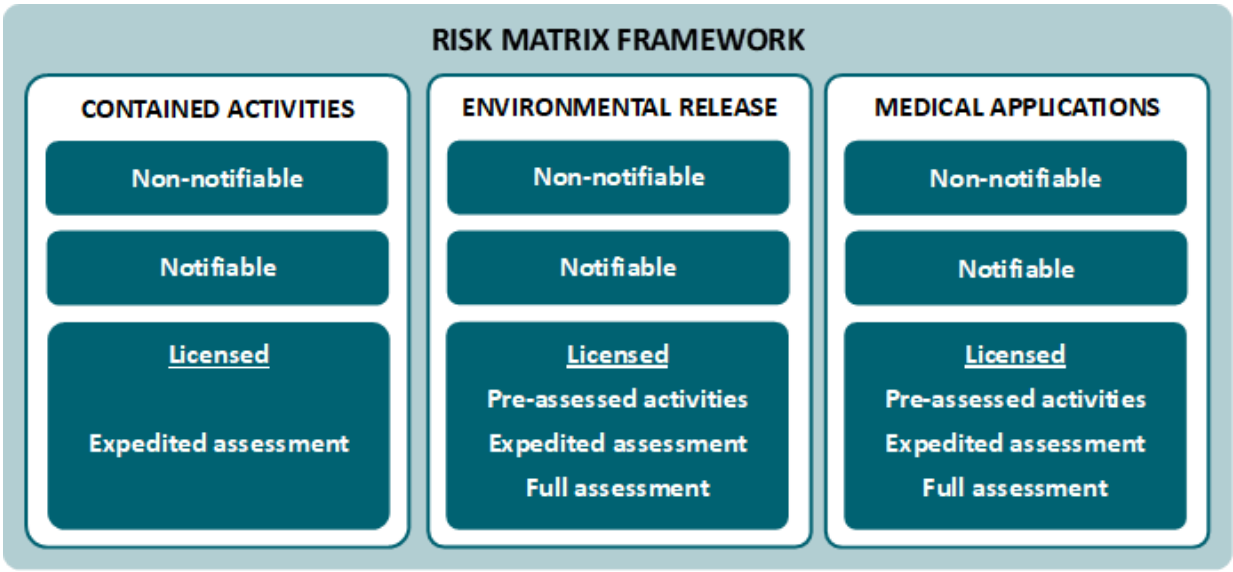
- For the organics sector:
  - Approvals for non-medicine GMOs to be released into the environment would be more likely. When this occurs, the organics sector would need to be able to assure their markets their products are GMO-free. This would entail costs to establish and implement frameworks to coexist with GMO supply chains and for additional assurance processes.

- For society as a whole:
  - Increased innovation from simpler and less costly pathways for lower-risk research activities would be expected to lead to greater benefits for society as a whole than Option One.

Option Three (preferred) – Modified Australian legislative framework

221. This option is to adopt changes to the Australian legislation that were proposed in a recent review of the Australian regime.[40] Key differences between this option and Option Two are described below.

222. GMO activities would be categorised into three broad categories of use – laboratory/industrial use, environmental release, and clinical trials and medical applications. A range of risk-based authorisations would be available under each use category, creating a matrix of authorisations, as shown in the diagram below.



223. In addition to laboratory and industrial activities, environmental releases and medical applications that are very low or low risk may be authorised as non-notifiable or notifiable activities, i.e., they would not require a case-by-case assessment by the

40 Option C, discussed in Modernising and future-proofing the National Gene Technology Scheme: Proposed regulatory framework to support implementation of the Third Review of the Scheme. Source: https://www.genetechnology.gov.au/sites/default/files/2022-02/2017-review-consultation-regulation-impact-statement-explanatory-paper.pdf

regulator. This differs from Option Two, which requires that exempted and notifiable activities must not be released into the environment and requires that environmental releases are assessed by the regulator unless they are already included on the GMO Register.

224. Rather than a GMO Register, the regulator would administer a list of 'Activities Approved for General Use', which would perform largely the same function. Unlike the GMO Register, the regulator would be able to add to this list both previously licensed activities as well as activities not previously authorised.

225. The licence types in Option Two are replaced with three new licences for activities with medium-to-high or uncertain indicative risk, with assessment requirements increasing based on indicative risk. All licensed activities would need to be assessed by the regulator before the activity could commence. Further information on each licence type is provided below.

226. The key change in licence types between Option Two and this option is to shift the focus to identifying potential risk and to adapt the assessment requirements accordingly, rather than focusing on whether the GMO will be contained or released or will be intentionally released or not intentionally released. This approach means as risks and suitable management conditions become more well understood, a more proportionate assessment process can be used, reducing the administrative costs of authorisation over time.

Authorisation	**Types of activity / Indicative risk**	**Involvement of the regulator and conditions**
Pre-assessed activities licence	Activities that have a medium indicative risk, about which the regulator has extensive experience and has determined can be managed through a set of defined licence conditions.	Regulator will only verify that the activity is eligible for a pre-assessed activities licence and perform applicant suitability checks, including the capability to meet the licence conditions. Conditions are pre-set.
Expedited assessment	Activities that have a medium-high indicative risk which require case-by-case assessment and tailored licence conditions. Expedited assessments would be appropriate for activities that have risks already well understood by the regulator, such that only some components of the activity would require assessment.	Regulator will prepare a risk assessment and risk management plan. Regulator may or may not impose conditions on the licence.
Full assessment	Activities that have a high indicative risk or substantial uncertainty as to risk. Full assessment would be appropriate for GMO activities for which the regulator has no or limited regulatory experience.	Regulator will prepare a risk assessment and risk management plan. Regulator may or may not impose conditions on the licence.

227. Unlike Option Two, there would not be a specific authorisation for the inadvertent possession of a GMO. It is proposed instead to include similar offences to the HSNO Act relating to knowing, reckless or negligent possession or disposal of a GMO in contravention of the Act. Inadvertent possession would then would not be an offence under new legislation. The regulator would provide information to persons that may inadvertently come into possession of a GMO about proper disposal.

228. Regulations would set out the criteria for the regulator to categorise activities into authorisation types and the requirements that must be met for the activity to be conducted (e.g. specific containment facilities, notifications, etc.). The regulator would make notices specifying activities that it has assessed as meeting the criteria for non-notifiable risk tiers, notifiable risk tiers, and eligible for a pre-assessed activities licence.

229. Public consultation would be required on proposed changes to these notices. A Māori Advisory Committee and a Technical Advisory Committee would be consulted as part of this process (sections A and E provide more information about these proposed bodies). The decision-making processes section identifies options for the decision-maker to obtain expert, Māori, and public input in respect of licensed activities.

230. This option would be combined with Option Four to form a package.

Would this option deliver the identified policy objectives?

Enabling

231. This option would enable a greater amount of safe use of gene technologies in research and development, and in industrial, medical, and environmental applications, to occur. This approach to authorisations provides for greater flexibility for gene technologies to be used in medicines and the laboratory. This is expected to deliver better outcomes for New Zealanders than Option Two.

Risk-proportionate

232. This option provides significant flexibility to categorise GMO activities according to their indicative risk, given the range of authorisation types available.

Efficient

233. This option provides for a more cost-effective authorisation framework as assessment requirements will increase according to risk level, and increased certainty to researchers and firms about obligations when carrying out activities with GMOs.

Future focused

234. Providing the regulator with the ability to publish notices that specify the types of activities in different risk tiers enables the regulatory system to better accommodate future technological developments and increased knowledge of risks.

Internationally aligned

235. This approach would align with the regulatory regimes of several countries comparable to New Zealand including Canada, the United States and Australia, which more proportionately regulate very low and low-risk GMO activities. This option would align with the recommended changes to the Australian legislation, taking advantage of their

experience operating the framework described in Option Two. It would, however, be different from the current Australian legislation.

Rights and interests under the Treaty of Waitangi

236. The greater number of authorisation types, based on indicative risk, is expected to increase the number of applications that would deliver benefits to Māori as well as non-Māori, including economically, environmentally and in health.

237. However, as with Option Two, by establishing an authorisations framework where very low and low-risk activities can be undertaken without notification or with notification after the fact, this would change the opportunities for Māori to provide input to decision-makers on how their rights and interests may be affected by activities. It would change from predominantly case-by-case input under the status quo to providing input on the class of activities that qualify for those types of authorisations. This has efficiency gains for the regulator and for Māori. However, this trades off the ability for Māori to provide input for most individual low-risk activities.

Level of stakeholder support

238. Stakeholders engaged with by MBIE across a range of sectors have broadly expressed support for a framework which proportionately reduces authorisation requirements for low-risk activities that use GMOs, which this option provides.

239. Some primary producer stakeholders have raised concerns about the risk of inadvertent contamination to non-GMO supply chains when environmental releases are authorised.

240. MfE's 2023 consultation found support for reducing requirements for research conducted on GMOs in containment MfE published 10 recommendations to address the problems raised, of which this option incorporates several proposals of the proposals.[41]

Impacts

- For firms and researchers:
  - Reduced administrative costs from not having to obtain a case-by-case assessment for proposed very low-risk or low-risk activities not already covered by an approval.
  - Reduced administrative costs from being able to apply for an expedited assessment or a pre-assessed activities licence, instead of only a full assessment.

- For all government agencies involved in administering the regime:
  - Lower administrative costs for the regulator.
  - Confidential advice to Government
  - This option would require the same measures as Option Two to ensure New Zealand meets its Cartagena Protocol obligations.

[41] See Improving our GMO regulations for laboratory and biomedical research: Consultation document | Ministry for the Environment; with recommendations 1, 2, 6, 7, and 8 incorporated.

- For the organics sector:
  - Approvals for genetically modified plants and other non-medical GMOs to be released into the environment would be more likely. When this occurs, the organics sector would need to be able to assure their markets their products are GMO-free. This would entail costs to establish and implement frameworks to coexist with GMO supply chains and for additional assurance processes.

- For society as a whole:
  - Increased safe research and development using gene technologies due to simpler and less costly authorisation pathways, and increased safe use of gene technologies in industrial, medical, and environmental applications, which is ultimately expected to lead to greater benefits for society.

Option 4 (preferred in combination with option three) - Requiring providers of synthetic nucleic acid to screen customer orders

241. This option would be combined with Option Three to form a package.

242. Advances in gene technologies now enable nucleic acids (DNA and RNA) to be chemically synthesised and acquired without needing to be derived from an existing organism. National security or defence

243. National security or defence

244. Under this option, legislation would provide the ability for the regulator to require:
   - any commercial producers of nucleic acids based in New Zealand to screen customer orders, and
   - any manufacturers of nucleic acid synthesisers based in New Zealand to incorporate screening mechanisms into their equipment.

245. While there are no companies currently providing this service in New Zealand, screening requirements are likely to become an international norm, or at the very least an expectation of security partners. A better opportunity to introduce these requirements is unlikely to present itself in future.

246. National security or defence

247. In the interests of efficiency and regulatory harmonisation, New Zealand would not independently develop the criteria and processes for determining "responsible

suppliers" but would align these requirements with those of the US and UK. Requirements will also be designed to minimise any administrative burden on producers and manufacturers.

Would this option deliver the identified policy objectives?

Enabling

248. It is not clear whether this option would enable the greater use of safe gene technologies, but it would help ensure that gene technologies used in New Zealand are safe.

Risk-proportionate

249. These requirements would increase the risk proportionality of the overall regime, given the status quo has no management of these higher-level risks.

Efficient

250. This option is likely to have no discernible effect on the efficiency of assessments, approvals, and the system overall.

Future focused

251. This option would help address risks that are increasing due to a number of factors and aligning approaches with those of overseas partners would help ensure the requirements remain up to date.

Internationally aligned

252. Key national security partners are implementing, or looking to implement, the same or similar requirements.

Rights and interests under the Treaty of Waitangi

253. This requirement would help ensure that risks to New Zealanders are reduced, including risks to Māori. As evidenced by Covid-19 and other health statistics, Māori suffer disproportionate health outcomes during pandemics.

Level of stakeholder support

254. New Zealand researchers have expressed awareness and growing concern about the risks from engineered pathogens and the need for New Zealand to prepare for these risks.[42] In 2023, Te Niwha and the Public Health Agency release a new preparedness framework to respond to future pandemics, which included engineered pathogens as a potential pandemic agent.[43]

255. Researchers spoken to expressed concern with any requirements that might be placed on nucleic acid imported into New Zealand, however this is not an aspect of this

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[42] University of Otago. Two pandemics more than 100 years apart – comparison reveals best strategies for the future. Source: https://www.otago.ac.nz/news/newsroom/two-pandemics-more-than-100-years-apart-comparison-reveals-best-strategies-for-the-future

[43] Te Niwha and the Public Health Agency. *Likely Pandemic Agents and Scenarios - an Epidemiological and Public Health Framework*. Source: teniwha.com/assets/Resources/Te-Niwha_Full-Report_Likely-future-pandemic-agents-and-scenarios_Web.pdf

proposal. They did not oppose requirements being placed on companies based in New Zealand.

Impacts

- For firms and researchers:
  - Any nucleic acid synthesis companies basing themselves in New Zealand would have to comply with the screening requirements, however most of these companies screen orders currently or are likely to implement these screening protocols in future.

- For all government agencies involved in administering the regime:
  - There would be a small upfront resourcing requirement to implement these requirements.

- For the organics sector:
  - N/A

- For society as a whole:
  - Reduced risks from engineered pathogens which would have negative health, economic, and social effects.

How do the options compare to the status quo/counterfactual?

0/neutral = no change; **+** = improvement; **-** = less than status quo

	Option One – *Status Quo*	**Option Two – *Unmodified Australian legislative framework***	**Option Three – *Modified Australian legislative framework***	**Option Four – *Requiring nucleic acid screening (add on to option Two or Three)***
Enabling	**0** Enables contained lab research into GMOs and authorises some low-risk medicines, however, some routine low-risk lab research still requires assessment.	+ This option would enable a greater amount of research using GMOs to be undertaken, ultimately leading to better outcomes for New Zealanders.	++ This option would significantly enable a greater amount of research and development to occur, and products and therapies to be authorised for use, ultimately leading to better outcomes for New Zealanders.	**0** It is not clear whether this option would enable the safe use of gene technologies, however it would help ensure the use of gene technologies are safe.

	Option One – *Status Quo*	Option Two – *Unmodified Australian legislative framework*	Option Three – *Modified Australian legislative framework*	Option Four – *Requiring nucleic acid screening (add on to option Two or Three)*
Risk-proportionate	**0** The status quo is not consistently risk-proportionate when requiring a full assessment process for applications where the risks are understood and can be safely managed.	+ This option would be more risk-proportionate for very low and low-risk activities compared with the status quo.	++ This option would be significantly more risk-proportionate compared with the status quo due to the greater number of risk tiers, authorisation types, and assessment pathways.	++ By only placing restrictions on the nucleic acids of highest risk, this option would be significantly more risk-proportionate than the status quo, which has no management of these risks.
Efficient	**0** This option preserves greater administrative cost and regulatory oversight than is necessary for some applications not covered by existing authorisations. It provides only limited certainty and predictability for regulated parties about rights and obligations given only two approval pathways.	+ This option would result in fewer administrative and regulatory requirements and more certainty for regulated parties about rights and obligations for research that could be undertaken under the non-notifiable or notifiable risk tiers.	++ This option would result in much fewer administrative and regulatory requirements and more certainty for regulated parties about rights and obligations for research, products, and therapies, due to the greater number of risk tiers, authorisation types, and assessment pathways.	**0** This option would have no effect (positive or negative) on the efficiency of assessments and approvals.
Future - focused	**0** Does not enable environmental release to be assessed under an alternative pathway that accounts for new knowledge of risks and techniques.	**0** It is not clear that this option would result in the better accommodation of future technological developments, compared with the status quo.	+ By simplifying the process required to amend risk tier details, this option would increase the likelihood that future technological developments would be most appropriately accommodated by the regime.	++ This option would help address ever increasing risks from gene technology ahead of time.

	Option One – *Status Quo*	Option Two – *Unmodified Australian legislative framework*	Option Three – *Modified Australian legislative framework*	Option Four – *Requiring nucleic acid screening (add on to option Two or Three)*
Internationally aligned	**0** The current regime is not well aligned and is viewed as one of the most stringent regimes (regarding the regulation of gene technologies).	+ This option would better align New Zealand's legislation with that of other comparable jurisdictions, including Canada, the United States and Australia.	+ This option would better align New Zealand's legislation with that of other comparable jurisdictions including Canada, the United States and Australia.	++ Key national security partners are implementing or looking to implement similar requirements.
Rights and Interests under the Treaty of Waitangi	**0** It is unclear the extent to which the current regime adequately protects Māori rights and interests.	+ A greater number of beneficial research outcomes are likely to deliver benefits to Māori, though these benefits may be marginal compared to Option One. Maintains ability for Māori input to be considered but trades off opportunities for Māori to provide input for individual activities.	+ The greater number of authorisation types, based on indicative risk, will increase the number of applications that would deliver benefits to Māori, including economically, environmentally and in health. Maintains ability for Māori input to be considered but trades off opportunities for Māori to provide input for individual activities.	++ As evidenced by mortality rates during Covid-19, Māori suffer disproportionately during pandemics and would be expected to in the event of an engineered pandemic.
Overall assessment	**0**	**+**	**++**	**+**

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

256. Our preferred option is a combination of Option Three and Option Four, which will establish an authorisation system that regulates activities using GMOs based on the risks they pose to the health and safety of people and the environment.

