Departmental Disclosure Statement

Gene Technology Bill

The departmental disclosure statement for a government Bill seeks to bring together in one place a range of information to support and enhance the Parliamentary and public scrutiny of that Bill.

It identifies:

- the general policy intent of the Bill and other background policy material;
- some of the key quality assurance products and processes used to develop and test the content of the Bill;
- the presence of certain significant powers or features in the Bill that might be of particular Parliamentary or public interest and warrant an explanation.

This disclosure statement was prepared by the Ministry of Business, Innovation and Employment (MBIE).

MBIE certifies that, to the best of its knowledge and understanding, the information provided is complete and accurate at the date of finalisation below.

Date finalised: 6 December 2024.

Contents

Part One: General Policy Statement

Purpose of the Bill

The Gene Technology Bill 2024 (the Bill) is an omnibus Bill introduced in accordance with Standing Order 267(1)(a). The purpose of the Bill is to enable the safe use of gene technology and regulated organisms in New Zealand.

Objectives of the Bill

The intention is to establish a new regulatory regime for gene technology and genetically modified organisms (GMOs). The Bill will replace the current regime with a more enabling and modern regulatory system for managing the use of gene technology. The Bill seeks to provide for—

- risk-proportionate regulation;
- efficient application and decision-making processes;
- a flexible legislative framework able to accommodate future technological and policy developments without frequent amendment;
- international alignment, including with key trading partners, to facilitate trade and improve access to new technologies; and
- ways to recognise and give effect to the Crown's obligations under the Treaty of Waitangi.

A bespoke legislative regime is considered the most efficient way to achieve these objectives.

How the Bill will achieve its purpose and meet its objectives

The regime will replace parts of the Hazardous Substances and New Organisms Act 1996 (the HSNO Act) that regulate GMOs with a standalone regime that future-proofs the law. The Bill will—

- establish a Gene Technology Regulator (the **Regulator**) within the Environmental Protection Authority (the EPA) to be the independent decision-maker;
- establish a Technical Advisory Committee and a Māori Advisory Committee to provide the Regulator with expert advice;
- create an authorisation framework to regulate gene technologies and GMOs and manage any risks they pose to human health and safety and the environment by imposing risk-proportionate conditions;
- create a process to enable the management of risks to Māori kaitiaki relationships with indigenous species;
- enable the Regulator to undertake joint assessments with overseas regulators and to draw on their expertise;
- include definitions of terms such as regulated organism and gene technology that can be clarified to account for potential future changes to gene technologies;
- enable some products of minimal risk gene editing to be exempted from regulation;
- establish offences and penalties for breaches of the regime;
- ensure a nationally consistent approach to regulation of gene technology by removing local authorities' ability to restrict its use; and
- ensure New Zealand continues to be able to comply with its international legal obligations.

What will be regulated

The regulatory regime covers gene technology activities (for example making, breeding, culturing, supplying, importing, or releasing a regulated organism) and regulated organisms (organisms – often referred to as GMOs – that have been modified or constructed by gene technology, but excluding human beings).

Risk tiers and authorisations

Activities will be categorised depending on the nature of the activity: medical, contained, or environmental. For each activity category, the Bill will establish risk tiers to enable proportionate management of risks to human health and safety and the environment, and associated authorisations. The risk tier framework and risk management approach includes:

- *Exempt organisms*: minimal-risk products of gene editing, for example products of editing techniques that result in organisms that cannot be distinguished from those produced by conventional processes.
- *Non-notifiable activities*: very low-risk activities that do not require active monitoring by the Regulator, for example gene therapies that are also regulated by Medsafe.
- *Notifiable activities*: low-risk activities that require the Regulator to be notified, for example laboratory research with mice.
- *Licensed activities:* medium- and higher-risk, or uncertain-risk, activities that require a case-by-case assessment before they can be authorised to determine that all risks of the proposed activity can be managed.

