MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

COVERSHEET

Minister	Hon Judith Collins KC	**Portfolio**	Science, Innovation and Technology
Title of Cabinet paper	Regulation of gene technology - policy decisions	**Date to be published**	10 December 2024

List of documents that have been proactively released		
Date	**Title**	**Author**
August 2024	Regulation of gene technologies – policy decisions	Office of the Minister of Science, Innovation and Technology
12 August 2024	Regulation of gene technologies – policy decisions CAB-24-MIN-0296 Minute	Cabinet Office
24 July 2024	2425-0421 Regulation of gene technology – regulatory impact statement	MBIE
7 December 2023	2324-1263 Regulation of Biotechnology: Initial Advice	MBIE
8 February 2023	2324-1836 Regulation of Biotechnology: Process	MBIE
13 March 2024	2324-2241 Regulation of biotechnology – joint ministers meeting	MBIE
1 May 2024	2324-3096 Regulation of gene technology – second joint ministers meeting	MBIE
5 June 2024	2324-3529 Regulation of gene technology – third ministers meeting	MBIE
19 June 2024	2324-3917 Regulation of Gene Technology – Fourth Ministers Meeting	MBIE
3 July 2024	2324-4026 Regulation of gene technology – draft Cabinet paper	MBIE
11 July 2024	2425-0261 Regulation of gene technology – draft Cabinet paper for Ministerial consultation	MBIE
16 July 2024	Ministerial call-in provisions, directions and appeals	MBIE

Information redacted **YES / NO** *(please select)*

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Some information has been withheld for the reasons of privacy of natural persons, national economy, national security, confidential advice to government, legal professional privilege and free and frank opinions.

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of gene technology – regulatory impact statement

Date:	24 July 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2425-0421

Action sought		
	Action sought	**Deadline**
Hon Judith Collins KC MP **Minister of Science, Innovation and Technology**	**Note** the attached regulatory impact statement for your information. **Note** the RIS prefers three different options from those in the Cabinet paper. **Note** it is likely RIS will give receive a "Partially Meets" or "Does Not Meet" review grade.	31 July 2024

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

The following departments/agencies were consulted (on the regulatory impact statement)
Ministry for the Environment, Ministry of Foreign Affairs and Trade, Ministry of Health, Ministry for Primary Industries, Public Services Commission, Te Puni Kokiri, the Treasury, Environmental Protection Authority, and the Department of Conservation.

Minister's office to complete:

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

Comments

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of gene technology – regulatory impact statement

Date:	24 July 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2425-0421

Purpose

To provide you with MBIE's regulatory impact statement on the proposed gene technology legislation for your information.

Recommended action

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

a **Note** the attached regulatory impact statement for your information.

Noted

b **Note**, consistent with earlier advice on these matters, the RIS prefers different options from those in the Cabinet paper regarding decision making, the location of the regulator, and Māori interests.

Noted

c **Note** constraints on the policy process means it is likely the RIS will receive a "Partially Meets" or "Does Not Meet" review grade.

Noted

Tony de Jong
Manager, Biotechnology Policy & Regulation
Labour, Science and Enterprise
MBIE

24 / 07 / 2024

Hon Judith Collins KC MP
Minister of Science, Innovation and Technology

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Background

1. MBIE is required by Cabinet's impact analysis requirements to submit a regulatory impact statement (RIS) alongside your Cabinet paper to support Cabinet's consideration of the proposed gene technology legislation.

2. A RIS is an independent document from the responsible agency that summarises its advice on the problem being addressed, the options and their associated costs and benefits, the consultation undertaken, and the proposed arrangements for implementation.

3. We have provided you with MBIE's RIS for the gene technology reforms for your information, and to support you in any relevant discussions at Cabinet.

There are three policy differences between the RIS and the Cabinet Paper

4. A RIS details any material differences between the agency's advice and ministers' decisions. This is to support Cabinet's consideration of regulatory proposals and ensure that the process is open and transparent.

5. MBIE's RIS broadly supports the proposed options in the Cabinet Paper and provides additional argumentation and research to support those positions. However, consistent with earlier advice on these matters, the RIS notes three cases where MBIE's preferred option is different from that in the Cabinet paper. These are:

Topic	Cabinet Paper	RIS
Māori Rights and Interests	Recommends adopting the Plant Variety Rights Act model but changing the Māori Committee from a decision making to advisory body.	MBIE considers an advisory committee would not fully meet Māori expectations for partnership in decision making under the Treaty of Waitangi.
Decision making	Recommends the responsible minister has powers to give general policy directions and to call-in on decisions.	MBIE prefers the option for an independent regulator without ministerial call-in or policy direction powers because it provides greater certainty to applicants and may improve public confidence in the regime.
Location of regulator	Poses options for either MBIE or the EPA to host the regulator but does not express a preference.	Notes that Public Service Commission criteria slightly favour the EPA hosting the regulator, but there are different advantages to each host and on balance either choice would be effective.

6. It is not uncommon for there to be policy differences between a Cabinet paper and RIS, and you are not required to take any action as result.