257. This framework allows a greater recognition that there is a spectrum of risk and enables risk-proportionate adjustments to regulatory requirements over time. This framework also imposes compliance requirements in a way that protects the health and safety of people and the environment from higher risk activities and uses of gene technology.

258. The preferred option considers the context of the activity as well its particular risk to set assessment requirements that are proportionate to risk. This model will separate activities of gene technology into categories (contained, environmental release or medical use), and within these categories, tier activities by risk profile (non-notifiable, notifiable, licensed).

259. This enables the authorisation process and levels of regulatory oversight to be based on the application of the technology, the organism in question, and evidence about the risk of the modification. Under this model, authorisation requirements are removed or reduced for very low/low-risk activities and activities that carry higher levels of risk have more intensive authorisation processes.

260. This will create a navigable and enabling environment for regulated parties, which we expect to lead to increased research and development activity using gene technology while ensuring any risks are appropriately managed, and ultimately more safe use of GMOs in industrial processes, medicines, and environmental applications. This will enable New Zealanders to increasingly benefit from gene technologies.

D. Decision-making factors

261. This section covers the factors that the regulator would consider when assessing an application and authorising an activity.

Option One – Status Quo

262. Under the status quo, the basis for a decision to authorise a GMO activity stems from the authorising provision (s 38 in the HSNO Act) and decisions must be consistent with the purpose of the HSNO Act "…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."

263. When making a decision, the decision-maker must comply with provisions which require providing for and recognising two principles, and taking into account a wide range of matters relevant to the purpose, including the application of the precautionary approach, and the principles of te Tiriti /the Treaty:
    - The principles relevant to the purpose of the HSNO Act are:
        - the safeguarding of the life-supporting capacity of air, water, soil, and ecosystems, and
        - the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing and for the reasonably foreseeable needs of future generations.

    - The matters relevant to the purpose of the HSNO 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, waahi tapu, valued flora and fauna, and other taonga
        - the economic and related benefits and costs of using a particular hazardous substance or new organism, and
        - New Zealand's international obligations.

Would this option deliver the identified policy objectives?

Enabling

264. Maintaining the status quo will not enable greater use of gene technologies to deliver better health, environmental, societal, cultural, and economic outcomes for New Zealanders.

265. The HSNO Act's purpose does not include any reference to enabling the use of gene technologies, nor do the two principles or six matters relevant to the purpose. As a result, the basis for a decision to authorise an activity is weighted towards a high level of caution to the degree that to date, only three GMO products, all medicines, have been approved for release in full in New Zealand.

Risk-proportionate

266. The status quo is not risk-proportionate. The basis for authorising an activity requires the applicants to demonstrate the benefits of the activity, which may not be known or are difficult to prove. The benefit of an activity is not tied to the risk that the activity presents, rather the benefit may be tied to market factors outside the applicant's control, the level of innovation or how novel the activity is. For example, a low-risk

activity with a novel use case may struggle to prove its benefits simply because they are unproven.

267. The regulatory burden of proving the benefits of an activity is unlikely to be evenly distributed, with applicants with greater resources (e.g., large firms) more able to provide information on the benefits of the activity compared to applicants with fewer resources (e.g., researcher). This outcome is not risk-proportionate because the level of resourcing of the applicant is also not tied to the level of risk of the activity.

Efficient

268. This option is not efficient. The basis for authorising an activity requires the regulator to consider a wide range of matters from public health and the intrinsic value of ecosystems to the economic and related costs and benefits of an activity. The wide breadth of considerations is a significant regulatory task, and when combined with the assessment of the benefits of an application it drives unnecessary cost and complexity for applicants. For example, benefits assessments can lead regulators to require applicants to prove benefits outweigh the risks. This increases the evidential burden on applicants and creates a practical problem, which is that benefits can be difficult to assess and challenging to compare to potential environmental or human health risks. This is a particular problem when benefits are uncertain or unproven, which is typically the case for innovative products, or subject to the success of the development itself or other market forces outside the applicant's control.

269. Assessing benefits also invites the regulator to make judgments about the appropriate distribution of benefits and risks that it is not well-placed to make – it is reasonable to assume that at least the applicant perceives a benefit in a new technology, because they are undertaking research or have developed the technology (often at significant financial risk) and made the application.

Future focused

270. The status quo may be unable to accommodate future technological and scientific developments because of the requirement to assess the "economic and related benefits" of an application. Each new technological or scientific development may result in a broad range of potential economic and related benefits.

Internationally aligned

271. The status quo is not aligned with comparable jurisdictions, including key markets such as Australia, England, and the proposed changes in the EU.

Rights and interests under the Treaty of Waitangi

272. The status quo requires the decision-maker to take into account the principles of te Tiriti / the Treaty and the relationship of Māori to, among other things, their taonga species. This is operationalised by the EPA considering advice from NKTT. This provides strong protection for Māori rights and interests.

Level of stakeholder support

273. Some stakeholders have indicated that the assessment of benefits generally should not be included in the scope of the regime because a decision could be 'leveraged'. However, for GMOs with significant impacts to New Zealand's economy, benefits should be considered if the activity is considered high risk and this assessment should be include whether the risks can be managed to an acceptable level.

274. The Industry Focus Group have expressed support for the assessment of benefits.

Impacts

275. Continuing with the status quo would result in:
    - For firms and researchers:
        - Continued regulatory burden on applicants to demonstrate the benefits of their proposed activity, despite the practical issues with this requirement including when the benefits are uncertain or unproven and not directly tied to the risks of the activity.
        - Continued low levels of applications and authorisations for the development and use of gene technologies.
        - Continuation of the dual-authorisation approach where a local authority can block an activity even if the regulator has authorised it.

    - For all government agencies involved in administering the regime:
        - No additional administrative cost to amend legislation, regulations, and processes.
        - Continuation of a complex and wide range of factors for consideration, which may become more complex over time as new gene technologies, activities, and GMO are developed.

    - For Māori:
        - Continued use of NKTT to engage with and influence the EPA's decision-making.
        - Continued provision for public consultation on applications, when required or provided for by the EPA.

    - For the organics sector:
        - No additional costs to what they currently bear to comply with national and international requirements.
        - Certainty of GE-free status for export products due to the effective ban on all environmental releases of GMOs.

    - For New Zealand generally:
        - Potentially missing out to positive economic, environmental, and health outcomes because the current basis for authorising an activity does not enable the development of gene technologies that could be used to promote health and advance New Zealand's economy.

Option Two [preferred option] – Assessing risks to health and the safety of people and the environment.

276. The regulator will base decisions about GMO activities on whether it is satisfied any risks to the health and safety of people and the environment can be managed to an acceptable level.

277. In contrast to the status quo, this option would allow researchers and firms to make their own assessment about the potential benefits from the gene technology application they are developing or selling – provided risks to the health and safety of people and the environment can be managed. It would also avoid the regulator having to predict how the gene technology / regulated organism could affect communities' intergenerational economic, social, and cultural wellbeing.

278. The regulator will develop a risk analysis framework to support its decision making, specifying a range of factors to be assessed in order to identify risks, their likelihood, and the consequences of potential harm (such as whether the GMO may be a pathogen or pest, whether the host or donor organism is native/indigenous, the GMO's expected effects and impact on health and safety of people and the environment, and potential for spread or persistence and provisions that would limit spread/persistence).

279. The regulator will also establish a technical committee responsible for advising the regulator on technical matters relating the gene technologies and the management of their risks. Further detail on the role of the Technical Advisory Committee is provided in Section E.

280. The regulator will establish a Māori Advisory Committee to advise the regulator whether Māori kaitiaki relationships with specific species (often translated as guardianship or stewardship) would be adversely affected by an application, along with potential mitigations. The Māori Advisory Committee will also issue engagement guidelines and provide advice to applicants and Māori on the application process. (Further detail on this aspect of the proposal was provided in Section A).

Would this option deliver the identified policy objectives?

Enabling

281. This option would be enabling. The narrower focus on risks to human health and safety and the environment will enable a consistent, evidential, and transparent approach to evaluating applications and making decisions. A focus on whether these risks can be managed will enable activities to be approved where there is evidence that the risks associated with them can be managed to an acceptable level. This is expected to deliver better outcomes for New Zealanders given it will free researchers and firms to develop applications using gene technologies and commercialise those for which there is a market and demand.

Risk-proportionate

282. This option would be risk-proportionate. A focus on managing risks means that the regulatory burden will scale alongside the level of risk in contrast to the status quo, where the regulator may require information that is not tied to the level or risk. For example, when making difficult to quantify assessments about the distribution of economic and related benefits against those risks.

Efficient

283. This option would be more efficient than the status quo. Simplifying the wide and complex range of considerations for the regulator to base a decision on will better enable the regulator to use its resources to assess the risks to human health and safety and the environment.

284. Removing the requirement for the regulator to consider the benefits of an application will increase the efficiency of the regime by simplifying the process and reducing the administrative burden on both the applicant and the regulator, including through clarifying the applicant's obligations.

Future focused

285. This option would be future focused. A narrower focus on the managing the risks to human health and the environment will free up capacity within the regulator, enabling them to respond flexibly to new developments.

Internationally aligned

286. This option would be internationally aligned. A focus on manging risks to human health and safety and the environment is in line with key partners such as Australia's Gene Technology Act, the first objective of the EU regulatory regime, and the Precision Breeding Act in England.

Rights and interests under the Treaty of Waitangi

287. The status quo may meet the obligations to actively protect Māori rights and interests under te Tiriti /the Treaty to a greater extent than this option because this option removes the requirement for the regulator to take into account the principles of te Tiriti /the Treaty when making decisions.

Level of stakeholder support

288. The TAG consider that the regulator should focus on the assessment of risk grounded in established scientific information rather than attempting to assess the benefits of new activities.

Impacts

289. The proposals in this option would result in:
    - For firms and researchers:
        - A simplified focus on risk will reduce the regulatory burden on applicants, reducing unnecessary cost and complexity, provide greater transparency and certainty of the basis for authorising an activity.
        - No requirement to demonstrate the benefits of an activity, which will simplify applications for novel, innovative activities where the benefits are uncertain or difficult to prove.
        - An enabling environment for applicants and implements a navigable, risk-proportionate process for approving applications.

    - For the organics sector:
        - The organics sector would be uniquely impacted by any eventual GMO release under a new regulatory regime. Currently, New Zealand organics exporters enjoy a de facto GE-free certification for their products. This sector currently certifies 'organics operators' which can enable access to certain markets. However, other primary industry sectors such as King Salmon also market product based on New Zealand's GE-free status.
        - In 2020, organics made up 0.74% of New Zealand's total exports and 0.87% of New Zealand's primary sector exports, returning $420.4 million NZD. New Zealand's organic market is focused on exports, and 58% of organic produce is exported. Of this, 80.9% goes to 5 markets: USA, China, Europe (excl. UK), Australia and Japan.
        - If New Zealand no longer has a de facto GE-free status, a new certification would be required for organics producers. Importantly, this certification will only be required if there is an economic incentive. Confidential

- For New Zealand generally:
  - Positive economic, environmental, and health outcomes resulting from increased safe use of gene technologies.
  - Increased activity across the entire innovation pipeline, from basic research to frontier innovation and through to commercialisation of intellectual property, products, and techniques.
  - Increased economic activity resulting from new market activity.

- For all government agencies involved in administering the HSNO Act:
  - Increased level of applications and assessments for genetic activities.
  - Reduced administrative burden associated with assessing complex set of factors to base an authorisation decision on.
  - The removal of the complex requirement to weigh up costs and benefits across multiple domains, instead prioritising risk management.
  - MFAT considers not requiring assessment of costs and benefits across multiple domains may create international trade risks for some of New Zealand's exports, such as where there are complex assurance processes for gene technologies in key markets. This concern is addressed in greater detail in Option Three.

Option Three – Assessing risks to health and the safety of people, the environment, and to trade and market access

290. Under this option, in addition to basing decisions to authorise activity on risks to human health and safety and the environment, the regulator would also assess whether there are any adverse impacts on trade and market access and to what extent these risks can be mitigated. The other factors to base a decision to authorise an activity on remain the same as under Option Two above.

291. The expected eventual release into the environment of some GMOs would involve potential risks for trade and market access because trading partners may not accept exports that have been 'contaminated' by GMOs, incidentally or otherwise.

292. This option is not preferred because considering market access and trade risks would complicate the assessment process and expand the regulatory scope beyond most international gene technology regulators.

293. Risks to existing trade and market access sit within the context of the potential benefits of gene technology / GMOs. A risk-only approach focuses on threats to existing producers without considering the opportunities offered by innovation. However, this would require the regulator to make a speculative economic judgement outside of its scientific expertise. The assessment would also create an avenue for opponents to GMO use to disrupt or prevent GMO applications beyond arguments based on risks to human health and safety and the environment.

294. We have considered and discounted Option Three because unintentional contamination and trade risks can be managed through the conditions and limits used to manage environmental risks. For example, existing conditions under the Resource Management Act 1991 (RMA) manage the risk of non-organic sprays drifting to organic farms by placing conditions on the user at time of spraying. New Zealand would also need to implement an assurance programme for organic products and develop supply chain separation programmes that prevent unintentional crossover. These tools are

used successfully internationally for GMOs, such as in Australia and North America, and are already used in New Zealand for the organics sector.

Would this option deliver the identified policy objectives?

Enabling

295. The changes proposed under this option that are also proposed under Option Two (focus on human health and safety and the environment, and the removal of local authorities power to restrict activities under the RMA) would be enabling. However, when balanced against the inclusion of the consideration of trade and market access this option will not be any more enabling than the status quo.

296. A requirement to assess trade and market access risks may add cost and complexity to the regulatory regime. The increased scope of the regulatory assessment will require the regulator to have additional expertise in trade and economics that are not focused on the primary objectives of the reform. Providing information to inform an assessment of trade risks will add regulatory burden to applicants, especially when the use case, benefits, and market rationale for an innovative, novel product or activity is uncertain.

Risk-proportionate

297. This option would not be risk proportionate. Including trade and market access assessments would place a larger regulatory burden on applications that are more commercially driven, regardless of the level of risk.

Efficient

298. The changes proposed under this option that are also proposed under Option Two would be more efficient than the status quo, however, this is balanced against a requirement that adds extra regulatory burden for the regulator and applicants. As a result, this option would less efficient than the status quo.

Future focused

299. This option would be future focused. It is non-prescriptive, flexible approach. A narrower focus on managing the risks to human health and the environment will free up capacity within the regulator, enabling them to respond flexibly to new developments. However, some of this extra capacity would be used to assess the trade and market assess considerations.

Internationally aligned

300. This option would be partially internationally aligned. The changes proposed under Option Two would be aligned with key trading partners, however, the requirement to assess trade and market access risks goes beyond the scope of most other international regulatory regimes. These risks are managed via other mechanisms managed outside the gene technology regulator, such as adherence to free trade agreements or through trade standards (for example ensuring exports meet requirements under the Agreement on the Application of Sanitary and Phytosanitary Measures and broader WTO trade standards).

301. Organic product export alignment with different markets will depend on the nature of the organic assurance programmes.

Rights and interests under the Treaty of Waitangi

302. This option would be as effective in protecting Māori rights and interests as Option Two.

Level of stakeholder support

303. Some stakeholders expressed support for including assessment of trade and market access risks in decision-making factors. This support is based on New Zealand's reliance on primary sector exports, the role market access plays in this, and the importance of New Zealand's default GE-free status. However, only one of New Zealand's top five goods export markets (South Korea) does not have a GMO regulatory regime and a history of environmental releases.

304. There was also support from industries that rely on non-GMO export certification, noting there is likely to be increased cost on exporters to verify this status once GMOs enter New Zealand's environment.

305. Officials agree that when GMOs are eventually released into the environment under the proposed regime, there will be additional costs to certify products as GMO-free. The costs associated with certification and any supply chain assurance programmes will vary depending on the sector and product.

306. Importantly, this certification will only be required if there is an economic incentive. It is expected that any additional costs to obtain this premium should be borne by those seeking to obtain value from it (i.e. non-GMO/organics producers).