In addition, the Bill will enable two further types of authorisation in specific circumstances, namely—

- *Mandatory medical activity authorisations:* for a human medicine that is or contains gene technology that has been approved by at least two recognised overseas gene technology regulators.
- *Emergency authorisations*: when there is an actual or imminent threat to the health and safety of people or to the environment, for example, threat from a disease outbreak, or an industrial spillage. The Minister responsible for the Gene Technology Act (the **Minister**) will have the power to grant an emergency authorisation.

Risk assessment and management

A key component of the Bill is to manage any risks gene technologies and GMOs pose to human health and safety and the environment. Any authorised activity may be subject to conditions to manage any risks the Regulator identifies. An example of a condition is that an activity must be carried out in a facility compliant with containment standards. Using conditions to manage risk will allow for an enabling, flexible and risk-proportionate regulatory approach.

To identify risks, the Regulator will be required to prepare a risk assessment and risk management plan in relation to an application for a licensed activity. The plan will identify and detail any risks posed by the activity to human health and safety and the environment and ways to manage these risks, which will be given effect as conditions if the Regulator grants the licence.

The Bill will empower the regulator to declare some activities to be non-notifiable, notifiable or pre-assessed licensed activities. The Regulator will identify any risks and ways to manage the risks, which will be given effect as conditions in the declaration.

Risk assessment will also be one of the mechanisms the Regulator uses to ensure New Zealand complies with our international obligations in respect of modified organisms and management of risks to the conservation and sustainable use of biodiversity arising from GMOs.

Decision making, transparency and public participation

In making its decisions on declarations, licences, and conditions, the Regulator will take expert advice from the Technical Advisory Committee, and may seek advice from the Māori Advisory Committee where an activity may have a material adverse effect on Māori kaitiaki relationships with indigenous species. The Regulator may also seek and receive advice from other agencies.

The public will also be invited to participate in some processes. For example,—

- the Regulator will be required to publicly notify its proposals to declare activities as non-notifiable, notifiable, or pre-assessed and seek input;
- the Regulator must consult on the draft risk assessment and draft risk management plan for a licensed activity unless there has been previous consultation about a similar activity and the Regulator is not aware of any significant new information.

The Bill sets expectations for transparency of the regime by requiring public notification of a range of matters including receipt of licence applications and notification of the Regulator's final decisions and any changes to decisions.

Leveraging international expertise

The Bill provides the Regulator with the ability to recognise overseas gene technology regulators that operate within a comparable legislative framework. The Regulator can develop an agreement with another regulator for the purposes of undertaking joint risk assessments to increase the efficiency of decision making.

Streamlining interactions with domestic regulators

Where approval is required under both the Gene Technology Act and the HSNO Act (for example, where a regulated organism may also be a new organism), the Bill enables joint applications and joint assessments to remove duplicative processes for the applicant.

The Bill enables the Regulator to issue a licence for a medicine or veterinary medicine that is, or contains, gene technology that the Regulator considers is low risk. A regulation-making power will provide for regulations to set a shorter time-frame for this assessment, thereby providing timely decisions for the applicant. The medicine or veterinary medicine cannot be used until it has approval under the Medicines Act 1981 or Agricultural Compounds or Veterinary Medicines Act 1997

Changes to existing authorisations

The Regulator will be able to make changes to authorisations, such as varying licence conditions, transferring licences, and amending or preparing new risk assessments and risk management plans on the basis of significant new information about the relevant risks of the activities. Licence holders will be able to apply to vary or transfer a licence.

The Regulator will have the ability to suspend and cancel licences, and to amend and revoke the declarations of non-notifiable, notifiable, and pre-assessed licensed activities.

Reviews and appeals

Applicants and licence holders will have a right to request the Regulator review certain licence decisions. This is a first opportunity for the Regulator to review the facts of the decision and make any changes, prior to a formal court process.

The Bill also provides a right of appeal direct to the High Court on matters of law for parties directly affected by a decision.

Compliance, monitoring, and enforcement

The Director-General of the Ministry for Primary Industries (MPI) will be responsible for compliance, monitoring, and enforcement of the regulatory regime, consistent with comparable enforcement responsibilities for other regimes, including for hazardous substances and new organisms. The Director-General of MPI will appoint enforcement officers who will monitor and enforce compliance.