Constraints on the policy process mean the RIS will not fully meet review criteria

7. Each RIS is assessed by an independent review panel of officials (the Panel) prior to lodgement as part of a 'quality assurance assessment' on whether the RIS provides sufficient information for Cabinet to make informed decisions on the proposals. There are three possible grades: 'Meets', 'Partially Meets', and 'Does Not Meet' review criteria. The Cabinet paper is required to summarise the Panel's grading and rationale.

8. The RIS is currently being reviewed by a panel of six officials from MBIE, the Ministry for Primary Industries and the Ministry for the Environment. Due to timing constraints, it has been necessary to provide you a copy of the version being graded, as a final version will not be available until just prior to Cabinet lodgement next week.

9. We have incorporated changes recommended from the Panel's initial assessment including more:

    a. information on the status quo and why it limits benefits from gene technologies

    b. balance between different options

    c. analysis on 'social licence' towards gene technologies and how reforms would affect it

    d. detail on Treaty obligations and impacts.

10. However, we consider the RIS will at best achieve a "Partially Meets" grade because the constrained policy timeframes and lack of public consultation has limited the evidence we could provide.

11. This means there is also a risk that the RIS will receive a "Does Not Meet" grade. If so, the Cabinet Committee Chair has discretion whether to accept the Cabinet paper for discussion and, if accepted, MBIE would be required to prepare a supplementary RIS following Cabinet's decisions. We understand a "Does Not Meet" assessment would not be unusual and is unlikely to cause delays because other ambitious legislative proposals in other portfolios have received this grade recently and were still accepted for discussion by Cabinet.

Next steps

12. We expect to receive the Panel's final assessment by close of business on Monday 29 July and will inform your office of the result. We will include the assessment and related commentary in the Cabinet paper.

13. The RIS and Cabinet paper would be lodged together into CabNet. The papers must be lodged by 10am Thursday 1 August if you intend to discuss the papers at the Cabinet Economic Policy Committee on Wednesday 7 August.

14. MBIE is required to publish the RIS at the time the relevant bill is introduced to Parliament, or at the time of ministerial release of Cabinet's policy decisions.

Annexes

Annex One: Regulatory Impact Statement

Annex One: Regulatory Impact Statement

Attached separately.

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of Biotechnology: Initial Advice

Date:	7 December 2023	**Priority:**	High
Security classification:	In Confidence	**Tracking number:**	2324-1263

Action sought		
	Action sought	**Deadline**
Hon Judith Collins **Minister of Science, Innovation and Technology**	**Confirm** your intent for the reform and proposed timeline. **Agree** to refer this briefing to Minister of Health, Minister of Agriculture, Minister for the Environment and Minister for Food Safety and for Biosecurity for their information	11 December 2023

Contact for telephone discussion (if required)				
Name	**Position**	**Telephone**		**1st contact**
Iain Cossar	General Manager, Science, Innovation and International		Privacy of	
Simon Rae	Policy Director, Emerging Technologies		Privacy of	✓

The following departments/agencies have been consulted

Minister's office to complete:

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

Comments

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of Biotechnology: Initial Advice

Date:	7 December 2023	**Priority:**	High
Security classification:	In Confidence	**Tracking number:**	2324-1263

Purpose

This briefing seeks to confirm your intent for changes to biotechnology regulation in New Zealand and to set out an initial path forward.

Recommended action

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

a **Agree** that the scope of a work programme to reform biotechnology regulation should be:

a. to put in place new legislation and a new regulator to regulate the use of gene technologies in New Zealand

b. that the reform process will encompass a wide range of genetic techniques, and that it will also include regulation of gene therapies used in health within its scope

c. that you do not intend for the reform process to consider the regulation of hazardous substances

d. that whether new organisms that are not the result of biotechnology are encompassed within new legislation is an open decision

Agree / Disagree

b **Agree** that we should focus our efforts on legislative reform and aim to have a discussion document for public consultation before Cabinet by the end of June 2024

Agree / Disagree

c **Agree** to refer this briefing to the Minister of Health for his information

Agree / Disagree

d **Agree** to refer this briefing to the Minister of Agriculture for his information

Agree / Disagree

e **Agree** to refer this briefing to the Minister for the Environment for her information

Agree / Disagree

f **Agree** to refer this briefing to the Minister for Food Safety and for Biosecurity for his information

Agree / Disagree

Iain Cossar
General Manager, Science, Innovation and International
Labour, Science and Enterprise, MBIE

07 / 12 / 2023

Hon Judith Collins
Minister of Science, Innovation and Technology

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Background

1. In officials' first meeting with you, you indicated that biotechnology regulatory reform, as set out in the National Party manifesto document *Harnessing Biotech*, was your top priority for the Science, Innovation and Technology portfolio, and that your aim was to have legislation passed and a new regulator in place by the end of 2024.

2. The Government's intention to undertake these reforms has been widely welcomed in the science and innovation sector. New Zealand has significant potential in biotechnology, which has been identified globally as a critical technology. Reform of the regulation of biotechnology offers the opportunity to realise this potential and to open up significant economic opportunities for New Zealand in the biotechnology sector.