307. MFAT supports this option, as it has concerns that risks, particularly in the agricultural sector, will arise due to the complex assurances processes for gene technology in key export markets, and the unpredictable nature of the international trading environment where gene technology has historically been controversial (including in New Zealand). To mitigate these risks to exports, MFAT considers the impact on New Zealand's trade and market access an important decision-making factor for the regulator. Alternatively, MFAT suggests these risks could be mitigated using a ministerial call-in power to consider nationally significant trade risks with respect to individual gene technology applications.

Impacts

308. The impacts of this option would be the same as Option Two, with the exception of the impacts discussed below:
    - For firms and researchers:
        - Increased regulatory burden for applicants (particularly for environmental release activities) to provide information on the trade and market risk aspects of their applications, which may be uncertain.
    - For all government agencies involved in administering the current regime:
        - Increased administrative burden associated with assessing complex trade and market access factors outside the typical scope of a gene technology regulator.
    - For the organics sector and other primary sector exporters:
        - The organics and primary export sectors' trade and market access interests would have to be considered by the regulator. This would likely weight decision-making about the environmental release of a given organism

towards how it would affect incumbent sectors rather than towards the potential for innovation and increases in productivity.

- For New Zealand generally:
  - Lower rate of commercialised gene technologies and activities (compared to Option Two) due to a disproportionate regulatory burden associated with providing information regarding trade considerations.

How do the options compare to the status quo/counterfactual?

0/neutral = no change; **+** = improvement; **-** = less than status quo

	Option One – *Status Quo*	Option Two – only assess risks to health and safety of people and the environment	Option Three – assess risks to trade and market access in addition to Option Two
Enabling	**0** Applications can be delayed, or rejected, due to the need to have multiple analyses and rationale in relation to a range of factors that may not be initially relevant to the technology development and application process (e.g. economic benefits)	**++** Will enable a nationally consistent, evidential, and transparent approach to evaluating applications and making decisions based on technical, scientific risk assessment	**0** Will constrain authorisation of safe use of gene technologies, particularly commercial activities and/or products
Risk-proportionate	**0** Not a risk-proportionate approach as it requires applications at all risk levels to demonstrate rationale against all factors	**++** Will require varying levels of evidence and assessment, proportionate to risk level	**+** Will place additional regulatory burden on commercially oriented applications
Efficient	**0** High level of evidence required from applicants prior to application, with potential for a long pre-application period	**++** Simplifies the process and reduces the administrative burden on applicants and the regulatory system	**+** Additional regulatory burden for commercially oriented applications and additional assessment scope for the regulator
Future-focused	**0** Some or limited ability for regulator to identify processes and capabilities requiring change in line with emerging trends	**+** Frees up regulatory capacity, enabling them to respond flexibly to new developments	**0** Some or limited ability for regulator to identify processes and capabilities requiring change in line with emerging trends

Internationally-aligned	**0** Not aligned to international regimes	**+** Aligned with regimes in Australia, Europe, and England	**-** Not aligned to international regimes
Rights and Interests under the Treaty of Waitangi	**0** Decision-makers are required to take into account the principles of te Tiriti o Waitangi/the Treaty of Waitangi and to consider the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga	**-** Provides less protection than the status quo given no requirement for the regulator to consider the principles of te Tiriti /the Treaty	**-** Provides less protection than the status quo given no requirement for the regulator to consider the principles of te Tiriti /the Treaty
Overall assessment	**0** Decision-making factors are complex and lead to a more cautious approach to the use of gene technologies	**++** Will enable more use of gene technologies and regulate their safety in a more risk-proportionate way, with a reduced regulatory burden	**+** Will enable more use of gene technologies and regulate their safety in a more risk-proportionate way, though with a lower reduction of regulatory burden

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

309. Option Two (preferred) will simplify the basis for a decision to authorise an activity to the extent to which the risks to the environment and the health and safety of people can be managed to an acceptable level. This option will enable safe use of GMOs across multiple applications, align our regulatory regime with key international partners, and create an efficient, transparent, and nationally consistent assessment process.

310. This option will simplify the assessment criteria for authorisations to reduce unnecessary cost and complexity for applicants. For example, by removing the requirement to weigh up cost and benefits across multiple domains, which invites the regulator to make judgments about the appropriate distribution of benefits and risks that it is not well-placed to make. Removing the assessment of benefits also reduces the evidentiary requirement for applicants, who would not need to attempt to prove the benefits of the activity, which can be difficult when the benefits are uncertain or unproven.

311. Under Option Two, legislation will authorise the regulator to establish a technical committee to ensure that the decision made by the regulator is informed by science and upholds the Crown's obligations to protecting Māori rights and interests. The regulator will be able to seek advice from other agencies, councils, expert advisors, and any other person it deems appropriate.

312. This option sets clear considerations for decisions made under the proposed Act. Officials consider that other risks (such as trade risks) posed by using GMOs are appropriately managed by other legislation or operative processes. Confidential advice

E. Assessments, decision-making and approvals

Option One – Status Quo

313. As already outlined, applications can either be assessed under a rapid assessment pathway (having met the criteria), under a non-notified assessment pathway, or under a full assessment pathway. Applications for a field trial, conditional release, or release of a GMO (except for medicines) are not eligible for a rapid, or non-notified assessment.

314. All applications involve a pre-application period, where an applicant informs the EPA of their intention to apply and provides a draft application for review. During this period, applicants may need to consult with relevant stakeholders, including Crown partners such as Māori. Significant pre-application interactions may incur an EPA charge.

315. In all assessment pathways, the EPA notifies the Department of Conservation and any department, Crown entity, agencies, or local authority that in the opinion of the EPA are likely to have an interest in the application.

Rapid assessments

316. When an activity subject to an application is deemed 'low-risk', the EPA may make a rapid assessment of the application. The criteria, specified in regulations, for whether an activity is deemed low-risk relates principally to the pathogenicity, virulence, or infectivity of the host organism and the modifications intended to be made.

317. Additionally, medicines that are, or contain, GMOs can also be rapidly assessed under HSNO if they meet the criteria of a 'qualifying organism'. After a rapid assessment, the EPA may approve the application, including deciding whether to attach conditions.

Full assessments

318. When an application does not meet the criteria for a rapid or non-notified assessment, the EPA undertakes a full assessment.

319. The decision on each assessment is made by a decision-making committee, appointed by the EPA under Clause 14 of Schedule 5 of the Crown Entities Act 2004. The EPA delegates the power to approve, decline, and to attach conditions to an approval to the decision-making committee. The three-person decision-making committee is drawn from a pool of potential members and conflicts of interests are identified before a committee is formed.

320. Applications would require the regulator to publicly notify of an application (i.e., publicly consult) and hold hearings.

321. After receipt of an application, the process for a full assessment involves:
    - public notification of the application, after which the public has 30 working days to lodge a submission on the application,
    - the EPA notifying any department, Crown entity, agency, or local authority that in the opinion of the EPA are likely to have an interest in the application,
    - the EPA having to assess the application and consider submissions, and recommendations from agencies and advisory committees, and draft a report,
    - a hearing, if requested by public submitters or the applicant, or the EPA considers it is necessary,

- the EPA notifies the decision-making committee pool, provides an overview of the application for the purposes of identifying conflicts of interest, and then forms a decision-making committee,
- the decision-making committee considers the application, and may seek advice from NKTT on matters relating to Māori rights and interests, and
- the decision-making committee or decision-maker may approve the application. The approval may or may not have conditions attached.

322. In making its decision under a full assessment pathway, the EPA must decline the application if the GMO activity would be unlikely to meet minimum standards, including causing significant displacement of any native species, causing significant deterioration of natural habitats, causing significant adverse effects on human health and safety, or causing significant adverse effect to New Zealand's inherent genetic diversity, or cause disease, be parasitic, or become a vector for human, animal, or plant disease, unless the purpose of that importation or release is to import or release an organism to cause disease, be a parasite, or a vector for disease.

323. When considering an application for the importation of a GMO or the environmental release of one, the EPA must also decline if the adverse effects of the organism, and any inseparable organism, outweigh the positive effects, or insufficient information is available to enable the EPA to assess the adverse effects of the organism.

324. The EPA must also have regard to the ability of the GMO to establish an undesirable self-sustaining population and the ease with which it could eradicated if it did so.

325. A further feature of the status quo is that the RMA allows regional councils, and territorial and unitary authorities to set restrictions on the use of GMOs under regional policy statements and plans. This results in a system where councils can restrict the use of GMOs despite being approved by the regulator and resulting in a regulatory regime that is not nationally consistent.

Would this option deliver the identified policy objectives?

Enabling

326. The current assessment and decision-making process could enable the use of gene technologies, though currently it is an effective ban. This is because many applications are not eligible for a rapid assessment and the process applicants ultimately must follow is long, time consuming and administrative heavy. This in turn translates in a low number of beneficial gene technologies being made available to New Zealanders during the time the current decision-making process has been in place.

Risk-proportionate

327. The status quo is not risk-proportionate and the HSNO Act is viewed as overly conservative.

Efficient

328. The status quo provides a less efficient regime, as an overly conservative approach to decision making has been adopted over time following judicial challenge. The previously cited High Court 'Scion case' judgement has possibly the greatest implications for the regulation of gene technologies under the status quo. As previously outlined, the High Court ruled the HSNO Act and regulations do not implicitly give the EPA discretionary power to add to the exemption list and ruled that the EPA could not expand the exemption list to include techniques like chemical mutagenesis. This has

resulted in a regime that cannot change to increase efficiency, for example by adding techniques that are indistinguishable from non-GMO processes to the exemption list.

Future focused

329. N/A

Internationally aligned

330. If we maintained the status quo, New Zealand would remain out of step with our major trading partners and other comparable jurisdictions.

Rights and interests under the Treaty of Waitangi

331. Maintaining the status quo would continue to support, but not fully provide for, active protection of Māori rights and interests under te Tiriti /the Treaty as it provides for Māori advisory input for all full assessments and requires the regulator to take into account the principles of te Tiriti /the Treaty. As noted in Section A, the Wai262 Waitangi Tribunal found that Māori values appeared to be subordinate to scientific considerations in decision making.

Level of stakeholder support

332. Stakeholders have indicated current approval processes are overly complex and often slow. Stakeholders dedicate a significant amount of resource (financial and time) to pre-application. As already noted, stakeholders have also expressed frustration that assessment pathways and processes do not adequately reflect the spectrum of risk that different GMOs pose.

333. Organics producers have expressed support for the status quo because it effectively prohibits environmental GMO release, which guarantees New Zealand GE-free export status. Environmental release also raises concerns from organics producers and the viticulture sector, including questions about who has responsibility for avoiding contamination.

Impacts

334. The status quo has developed a process for protecting Māori rights and interests. However, this has impacted and prolonged the pre application consultation process adding substantive time to prepare an application for regulator consideration.

335. The decision-making process for the status quo has had the following impacts:
    - For firms and researchers:
        - A prolonged application process requiring the applicant to dedicate substantive resource consulting with iwi and hapū.
    - For all government agencies involved in administering the current regime:
        - Certainty on agencies obligations under the current regime.

- For the organics sector:
  - Certainty for the organics sector under the current conservative regime.

- For society as a whole:
  - Potentially missing opportunities provided by gene technologies, particularly in the areas of human health and medical therapies and primary industries.

Option Two – Modified Australian processes: assessment, decision-making, approval process, and the removal of local restrictions under the RMA

336. Under this option we would adopt the current Australian process for assessments, decision-making and approvals, with two modifications: changing the Technical Advisory Committee's role in the assessment process and the addition of a Māori Advisory Committee.

337. Outlined below is the proposed assessment process for licences applied for through an expedited or full assessment pathway. Public consultation is a requirement for full assessments, whereas it is at the regulator's discretion to conduct a public consultation for an expedited assessment.

338. After receipt of an application, the process for expedited and full assessments would involve:
    - public notification of the application,
    - the regulator seeking advice from the Māori Advisory Committee on whether there might exist any kaitiaki relationship that might be affected by the proposed activity,
    - the regulator reviewing the application and preparing a risk analysis of the proposed activity, including a Risk Assessment and Risk Management Plan (RARMP),
    - the regulator seeking advice on the RARMP from the Technical Advisory Committee, and relevant agencies (including international regulators), and any other organisation or person necessary,
    - revision of the RARMP based on advice received if the regulator deems it necessary,
    - public consultation on the application and RARMP (for a minimum of 30 working days),
    - revision of the RARMP and any conditions based on public feedback, if deemed necessary by the regulator, and
    - decision by the regulator based on whether it is satisfied that the risks to the environment and health and safety of people can be managed.

339. The regulator would publish its decision (including any licence conditions), the finalised RARMP, and any submissions received.

340. As part of the regulator's assessments for licensed activities, it will take into account a number of factors to assess a GMO's potential risk to the environment and the health and safety of people. These factors will be tailored to the category assigned (Laboratory or Industrial, Medical Use, and Environmental Release), and will include whether the GMO is or could become a pathogen or pest, the effects or expected effects of the GMO, the potential of spread or persistence of the GMO, and the ability for potential risk management conditions to address these factors or risks.

341. Councils' powers to restrict GMOs will be removed to enable a nationally consistent scheme. Any local environmental risks from a particular GMO activity will be managed by the regulator through the risk management plans and conditions attached to individual licences. The regulator can seek input from relevant councils and agencies such as the Department of Conservation) to inform its decision making when an activity is likely to impact a particular region.

Modifications to the role of the Technical Advisory Committee

342. Under Australia's current licence assessment process, the Gene Technology Regulator is required to seek the advice from the Gene Technology Technical Advisory Committee (GTTAC) on an application that it has received ("application stage") and on that application's RARMP ("RARMP stage").

343. The modification would remove the requirement for the New Zealand regulator to seek the Technical Advisory Committee's advice on an application, before a RARMP has been prepared. In conversation with the Australian OGTR, the GTTAC has not identified any additional risks that the OGTR themselves weren't aware of at the application stage. This option retains the requirement for the regulator to seek the Technical Advisory Committee advice at the RARMP stage.

344. The primary function of the Technical Advisory Committee would be to provide scientific and technical advice at the regulator's request and will include technical information on gene technologies, organisms, GMOs, GM products and biosafety aspects of gene technology. The Technical Advisory Committee will also provide technical information for codes of practice, technical and procedural guidelines and assist the regulator with interpretation of research.

Establishing a Māori Advisory Committee

345. The consideration of Māori rights and interests would be incorporated into the assessment process. The regulator would seek advice from a non-binding Māori Advisory Committee.

346. The Māori Advisory Committee would advise the regulator on the existence of any kaitiaki relationship to species or places that may be adversely affected by the proposed GMO activity. This advice will be considered during decision-making and when considering controls and limits on any licences approved.

347. The Māori Advisory Committee may also advise the regulator who to consult with further when managing risks to kaitiaki relationships.

348. This option would be combined with Option Three to form a package.

Would this option deliver the identified policy objectives?

Enabling

349. This option would be significantly more enabling than the status quo (an effective ban). It's streamlined process would reduce barriers for applicants, facilitating greater numbers of applications.

Risk-proportionate

350. Decision-making under this option would include taking into account advice from a Technical Advisory Committee and a Māori Advisory committee, alongside a focus on

decision-making processes to manage risks to human health and the environment, which will result in a risk-proportionate regime.

Efficient

351. This option will be more efficient than the status quo because it will reduce the time applicants spend in the pre-application phase and simplifies the overall process for each pathway.

Future focused

352. N/A

Internationally aligned

353. This option is well aligned with the Australian regime and aligned with other key regimes, for example the UK and proposed EU regimes.

Rights and interests under the Treaty of Waitangi

354. By incorporating a Māori Advisory Committee into the assessment process, this approach enables the regulator to take into account adverse impacts on Māori rights and interests. It allows for the regulator to be fully informed about the concept of taonga, mātauranga Māori, and the classification and understanding of native flora and fauna when making a decision.

355. However, it would remove an existing pathway to locally restrict GMOs under the RMA through local authorities. This change may impact Māori influence in local resource management decision-making, including where a local authority has a joint management agreement in place with local Iwi or Hapū or where there is a Mana Whakahono a Rohe (a mechanism for councils and iwi to reach an agreement on ways tangata whenua may participate in RMA decision making). This is because these agreements would no longer be able to include discussions on restricting environmental releases of GMOs.

356. However, there is still scope to influence under the RMA. For example, if a fish was genetically modified, any restrictions or avenues for restriction on the original (or host) organism remain.

357. While this option would remove the requirement for decision-makers to take into account the principles of te Tiriti / the Treaty of, obligations under te Tiriti / the Treaty still apply.

358. Decisions will still need to take into account whether Māori kaitiaki relationships with specific species would be adversely affected by an application when making a decision, setting exemptions, or any other authorisation.

Level of stakeholder support

359. On the role of the Māori Advisory Committee, Māori partners have noted that a focus on kaitiaki relationships does not fully capture Māori rights and interests, such as benefit sharing and rangatiratanga over taonga species.