The Bill includes offences for breaches of the regime. The Bill also establishes a pecuniary penalty regime to deter financially motivated offending.

Part Two: Background Material and Policy Information

Published reviews or evaluations

2.1. Are there any publicly available inquiry, review or evaluation reports that have informed, or are relevant to, the policy to be given effect by this Bill?	**YES**
Interim Regulatory Impact Statement: Improving our GMO regulations for laboratory and biomedical research. Ministry for the Environment. 2023. https://environment.govt.nz/what-government-is-doing/cabinet-papers-and-regulatory-impact-statements/improving-our-gmo-regulations-for-laboratory-and-biomedical-research/ *The Third Review of the National Gene Technology Scheme.* Commonwealth of Australia as represented by the Department of Health. 2018. https://www.genetechnology.gov.au/reviews-and-consultations/past/2017-third-review *Ko Aotearoa Tēnei: A Report into Claims concerning New Zealand Law and Policy Affecting Māori Culture and Identity, Taumata Tuatahi;* and *Ko Aotearoa Tēnei: A Report into Claims concerning New Zealand Law and Policy Affecting Māori Culture and Identity, Taumata Tuarua (Volumes 1 and 2).* Waitangi Tribunal. 2011. All reports are available at https://www.waitangitribunal.govt.nz/en/publications/tribunal-reports *Gene editing: Legal and regulatory implications; Gene editing in healthcare; Gene editing for pest control;* and *Gene editing for the primary industries.* Royal Society Te Apārangi. 2019. All reports are available at https://www.royalsociety.org.nz/major-issues-and-projects/gene-editing-in-aotearoa/ Further reports can be found at Appendix One.	

Relevant international treaties

2.2. Does this Bill seek to give effect to New Zealand action in relation to an international treaty?	**NO**
However, the Bill is consistent with New Zealand's international obligations – refer to question 3.1 response.	

Regulatory impact analysis

2.3. Were any regulatory impact statements provided to inform the policy decisions that led to this Bill?	YES

MBIE completed *Regulatory Impact Statement – Reform of Gene Technology Regulation* in July 2024 to inform the policy decisions of Cabinet in August 2024 on the Bill. It can be accessed at:

https://www.mbie.govt.nz/science-and-technology/science-and-innovation/agencies-policies-and-budget-initiatives/gene-technology-regulation

https://www.regulation.govt.nz/mfr-what-we-do/regulatory-impact-analysis-ria/regulatory-impact-statements-riss

Some information in the Regulatory Impact Statement is withheld, on the grounds of confidential advice to Government; damage to New Zealand's economic interests; free and frank opinions; national security; and legal professional privilege.

2.3.1. If so, did the RIA Team in the Treasury provide an independent opinion on the quality of any of these regulatory impact statements?	NO

The RIS identified above did not meet the threshold for receiving an independent opinion on the quality of the RIS from the RIA Team based in the Treasury.

2.3.2. Are there aspects of the policy to be given effect by this Bill that were not addressed by, or that now vary materially from, the policy options analysed in these regulatory impact statements?	YES

Aspects of policy to be given effect by the Bill that were not addressed by the policy options analysed in the RIS

Given time constraints and the stage of policy development when the RIS was completed, the RIS did not cover the following policy matters that are to be given effect by the Bill:

- statutory determinations
- suspension, cancellation, surrender, variation, and transfer of licences
- reassessments, and reviews and appeals
- inspection, enforcement and ancillary powers
- offences, defences and penalties
- civil liability
- information sharing
- interaction with the Official Information Act 1982
- various administrative matters including the Gene Technology Regulator's register.

Policy settings for these matters have since either been agreed by the Minister responsible for the Bill under delegated authority from Cabinet following consultation with relevant Ministers or are being proposed to Cabinet when it considers the Bill for introduction.