Design intent

3. We have reviewed the *Harnessing Biotech* report, and previous independent reports by the Royal Society Te Apārangi and the Prime Minister's Chief Science Advisor on biotechnology regulation to identify critical issues in the potential reform of biotechnology regulation, and to ensure we have correctly understood your intent for regulatory reform. We have also engaged with colleagues in the Ministry for the Environment, Ministry of Primary Industries, and Ministry of Health to seek their views, including sharing an early version of this briefing.

The scope of legislative reform will need to be settled at an early stage

4. The *Harnessing Biotech* report sets out three key priorities:

    - End the effective ban on Genetic Engineering (GE) and Genetic Modification (GM) in New Zealand
    - Create a dedicated regulator to ensure safe and ethical use of biotechnology
    - Streamline approvals for trials of use of non-GE/GM biotechnology

5. Our current understanding of your intent with regard to scope of the regulatory reform process 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 Agency
    - that the reform process will encompass a wide range of genetic techniques, and that it will also include regulation of gene therapies used in health within its scope
    - that you do not intend for the reform process to consider the regulation of hazardous substances (note that Bovaer, a methane inhibitor referred to in the *Harnessing Biotech* report, is regulated as a hazardous substance)
    - that whether new organisms (particularly where these are not the result of the application of biotechnology – for instance insects, fungi or other organisms introduced as biocontrol agents) are encompassed within new legislation is an open decision.

6. We would welcome your confirmation that this is the scope you intend for the regulatory reform process.

Regulatory approach and definition of terms are an important first step to further refine scope

7. There is significant technical complexity in understanding the scope of what should be regulated under legislation targeting modern biotechnology techniques, particularly if the intent is also to ensure regulation remains fit for purpose as techniques develop.

8. Legislation for genetically modified organisms falls broadly into three regulatory approaches:

    - Process-based regulations, which focus on the process used to create a new product (which could be a plant, animal, microorganism or food)
    - Trait-based regulations, which focus on the product and its particular characteristics or traits (also known as outcome-based or product-based regulations)
    - Hybrid regulations, which combine elements of process-based and trait-based regulations, commonly by exempting certain techniques that can produce products similar to products produced through traditional breeding techniques.

9. New Zealand's current regulatory approach to GMOs is process-based, while Australia takes a hybrid approach by exempting certain gene-editing techniques from regulatory oversight. The emphasis of the *Harnessing Biotech* proposals on "biotechnology" suggests a process-based or hybrid approach, because it describes the process used to create a product. Trait-based approaches can be useful in achieving a consistent approach to risk, independent of the techniques applied to achieve a particular outcome.

10. The precise scope of what is regulated under a process or hybrid approach will depend on the definitions of key terms such as "genetic modification", "genetic engineering" and "biotechnology". The Royal Society Te Apārangi's report on genetic modification noted that there was some nuance required in defining what constituted genetic modification, and that definitions of important terms differ across various pieces of legislation. In particular it observed that New Zealand's current approach of deciding whether a technique created a new organism led to the potential for perverse outcomes.

11. Settling a clear definition of what we are intending to regulate, and having that agreed across relevant Ministerial portfolios (see below), will therefore be an important first step, especially if the intent is to create a single biotechnology regulator across different domains.

A comprehensive reform programme will require the active cooperation of several other Ministers and agencies

12. Our understanding of your intent with regard to scope as set out above would potentially entail substantive changes to several Acts. Key relevant legislation and Ministers responsible are set out in the table below.

Legislation	**Minister Responsible**	**What it covers**
Hazardous Substances and New Organisms Act 1996 (HSNO)	Minister for the Environment	• Assessment of new organisms (including genetically modified organisms) for import or release • Conditional release of new organisms • Approval of containment for new organisms • Inspection and enforcement • Additional rules in secondary legislation
Environmental Protection Authority Act 2011	Minister for the Environment	• Provides statutory framework for the existing HSNO regulator

Biosecurity Act 1993	Minister for Biosecurity	• Sets out powers of inspectors as enforcement officers under HSNO with regard to new organisms • MPI is the enforcement agency under the HSNO Act • Maintains joint standards with the EPA for some containment facilities for new organisms
Food Act 2014	Minister for Food Safety	• Regulates biotechnology products in food supply (does not specifically refer to genetic modification except in enabling the passing of specific regulations)
Agricultural Compounds and Veterinary Medicines Act	Minister of Agriculture	• Prohibits approval of a veterinary medicine where the product contains a new organism that has not been approved under HSNO
Medicines Act 1981	Ministry of Health	• Spells out a complex relationship between the powers of the Director-General of Health and the Environmental Protection Agency, including in emergencies • Regulates specified biotechnical procedures (currently only xenotransplantation)
Therapeutic Products Act 2023 (noting that the Government intends to repeal this Act)	Ministry of Health	• Regulates gene therapies as a therapeutic product

13. There are choices to be made about the specific changes to be made to each of these Acts, if any, but also a need to ensure that any remaining parts of Acts that are substantially altered continue to provide coherent and workable regulatory regimes (for instance hazardous substances regulation under the Hazardous Substances and New Organisms Act and regulation of new organisms that are not the result of biotechnology).