360. However, the focus on kaitiaki relationships is appropriate in a regulatory context because kaitiaki relationships can be proven and demonstrated while practical

mitigations could be developed in risk management plans. As discussed, this approach borrows from the recent PVR Act and approximately aligns to the gene technology recommendations in the Waitangi Tribunal's 2011 response to the Wai262 claim.

361. TPK have expressed concern that this option does not go far enough to provide scope for Māori to uphold kaitiaki relationships and directly benefit from gene technologies. Of particular concern is the proposed mandate of the Māori Advisory Committee. TPK would prefer that there is a requirement that the regulator, before making a decision, must agree with the Māori Advisory Committee a way forward regarding any detrimental impacts to the kaitiaki relationship and whether these can be mitigated.

Impacts

362. The modified Australian decision-making process provides an evidence-based and objective risk assessment and risk management regime, providing improved certainty to the applicant. The benefits are also realised for the regulator enabling surety in resource allocation and capability.

363. The decision-making process for the Australian modified option may have the following impacts:
    - For firms and researchers:
        - Certainty that any authorisation approved cannot be blocked by a regional authority under the RMA.
    - For all government agencies involved in administering the current regime:
        - Continuous improvement of the regulator's knowledge base through interactions with other regulators.
    - For local authorities:
        - Removal of decision-making powers regarding environmental releases of GMOs in their region.
    - For Māori:
        - Removal of influence in decision-making regarding environmental releases of GMOs in their region resulting in less protection for their rights and interests, particularly regarding the exercise of their kaitiaki relationship obligations.
    - For the organics sector:
        - A greater number of applications and GMO activity is anticipated.
        - removal of the ability to locally restrict activity using the RMA may result in GMO field trials near organic, GE-free producers.
    - For society as a whole:
        - Higher likelihood of innovative, new gene technologies being developed with the removal of the requirement to assess the benefits of an application.

Option Three (preferred) – Option Two plus interaction with domestic and international agencies and associated legislation

Option Three builds on Option Two through leveraging overseas expertise and streamlining interactions between domestic regulators.

364. The Industry Focus Group emphasised the need to streamline regulatory approvals to avoid some of the complex interactions with other regulators and legislation, including

any potential co-approvals between different regulators and different countries. To streamline the licensing and approval processes the regulator will be able to undertake joint assessment processes with other New Zealand regulators. The regulator will also leverage international expertise to accelerate assessments.

365. Stakeholders have indicated general support for using information from overseas regulators to assess risk and acknowledge New Zealand's unique ecosystem and environmental context and considered it important that the regulator can still take into account the New Zealand context during joint reviews and expedited assessments.

Joint assessments with other international gene technology regulators

366. The first proposed provision to leverage overseas expertise is adding the ability for the regulator to collaborate with other comparable overseas gene technology regulators when assessing licence applications. Joint assessments could be used for activities eligible for an expedited or full assessment under the environmental release and medical applications categories.

367. Joint assessments will enable applicants to apply for an environmental release or medical application licence under multiple jurisdictions simultaneously. Primary legislation would not set out how joint assessments would be carried out because these details may be dependent on the legislative requirements of international regulators.

368. However, in practice it is likely that a joint assessment would consist of parts of an application assessment being allocated to each member of the group of regulators. Regulators may also peer-review the assessment of other regulators. Joint assessments would inform the regulator's Risk Assessments and Risk Management Plans and would be completed prior to public consultation.

369. At the end of the joint assessment process each regulator would make its own independent decision on whether to issue a licence under its own legislative regime.

370. Joint assessment will require an enabling provision under primary legislation, such that the regulator could form joint assessment agreements with other regulators in advance of any joint assessments. However, the regulator would not be obligated to enter into agreements with international regulators, and may end an agreement, if it deems an international regulator does not offer the standard of assessment required.

Automatic authorisations for human medicines approved by 'recognised regulators'

371. The second proposed provision to leverage overseas expertise is the automatic authorisation of GM human medicines approved by two overseas 'recognised gene technology regulators'. Under the proposed legislation, the regulator would be enabled to recognise overseas gene technology regulators that:
    - assess GMO activities in a manner comparable to the New Zealand regulator, and
    - operate under a legislative framework comparable to the New Zealand gene technology legislation.

372. Once a human medicine (or treatment defined by Medsafe as a medical device) is approved by two 'recognised gene technology regulators' then that medicine could be automatically authorised under the New Zealand gene technology legislation. As now,

approval by Medsafe and/or the EPA (if the product is deemed a new organism under the HSNO Act) would still be required prior to any use in patients.

373. The automatic authorisation of the human medicine will be publicly notified along with any conditions. It will be at the regulator's discretion which conditions imposed by those recognised regulators are carried over to the New Zealand authorisation. The regulator may set extra conditions on the authorisation only if these conditions are, in the regulator's opinion, required to manage risks to the environment that are unique to New Zealand.

374. As opposed to GMO activities involving environmental release, this provision recognises that there is not the same need with GM human medicines to account for potential effects in the New Zealand environment.

375. Stakeholders stressed the importance of timeframes for medical approvals, noting that a lengthy assessment process would affect treatment accessibility and effectiveness. Automatic authorisations will create a mechanism to significantly increase the number of medicines and therapies available to New Zealanders.

Use of data and assessments from 'recognised gene technology regulators'

376. The third proposed provision to leverage overseas expertise is adding the ability for the regulator to make better use of data and assessments from regulators on the list of 'recognised gene technology regulators'. This provision would enable applications for GMO activities previously approved by 'recognised regulators' - specifically those regulators that publish data and assessment information – to go through an expedited assessment pathway, rather than a full assessment pathway.

377. This provision would be like the recently enacted 'recognised international regulators' provision under the HSNO Act, which enables better use of international data and assessments to expedite hazardous substance assessments.

378. These expedited assessments would not merely be a rubber-stamping exercise by the regulator. Rather, the provision would enable the better use of international data and assessments which the regulator would include in its overall assessment, including considering the New Zealand context.

Joint assessments with other New Zealand regulators

379. Analysis suggests that the key areas of potential overlap in applications between the gene technology regulator and other domestic regulators are:
    - medicines (Medsafe under the Medicines Act)
    - agricultural compounds and veterinary medicines (MPI under ACVM)
    - new organisms (EPA under the HSNO Act)
    - chemicals (EPA under the HSNO Act).

380. Under the status quo and all other options in this section, there are instances where a single approval (i.e. by the gene technology regulator) is not possible because each regulator assesses distinct risks to fulfil the purposes of their regimes that are outside the expertise of the others. For example, Medsafe assesses complex medical efficacy data to ensure patient safety that the gene technology regulator could not assess without significantly expanding its capability and capacity resource (and so increase duplication).

381. To streamline the licensing and approval processes under different pieces of legislation, it is proposed that there is a provision in primary gene technology legislation allowing for joint assessment processes to occur, to the extent possible. This will involve work between regulators to identify opportunities for alignment and streamlining. These could involve:
    - at application: alignment of common information requirements,
    - at assessment: information sharing between regulators; regulators taking ownership of different parts of a common assessment process and sharing results,
    - at decision: delegated decisions if there is complete (or very significant) overlap of assessed risks,
    - more broadly: alignment of timeframes and other processes where possible.

382. Proposed provisions include:
    - an ability for the regulator to enter into agreement with other domestic regulators, for the purposes of assessing an application,
    - an information-sharing power, which would allow regulators to share information in relation to applications, if authorised to do so by the applicant,
    - an ability to recognise the assessments of other domestic regulators,
    - a power to delegate decision-making on an application to another regulator where the risks are fully encompassed by another regulator (e.g. a gene technology that is a new organism),
    - an obligation to look more generally at where processes could be aligned between agencies to support streamlining of the assessment process.

383. Unless the decision is delegated to another regulator, the gene technology regulator will be the decision maker (approver) on the relevant application.

384. Provisions to support joint assessment processes would need to be made as consequential amendments to other regulators' primary legislation.

385. This option would be combined with Option Two to form a package.

Would this option deliver the identified policy objectives?

Enabling

386. This option would be enabling because it would streamline applications where possible, reducing a regulatory barrier where applicants are subject to duplicative assessment by multiple regulators. This option builds on the advantages of the previous option by extending the regulator's authority to access and consider international information.

Risk-proportionate

387. This option would allow the regulator to not only apply a risk-proportionate approach based on the legislation, but to also incorporate experience and knowledge from other regulatory regimes as well. The regulator remains the sole decision maker and can seek advice and consider assessments from other regulators.

Efficient

388. This option would be more efficient because it will reduce duplication of assessment where possible, will streamline the application process by sharing information between regulators where possible, and will reduce the regulatory burden on applicants

captured under multiple regimes. The applicant has the added flexibility of applying to more than one regulator in different jurisdictions at the same time.

Future focused

389. This option would be future-focused compared to the status quo and Option Two. The recognised regulator function enables New Zealanders to benefit from the expertise of comparable international regulators, the regulator to align and combine its knowledge with these regulators, encourages horizon scanning and provides a future focus on emerging gene technologies and their uses.

Internationally aligned

390. This option will be able to increase alignment with other regulatory regimes over time, by maintaining close and open communication and cooperation with those regimes. The recognised regulator function enables the regulator to align and combine its knowledge with international regulators.

Rights and interests under the Treaty of Waitangi

391. This option provides the same level of protect for Māori rights and interests as Option Two.

Level of stakeholder support

392. Industry stakeholders spoken to supported the use of joint assessments given their proven value in other regulatory regimes such as the ACVM Act and under the food standards system overseen by FSANZ. Researchers were supportive of the use of automatic approvals for human medicines, given the clear benefits and the reduced need to account for environmental risks given the route of administration of medicines and therapies.

393. The MoH supports parallel approval pathways to streamline decision making for medicines where both the gene technology regulator and medicines regulator (i.e., Medsafe) will have a role in the product's approval, and joint international assessments on gene technology applications, and reliance on international assessments and decisions. The MoH notes that there will need to be careful consideration of the differences in the nature of medicines assessment processes and how to operationalise efficient processes for information sharing.

Impacts

394. The modified Australian decision-making process provides an evidence-based and objective risk assessment and risk management regime, providing improved certainty to the applicant and improved certainty to the research community, therefore encouraging investment in New Zealand's primary industries. New Zealand applicants will capitalise on the assessments and research carried out in other jurisdictions with faster application processes. Authorisations in the medical use category would be able to proceed quickly. The regulator will be fit for purpose and focussed on global trends and emerging technologies.

395. This option is expected to have the following impacts:
    - For firms and researchers:
        - Ability for researchers and firms to operate globally and submit applications to regulators in more than one jurisdiction. Joint assessments will enable efficiencies for the regulator and improved certainty for the applicant.

    - For all government agencies involved in administering the current regime:

- The regulator will notify agencies of applications received and decisions made. The regulator can seek information from domestic and international regulators, improving the regulator's knowledge base and enabling alignment with international regulators.

- For Māori:
  - The impacts for this option would be the same as for Option Two.

- For society as a whole:
  - The regulator will acquire a global and future-focussed function, identifying opportunities and risk management approaches for consideration in a New Zealand context. The human health and medical therapy area is positioned to benefit from the automatic authorisations function enabling society ready access to GM therapies in New Zealand.

How do the options compare to the status quo/counterfactual?

0/neutral = no change; **+** = improvement; **-** = less than status quo

	Option One – *Status Quo*	**Option Two – *Modified Australian process***	**Option Three – *Interaction with other legislation***
Enabling	**0** The current regime can enable gene technologies, however, in many cases it acts as an effective ban.	**++** More enabling than the status quo.	**++** Reduced regulatory barriers.
Risk-proportionate	**0** The assessment and decision-making processes are viewed as overly conservative and not risk proportionate.	**++** More risk-proportionate process focusing on risks to human health and the environment.	**++** Ability to easily learn from other jurisdictions and flexibly adapt risk approach in New Zealand's regime.
Efficient	**0** The regulator's inability to add to the exemption list creates significant inefficiency.	**+** Reduced pre-application process and a streamlined application phase.	**++** Streamlined application process, reduced administrative burden.
Future-focused	**0** N/A	**0** N/A	**++** Ability to easily learn from other jurisdictions and their experiences.
Internationally-aligned	**0** The status quo is not aligned with our major trading partners and	**+** This option is well aligned with the Australian regime it is based on and is aligned	**++** This option is well aligned with the Australian regime it is based on and will maintain and increase

	other comparable jurisdictions.	with other international regimes.	alignment with other jurisdictions over time.
Rights and interests under the Treaty of Waitangi	**0** The decision-making process incorporates Māori perspectives through advice from NKTT. An additional avenue for Māori to protect their rights and interests is provided under the RMA.	**-** Decisions will need to take into account whether kaitiaki relationships are adversely affected, but not Treaty principles. Iwi, Hapū, and Māori organisations will no longer be able to engage with local authorities on the local release of GMOs.	**-** Decisions will need to take into account whether kaitiaki relationships are adversely affected, but not Treaty principles. Iwi, Hapū, and Māori organisations will no longer be able to engage with local authorities on the local release of GMOs.
Overall assessment	**0**	**+**	**++**

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

396. Based on our analysis, Option Three is the best option. This option will create administrative processes that are tailored to each authorisation type requiring a decision, resulting in assessment efforts proportionate to the risks associated with the activity.

397. The preferred option, in line with the proposed authorisation requirements, replaces the current conservative, expensive, and slow administrative process to make decisions on applications to use GMOs. This option will only require a decision (and therefore a decision-making process) for licensed activities. The preferred option dedicates regulator resource to decisions on applications which pose a risk to the health and safety of people and the environment.

398. Our preferred option will embed flexibility into the decision-making process to give the regulator control over the level of technical, cultural, and public consultation required for each application. It will provide the regulator with the ability to determine risks and assess how they are managed. This option will improve clarity for stakeholders on the application process and make administrative complexity and cost more proportionate to the decision that is being made.

399. This option enables the regulator to work with other regulators to reduce regulatory burden and streamline assessments and application processes. It also enables the regulator to learn from other regulators and jurisdictions by facilitating cooperation and communication, which will increase the risk-proportionate nature of the regime and enable it to be future focused by incorporating other regulators' experience.

F. Decision-making authority

400. The authority to decide an application is provided for in primary legislation, including the form of the decision-maker (committee or single statutory decision-maker), and what role and powers (if any) a minister has and in what circumstances.

401. This section covers the form of the decision-maker and options for ministerial intervention in decision making.

Option 1 – Committee-based decision making, with ministerial call-in power (Status quo)

402. Under the HSNO Act, the EPA can appoint committees and subcommittees, and can delegate powers and functions relating to assessing and deciding on applications to those committees.[44] Except for applications for low-risk genetic modifications that meet certain legislative criteria[45], decisions on GMO applications are made by its HSNO Committee. It considers and makes decisions on applications, via sub-committees of two to three members, who decide by resolution to either approve, approve with conditions, or decline to authorise the application.

403. Committee members are appointed with the approval of the Environment Minister as minister responsible for administering the HSNO Act and the Environmental Protection Authority Act 2011. The HSNO Committee is chaired by an EPA board member, and its members have scientific, legal, decision-making and mātauranga Māori expertise in various relevant fields. There are currently 15 HSNO Committee members (including a chairperson), plus an attendee from NKTT.

404. As outlined earlier, NKTT is the EPA's statutory Māori advisory committee, and its members are appointed by the EPA board. it provides the EPA with advice and assists it on matters relating to policy, process, and decisions under the EPA's various Acts. NKTT has the discretion to review applications and provide advice. Applications are not automatically sent to NKTT. NKTT only provides advice when requested by staff or when the HSNO Committee or other decision maker requests advice from NKTT.

405. Additional expert advice and submissions from the public may also inform the decision on the application.[46]

Ministerial call-in power under HSNO

406. The HSNO Act provides for the responsible minister to direct that they will decide an application under the Act ("call-in power" [47]) if the minister considers that the decision on the application will have:

    - significant cultural, economic, environmental, ethical, health, international, or spiritual effects; or

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44 See sections 18 and 19 respectively.

45 See Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003 (SR 2003/152) (as at 01 September 2005); these decisions can be made by EPA's General Manager HSNO.

46 See Section E of the RIS - Assessments, decision-making, and approvals.

47 Sections 68-73

- significant effects in an area in which the EPA lacks sufficient knowledge or experience.

407. Among several requirements, the minister must provide their reasons for calling in the application and their reasons for approving or declining the application. This call-in power has never been used.

Would this option deliver the identified policy objectives?

Enabling

408. Under the status quo, the regulator ensures that gene technologies used are safe, however, the current regime is not enabling and very few authorisations are made. However, it is unclear whether or how the fact that decisions are predominantly made by committees influences that fact. We understand it is mainly the complex decision-making factors under HSNO in combination with over-regulation and court decisions that stirred EPA to a conservative approach towards the introduction of more gene technologies in New Zealand.

409. A call-in power would continue to be available on a case-by-case basis for applications that have significant effects. The effects of this power are dependent on the minister's beliefs and appetite to drive change in gene technology.