Aspects of policy to be given effect by the Bill that now vary materially from the policy options analysed in the RIS

The Bill will establish mechanisms to enable the Gene Technology Regulator to consider material adverse effects on Māori kaitiaki relationships with indigenous species that may result from risks to the environment from a regulated organism.

This option, which differentiates between Māori kaitiaki relationships with indigenous species and non-indigenous species, was not analysed in the RIS. The RIS analysed options in relation to kaitiaki relationships with both indigenous species and non-indigenous species of significance (a list of 10 species in schedule 2 of the Plant Variety Rights Regulations 2022).

Extent of impact analysis available

2.4. Has further impact analysis become available for any aspects of the policy to be given effect by this Bill?	NO

2.5. For the policy to be given effect by this Bill, is there analysis available on:	
(a) the size of the potential costs and benefits?	YES
(b) the potential for any group of persons to suffer a substantial unavoidable loss of income or wealth?	YES
The Regulatory Impact Statement sets out the most up-to-date information used by MBIE in relation to potential costs and benefits, and likely affected parties. Refer to the Executive Summary section, and Section 2 on the marginal costs and benefits.	

2.6. For the policy to be given effect by this Bill, are the potential costs or benefits likely to be impacted by:	
(a) the level of effective compliance or non-compliance with applicable obligations or standards?	YES
(b) the nature and level of regulator effort put into encouraging or securing compliance?	YES
Expected benefits of the regime established by the Bill include a reduced compliance burden for regulated parties seeking to develop and use gene technologies. Further information and analysis is contained in the Regulatory Impact Statement (summarised in the Executive Summary). Regulator effort will be necessary to secure compliance by regulated parties with conditions associated with authorisations and applicable standards. The Gene Technology Regulator and the Ministry for Primary Industries (MPI) will both have roles in providing information and education to regulated parties about how to comply; MPI will also be resourced to implement an effective strategy to secure compliance.	

Part Three: Testing of Legislative Content

Consistency with New Zealand's international obligations

3.1. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with New Zealand's international obligations?

MBIE has consulted the Ministry of Foreign Affairs and Trade and other relevant agencies to identify how the policy to be given effect by this Bill needs to be consistent with New Zealand's international obligations under the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety. Of most relevance are New Zealand's obligations as a party to the Cartagena Protocol (accessible at https://bch.cbd.int/protocol/text).

To ensure the Bill is consistent with these obligations, subject to Cabinet agreement, it will require the Gene Technology Regulator to have regard to New Zealand's international obligations under the CBD and the Cartagena Protocol in its decision making.

MBIE has also consulted with the Ministry of Health to identify how the policy to be given effect by the Bill needs to be consistent with New Zealand's obligations relating to protecting the confidentiality of information related to certain medicines applications under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement, accessible at https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm) and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (refer Article 18.50, accessible at https://www.mfat.govt.nz/assets/Trade-agreements/TPP/Text-ENGLISH/18.-Intellectual-Property-Chapter.pdf).

To ensure the Bill is consistent with these obligations, subject to Cabinet agreement, it will mirror specific confidentiality provisions from the Medicines Act 1981 and the Agricultural Compounds and Veterinary Medicines Act 1997 in respect of applications the Gene Technology Regulator may receive for approval of a gene technology or regulated organism that is (or is part of) a medicine.

Consistency with the government's Treaty of Waitangi obligations

3.2. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with the principles of the Treaty of Waitangi?

MBIE conducted targeted engagement with Māori to inform policy development for the Bill. This involved:

- establishing a Māori Focus Group to provide advice and guidance to officials on policy including 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 of iwi across the country, including the Iwi Chairs Science Committee; and
- a hui with Māori from the research and innovation sectors.

This engagement, alongside advice from other government agencies, helped inform provisions in the Bill:

- requiring the Gene Technology Regulator to consider potential adverse effects on Māori kaitiaki relationships with indigenous species before making certain decisions;
- establishing a dedicated advisory mechanism for the Regulator in the form of a Māori Advisory Committee; and
- requiring the Regulator to have regard to that advice before making a decision.