14. To ensure the establishment of a coherent regime for biotechnology regulation we recommend setting up a Ministerial group to oversee the regulatory reform programme and to coordinate changes to legislation. We would recommend an early conversation with this group to confirm agreement on the scope of the reform, and to set out design objectives or principles to guide the development of policy. We also recommend you refer this briefing to these Ministers.

15. MBIE would intend to convene a similar interagency group at senior officials level to govern policy advice, with the aim of providing consistent (though not necessarily joint) advice to all Ministers. We are still working through with other agencies how we will coordinate our advice, but we are conscious that other agencies have significant expertise on key policy issues that we will want to rely on.

New Zealand also has international obligations with regard to genetically modified organisms

16. New Zealand is one of 173 parties to the Cartagena Protocol on Biosafety (the Cartagena Protocol) to the Convention on Biological Diversity (CBD). The Cartagena Protocol regulates the transboundary movement, transit handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account the risks to human health. The Cartagena Protocol has been in force since 2003 and New Zealand has implemented its obligations through the HSNO Act and other legislation and regulations.

Consultation

17. There has not been any comprehensive consultation on GM/GE regulation since the 2001 Royal Commission on Genetic Modification, and we expect this to be a topic that will attract a wide range of views and values. Consequently we consider it would be prudent to undertake a comprehensive consultation with the public and various stakeholders. We are conscious, however, of the need to balance engagement with the timely delivery of an improved regulatory framework .

18. There is also likely to be significant Māori interest in regulatory change. At this point in time we have not undertaken an analysis of the Crown's obligations to Māori under the Treaty of Waitangi in this policy area. We are conscious in particular of links to the WAI262 claim which asserted that there are rights that iwi and hapū have over flora and fauna (amongst other things) under Article Two of the Treaty, emphasising in particular their kaitiakitanga relationship with the natural environment.

Timeline

We could set up a new regulator (but not change legislation) by the end of 2024 but the benefits of doing so would be uncertain

19. Free and frank opinions We consider that it would be possible to stand up a new regulator by the end of 2024, but not to make comprehensive changes to existing legislation given minimum timelines for legislative drafting and parliamentary consideration.

20. There can be value in setting up a new regulator without making significant changes to legislation if trust in the regulator's decision-making process is itself a problem. We have seen some evidence that this may be the case (for instance in the lack of applications for environmental release of genetically modified organisms), but we are not confident that expectations of the innovation community can be met under the existing legislation.

Technical complexity and widespread public interest will limit the pace at which we can undertake reforms

21. There are two major considerations in developing a timeline for new legislation:

    - The complexity of technical issues to be addressed, and the range of legislation affected by a reform programme (and therefore the diversity of Ministerial portfolios affected)

    - The extent of public interest in the topic, and the need for broad and early engagement with key interested groups in addition to a formal consultation process.

22. We have provided a sense of the complexity of the reform and recommended level of consultation above. In addition, we are also mindful that because of the technical nature of the topic, secondary legislation plays an important role in the current HSNO Act. We would expect this to continue to be the case, especially if we are aiming to create a legislative framework that can evolve along with changes to technology. Putting in place secondary legislation will take additional time once primary legislation is enacted.

Our best estimate is that a comprehensive legislative reform will take at least two years

23. Taking into account these complexities we consider a thorough reform process is likely to take at least two years to complete legislation.

Proposed time frame for full regulatory review

Step	Time required	Target completion
1. Develop features and structure of new legislation and biotech regulator and draft discussion document, including some targeted consultation	6 months	June 2024
2. Public consultation	Six weeks/two months	August 2024
3. Policy work on final proposal	Two months	October 2024
4. Cabinet approval of policy proposals and issuing of drafting instructions	Four weeks/One month	November 2024
5. Legislative drafting	Confidential advice to	Con 2025
6. LEG/Cabinet consideration	Confidenti	Con 2025
7. Select committee	Six months	Confidenti 2025
8. Second reading, committee of the whole, third reading	Confidenti	Confidenti 2025

24. While this is significantly longer than you indicated was your aim, this remains an ambitious timeline with very limited time for rework following public consultation, and a short period for the development of initial policy advice given the complexity of the issues involved. We would prefer to take longer. While some processes such as select committee may be truncated, this is likely to be undesirable given our expectation that there will be widespread public and parliamentary interest in the legislation. This also does not allow time for the development of secondary legislation, although significant work could be undertaken on this prior to enactment of the bill.

Non-legislative improvements could be considered if you wanted to achieve an early harvest

25. In July 2023, the previous Government consulted on a set of 10 proposed changes to the regulations for genetically modified organisms. These proposals largely focussed on regulating laboratory research more proportionately, streamlining the approval processes for biomedical therapies, and ensuring regulations under the HSNO Act were more up-to-date and future proof. We understand the proposed changes would address issues that have been raised by the research community over several years. Some or all of these proposals could be progressed alongside a more comprehensive review, although they would add additional complexity to the reform process, and would require additional resources.

Technical Advice

26. There are a number of highly technical issues that will need to be resolved as part of the legislative process. We intend to establish a technical advisory group to provide support to the policy process, and have begun engaging with agencies through the network of departmental science advisors to identify suitable members. We will share the proposed membership with you for your comment prior to a group's establishment.