410. As the threshold for "significant" has not been tested and the effects covered are quite broad it could mean more applications for environmental release and field testing being approved. It could also mean an increased number of applications pulled into the ministerial purview, so the regulator would get a strong steer on acceptable levels of risk. The result could be a somewhat more enabling regime.

411. On the other hand, with such a broad call-in power available, a minister who does not have an appetite to drive change or has certain ideological beliefs or perspectives on the science could block approvals and ensure environmental releases or field testing of GMOs are not allowed in New Zealand. Therefore, the current call-in power neither enables nor hinders safe use of gene technology, rather the views of the person exercising it would determine the effect.

Risk-proportionate

412. It is unclear whether committee-based decision making has any influence in proportionately managing risks to the environment and the health and safety of people and communities. So far, the relevant EPA committees have applied the complex HSNO decision-making framework, which is not based on risk management principles, resulting in the successful protection of the health and safety of New Zealanders on one hand and hindering widespread introduction of gene technology on the other. This is because the regime itself is not risk proportionate, as for example it over-regulates low-risk gene technologies and unduly restricts field testing of regulated organisms.

413. It is difficult to assess whether a ministerial decision via the call-in power would be risk-proportionate because it would depend on the application, the rationale for intervention, and the decision made.

Efficient

414. The research community who apply for approvals view the current decision-making process as slow and inefficient. However, our understanding is that a key factor is the underlying regime that is making the process slow and inefficient, not just the fact that decisions are made by committees. Therefore, the current committee decision-making process in itself cannot be credibly assessed as efficient or inefficient, including around certainty and predictability of obligations and rights. That said, the most obvious disadvantage of the decision-by-committee approach is that it entails more discussion, which means it can take longer to arrive at an agreement.

415. The minister's call-in power up until this point has had no bearing on the efficiency of the regime as it has never been used. The potential of the power being used in the future creates regulatory uncertainty for applicants as the current scope for ministerial intervention is wide, the way it will be applied is untested and the results are unpredictable and dependent on the minister's views and inclinations.

Future focused

416. The regulator's ability to accommodate new developments is tied to the HSNO Act's provisions and the way courts have interpreted these.[48] The committee members' continuous professional development could have some bearing on how adaptable the regime is to new technological developments and applications, knowledge, understanding, and policy changes. However, it is the current HSNO legislation that is rigid as definitions do not encompass modern gene technologies, and it is not readily adaptable to emerging technologies. The minister's call-in power could theoretically be used to future proof the status quo if it was exercised in a way that considered new technological developments and applications, knowledge, understanding, and policy changes that the HSNO regulatory regime does not allow for.

Internationally aligned

417. Australia's gene technology regulator does not use a committee for decision making, having instead a single statutory officer as decision maker. The statutory officer is supported with technical advice by the Gene Technology Technical Advisory Committee. Given Australia's federal system, the activities of the regulator are governed by a Gene Technology Ministers' Meeting (comprising federal, state and territory ministers with relevant portfolios).

418. In the Australian regime, a minister can make an emergency authorisation under specific circumstances. However, there is no equivalent call-in power in the Australian, UK, or proposed EU regimes.

Rights and interests under the Treaty of Waitangi

419. The status quo provides a measure of protection of Māori rights and interests because the decision maker must take into account the principles of the Treaty of Waitangi and has access to advice from NKTT. While NKTT does not represent all Māori voices, it does provide a consistent opportunity for Māori perspectives to be considered during

[48] E.g. the earlier-cited Scion case.

the decision-making process. However, there is a risk that seeking advice from NKTT is considered the same as engaging with Treaty partners, which is not accurate[49].

420. In practice, the protection of Māori rights and interests under the status quo is not predominately reliant on NKTT's advice but mostly on the wide range of factors the regulator has to take into account when deciding on an application, the lengthy engagement required during the pre-application process and the wide range of techniques captured by the HSNO regime.

421. The Ministerial call-in power may be used to override rights and interests under te Tiriti o Waitangi / the Treaty of Waitangi. However, the inverse may also be true, and a minister may prioritise the protection of rights and interests under te Tiriti / the Treaty over the benefits the safe use of gene technology might have for all New Zealanders.

Level of stakeholder support

422. Applicants under the current regime for new organisms, including GMOs, have indicated dissatisfaction with the timeliness of EPA's decisions. However we understand that applicants are cognisant of the fact the delays are due the HSNO regime's provisions and not because of the committee-based decision-making approach per se.

Impacts

423. Continuing with a committee-based decision-making process with a broad ministerial call-in power is expected to have the following impacts.
    - For firms and researchers:
        - Retaining a committee decision-making process does not have any significantly positive or negative impact on stakeholders. This is because the committee process itself cannot directly be connected with any of the root causes of the problems and missed opportunities under the current regime.
        - Continuing with a broad call-in power would not align with the narrow decision-making factors the regime proposes to introduce and could indicate low confidence that the proposed changes will achieve the stated objectives without ministerial intervention.
        - It also undermines the regime's objective to be efficient, in the sense that it retains an element of unpredictability and uncertainty.

    - For government agencies:
        - Depending on whether and how it will be used, the broad call-in power could impact MPI's monitoring and enforcement functions (we propose that these are broadly carried over from HSNO). For example a minister could use it to approve a higher number of applications than the regulator would but with conditions that require significant resources for monitoring purposes.

    - For the organics sector:
        - Given the organics sector will be adversely impacted due to escalating certification costs when New Zealand is no longer GMO-free, the call-in

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49 How the EPA incorporates the principles of the Treaty of Waitangi into its regulatory practice (para 35) – The Productivity Commission, accessed from The Treasury.

power might provide an avenue for the sector to lobby the minister responsible for the gene technologies regime.

- For society as a whole:
  - Potential confusion regarding when the regulator is in charge and when the minister may influence or make decisions.
  - Equally, there may be comfort from the public that elected representatives (rather than an unelected statutory officer) can call-in decisions.
  - Could be seen as an opportunity for various lobbies with differing agendas to influence decision making regarding gene technologies and products.

Option Two – Statutory officer as decision maker advised by a technical and a Māori committee (preferred option)

424. Many regulatory regimes feature a statutory officer as the decision maker. This is the case for the Australian equivalent gene technology regime; and for regimes with comparable functions and powers in New Zealand (e.g. radiation safety, plant variety rights).

425. Under this option, primary legislation would establish a statutory officer as having the functions, powers, and duties to make authorisation decisions under the new regime. The statutory officer would exercise their functions and powers as regulator independently of the Chief Executive and the Minister and would be accountable for their statutory decisions.

426. The statutory officer would have access to, and in some cases would be required to consider, expert advice (via a technical advisory committee and a Māori advisory committee) and public input in line with the risk level of the decision the statutory officer is called to make.

427. The statutory officer could be appointed either by the chief executive of the agency within which the regulator is located or the minister responsible for the new regime. The statutory officer would be (or become) an employee of the host organisation (Section G sets out these options). The statutory officer would be accountable to the chief executive for the performance of their functions and duties and exercise of their powers.

428. Under this option, there would be no ministerial call-in power, making the regulator the sole decision maker.

Would this option deliver the identified policy objectives?

Enabling

429. Decision making by a statutory officer receiving advice from technical and Māori committees cannot be deemed as either enabling or hindering the increased use of safe gene technologies in isolation from the underlying legislative and regulatory framework. Therefore, enabling decisions are mainly dependant on the decision-making factors and to a lesser degree on the statutory officer's appropriate exercise of decision making in conjunction with committee advice received.

430. Nonetheless, the fact that the Māori committee will continue to have an advisory role the same way the NKTT has under the current regime could be enabling. This is because the new decision-making framework based on risk management and the

proposed de-regulation of certain activities in combination with the absence of decision power from a Māori committee could enable the introduction and ultimately the use of more gene technologies.

Risk-proportionate

431. The fact that decisions on applications will be made by a statutory officer advised by a technical and a Māori committee does not influence the risk proportionality of the actual decisions. The risk proportionality of this regime is based to a large degree on de-regulating certain activities and reducing the regulatory requirements for those that are very low or low risk, therefore removing from the application process many activities and resulting organisms.

432. Furthermore, whether the decisions of the statutory officer and the underlying advice they receive are risk proportionate is mostly dependent on the legislative and regulatory provisions they are based on, the knowledge and expertise of the decision maker and committee members and their idiosyncrasy. Single decision makers could be more risk averse as they are solely accountable for their decisions. In this instance this risk is mitigated by the fact that the statutory officer can or must take under consideration the advice of committees.

Efficient

433. The major disadvantage of committee decision making is the additional time needed to reach agreement compared to a single decision maker. This option provides for decisions made by a statutory officer, who with appropriate expertise and operating effectively could speed up the process. However, under this option the statutory officer may or must consider the advice of advisory committees, which could result in the same disadvantage.

434. Regarding the certainty and predictability aspect of decision making, this is mainly dependent on the underlying rules providing certainty and predictability of outcomes if the applicants follow them and not on the decision being made by a single or a cohort of decision makers.

435. The absence of a call-in power removes the unpredictability of ministerial involvement in decision making and therefore increases certainty of process. It also strengthens the regime's design principles, which are based on scientific knowledge and not factoring in elements that are unrelated to the risks gene technologies pose on human health and safety, and the environment.

Future focused

436. Choosing a statutory officer advised by committees to be the decision maker does not influence whether the regime allows for adaptation to new technological developments and applications, knowledge, understanding and policy changes.

437. Regardless of using best design principles, no regime can be fully future proof and flexible to accommodate all scientific progress. A minister's call-in power could theoretically be used to allow for factoring in new applications and scientific advancements that the provisions of the regime have excluded based on knowledge available at the time it was put in place.

Internationally aligned

438. A statutory officer decision maker is comparable to Australia's gene technology regulator, who have communicated to officials that this works well in their 20-year experience.

439. In the EU, decisions are made by member states through the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee). In the UK there is a single decision maker supported by an advisory committee.

Rights and interests under the Treaty of Waitangi

440. As outlined, providing for a Māori committee with advisory and not veto or decision-making powers in theory limits the extent to which legislation will protect Māori rights and interests under the te Tiriti o Waitangi / the Treaty of Waitangi.

Level of stakeholder support

441. Agencies have indicated a clear independence from ministerial influence would support the public perception of a regulator being science-based and technically focused.

442. TPK have registered concerns that this option does not go far enough to provide scope for Māori to uphold kaitiaki relationships and directly benefit from the reforms. Of particular concern is the proposed mandate of the Māori Advisory Committee as providing non-binding advice.

443. MFAT is supportive of a ministerial call-in power, to mitigate and consider nationally significant trade risks with respect to individual gene technology applications.

Impacts

444. Decision making by a statutory officer supported by technical and Māori advisory committees can only have a marginal positive or negative impact on stakeholders. This is because who is making the decisions (one person versus a committee) cannot directly be connected with any of the root causes of the problems and missed opportunities under the current regime.

445. The fact that the decision maker will not be bound by the advice of the Māori advisory committee could be interpreted as negatively impacting Māori interests. However, this is already the case under the status quo, where the regulator is not bound by the advice of NKTT. Any adverse impact on Māori rights and interests would stem from the change in decision making considerations and pre-application processes, as well as the deregulation of certain gene technologies.

446. The absence of a call-in power or other form of direct ministerial policy direction would send a strong signal that the legislative and executive branch of the government are confident that the proposed gene technology regime is able to deliver the desired outcomes leading to long-term impacts as depicted in the logic map.[50]

[50] See page 32.

Options that can be combined with Option Two

447. We have considered and analysed the potential impacts of a ministerial call-in power and a general policy direction power on a new gene technology regime. One or both powers could be combined with Option Two.

Option Three – Provide for Ministerial call-in power

448. Under this option, there would be a similar ministerial call-in power provision as in the HSNO Act enabling the responsible minister to decide on an application if the minister considers that the application would have nationally significant effects on the environment or human health and safety.

449. The regulator could also proactively provide applications to the Minister that may require ministerial consideration via the call-in power, with the Minister having discretion to use the power. The Minister would have to justify calling in the application and the basis for approving or declining an application.

450. In comparison to the wide range of instances the minister's call-in power could be exercised under HSNO Act this is a narrower approach given that the minister can use the call-in power for nationally significant applications, but any decision needs to apply the core decision making factors of the new gene technologies regime, i.e. impacts to human health and safety and the environment.

Would this option deliver the identified policy objectives?

Enabling

451. The potential for the minister to call in the regulator's decisions does not in itself enable increased use of safe gene technologies to deliver better outcomes for New Zealanders. Depending on the views of the minister of the day and the Government's objectives, the power could be used to enable or slow down the introduction of more gene technologies and products in New Zealand.

Risk-proportionate

452. The provision for a minister's call-in power has no bearing on managing health and safety, as well as environmental risks posed by gene technologies in a proportionate manner. What can impact the risk tolerance levels of the regime is the way the call-in power is exercised by the minister of the day.

453. A minister could use the call-in power to either raise or lower the overall risk tolerance of the regime, by declining applications that might have been deemed to proportionately manage risk or by approving applications where the regulator might have been hesitant that the risks to human health and safety and the environment could be safely managed.

Efficient

454. A minister's call-in power could undermine the regime's efficiency by adding an element of uncertainty. This is because the call-in power can be exercised in an unpredictable manner, capture an unknown number of applications, and be used to override one of the core objectives of the regime (enabling) to make it more restrictive, or equally override a conservative regulator depending on the values, and objectives of the minister and Government of the day.

Future focused

455. The fact that there is provision for a minister's call-in power does not allow for adaptation to new technological developments and applications, knowledge, understanding, and policy changes per se. That said if the regime at some point becomes outdated a minister could use it to approve applications based on new knowledge and technological developments.

Internationally aligned

456. There is no equivalent call-in power in the Australian, UK, or proposed EU regimes.

Rights and interests under the Treaty of Waitangi

457. The ministerial call-in power could potentially be used to signal that protection of Māori rights and interests cannot override the core objective of the regime, which is to enable the safe introduction of more gene technologies in New Zealand. Conversely it could be used to signal that protection of Māori rights and interest should be given priority consideration. This creates uncertainty and may not ensure appropriate protection of Māori rights and interests under te Tiriti o Waitangi / the Treaty of Waitangi.

Level of stakeholder support

458. The majority of agencies MBIE consulted on the proposed regime have indicated that the ability for ministerial influence would likely take away from a public perception of the regulator as being independent, science-based and technically focussed. However, MFAT is supportive of a ministerial call-in power, to mitigate and consider nationally significant trade risks with respect to individual gene technology applications. It is not proposed that the minister will be able to make decisions based on any factors other than human health and safety and the environment.

Impacts

459. Providing for a ministerial call-in power would likely result in the following impacts.
    - For firms and researchers
        - A minister's call-in power undermines regulatory certainty, which is one of the cornerstones for innovation and investment. Researchers and firms need regulatory certainty to base decisions on where they should invest their time, effort, and financial capital. The new gene technology regime is designed with that certainty in mind. Firms and researchers will not have to apply for authorisation to undertake very low and low risk activities. For higher-risk activities captured by the regime, a licence will be required, and licensing processes will intensify in proportion to potential risk.
        - A ministerial call-in power may over time result in unpredictable outcomes.
    - For government agencies
        - Depending on the decisions (e.g. a minister approves an increased number of environmental releases) it could have flow on effects on monitoring and enforcement functions of the regime as well decisions that touch upon the domain of other agencies (e.g. MedSafe).
    - For the organics sector
        - It opens an avenue to influence the minister's decision making to include conditions imposed to limit applications that if approved could negatively impact the sector's interests.

- For society as a whole
    - Potential confusion regarding when the regulator is in charge and when the Minister may influence or make decisions.
    - Equally, there may be comfort from the public that elected representatives (rather than an unelected statutory officer) can call in decisions.
    - Could be seen as an opportunity for various lobbies with differing agendas to influence decision making regarding gene technologies and products.

Option Four – General Policy Direction power

460. Under this option there will be provision for a general policy direction power, whereby the regulator is subject to general policy directions issued by the Minister. The general policy directions must not be inconsistent with the Act, regulations, or other legislative instruments.

461. A general policy direction is used in other regulatory regimes such as in the Biosecurity Act, where the Minister must make a national policy direction as a way of providing leadership. Ways the general policy direction could be used include:
    - Influencing the assessment process by providing direction on risk tolerance (the level of risk at which an application should be approved).
    - Providing specific guidance on how the scope of environmental and human health risks should be interpreted.
    - Setting binding operational expectations, such as approval timeframes (e.g. achieving a certain percentage of approvals within a percentage of the statutory maximum, and consultation requirements prior to application).
    - Requiring the regulator to make greater use of discretionary powers (e.g. joint assessment provisions).

Would this option deliver the identified policy objectives?