Consistency with the New Zealand Bill of Rights Act 1990

3.3. Has advice been provided to the Attorney-General on whether any provisions of this Bill appear to limit any of the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990?	YES
Advice provided to the Attorney-General by the Ministry of Justice, or a section 7 report of the Attorney-General, is expected to be available on the Ministry of Justice's website upon introduction of the Bill (accessible from https://www.justice.govt.nz/justice-sector-policy/constitutional-issues-and-human-rights/the-bill-of-rights-act/compliance-reports/)	

Offences, penalties and court jurisdictions

3.4. Does this Bill create, amend, or remove:	
(a) offences or penalties (including infringement offences or penalties and civil pecuniary penalty regimes)?	YES
(b) the jurisdiction of a court or tribunal (including rights to judicial review or rights of appeal)?	YES
Part 3 of the Bill creates offences and penalties and civil pecuniary penalties that will apply under the Gene Technology Act. Subpart 3 sets out offences; Subpart 4 sets out infringement offences; and Subpart 5 sets out pecuniary penalties. Part 5, Subpart 2 of the Bill creates rights of appeal. Judicial review is not limited in any way. Subject to Cabinet agreement, the Bill will not include statutory civil liability provisions, which is a departure from the status quo. HSNO includes a strict liability provision for civil liability, whereby a person is liable for damages for any loss or damage caused while carrying out activities in breach of the Act, regardless of whether they intended to do the thing that resulted in the breach or took reasonable care.	

3.4.1. Was the Ministry of Justice consulted about these provisions?	YES
MBIE engaged with the Ministry of Justice throughout development of the offences and penalties regime for the Gene Technology Act to seek both general and specific advice on the appropriate penalty settings and to ensure the offences and penalties achieved the policy intent. This included consultation on briefing materials seeking ministerial decisions. MBIE received feedback from MoJ to improve the construction of the regime both generally and specifically and incorporated these changes into final policy. The Ministry of Justice was informed of the detailed design of the appeals regime, which is comparable to the current appeals regime for genetically modified organisms under HSNO. The Ministry of Justice was informed about the proposal not to include statutory civil liability in the Gene Technology Act.	

Privacy issues

3.5. Does this Bill create, amend or remove any provisions relating to the collection, storage, access to, correction of, use or disclosure of personal information?	YES
The Bill creates a licensing regime for gene technologies and regulated organisms (Part 2, Subpart 3), and sets out what information, including personal information, will be required in applications for a licence. Some application information requirements will be set by regulations. Certain activities under the Bill will not require a licence, but a person carrying out the activity must notify the Gene Technology Regulator they are carrying out the activity. To make licensing decisions, the Regulator will assess an application, and for higher risk or uncertain activities this may include public consultation. The Bill includes a provision that the Regulator may withhold personal information for purposes under the Act, such as publicly	

notifying a consultation on an application for a licence, or publishing information on the Register (refer Part 2, Subpart 8).

The Bill also enables the Regulator to undertake joint assessments of licence applications with recognised overseas gene technology regulators, the intent of which is to gain efficiencies in the decision-making process. For such an assessment to take place, the Bill first requires an agreement to be in place with the relevant overseas regulator, and for the Privacy Commissioner to have been consulted on that agreement (refer Part 5, Subpart 4).

Part 5, Subpart 4 of the Bill sets out information sharing provisions that enable disclosure of information (including personal information) under certain Acts to support the effective operation of the gene technology regime. For example:

- the Regulator may obtain information collected under another Act to be satisfied that the applicant is a fit and proper person to hold a licence (refer Part 2, Subpart 3); and
- the enforcement agency (the Ministry for Primary Industries) may notify the Regulator of a breach of conditions attached to an authorised activity.

Part 5, Subpart 4 enables agencies to impose conditions relating to the disclosure of information.

These provisions will override the Information Privacy Principles contained in the Privacy Act 2020, particularly principles 2, 11, and 12.

Part 2, subpart 8 of the Bill also requires the Regulator to maintain a public register which will include details about licences, authorisations, activities, determinations, recognised overseas authorities, and persons approved under the synthetic nucleic acid screening regime.