Next steps

27. If you agree, we propose to work with agencies to develop further advice on:

    a. a set of design objectives to guide work on regulatory reform

    b. high level design choices to achieve these objectives

    c. an approach to consultation, with a particular view to any early targeted consultation required.

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of Biotechnology: Process

Date:	8 February 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2324-1836

Action sought		
	Action sought	**Deadline**
Hon Judith Collins **Minister of Science, Innovation and Technology**	**Provide feedback** on proposed candidates for the Technical Advisory Group. **Agree** to establish a Ministerial Group to support proposed regulatory reforms for biotechnology. **Agree** that the paper to support public consultation should: • clearly signal preferred government options • consult on adapting and improving the Australian Gene Technology Regulatory System as a first option.	12 February 2024

Contact for telephone discussion (if required)				
Name	**Position**	**Telephone**		**1st contact**
Simon Rae	Policy Director, Emerging Technologies		Privacy of	✓
Privacy of	Privacy of natural		Privacy of	

The following departments/agencies have been consulted
Ministry for Primary Industries, Ministry of Health, Ministry for the Environment, Department of Conservation, and the Department of the Prime Minister and Cabinet (through the Governance Group)

Minister's office to complete:

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

Comments

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of Biotechnology: Process

Date:	8 February 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2324-1836

Purpose

To seek your approval for the proposed approach on consultation and indicative timeframes to support reforms of New Zealand's biotechnology regulation.

Executive summary

Following your agreement in December 2023 to the proposed work programme scope for reforming our biotechnology regulations [Briefing 2324-1263 refers], we have progressed work on:

- regulatory reform objectives and core legislative components
- proposed governance, targeted engagement, and an approach to public consultation
- a detailed timeframe to support public consultation and decisions to be taken by Cabinet during 2024.

To meet these timeframes we propose the following actions:

- establish a high-level Ministerial Group, a multi-agency Governance Group, and a Technical Advisory Group
- begin targeted engagement with a small set of key stakeholders to allow us to surface potential issues early, ahead of full public consultation
- signal the preferred options for legislative reform in the public consultation paper so that stakeholders have visibility of the proposed direction of the reforms
- adapt and improve an existing international regulatory model (specifically Australia's) as a basis for consultation, to help reduce the risks and the time and resource required to reform the legislative framework, and to offer stakeholders greater certainty in the reform outcomes.

The timeframe for this work is fast-paced and ambitious, and despite mitigations it is possible that the programme may be affected by factors outside our control, such as delays in the Parliamentary Counsel Office drafting process or if public opposition is stronger than expected. We will continue to consider how best we manage these factors to avoid unnecessary delays.

We have already convened the Governance Group. Our next steps are to:

- establish a Technical Advisory Group, pending any feedback you might have on the proposed candidates (Annex One)
- start targeted engagement with key stakeholders on their views
- seek your preferences in early March on the high-level regulatory reform objectives and the core legislative components for public consultation.

Recommended action

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

a **Note** that we will seek your preferences in early March 2024 for the regulatory reform objectives and the core legislative components for public consultation

Noted

b **Note** that we will establish a Technical Advisory Group, pending any feedback you might have on the proposed candidates, and start targeted consultation with key stakeholders

Noted

c **Agree** to establish a Ministerial Group to support the reforms, including membership and decision-making rights

Agree / Disagree

d **Agree** that the public consultation paper should signal the preferred options for the core legislative components

Agree / Disagree

e **Agree** that we consult on adapting and improving the Australian Gene Technology Regulatory System as a first option for regulatory reform to expedite the legislative process

Agree / Disagree

f **Agree** the proposed timeframe for public consultation and Cabinet policy decisions

Agree / Disagree

Simon Rae
Policy Director, Emerging Technologies
Labour, Science and Enterprise, MBIE

08 / 02 / 2024

ss
Hon Judith Collins
Minister of Science, Innovation and Technology

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Background

1. In December 2023 you confirmed your intent for the proposed scope of the biotechnology reform work programme [Briefing 2324-1263 refers]. This briefing seeks your direction on the policy work and the approach to be taken for public consultation.

2. We have already drafted a legislative bid for a Gene Technology Bill, which will be available to you on 12 February 2024.

Direction on objectives and core legislative components for consultation

Regulatory reform objectives

3. There is concern that the regulatory settings of New Zealand's current legislative framework for biotechnology are neither fit for purpose nor delivering the strongest benefit for New Zealanders. Agreeing the regulatory reform objectives to address these shortcomings and deliver a legislative framework of benefit to New Zealanders should be agreed early, so that Cabinet, relevant Ministers, key stakeholders and government agencies have clarity about the outcomes sought and the rationale behind the options being put forward.

4. A clear set of regulatory reform objectives will form a critical component of the regulatory impact analysis that will underpin policy work. In drafting these objectives to test with you, we will build on the key priorities set out in the *Harnessing Biotech* manifesto document and your regulatory reform intent and preferences you have expressed in initial meetings.

5. Based on these and the issues identified with the current framework, the reform objectives could include that the proposed legislative settings:

    - are proportionate to the risks
    - deliver outcomes of benefit to New Zealand while appropriately managing risks to the environment and people
    - should be future proof as technology advances over time.