Enabling

462. Depending on the minister's objectives and the overarching aims of the Government of the day, ministerial direction via a general policy power could be used either to promote elements of the scheme that will lead to more gene technologies being available in New Zealand or to support a more conservative approach.

Risk-proportionate

463. As per above ministerial direction could be used to shift the balance and either ensure the regulator's decisions are risk proportionate in accordance with scientific evidence or to steer the regulator towards a more conservative approach.

Efficient

464. As discussed in regard to a call-in power, allowing for ministerial influence via general policy directions would introduce an element of uncertainty into the regulatory decision-making process, albeit to a lesser degree as in this instance a minister cannot completely override the regulator.

Future focused

465. Ministerial direction could in theory be used to ensure that new technologies and developments are properly assessed and integrated into the risk tolerance of the new regime in instances that the regulator is tending towards conservative application of the Gene Technology Act.

Internationally aligned

466. The Australian regime provides for ministerial direction via the gene technology ministerial council (the grouping of federal, state and territory ministers with relevant portfolios) issuing policy principles for a very narrow area. In particular, the ministerial council can only issue policy principles in relation to ethical issues or recognising areas designated under State law for the purposes of preserving the identity of GMO or non-GMO crops.

Rights and interests under the Treaty of Waitangi

467. General policy direction provisions could be used to increase or decrease the weight given to Māori rights and interests by the regulator, such as through assigning more or less weight to the advice of the Māori Advisory Committee. This approach would create uncertainty and may impact on appropriate protection of Māori rights and interests.

Level of stakeholder support

468. As for Option Three, agency feedback is that the ability for ministerial influence would likely take away from a public perception of the regulator as being independent, science-based, and technically focussed.

Impacts

469. Providing for the minister to be able to influence the regulator through general policy directions would likely result in the following impacts.
    - For firms and researchers
        - For a new regime which has as its main objective to safely introduce more gene technologies in New Zealand, a general policy direction could be used to give the regime an initial push to that direction.
        - It does also introduce an element of uncertainty for the future (even if it is to a lesser degree compared to a minister's call-in power).

    - For government agencies
        - Depending on how it is used to steer the regulator's approach (e.g. direction to approve more applications for field testing more quickly but to impose strict conditions) it could have flow on effects on monitoring and enforcement functions as well as on assessments that need collaboration with other agencies.

    - For the organics sector
        - It opens an avenue to influence decision making and conditions on applications that if approved could negatively impact the sector's interests.

    - For society as a whole
        - Potential confusion regarding when the regulator is in charge and when the minister may influence or make decisions.
        - Equally, there may be comfort from the public that elected representatives (rather than an unelected regulator) can influence decisions.
        - Could be seen as an opportunity for various interests to influence decision making regarding gene technologies and products.

How do the options compare to the status quo/counterfactual?

0/neutral = no change; **+** = improvement; **-** = less than status quo

	Option One – *Committee-based decision making, with Ministerial call-in power [Status Quo]*	**Option Two – Statutory officer as decision maker, advised by technical and Māori advisory committees**	**Option Three (combined with Option Two) – *Ministerial call-in power***	**Option Four (Combined with Option Two) – *General policy direction power***
Enabling	**0** Committee decision making in neither enabling nor blocking the safe use of gene technologies. The minister's call-in power could be used in either direction.	**+** A statutory officer (advised by committees) as decision-maker is likely to be as enabling as a committee. Decisions are mostly dependant on the legislation and regulations underpinning the regime, which in this instance is designed to be enabling.	**0** The call-in power could be used to make the regime more enabling or block new gene technologies.	**0** Ministerial direction could be used to make the regime more enabling or slow down the introduction of new gene technologies.
Risk-proportionate	**0** The underlying regime and not the committee decision making determines the risk-proportionality of decisions. The minister's call-in power could be used in either direction.	**+** Single decision makers could be more risk averse. However because the regime provides for the support of advisory committees this is mitigated. No call-in power available that could skew risk tolerance.	**0** The call-in power could be used to influence the regulator's approach to risk to either keep it proportionate or make it more conservative.	**0** Ministerial direction could be used to influence the regulator's approach around risk to either keep it proportionate or make it more conservative.
Efficient	**0** One of the main disadvantages of committee-based decisions is potentially	**++** Single decision maker could operate faster than a decision-making	**0** The call-in power creates uncertainty.	**0** Depending on the views and objectives of the minister and Government of

	lengthy timeframes. The call-in power creates uncertainty.	committee but taking time to receive and consider advice from committees could negate this. No call-in power removes uncertainty in process.		the day, general policy directions could result in more efficient operation of the regulator especially regarding timeframes for decision making. However, they could also result in a more conservative regime than intended, creating uncertainty for applicants.
Future-focused	**0** Continuous professional development and appropriate capabilities in committee members could be seen as supporting the introduction of new knowledge and applications, however it is the underlying regime that has the most influence. Call-in power could be used to override a regime fixed in time.	**0** Whether the decisions of the statutory officer are keeping up with scientific advancements depends partly on their continuous professional development but is also supported by an effective technical advisory committee of experts.	**0** Call-in power could be used to override a regime fixed in time as per the status quo.	**0** A ministerial policy direction could be used to support the regime flexibly accommodating new developments and technologies.
Internationally-aligned	**0** Some alignment regarding the use of decision-making committees. Call-in power is not found in gene regimes of our major trading partners.	**++** The Australian regime relies on a statutory officer for decision making while the EU uses committees. An absence of call-in power aligns New Zealand with the gene tech	**-** Does not align with key international regimes.	**-** Does not align with key international regimes.

		regimes of our major trading partners regarding.		
Rights and Interests under the Treaty of Waitangi	**0** NKTT has advisory role. Broad decision-making factors and EPA approach to date allows for consideration and protection of Māori rights and interests.	**0** A statutory officer as decision-maker is as able as a committee to protect Māori rights and interests. The Māori committee will have an advisory and not a veto or decision-making role, as per the status quo.	- Call-in power could be used to discount the advice of the Māori Advisory Committee or strengthen the protection given to Māori rights and interests. The level of protection is uncertain.	- General policy directions could be used to discount the advice of the Māori Advisory Committee or to strengthen the protection given to Māori rights and interests. The level of protection is uncertain.
Overall assessment	**0**	++	-	-

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

470. Based on our analysis a single decision maker that may or must take advice from committees has marginal or no advantages compared to committee-based decision making. That said, we do not see any disadvantages in the decision maker being a statutory officer supported by advisory committees.

471. Option Two is most likely to meet the policy objectives and deliver the greatest benefit because it is the one with the lowest level of uncertainty for applicants and supports confidence in the proposed gene technology regime.

472. The proposed regime is designed to focus on scientific knowledge and risk management principles. This is why it limits the regulator's decision-making to health and safety of people and the environment, rather than extending the assessment to consider broader effects incorporating market access, economic, and cultural and social considerations. A minister's call-in or a general policy directions power could undermine the regulator's authority and public trust. The public may perceive the minister's decisions or directions as politically driven and the result of industry lobbying.

473. Most importantly, to support the desired long-term outcome of innovation and investment in gene technologies, all decisions under the new regime should be the result of the rigorous application of the proposed decision-making framework and not minister's intervention via a call-in power or general policy direction. This would strengthen confidence in the regime and the regulator and allow for regulatory certainty

which is desirable from an economic perspective since it has a central role in promoting efficient economic activity[51] – i.e. low-cost, economically innovative behaviour.

474. Under Option Two the responsible minister can appeal any of the decisions of the regulator. Furthermore, if the regulator is located:
    - within the EPA, the responsible Minister can set out government-wide priorities, high-level priorities for the EPA, and operational expectations through the Letter of Expectations, including for the gene technology regulatory function.
    - within MBIE, they will report to the chief executive, who will be holding the statutory officer accountable for day-to-day operations and performance. The Ministry must give effect to any lawful instruction by the responsible minister as per the ministerial power to direct government policy (within the bounds of any statutory independence) and the statutory officer may have direct a reporting line to the minister.[52]

51 For more details see New Zealand Treasury *The Best Practice Regulation Model: Principles and Assessments (July 2012).*

52 For example, as per the Commissioner of Crown Lands and the Valuer-General.

G. Location of the regulator

475. Options for the regulator's location have been assessed against the PSC guidance on identifying a suitable entity to which a function is allocated, including strategic fit, compatibility of functions and powers, and processes and technology.

476. The regulator's location should also be selected based on cost-effectiveness, including the cost and timeliness of establishment. Additionally, the location of the regulator would promote the regulator's prospects to become an integral part of the wider technology and innovation, environmental and biosecurity systems.

477. The options for this decision were established based on the assumption that a single statutory officer (SO) would be vested with decision-making authority. The SO and its operational arm will be housed in the preferred entity.

Option 1 – The EPA

478. Housing the SO within the EPA as a separate regulatory function operating in parallel with the HSNO regime would leverage its existing technical capabilities, relationships with the sector and with Māori, relevant committees (such as NKTT), and complementary regulatory functions in relation to new organisms. This would be cost effective and efficient.

479. While the EPA would be expected to appropriately manage processes across two regimes, there is a perceived risk (including from some industry and research stakeholders) that the SO within the EPA could be influenced in its decision making by the existing legacy processes and tendencies from the more restrictive HSNO Act regulatory functions. However, it can be argued that EPA's history (particularly in the last 10 years) of statutory determinations and attempt to change the 'Not GM' regulations to exempt gene editing techniques, counterbalances this.

480. Based on available information at this stage of policy development, it is estimated that locating the regulator within the EPA would have a cost of Confidential over the 4.25 years from 1 April 2025. This estimate does not take into account compliance, monitoring and enforcement costs relating to the new regulatory regime (which MPI has estimated at Confidential over this period).

Option 2 – branded business unit within an existing departmental agency (preferably MBIE)

481. Ministers envisaged MBIE becoming the home of the new gene technology regulator (based on election commitments). Nonetheless, officials also considered the potential for the regulator to be located in MPI and MoH.

482. MBIE, MPI and MoH all have existing scale and expertise as regulatory agencies. While MPI and MoH offer some advantages, including being part of the wider biosecurity and health systems, there are no compelling reasons to choose these agencies above MBIE.

483. MPI is also likely to hold responsibility for compliance, monitoring and enforcement of the regime (as it does for the HSNO regime), and there would be benefits in aligning regulator and enforcement functions (consistent with other regimes overseen by MPI such as for the Biosecurity Act, Food Act 2014, and Animal Products Act 1999).

However, while the primary sector will be a beneficiary of advancing gene technology, the regime under which the new regulator will operate will span more than just the primary sector (e.g. health, industrial, and the science, research, and innovation sectors). Additionally, the primary sector includes both those that are supportive and not supportive of the proposals, creating the potential for conflicts within the primary sector which may unduly influence the regulator if it were to be located in MPI.

484. As with MPI and MoH, MBIE administers a variety of regulatory regimes, including the Outer Space and High-altitude Activities Act 2017 and aspects of the Imports and Exports (Restrictions) Act 1988. MBIE also holds oversight of other related technology and innovation policy and strategic functions that advise the Minister of Science, Innovation and Technology. With the coalition Government indicating that this minister will be the responsible minister for the new legislation, housing the function of the new legislation within the ministry where the minister is most directly linked is the most efficient option.

485. Based on available information at this stage of policy development, it is estimated that locating the regulator within MBIE Confidential advice to Government over the 4.25 years from 1 April 2025, plus Confidential advice (plus, as with the Option 1, an estimated Confidential compliance, monitoring and enforcement cost for MPI). The higher cost of an MBIE location compared to EPA reflects a combination of factors, including the need to establish new systems and committees, differences in staff-related and property costs, and differing approaches to regulator resourcing. After the first three years, the estimated operational costs are more similar, with MBIE annual costs being approximately Confidenti more than comparable EPA costs.

Option 3 – new departmental agency or Crown entity

486. The PSC has advised it would not support a new dedicated entity (either a departmental agency or Crown entity) being established given the expected small size of the regulatory function, the cost of an additional chief executive and/or board, and the risk of duplicating or overlapping activity with other agencies.

487. As with Option Two, a new entity would require recruitment of new staff, likely drawing from the already small pool of expertise within EPA or other regulatory bodies in New Zealand, as well as establishment of new operational policies and processes. A new Crown entity or department would also incur accommodation and IT costs that would not occur (or would be lower) if the regulator was part of the EPA or MBIE.

How do the options compare to each other?

0/neutral = no change; **+** = improvement; **-** = less than status quo

	Option One – Environmental Protection Authority	Option Two – branded business unit within MBIE	Option Three – new departmental agency or Crown entity
Strategic fit, including in wider system	**+** Strong fit for its existing remit.	**+** Good fit within broader technology and trade regulatory system. Aligns responsible minister with agency	**0** Would need to establish itself within broader system.

		responsible for portfolio.	
Compatibility of functions and powers	**0** Aligns with existing functions. Concern (including real or perceived) from stakeholders that conservative tendencies from the restrictive HSNO regime could influence application of new, more enabling regime. Conversely, there is recognition of EPA's efforts within the existing legislative framework to adjust to new technologies (e.g. medical approvals, statutory determinations, and proposal for new regulations to exempt gene editing).	**+** MBIE could effectively host the regulator without any notable impacts on broader functions or the regulator's decision making. MBIE hosts a number of regulatory regimes and has extensive experience with regulatory functions and powers.	**0** New entity would be established to implement new regime.
People / capabilities	**+** EPA has existing technical capability.	**-** MBIE would need to recruit and establish capabilities.	**-** New entity would need to recruit and establish capabilities.
Reputation, relationships and responsiveness	**0** Perceptions from existing regulatory functions would be carried over to new regime both positive (perception of existing capability) and negative (e.g. some stakeholders describe experiencing significant delays to application process).	**+** Good relationships with tech/innovation sector, although would need to improve environmentally centric relationships with Māori, and build up relationships with some relevant industries. Strong experience standing up new functions quickly.	**0** No existing perceptions or relationships.
Processes and technology	**+** Can leverage existing regulatory technology and processes, although anticipate some system upgrades necessary and will need to go through process of ensuring new processes are distinct from HSNO regime.	**-** Would need to implement new processes and technology, with some ability to leverage from other regulatory regimes housed at MBIE.	**-** Would need to implement new processes and technology.
Physical assets	**++** Can leverage existing assets.	**+** MBIE has large national footprint but would need to invest in some specific new assets.	**-** Would need to invest in assets.

Cost effectiveness, including establishment	++ Can leverage existing function, technology, processes and assets, assessed lower cost than Option Two.	+ Can leverage MBIE capability, although would need to establish new regulatory capability specific to gene tech regime.	- Not cost-effective given need to establish new entity and relevant processes, resources and technology.
Overall assessment	+	+	-

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

488. Based on the assessment above using PSC's criteria guidance:
    - We are not in favour of establishing a new department or an independent Crown entity to house the regulator (this also aligns with the PSC's support for a public service department (e.g. MBIE) or the EPA as the most appropriate options for the regulator's home)
    - Both the EPA and MBIE housing the regulator are viable options with specific positives and negatives, but with the EPA option scoring more highly in total on these criteria.

489. The positives and negatives for the EPA and MBIE are necessary considerations for the location of the regulator, and are outlined further below:

Housing the regulator within EPA

490. The most significant advantages of housing the regulatory function within the EPA could be summarised as:
    - EPA's existing technical capabilities
    - ability to leverage existing relationships with the sector and with Māori
    - relevant committees (such as NKTT)
    - complementary regulatory functions in relation to new organisms, and
    - less upfront cost to establish a new regulatory function.

491. However, as described in the problem definition section, the EPA had previously sought to take a more permissive approach to GMO regulation historically but was perceived to act conservatively in its decision making following the loss of several court cases. While the new gene technology regulator is proposed to operate under a clear legislative direction to be enabling, there are concerns, including from industry stakeholders, that despite this the EPA may continue to take a conservative approach to GMO regulation.

Housing the regulator within MBIE

492. The advantages of housing the regulatory function within MBIE could be summarised as:
    - ability to implement the new regulatory regime on a clean slate basis, free from any perceived or actual regulatory tendencies associated with the more restrictive HSNO regime
    - experience efficiently setting up new regulatory systems (for example a new regulator as part of the Outer Space and High-altitude Activities Act 2017)
    - direct link between the ministry housing the regulatory function and the minister legislatively responsible for the new regime, and

- ability to leverage strong relationships with the science and innovation sector to better support the growth and evolution of gene tech and wider biotech sectors in New Zealand, in turn enhancing the ability of gene technologies to deliver the outcomes sought.

493. However, while MBIE has ongoing relationships with many relevant stakeholders (such as Iwi), these relationships are generally in an economic context. If MBIE was to house the regulator it would need to build up relationships with relevant stakeholders in the context of gene technology use (such as with industry users) and environmental considerations regarding taonga species and recognition of kaitiaki relationships.

What are the marginal costs and benefits of the package of options that will deliver the new gene tech regime?