3.5.1. Was the Privacy Commissioner consulted about these provisions?	**YES**
MBIE has initiated engagement with the Office of the Privacy Commissioner (OPC) about the proposed information sharing provisions. OPC indicated it is concerned that the need for the Bill to override the Information Privacy Principles has not yet been justified. MBIE officials will work with the Office of the Privacy Commissioner to identify any necessary safeguards that are required to ensure the protection and proper use of personal information under the Bill.	

External consultation

3.6. Has there been any external consultation on the policy to be given effect by this Bill, or on a draft of this Bill?	**YES**
MBIE conducted targeted engagement and convened a Technical Advisory Group, Industry Focus Group and Māori Focus Group to advise MBIE on the policy proposals. For further detail refer to Annex B of the Regulatory Impact Statement (links provided in the response to question 2.3). In the course of refining policy for the Bill, MBIE has: • continued to seek advice from the Technical Advisory Group • had regular engagement with the Environmental Protection Authority, and • engaged on specific policy elements with the Office of the Ombudsman and the Office of the Privacy Commissioner.	

Other testing of proposals

3.7. Have the policy details to be given effect by this Bill been otherwise tested or assessed in any way to ensure the Bill's provisions are workable and complete?	**NO**

Part Four: Significant Legislative Features

Compulsory acquisition of private property

4.1. Does this Bill contain any provisions that could result in the compulsory acquisition of private property?	NO

Charges in the nature of a tax

4.2. Does this Bill create or amend a power to impose a fee, levy or charge in the nature of a tax?	NO

Retrospective effect

4.3. Does this Bill affect rights, freedoms, or impose obligations, retrospectively?	NO

Strict liability or reversal of the usual burden of proof for offences

4.4. Does this Bill:	
(a) create or amend a strict or absolute liability offence?	YES
(b) reverse or modify the usual burden of proof for an offence or a civil pecuniary penalty proceeding?	NO

The Bill creates strict liability offences (refer Part 3, Subpart 3) if a person:

- carries out an activity in relation to a regulated organism, without authorisation
- breaches a condition attached to a licence
- breaches a condition attached to a notifiable or non-notifiable activity
- fails to comply with a requirement, direction or compliance order
- gives information that is false or misleading when required to provide information under the Act, or
- fails to comply with the synthetic nucleic acid screening regime.

Under the new regime, there is likely to be a greater prevalence of genetically modified organisms in New Zealand. These offences are considered appropriate as they create an incentive for people carrying out regulated activities to adopt appropriate precautions, given that breaches could result in severe damages to New Zealand's environment and the health and safety of people. The Bill provides that the person has a defence against a strict liability offence if they can prove that the circumstances were outside their control, or their actions were necessary for certain purposes or were reasonable in the circumstances.

Civil or criminal immunity

4.5. Does this Bill create or amend a civil or criminal immunity for any person?	YES
The Bill provides protection from civil and criminal liability for the Gene Technology Regulator, an employee or agent of the Regulator, an enforcement officer, a member of the Technical Advisory Committee or Māori Advisory Committee, and a member of any subcommittee of those committees. Refer to Part 5, Subpart 8, clause 187. This is in line with protections afforded to officials when carrying out their functions and duties and exercising their powers in good faith.	

Significant decision-making powers

4.6. Does this Bill create or amend a decision-making power to make a determination about a person's rights, obligations, or interests protected or recognised by law, and that could have a significant impact on those rights, obligations, or interests?	NO

Powers to make delegated legislation

4.7. Does this Bill create or amend a power to make delegated legislation that could amend an Act, define the meaning of a term in an Act, or grant an exemption from an Act or delegated legislation?	YES
Part 5, Subpart 5, clause 155(1)(a) creates a power to make regulations for the matters prescribed in clause 163 "Power to make further exemptions from operation of Act and nonregulated activities". This clause provides for delegated legislation to be made that will exempt organisms or categories of organisms and gene-editing techniques from being regulated under the Act. Part 5 Subpart 5, clause 155(1)(d) creates a power to make regulations prescribing circumstances in which the Regulator may waive any fee or levy under this Act. Part 2, Subpart 1 enables specific terms to be amended by regulations, for example including or excluding things from the definition of regulated organism, gene technology and conventional processes. Additional detail in response to this question is included in Appendix Two.	