Legislative components to be canvassed through consultation

6. Broadly, the core legislative components that we consider should be canvassed in a consultation paper are:

    - the scope of legislation
    - the legislation's regulatory approach
    - Treaty considerations for genetic technologies
    - the regulator
    - authorisations.

The scope of legislation will determine what things will be regulated

7. At a high level, the scope of legislation describes those technologies, techniques or outcomes that would be encompassed and likely regulated by that legislation. The consultation paper would outline those technologies and techniques to be encompassed by the proposed scope and those that would fall outside this scope. The consultation paper would also detail aspects such as how this scope will interact with other legislation and how we propose to define the scope and other key terms.

The regulatory approach or focus will determine how things will be regulated

8. Legislation for genetically modified organisms can have a regulatory approach (ie focus) on either the process used, the outcome or product produced, or can take a hybrid approach that focuses on equivalency to conventional breeding techniques as well as process. The regulatory approach that is chosen as the preferred option will in turn determine whether the scope of legislation references technologies and techniques or particular outcomes.

9. Given the stated objectives in the *Harnessing Biotech* manifesto document are a shift away from the current legislative focus on the process used, we have discounted improvements to the current process-based status quo as an option for consultation. We will develop and assess product-based and/or hybrid approaches as options for the consultation paper. Our regulatory impact analysis will need to assess these options against the process-based status quo.

10. Should the preferred option proposed be a hybrid approach, the consultation paper will need to detail which technologies or techniques, such as certain gene editing techniques, are to be exempt from regulation and why.

Treaty considerations for gene technology

11. We will need to give careful consideration to how legislation would address the interests and expectations that iwi and Māori have in this area. We will need to take any concerns into account during the policy development process and clearly communicate this in the consultation paper.

12. Of particular relevance to this topic is the Wai 262 Treaty of Waitangi claim. While this claim encompasses a range of considerations including data sovereignty and intellectual property, a key relevant aspect is the protection of taonga Māori by tāngata Māori. A particular area of concern for iwi and Māori will be whether new legislation will provide sufficient protection of taonga species and whether it will allow iwi and Māori to sufficiently exercise kaitiakitanga (guardianship) over those taonga species.

The regulator's form, functions and powers – what it will do and how it will work

13. The consultation paper will need to outline what the proposed regulator will do, how it will work, and how its role and functions interact with that of other agencies:

    - Form – the type of agency proposed for the regulator, for example a departmental agency or Crown agent, and where it is proposed to be located

    - Functions – the areas of responsibility the agency would have, both broadly in terms of functions such as assessments or compliance monitoring and enforcement and the more specific responsibilities related to these broad functions, and how these interact with the functions of other agencies, ensuring clarity where there is overlap and streamlining where possible

    - Powers – what decisions, authorisations and potentially regulatory amendments that the regulator could make, as well as its level of independence and broader authority.

14. Given the importance of adequate resourcing to the prompt assessment of applications, funding of the regulator will be a crucial consideration of the reform. Cabinet will need to make decisions at the relevant time on funding alongside the transitional arrangements and other aspects of establishing the regulator. The consultation paper should ideally canvas the broad approach to how the regulator will be funded.

Legislative authorisations will include applications, assessments and approvals

15. Authorisations encompass the activities that individuals and groups are permitted (and not permitted) to carry out and their obligations in doing so. The consultation paper would outline

the details of each application type, such as field trials or full environmental releases, the specific requirements of applications, and the details of how assessments and approvals are made including provisions for public participation. The paper should also canvass where there are opportunities to streamline applications and approvals that are required across more than one regulator.

Overarching approach for legislative reform

16. Sitting above the core legislative components outlined above, we can also consult based on options for the overarching approach to the legislative reform. These are creating bespoke legislation from scratch, adapting and improving the legislative framework of another jurisdiction, and amending the current legislative framework.

17. Given the ambitious timeframes for this reform programme, we consider that adapting and improving the legislative framework of another jurisdiction that is both well regarded and that is likely to meet the design objectives of this reform programme would be the most efficient approach. Adapting and improving an existing framework will reduce the risk, time and resource required to reform New Zealand's legislative framework and will offer stakeholders greater certainty in the reform outcomes.

18. Given Australia's highly-regarded framework is likely to meet many of the design objectives and has a proven track-record, we recommend consulting on adapting and improving the Australian regulatory system. Should you agree to this recommendation, the consultation paper would outline how the Australian legislative framework would be adapted and improved upon for each of the core legislative components outlined above. Amending and improving on Australia's current regulations would ensure that New Zealand's new framework would be best adapted to New Zealand's specific context and circumstances. Potential improvements could encompass changes proposed by Australia's Office of the Gene Technology Regulator but not yet adopted, as well as regulatory changes recently proposed or adopted by Norway, England and the European Union.

19. While creating a bespoke legislative framework for New Zealand has the potential to be best suited to New Zealand's specific context and circumstances, the work required of bespoke policy development would mean the ambitious timeframes of this reform programme would not be met. There is also a risk that a bespoke legislative framework developed so quickly would not deliver the outcomes it was intended to.