Affected groups *(identify)*	**Comment** *nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.*	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.*	**Evidence Certainty** *High, medium, or low, and explain reasoning in comment column.*
Additional costs of the preferred option compared to taking no action			
Regulated groups (researchers and businesses)	Researchers and parties wanting to use GMOs will need to learn how to comply with the new system (one-off).	Low	High
Regulators (EPA or MBIE, and MPI)	There will be additional costs to administer the new regulatory regime, only a small portion of which is expected to be recovered from regulated parties (ongoing). Confidential advice	• If EPA hosts gene tech regulator: Confi over 4.25 years from 1 April 2025 (incl CME costs) • If MBIE hosts gene tech regulator: Confi over 4.25 years from 1 April 2025 plus Confidential (incl CME costs) *Reducing in outyears to* Conf *annually (MBIE) or* Conf *(EPA)*	High Medium
Others (e.g., wider govt, consumers, etc.)	Primary producers supplying the organic / GE-free markets will face costs to implement and maintain assurance and supply chain separation programmes to meet requirements of their markets (one-off and ongoing). Confidential advice to Other regulators for intersecting regulatory systems will be operating in a more complex regulatory landscape, requiring upfront learning and adapting (one-off).	High Medium Low	Low Medium High

Total monetised costs		If EPA: Confidential April 2025 If MBIE: Confidential over 4.25 years from 1 April 2025 plus Confidential	High
Non-monetised costs		High	
Additional benefits of the preferred option compared to taking no action			
Regulated groups (researchers and businesses)	Reduced compliance costs for researchers due to risk-proportionate authorisations approach (ongoing).	High	High
	Increased research and development, start-up activity and commercialisation of GMOs in areas such as health, food production, environmental management, conservation, and climate change mitigation and adaptation (ongoing).	High	Medium
Regulators	(Ongoing): EPA will have a new counterpart regulator (either internally with defined scope or at MBIE). EPA will no longer need to make decisions on gene technologies (unless they are also new organisms). EPA will be able to partner with the gene technology regulator on matters of joint interest, from respective areas of expertise.	Medium impact Some potential cost savings from no longer making certain decisions now covered by the new gene tech regime; however these are likely to be either absorbed into an under-resourced EPA and/or offset by operating in a more complex landscape	High
Others (eg, wider govt, consumers, etc.)	Long term, a greater ability for consumers to access and benefit from gene technologies (ongoing).	Medium	Medium
Total monetised benefits		-	
Non-monetised benefits		High	

494. A key assumption underlying this cost-benefit analysis is that the research and development activity into gene technologies that the new regulatory system enables will result in high-impact benefits for society over time. We consider a medium

likelihood is a reasonable assumption given real-world international developments using gene technologies.

495. We therefore anticipate there would be benefits to the biotechnology, food and fibre, and health sectors from the new regime enabling the development of new products and services. As outlined, key innovations could include climate change resistant crops, new cancer treatments and new animal feeds (e.g. clover) with reduced methane emissions. It is difficult to quantify potential benefits as the technology development and commercialisation is uncertain, there are few "ready for market" gene technologies in New Zealand currently (partly due to the restrictions on field trials regime) and the make-up of the New Zealand food and fibre industry is very different from other countries (such as Australia, where gene technologies have been mainly used for canola and cotton).

496. Over the longer term, gene technologies could also provide products to address significant ongoing biosecurity costs on industries, such as wilding pines, bovine tuberculosis (often caused by infected possums) and the Kiwifruit PSA virus. Issues from introduced species and pests are, in general, New Zealand-specific due to our unique environment, and so solutions are unlikely to be provided by international research efforts. Current management costs that could be reduced include at least $80m annually to address bovine tuberculosis ($50m from industry and $30m from the Crown)[53] and $25m over 4 years for wilding pine management from Budget 2020.

497. Realising these benefits in New Zealand also depends on other factors, including how well the science and research and development systems function, and industry's ability to commercialise innovations. A further factor in achieving the benefits is the degree of social licence for particular gene technology uses.

498. It is clearer, however, that there will be direct benefits for the regulated parties seeking to develop and use gene technologies from an enabling and risk-proportionate regime. There will be time and cost savings for researchers and entities operating under the new regime compared to the status quo. These efficiencies will come from a reduced need to interact with a regulator given the new regime's exemptions for techniques that introduce no new risks when compared to conventional breeding techniques and the risk-tiering approach for regulated activities which provides for proportionate authorisation processes.

499. We have identified that a potential cost of a more enabling system that sees greater release of GMOs in the environment is to the organics / GMO-free sector in New Zealand. As previously stated, in 2020, organics made up 0.74% of New Zealand's total exports and 0.87% of New Zealand's primary sector exports, returning $420.4 million. New Zealand's organic market is focused on exports, and 58% of organic produce is exported. Of this, 80.9% goes to five markets: USA, China, Europe (excluding the UK), Australia and Japan.

500. In New Zealand, producers must be certified by a government-recognised certification agency to operate as organics operators. Certified operators may then apply to export under MPI's Official Organics Assurance Programme to help access some markets.

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53 Bovine Tuberculosis Regulatory Impact Statement 2016 - Ministry of Primary Industries

Inadvertent contamination by nearby GMOs that have been released into the environment may put organic certification and resulting market access at risk.

501. This risk can be mitigated by establishing coexistence frameworks across the GMO and non-GMO supply chains. Supply chain segregation is common in the primary sector (quality differences, varieties, export requirements). A similar approach could be used to keep GMO and non-GMOs separate but would take time to develop and may involve additional costs to implement. Australian industry has set up such framework for canola production, which took 3-4 years to establish.

502. GMO producers will be required to meet conditions of authorisations and will also face an economic incentive to minimise the risk of unintentional spread as they may be responsible for any negative impact on other producers. GMO producers will need to ensure that they adhere to any coexistence frameworks stood up in industry.

503. As many countries have begun introducing GMOs into supply chains, some (such as the EU, USA and Australia) have implemented a maximum contamination percentage threshold for food products to allow for inadvertent GMO presence. This may create a safety net for organic producers in the event of incidental contamination National

504. When GMOs are eventually released into the environment under the proposed regime, there will be additional costs to certify products as GMO-free. In the Australian canola example, the additional certification costs were estimated to be A$14.00 per tonne. However, it is not possible to make any real inferences from this, as costs will vary depending on certification requirements and processes.

505. We note that additional certification costs would only be accepted by the organic sector if there is an economic incentive to maintain the market, i.e. the premium that can be obtained for the product outweighs the additional costs. It is expected that additional costs to obtain this premium should be borne by those seeking to obtain value from it.

Section 3: Delivering an option

How will the new arrangements be implemented?

Responsibility for the operation of the new arrangements

506. As outlined, new primary and secondary legislation will be introduced to establish a gene technology regulatory regime. The Act will be implemented through a combination of administrative and enforcement powers.

507. A statutory officer will be responsible for the new regime. Depending on Cabinet decisions the regulator will be housed within the EPA or MBIE. The statutory officer will be an employee of the organisation but will exercise their powers independently of the chief executive or minister. The intent is for the regulator to be independent in its decision making, in line with the purpose, regulatory approach and processes set out in the legislation.

508. That said, the Minister's preference is that the legislation will also include a provision to enable the Minister to specify policy directions the regulator must give effect to in complying with the legislation. This provision could be used by the Minister to address operational matters such how to set risk tolerance, specifying performance targets and providing direction on use of discretionary powers.

509. Officials expect the regulator will develop relationships with other regulatory agencies that deal with GMOs to establish effective cross-agency work programmes to implement the regime. For agencies with direct responsibilities under the Act, information should be shared proactively in regular operations. For agencies with indirect responsibilities, information should be requested and shared as required.

Responsibility for enforcing the new arrangements

510. The Act will allow for the regulator to delegate enforcement functions, most of which are expected to be delegated to MPI. This will allow for most effective implementation, and will meet the objectives of the reform as:
    - MPI has enforcement responsibilities under the Biosecurity and HSNO Acts which GMOs will interact with, meaning all monitoring can be performed by a single inspector, reducing the number of compliance visits to places that use GMOs.
    - MPI already has resource and staff capability to perform enforcement functions where GMO activities will be undertaken.
    - MPI has developed a strong and robust "system-based" approach to compliance over two decades. This approach serves to meet the purpose of enforcement while reducing regulatory burden on inspectors and customers alike.
    - The Biosecurity Act provides a mechanism for cost recovery, though this may need to be amended to cover functions under the proposed new Act.

511. We recommend against embedding enforcement functions in the new regulator as:
    - Standing up an enforcement branch of the regulator would create significantly more cost.
    - Places where GMOs interact with other regulatory systems may duplicate enforcement functions (such as in regulated facilities), increasing costs to customers and the regulators.
    - Overlapping compliance functions may have disharmonised processes or standards, which adds complexity and ambiguity to the regulatory framework.

- A new cost recovery scheme would need to be developed and implemented.

512. The new Act will prescribe a range of powers to ensure compliance with conditions imposed on regulated activities. Compliance functions will create a mechanism to prevent, detect, manage, and escalate non-compliance to the Act, to protect against related risks to the health and safety of people and the environment. These powers will include:
    - Licensing and conditions: The regulator will have the authority to grant, modify, or revoke licenses for activities using GMOs. This includes imposing conditions on licenses to ensure that risks to health and safety of people and the environment are managed appropriately.
    - Monitoring and compliance: The enforcement agency will be authorised to monitor compliance through inspections, which includes the right to access premises where GMOs are handled.
    - Investigation and evidence collection: The enforcement agency can investigate potential breaches of the Act and collect evidence related to suspected offences. This includes the power to enter premises, examine and seize items, and request information relevant to the investigation.

513. The operational environment for compliance monitoring and enforcement will be designed in consultation with MPI. To support this, MfE has provided expertise and an analysis of the submissions it received last year on proposals to improve the compliance requirements for laboratory and biomedical research using GMOs. Insights from this consultation have and will be incorporated into this reform where possible to further improve regulations for New Zealand researchers.

Arrangements coming into effect

514. The Minister has expressed an intention to introduce the Bill in December 2024. On that basis, MBIE expects the regulator could be operational by late 2025 and the first applications assessed in early 2026.

515. Implementation work will be required prior to the regulator becoming operational, including policy work and systems development. Establishment work includes but would not be limited to:
    - establish the regulator
    - develop regulator codes of practice
    - develop risk analysis framework
    - inform and educate stakeholders on regulatory operations through dedicated material
    - develop guidance on how the Act will be enforced
    - establish operational frameworks and agreements with other agencies as required (e.g. memorandum of understanding with MPI to determine operation of compliance system)
    - develop enforcement programme
    - develop and deliver training programme to enforcement officers for the new Act
    - scope and deliver changes that need to be made to non-GMO government certifications.

516. Confidential advice to Government

Transitional Provisions

517. Because there are GMOs that are approved under the HSNO Act in New Zealand, transitional provisions will need to be included in the new Act to allow for effective transfer between the old and new system.

518. Currently there are many approvals for import and development of GMOs under the HSNO Act, most of which are for contained use and there are 10 for medical release. Following the reform, HSNO approvals will broadly fit into the following categories:
    - not regulated under the Gene Technology Act or the HSNO Act
    - not regulated under the Gene Technology Act, but still regulated under the HSNO Act
    - regulated by the Gene Technology Act and no longer regulated by the HSNO Act
    - regulated by the Gene Technology Act and still regulated under the HSNO Act.

519. Saving provisions will be required to allow for approvals under the HSNO Act to remain operational until such time as they are reviewed under the new regulatory regime. The regulator will then be responsible for transferring the approvals to the new regime.

How will stakeholders and other agencies be involved in the arrangement's implementation and ongoing operation

Government Agencies

520. The new Act will take over regulation of GMOs from the HSNO Act. The HSNO Act will still regulate non-GMO new organisms, including zoo animals and biocontrol agents. There is not expected to be much direct overlap between the two regimes, but some additional change will need to be made to the HSNO Act to ensure there is regulator coherence. These may include the following:
    - removal of GMOs
    - aligning definitions
    - ways for the regulators to share information and work together
    - application pathways in HSNO updated to allow for joint applications
    - transitional provisions, and
    - other consequential amendments, as analysed by MFE.

521. Consequential amendments to other legislation may include:
    - Amending the definition of "organism" to achieve consistency across the new Gene Technology Act, the HSNO Act, and the Biosecurity Act, should it be deemed necessary to remove inconsistencies and complexity between statutes.
    - Updating other Acts that refer to definitions in the HSNO Act that relate to GMOs.

522. Further work will be required to determine what other changes need to be made to other legislation to ensure that there is regulatory coherence. This work will include:
    - Confidential advice to Government

523. There will be an operational impact on other government agencies as this regime is implemented. Agencies will require dedicated resource to adjust operational processes to accommodate the new act. Confidential advice to Government

524. Agencies have been consulted throughout the policy development, and they have begun work on determining the subsequent operational changes required. MBIE will continue to engage with agencies as policy develops.

Public perceptions of gene technology and products pose a risk to the successful implementation of regulatory reform

525. As discussed in Section 1, while there is some, limited evidence of an increase in levels of public acceptance for gene technology and associated products in New Zealand, it is difficult to draw a broad conclusion about this.

526. Regardless of the perceived or actual views on gene technologies in New Zealand, various reports have called for a national conversation on New Zealand's gene technology regime or have acknowledged that public opposition could be a barrier to the growth of a New Zealand's gene technology sector.[54]

527. As set out, officials have conducted targeted consultation with stakeholders from industry, research, other government agencies, and a Māori focus group (see Annex B). These consultations will be ongoing throughout the passage of the Bill through the House and after to ensure the appropriate steps are taken to implement the regime effectively. Wider public consultation will take place at select committee.

528. MPI is planning on conducting a survey to gauge consumer attitudes towards gene technologies in the primary sector domestically and internationally. This may provide more information on how applications of gene technologies in food will be received by the public.

Free and frank opinions

530. A partial mitigation of this risk is for the regulator to make available plain language, objective and up-to-date information about scientific evidence around safety of technologies and approvals, and to be transparent about its activities.

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[54] Royal Society – Gene Editing Legal and Regulatory Implications 2019
Productivity Commission – Frontier Firms study 2021
Aotearoa Circle – Modern Genetic Technology: Applications in Aotearoa Food and Fibre Production

How will the new arrangements be monitored, evaluated, and reviewed?

531. We propose that we provide for dedicated resource within the regulator to collect, and share as appropriate, an agreed set of data and wider information for the purposes of monitoring and evaluating the new regime, future policy development, and other related research. This in turn will feed into future wider system assessment and will inform our conclusions as to whether the reform has contributed to the long-term desired outcome of greater use of safe gene technologies.

532. Of particular importance are the post-licence data as they can be used to improve regulation and the effectiveness of risk management measures. MBIE will develop an initial monitoring and evaluation framework within the first quarter the regulator is operational. Indicatively the data/information collected will include:
    - number of applications submitted by type, sector, including firm level information
    - number of applications approved by type, sector, including firm level information
    - number of days necessary for approval by application type, sector etc
    - interactions of the regulator with applicants to request additional information
    - number of joint approvals with EPA
    - number of approvals in conjunction with Medsafe and the ACVM regimes
    - number of approvals in co-operation with international regulators, and
    - regular surveys regarding the applicants' experience including proposals on improvements, concerns regarding processes followed etc.

533. Information on compliance and enforcement functions of the system will be shared by relevant agencies. This will be undertaken in a concise manner, potentially formalised via an MoU, with information to be shared indicatively including:
    - efficiency of imposed conditions in managing risks to health and the environment
    - issues with monitoring the imposed conditions
    - number of instances of non-compliance with conditions and severity of non-compliance, and
    - license holders that have been repeatedly non-compliant.

534. Three years after the regulator has received the first application MBIE will undertake the first evaluation of the new regime based on the data and wider information collected (including from MPI). However, if the available data are deemed insufficient to conduct a review or the regulator is still facing teething problems as expected when embedding a new regime, the policy team may propose to the Minister to postpone the review for six months to a year.

535. Following the review MBIE, in consultation with the regulator, will report back to the Minister and may propose any changes or improvements necessary, based on the review findings. Depending on the nature of the proposed changes/improvements (e.g. need to collect additional data, process improvements, operational changes, regulatory changes), authorisation for next steps will be sought as appropriate.

536. In alignment with regulatory stewardship expectations, regular wider system assessments are needed to keep technical aspects of the legislation up to date with technological progress and changes in scientific understanding of the risks posed by gene technology. Therefore, we propose that a wider system assessment is conducted every three years except for the first one, which we propose to happen five years from the introduction of the new legislation.

537. This plan may change and is based on current knowledge and resources.

Annex A – Proposed regulatory regime

- The legislation is intended to enable New Zealand to safely benefit from gene technologies by managing risks to the health and safety of people and risks to the environment.
- It will achieve this by managing the risks that organisms modified using gene technology pose, proportionate to their risks to the health and safety of people and the environment.