4.8. Does this Bill create or amend any other powers to make delegated legislation?	YES
Part 2, Subpart 3 clause 23, and subpart 4 clauses 47 and 48 provide that the Gene Technology Regulator has the power to declare by notice in the Gazette that an activity in relation to a regulated organism is a pre-assessed, non-notifiable or a notifiable activity. Part 5, Subpart 3 provides for the Regulator to make delegated legislation in the form of issuing or approving standards for minimising the risks to health and safety of people and the environment. Part 5, Subpart 5 provides for specific regulation making provisions, general provisions for secondary legislation and the process for making regulations. The regulation making powers cover a wide range of matters including joint applications, setting criteria for placing an activity under a risk tier, exemptions from the operation of the Act and offences. A detailed list of the regulations provisions can be found in Appendix Two. Additional detail in response to this question is included in Appendix Two.	

Any other unusual provisions or features

4.9. Does this Bill contain any provisions (other than those noted above) that are unusual or call for special comment?	YES

Appointment and accountability of the Gene Technology Regulator

The Bill provides for the minister responsible for the Gene Technology Act (the Minister) to appoint the Gene Technology Regulator, who will be an employee of the Environmental Protection Authority (EPA). This is a unique arrangement, as ministers do not normally appoint staff of Crown entities. The principle embodied in the Public Service Act 2020 and the Crown Entities Act 2004 is that those with legal accountability for an organisation's work appoint its staff. The Gene Technology Regulator will be a statutory officer, employed by but not accountable to the EPA board in relation to their statutory functions. The Bill provides that the Regulator will be accountable to the responsible minister but does not specify the arrangements for reporting on its activities and use of appropriations.

Limitation on the application of the Official Information Act 1982

The Bill includes a limitation on the application of the Official Information Act 1982 (OIA). It will not apply to information received by the Gene Technology Regulator that is likely to relate to a licence application that has not yet been made. The OIA will apply once the application is received by the Regulator. This limitation is necessary to protect confidential information while an application is being developed and to avoid discouraging pre-application engagement with the Regulator.

Amendments to the Resource Management Act 1991

The Bill will amend the Resource Management Act 1991 (the RMA) to remove the ability for regional councils and territorial and unitary authorities to restrict the use of genetically modified organisms (GMOs).

It will also amend the RMA to address operative plan rules, and consents and consent applications relating to activities with GMOs at the time the Gene Technology Act commences.

Any operative plan rules about activities with GMOs will cease to have effect immediately, so that the transition to a nationally consistent regime for regulating GMOs can occur as quickly as possible. Consent holders and applicants (if any) may choose to continue with the consent or application if that suits their circumstances or choose to surrender or withdraw it.

Appendix One: Further Information Relating to Part Two

Published reviews or evaluations – question 2.1

Briefing to the Prime Minister on the Report on Gene Editing from Royal Society Te Apārangi, Office of the Prime Minister's Chief Science Advisor. 2019.

Updated briefing letter, Office of the Prime Minister's Chief Science Advisor. 2023.

Both evaluations are available at https://www.pmcsa.ac.nz/topics/gene-editing/

Science & Innovation System Performance Report, Rhadegund Life Sciences for Callaghan Innovation. 2016

https://www.mbie.govt.nz/assets/5794b50a6f/2016-science-and-innovation-system-performance-report.pdf

Aotearoa New Zealand Boosted by Biotech – Innovating for a sustainable future, BioTechNZ. 2020.

https://biotechnz.org.nz/about-biotechnz/reports/

WELL_NZ: Modern genetic technology – what is it and how is it regulated, Te Puna Whakaaronui. 2023.