20. The regulatory impact analysis process requires us to also consider options that retain the status quo or reform HSNO without establishing new legislation. We will assess these options in more depth in the consultation document. However, at this stage we consider that the current legislation framework is unfit for purpose and does not meet the objectives of this reform programme. Likewise, a program of reform to amend and improve the HSNO Act is unlikely to be completed in the timeframes set or achieve the intended outcomes of this reform programme.

The consultation paper should signal the preferred options

21. The consultation paper will canvas a range of options in each of the above domains, as required for regulatory impact analysis. We recommend that we signal the preferred options in the document, so that stakeholders have visibility of the proposed direction of reform and can provide considered feedback on the implications, impacts, and expected outcomes of the reform.

22. We expect to brief you in early March to seek your preferences on the regulatory reform objectives sought through this work, and the core legislative components for consultation.

Starting targeted consultation early to identify and address issues

23. As we expect this topic to attract a wide range of views and values, we intend to begin targeted engagement with sector experts and key stakeholders over the next few weeks on their views, to identify potential issues and mitigations at an early stage. These stakeholders will likely include universities and research institutes, iwi and Māori groups, industry associations, Crown Research Institutes, biotech companies, and primary industry and export sector groups. We expect they will likely already be familiar with and have views on the proposals in the *Harnessing Biotech* manifesto document.

We recommend you establish a group of ministers to engage with on the reforms

24. The support of key ministers early and throughout the process is essential to ensuring Cabinet approval processes go smoothly and do not require substantial changes to the proposals. This is required to meet the December 2025 commencement deadline.

25. Establishing a Ministerial Group – which you would Chair – would be the most efficient approach to engagement given the number of interested portfolios. You would decide which portfolios are included and whether other ministers have any decision-making rights. Potential options include:

Option	Ministers involved
1. HSNO focused	You and Environment
2. Portfolios with affected legislation	You, Environment, **Health** and **Biosecurity**
3. Relevant sectors (recommended)	You, Environment, Health, Biosecurity, **Agriculture, Food Safety, Conservation** and **Māori Crown Relations**

26. We recommend option 3 (relevant sectors) as this would include both ministers with responsibility for legislation that may be affected by the reforms and those who oversee sectors that are likely to have very strong views on the proposals. This means issues affecting wider portfolios can be identified and addressed early in the process, supporting smoother Cabinet processes.

27. Option 3 involves only two additional ministers from option 2 as Minister Hoggard holds both the Biosecurity and the Food Safety Portfolios, while Minister Potaka holds both the Conservation and Māori Crown Relations portfolios.

28. Our timeline would be most achievable if you engaged with a wide group but kept decision making more limited, such as retaining sole decision making or in partnership with a key minister (e.g. Environment or Biosecurity).

We seek your feedback on membership of a Technical Advisory Group

29. MBIE is establishing a technical advisory group to provide support to the policy process. A list of potential candidates and biographies for the technical advisory group is provided in **Annex One**. We would welcome your feedback by exception on these candidates. Once you are comfortable with the prospective members of the group, we will proceed to final stages of establishment.

30. We have also convened an interagency group of senior officials from the following Ministries and Departments to govern policy advice: Primary Industries, Health, Environment,

Conservation, and the Department of the Prime Minister and Cabinet. The first Governance Group meeting was held on 5 February 2024.

Risks and mitigations

31. Possible risks to the regulatory reform process arise from the ambitious timeframe and the potential for public opposition, as outlined in the table below.

Risk	Proposed mitigations
Tight timeframes leave little room for delays in meeting the December 2025 deadline Working at pace may lead to lower quality proposals	• Adapt and improve an existing model such as Australia's regulatory system, to reduce the risk, time and resource required • Seek advice from international counterparts on lessons learned • Establish ministerial group, technical advisory group, inter-agency governance group
Significant public opposition develops that risks the reform's timely completion and longevity	• Conduct early targeted consultation with key groups such as primary industry groups, iwi, and universities and research institutes • Develop a practical and accessible consultation paper that speaks to likely concerns • Hold full length consultation (eight weeks) and select committee (six months) processes to ensure concerned parties feel their input is appropriately considered

32. Significant risks remain despite the above mitigations and it is possible that the programme may be affected by additional factors outside our control, such as delays in the Parliamentary Counsel Office drafting process or if public opposition is stronger than expected. We will continue to consider how best to manage these.

Timeframe and next steps

33. The table below sets out the proposed timeframes for public consultation and Cabinet decisions till the end of 2024, for your consideration and agreement, together with the timing for progressing through the House in 2025. A new regulator will also need to be established within this timeframe.