KEY FEATURES OF THE REGULATORY REGIME

- Risk-proportionate and evidence-based
- Internationally aligned
- Leverages overseas expertise
- Retains public participation
- Streamlined, efficient and transparent processes
- Allows greater use of gene editing
- Focuses on the management of risk

NON-REGULATED TECHNOLOGIES AND ORGANISMS

GENE EDITING TECHNIQUES

- Techniques producing results indistinguishable from those achievable with conventional breeding would be exempt. Example applications include:

- STERILE WILDING PINES
- GRASS ENDOPHYTES
- GABA TOMATOES
- NON-BROWNING MUSHROOMS
- DISEASE-RESISTANT MAIZE
- DISEASE-RESISTANT POTATOES

EXEMPT TECHNOLOGIES AND ORGANISMS

- Technologies and organisms commonly regarded as not creating or being a GMO would be exempt, including:

- NULL SEGREGANTS
- RNA INTERFERENCE
- REPLICATION-DEFICIENT VIRAL VECTORS
- EPIGENETICS
- MUTAGENESIS
- PROTOPLAST FUSION

RISK MATRIX FRAMEWORK

The regulator would assign activities to non-notifiable and notifiable risk tiers, the requirements of which will be graduated based on risk. Categories would be tailored for contained activities, activities involving intentional environmental release, and clinical trials and medical applications.

CONTAINED ACTIVITIES	ENVIRONMENTAL RELEASE	MEDICAL APPLICATIONS
Non-notifiable	Non-notifiable	Non-notifiable
Notifiable	Notifiable	Notifiable
Licensed - Expedited assessment	Permit Licensed - Expedited assessment Licensed - Full assessment	Permit Licensed - Expedited assessment Licensed - Full assessment

- **Non-notifiable activities** would be very low risk and would include CAR T-cell therapies and routine laboratory research.
- **Notifiable activities** would be low risk and would include research with laboratory animals.
- **Permits and licences** would cover field trials, clinical trials, and commercial releases.

ASSESSMENTS AND APPROVALS

Licensed activities would require assessment and approval by the regulator. Permits would not require a Risks Assessment and Risk Management Plan and only full assessments would require public consultation.

Application is received → Regulator prepares a Risk Assessment and Risk Management Plan → Public consultation → If satisfied risks can be managed, regulator issues license

GENE TECHNOLOGY REGULATOR

- The regulator will be a single decision-maker, supported in their functions by an office, a technical advisory committee, and a Māori advisory committee.
- Their responsibilities will include assessing and authorising activities, developing regulations, providing advice on technical matters to Ministers and other agencies, and providing information and guidance to the public and regulated parties.

STREAMLINED ASSESSMENT PROCESSES

- Overlapping processes with other domestic regulators will be streamlined through information sharing, cooperation and delegation, where appropriate.
- This will apply where gene technologies considered by the Regulator are also new organisms, medicines, agricultural compounds and veterinary medicines.

LEVERAGING THE EXPERTISE OF OVERSEAS REGULATORS

- Joint review provisions will enable the regulator to undertake joint assessments with other overseas regulators. Following the joint assessment, the regulator would make their own independent decision.
- Automatic authorisation of human medicines under the gene technology legislation would apply to medicines approved by at least two overseas gene technology regulators recognised by the New Zealand gene technology regulator.
- Expedited assessments would apply to activities approved by overseas gene technology regulators previously recognised by the New Zealand gene technology regulator.

Annex B – Targeted engagement

Advisory/focus groups

MBIE established advisory/focus groups to provide advice on issues, barriers, potential solutions, and risks in relation to both the existing gene technology/GMO regime as well as a prospective future regime. These groups were:

- Technical Advisory Group
- Māori Advisory Group
- Industry Focus Group

MBIE has also held two wider sector hui with representatives from the research and innovation sectors, including one specifically for Māori researchers.

Advisory/focus group participants are detailed below:

Group and description	**Number of engagements / sessions (as of RIS drafting)**	**Participants**
Technical Advisory Group *Formal advisory group to provide technical and science advice to MBIE.* *Expected to provide advice until late 2025.*	5	Professor Emily Parker – Chair (Science Advisor, MBIE & Professor Chemical Biology Ferrier Institute) Dr William Rolleston (Co-founder South Pacific Sera Ltd – biotechnology company) Dr Tim Hore (Epigenetics and development, University of Otago) Professor David Ackerley (Professor of Biotechnology, Victoria University of Wellington) Dr Hilary Sheppard (Senior Lecturer Stem Cell and Developmental Biology, University of Auckland) Dr Alec Foster (Bioproducts and Packaging Portfolio Leader, Scion) Professor Jasna Rakonjac (Professor in Microbiology, Massey University) Associate Professor Maui Hudson (Faculty of Māori and Indigenous Studies, University of Waikato) Dr Andy Allan (Biological Sciences, University of Auckland) Dr Nikki Freed (Genomics, University of Auckland & Chief Scientific Officer, Daisy Lab) Dr Rachel Perret (Research Team Leader, Malaghan Institute of Medical Research) Ariana Estoras (Director Māori Strategy, Research and Partnerships, AgResearch) Professor Neil Gemmell (Department of Anatomy, University of Otago)

Māori Focus Group *Formal advisory group to discuss and provide advice to MBIE on matters pertaining to Māori rights and interests.* *Participants are appointed until 31 December 2025.*	2	Willy-John Martin – Chair (MBIE) Melanie Mark-Shadbolt (Co-Founder, Te Tira Whakamātaki (Māori environmental advocacy)) Stephanie Dijkstra (Te Rūnanga o Ngāi Tahu (Te Rūnanga) HSNO Komiti) Tehoripo Karaitiana (Leader across Māori agribusiness contexts) Maia Brewerton (Auckland Hospital and Malaghan Institute) Dr Alana Alexander (Molecular ecology, University of Otago) Hema Wihongi (Taumata Whakapūmau) Amanda Black (Lincoln University and Bioprotection Aotearoa)
Industry Focus Group *Expert industry forum to test proposals, identify issues and opportunities.*	2	John Caradus (Grasslands Technology) Matt Glenn (Kiwi Fruit breeding centre) Julie Jones (BioValeo) Philip Gregan (NZ Wine) Lesley Van (Zespri) Cathy Webb (Seafood NZ) Carole Inkster (Infant Nutrition Council) Eve Pleydell (HortNZ) Ben Cunliffe (Fonterra) Carl Ramage (Rautaki Solutions) Rock Hudson (SGA solutions) Dorian Garrick (AL Rae Centre for Genetics and Breeding - Massey University) Suzanne Keeling (Beef and Lamb NZ) Tanya Baker (Medicines NZ) Zhara Champion (BiotechNZ) Donnell Alexander (Food and Grocery Council)
Māori Researchers hui *Māori experts in gene technology to provide perspectives on policy proposals and understand impacts and implications for Māori.*	1	Universities of Otago, Wellington, Auckland, Waikato, and Canterbury, Massey University, Lincoln University CRIs: Plant & Food Research, Landcare Research, GNS, ESR, AgResearch, Scion, NIWA Government: Ministry for the Environment, EPA Others: Te Pū Oranga Whenua, Te Tira Whakamātaki, Kahui Legal, Taiuru & Associates, other Māori research leaders
Wider Science Sector hui	1	Universities of Otago, Wellington, Auckland, Waikato and Canterbury, Lincoln University,

Experts in gene technology science and research in order to test policy proposals.		Massey University, Auckland University of Technology, and Unitec CRIs: Plant & Food Research, Landcare Research, ESR

Targeted engagement sessions

MBIE conducted a series of engagements with relevant stakeholders to understand key problems, barriers, potential solutions, and any risks in relation to both the existing gene technology/GMO regime as well as a prospective future regime.

These engagements were mostly one-off engagements. The stakeholders were identified because they (or those they represent):

- are directly involved in gene technology / GMO research, development and commercialisation
- would be impacted by a new regulatory regime that would oversee technologies or products used in their value chain, or
- offered a level of expertise relevant to understanding issues in the sector

The table below details who these stakeholders are, largely grouped as follows:

- Key science and research foundations, associations and personnel
- Biotechnology / gene technology sector representation bodies
- Primary sector representation bodies (horticulture, agriculture/food, forestry, fisheries/aquaculture)
- Key private businesses
- Biosafety and food safety associations
- Relevant government, industry and Māori partnership organisations/programmes.

Key Stakeholders	**Description / relevance to the programme**
Genomics Aotearoa	Alliance of universities and Crown Research Institutes, and a members' association for researchers or end-users of genomics and bioinformatics
Biotech NZ	Members' association consisting of biotechnology-related investors, companies, regulators, researchers.
Science NZ and CRI CEOs	Representative body for New Zealand's Crown Research Institutes
Universities New Zealand	Representative body for New Zealand's eight universities
Parliamentary Commissioner of Environment	Independent Officer of Parliament with powers to investigate environmental concerns
Royal Society Te Apārangi	Independent national academy of sciences

Key Stakeholders	Description / relevance to the programme
HortNZ (Zespri, KBC, Apples and Pears, Potatoes, Tomatoes, Vegetable Growers, Onions)	Horticulture industry advocacy body and members' association
Primary sector (Fed Farmers, NZFOA, MIA, DairyNZ, Fonterra, Beef and Lamb, DCANZ)	Group of industry advocacy bodies / members' associations for food and fibre producers
Community Supported Agriculture partnerships	Partnership model between consumers and farmers
Te Puna Whakaaronui / 'Fit for a Better World'	Food and fibre sector transformation group – government, industry and Māori
New Zealand Agricultural Greenhouse Gas Research Centre	Partnership of agricultural greenhouse gas emissions research providers
New Zealand Food Safety Science & Research Centre	Food safety partnership group between industry, government, Māori and research organisations
Association of Biosafety for Australia and New Zealand	Biosafety advocacy body
Food and Grocery Council	Industry advocacy body / members' association for food, beverage and grocery manufacturers and suppliers
Food and Fibre Leader Forum	Forum for leaders of industry advocacy bodies
Food Safety Australia New Zealand	Independent statutory agency in the Australian Government Health portfolio, develops food standards for Australia and New Zealand
Office of the Gene Technology Regulator Australia	Independent statutory office responsible for administering Australia's Gene Technology Act 2000.
Privacy of natural (Rautaki Solutions) and Privacy of (SGA Solutions)	Experts in biotech, specifically in the agriculture supply chain
New Zealand Veterinary Council	Statutory body responsible for upholding veterinary standards
Forest Owners Association and Scion	Forestry industry advocacy body Crown Research Institute for forestry and wood products

Key Stakeholders	Description / relevance to the programme
Fonterra	Dairy co-operative
Independent Research Association of New Zealand	Members' association for science and research organisations in New Zealand
Gene Technology and Our Environment Research Team	Experts in social research undertaking research into the role that gene technologies may play in the future of environmental conservation in Aotearoa
Beef and Lamb NZ	Meat sector industry advocacy and export facilitation body
Cawthron Institute	Independent science organisation specialising in primary industries
Seafood sector: King Salmon, Sandford	Major New Zealand seafood sector companies
Organic Exporters Association of New Zealand Executive Board	Elected members representing most organic exporting sectors
Hawkes Bay Regional Council, Bay of Plenty Regional Council	Regional council policy advisors

Annex C – Regulatory approaches in other jurisdictions

Outcome- or product-based approaches focus on regulating the outcome or trait produced in an organism rather than the process or technique used. This approach is more future proof to advances in technology compared to process-based or hybrid approaches because it can regulate the outcome of new processes and techniques beyond those in use when the regime is established.

While outcome-based approaches are well regarded in the scientific community given their focus on the ultimate traits produced, it not clear whether outcome-based regulatory approaches in other jurisdictions are more enabling, such that they have produced higher rates of approved applications and products compared to hybrid regulatory approaches.

USA

The United States of America implemented an outcome-based regulatory approach, but definitions intended to manage risk to the environment of GMOs developed using genetic material from plant pathogens meant crops with similar traits developed using conventional techniques were not subject to these requirements. This provided a significant regulatory advantage for non-GMO products. Only recently have GMO products been unregulated by using genetic constructs that did not contain any genetic material from potential plant pests.

Canada

Canada has implemented a federal regulatory framework that regulates novel products produced through biotechnology, under existing regulatory regimes for conventional products. Canada regulates on a case-by-case basis, focusing on the risks associated with the outcome of the modification (new traits) rather than the process used to generate the trait change. All organisms that contain ‘foreign’ DNA require authorisation from the relevant regulatory agency prior to release.

Australia

Australia operates a hybrid regulatory regime; their Act states an organism developed using gene technologies is considered a GMO unless otherwise stated by the regulations. Techniques that are not gene technologies and organisms that are not genetically modified are provided through schedules to the regulations. These lists are similar to HSNO regulations. However, they have codified that organisms developed using a specific a gene editing technique, unguided repair, are not considered GMOs and therefore are exempt from regulation. This level of permissiveness is considered by both research and industry stakeholders to be lagging behind international approaches.

England

England have recently introduced the Precision Breeding Act, which has introduced a hybrid regulatory approach. They deem organisms developed using precision breeding techniques (including gene editing techniques) that could have resulted from traditional processes as Precision Bred Organisms that are not subject to regulation as GMOs. They have specified that this only applies to plants and animals, and all other organisms developed using these techniques remain regulated as GMOs.

EU

The European Union recently proposed introducing a hybrid system through proposal 2023/0226. If enacted, this proposal would create two categories for plants developed using new gene technologies, including gene editing techniques. If a plant developed using gene

technologies satisfies a set of criteria provided as an annex to the regulations, it is deemed an NGT1 class plant. This classifies it as equivalent to a conventionally bred plant. Due to a well-established evidence base on the risks associated with genetically modified plants, they have set these criteria around what could be achievable through traditional processes (i.e., no changes from outside the breeders' genetic pool). If a plant developed using gene technologies does not satisfy the criteria and therefore is not considered to be equivalent to a conventionally developed plant, it is subject to regulation as a GMO.

Argentina

Argentina is considered to be at the forefront of international regulation as a highly permissive hybrid system, as they do not regulate products of the gene technologies when there is no "new combination of genetic material", regardless of the type of organism developed. Products are reviewed on a case-by-case basis and researchers can ask the regulatory agency to determine if their product is regulated or not. This can happen before the product is developed.

Annex D – Glossary

Biotechnology	A multidisciplinary field that involves harnessing biology to create valuable products.
Conventional breeding	Choosing parent organisms with desirable traits and breeding these to produce offspring with the same desirable traits. Results can be variable, and the trait is not always passed from parent to offspring. Also sometimes called Traditional Breeding. Tools and techniques in this category do not fall under genetic modification regulations.
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats, which are the hallmark of a bacterial defence system that forms the basis for CRISPR-Cas9 gene-editing technology.
DNA	Deoxyribonucleic acid, the hereditary material in humans and almost all other organisms.
Gene	A gene is the basic physical and functional unit of heredity. Genes are made up of DNA.
Gene editing	A technique to induce specific targeted changes in an organism's existing genome to achieve a specific desired outcome. Transgenic modification, often crossing species boundaries, is typically excluded from this definition (see definition below for transgenic). What technology and resultant organisms are encompassed under this definition varies by country. Gene edited organisms can be indistinguishable from conventionally bred counterparts and this is dependent on a number of factors including the change made, the size of the change and how much is already known about the genome and genetic variation of the organism and species.
Genetic engineering	Synonymous with genetic modification
Genetic modification	A technique to change the characteristics of an organism by modifying its genome. What technology and resultant organisms are encompassed under this definition varies by country.
Genetic technology	A subset of biotechnology which includes any techniques used for the modification or construction of genes or other genetic material but does not include traditional breeding techniques or natural selection.
Genome	All the genetic information of an organism or species.
In vitro	(Meaning in glass, or in the glass.) Studies or treatments that are performed with microorganisms, cells, or biological molecules outside their normal biological context.
In vivo	Studies or treatments that are performed within the body of a living organism.
Mutagenesis	Process by which DNA of an organism is changed due to a mutation. Can occur spontaneously in nature or via exposure to mutagens such as chemicals or radiation.
RNA	Ribonucleic acid. Can have multiple functions within an organism, including being the intermediate product between a gene (encoded by DNA) and a protein.
Selective breeding	The controlled breeding of organisms by human intervention to selectively produce traits.

Synthetic biology	A subset of biotechnology which includes the design and construction of biological systems and devices, as well as the redesign of existing biological systems for useful purposes.
Synthetic nucleic acid	Nucleic acid molecules (DNA or RNA) that are chemically synthesised or amplified but can base pair with naturally occurring nucleic acid molecules.
Traditional breeding	Synonymous with conventional breeding
Trait	A genetically determined characteristic, sometimes called a phenotype.
Transgenic	Introducing specific genetic material from one donor organism to another host organism to produce a desired trait, where the two organisms are not sexually compatible species.