https://fitforabetterworld.org.nz/partnership-groups/te-puna-whakaaronui/publications/

Modern Genetic Technology: Applications in Aotearoa Food and Fibre Production, The Aotearoa Circle. 2024.

https://www.theaotearoacircle.nz/reports-resources/modern-genetic-technology-applications-in-aotearoa-food-and-fibre-production

Proposal for relaxation of European regulations for deliberate release of genetically modified organisms (GMO), The Norwegian Biotechnology Advisory Board. 2019.

https://www.bioteknologiradet.no/filarkiv/2019/01/Proposal-for-relaxation-of-GMO-regulations-with-annexes.pdf

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, European Commission. 2023.

https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en

Gene editing: Evidence update, Royal Society Te Apārangi. 2016.

https://www.royalsociety.org.nz/what-we-do/our-expert-advice/all-expert-advice-papers/gene-editing-technologies/gene-editing-resources/

Regulatory framework for gene editing and other new breeding techniques (NBTs) in Argentina, Whelan, A and Lema, M. 2015.

https://www.tandfonline.com/doi/full/10.1080/21645698.2015.1114698

Cultures in the laboratory: mapping similarities and differences between Māori and non-Māori in engaging with gene-editing technologies in Aotearoa, New Zealand. Kathlene, L., Munshi, D., Kurian, P. et al. 2022.

https://www.nature.com/articles/s41599-022-01104-9

Public perceptions of genetic technologies, Primary Purpose. 2024.
https://static1.squarespace.com/static/5991327b9f74563f03253a11/t/66832f576083fc1c428cadeb/1719873382191/Public+percpetions+of+genetic+technologies+report+June+2024.pdf

Genetic Modification – What do we know? Dairy Exporter. 2024.
https://dairyexporter.co.nz/exclusive-survey-genetic-modification-what-do-we-know/

Community attitudes towards gene technology, David Donnelly, Craig Cormick, Danica Jobson, Zhinan Li. 2021.
https://www.ogtr.gov.au/sites/default/files/2021-11/community_attitudes_report_2021_.pdf

Appendix Two: Further Information Relating to Part Four

Powers to make delegated legislation – question 4.7

The power that provides for delegated legislation to be made that will exempt organisms and techniques from being regulated under the Act is necessary to future-proof the legislation. This is so that new scientific knowledge about the risks that regulated organisms, techniques and processes pose to the health and safety of people and the environment can inform decisions about appropriate exemptions from the regulatory regime without having to amend primary legislation.

Clause 167 “Procedure for making regulations” provides safeguards to ensure the power is properly constrained and used appropriately. This clause requires that the Minister must undertake public consultation on any proposed regulations, as well as consult the Gene Technology Regulator and persons or representatives of persons who the Minister considers are likely to be affected by the proposed regulations, including iwi and Māori.

Powers to make delegated legislation – question 4.8

List of empowering provisions to develop regulations (clause reference)

155 Regulations

156 Regulations relating to joint applications

157 Regulations relating to synthetic nucleic acid providers, manufacturing third party vendors, and customer screening requirements

158 Regulations relating to non-notifiable activities

159 Regulations relating to notifiable activities

160 Regulations relating to timetables

161 Regulations setting criteria and conditions for activities, risk assessment and risk management plans, etc

162 Regulations relating to fit and proper persons

163 Power to make further exemptions from operation of Act and nonregulated activities

164 Regulations providing for transitional matters

165 Regulations relating to offences

Rationale and safeguards

The powers to make delegated legislation described in response to this question are necessary due to the nature of gene technology, which means that the regime needs to address highly technical, detailed, and operational matters best reserved for regulations and other secondary legislation. Furthermore, delegated legislative powers are appropriate as they allow incorporation of advancements in scientific knowledge without having to amend primary legislation. Such powers are also necessary to allow the Regulator to perform its functions.

Safeguards on the use of these powers include consultation and publication requirements to ensure affected parties have the opportunity to provide input, and to promote transparency. All secondary legislation under this Bill must be presented to, and may be disallowed by, the House of Representatives.