Step	Timeframe
Briefing on regulatory reform objectives and core legislative components for consultation	Early March 2024
Develop consultation paper and Cabinet paper	March – end April 2024

Briefing with draft consultation paper and Cabinet paper for approval and Ministerial/Coalition consultation	Early May 2024
Consultation paper approved for release	29 May 2024: Cabinet Economic Policy Committee (ECO) 3 June 2024: Cabinet
Consultation period	4 June – 31 July 2024
Analysis of submissions and policy work on final proposals	August – mid September 2024
Briefing to agree final design of reforms	Mid September 2024
Briefing with draft Cabinet policy paper and Regulatory Impact Statement for approval and Ministerial/Coalition consultation	Late September 2024
Cabinet policy decisions	23 October 2024: Cabinet Economic Policy Committee (ECO) 29 October 2024: Cabinet
Issue drafting instructions	Confidentia 2024
Drafting	Confidentia 2024 – Conf 2025
Cabinet approval for introduction	Con 2025
Select Committee	Confidentia 2025
Second reading, Committee of the Whole, Third Reading	Confidentia 2025
Commencement	Confidentia 2025

34. Our next steps are to:

- establish the Technical Advisory Group, pending any feedback you might have on the proposed candidates (Annex One)
- start targeted engagement with key stakeholders on their views
- seek your preferences in early March 2024 for the regulatory reform objectives and the core legislative components for public consultation.

Annexes

Annex One: Technical Advisory Group candidates

Annex One: Technical Advisory Group candidates

Name	Organisation	Sector	Expertise
Professor Emily Parker (chair)	Ferrier Institute – Professor Chemical Biology MBIE – Department Science Advisor	Health	Reprogramming fungi to produce valuable commodities and structural and chemical Biology to generate new solutions to treat disease.
Associate Professor Tim Hore	University of Otago – Associate Professor, Department of Anatomy	Medical and animal transgenics	Modification of DNA and associated proteins associated for animal health applications
Dr Richard Scott	AgResearch – Science Team Leader, Plant Biotechnology	Agriculture	Application of gene technology for forage innovation to combat climate change
Professor David Ackerley	Victoria University of Wellington – Professor of Biotechnology, School of Biological Sciences	Microbiology	Applications of gene technology for production of novel antibiotics
Dr Hilary Sheppard	University of Auckland – Senior Lecturer Biological Sciences	Health	Use of gene editing and stem biology for applications in the field of cancer therapies and personalised treatment of skin conditions
Dr Alec Foster	Scion – Manager Bioproducts and Packaging portfolio	Industrial biotechnology	Utilisation of biotechnology to produce plastics and other bioproducts from plants. Led one of Europe's largest synthetic biology programmes, developing new materials with genetically engineered microorganisms.
Professor Jasna Rakonjac	Massey University – Professor of Microbiology, School of Natural Sciences Nanophage Technologies – President and Chief Science Officer	Microbiology	Expertise in phage display, nanorod production and structure, microbiology and immunology.

Associate Professor Maui Hudson Whakatōhea, Ngāruahine, and Te Māhurehure	University of Waikato – Director Te Kotahi Research Institute	Interdisciplinary	Application of mātauranga Māori to decision-making across a range of contemporary contexts from new technologies to health, the environment to innovation.
Dr Andy Allan	University of Auckland – Professor of Biological Sciences Plant & Food Research – Principal Scientist	Horticulture	Genetic controls of key plant characteristics, such as fruit colour and flowering, and applications for breeding new cultivars for the horticultural sector.
Dr Nikki Freed	Daisy Lab – Co-Founder and Chief Scientific Officer University of Auckland – lead technologist at Auckland Genomics	Biotechnology	Precision fermentation food technology in New Zealand. DNA/RNA sequencing.
Dr Rachel Perret	Malaghan Institute – Team leader, Weinkove Laboratory	Health	Engineering and redirecting T lymphocytes to recognise cancer cell proteins more effectively
Ariana Estoras Ngāti Uekaha and Ngāti Maniapoto	AgResearch – Director Māori Research and Partnerships	Māori agriculture	Enabling kaupapa Māori centred research and partnerships at AgResearch
Professor Neil Gemmell	University of Otago – Professor and Acting Deputy Pro Vice-Chancellor Department of Anatomy	Ecology and conservation biology	Evolutionary genetics and genomics, molecular ecology, conservation biology Chair for AgResearch Centre for Reproduction and Genomics
Privacy of	Privacy of natural persons	Privac	Privacy of natural persons

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of biotechnology – joint ministers meeting

Date:	13 March 2024	**Priority:**	High
Security classification:	In Confidence	**Tracking number:**	2324-2241

Action sought		
	Action sought	**Deadline**
Hon Judith Collins KC MP **Minister of Science, Innovation and Technology**	**Discuss** with officials the proposed gene technology reform objectives and options **Agree** to forward this briefing to the Gene Technology Ministerial Group **Note** that MBIE will work with the relevant agencies where the reforms interact with existing legislation **Agree** to introduce the Gene Technology Bill into the House by December 2024	18 March 2024

Contact for telephone discussion (if required)				
Name	**Position**	**Telephone**		**1st contact**
Simon Rae	Policy Director, Emerging Technologies		Privacy of natural	✓
Privacy of natural persons	Privacy of natural persons		Privacy of natural persons	

The following departments/agencies have been consulted
Ministry for the Environment, Ministry for Primary Industries, Department of Conservation, Ministry of Foreign Affairs and Trade, Environmental Protection Authority, Te Puni Kōkiri

Minister's office to complete:

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

Comments

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of biotechnology – joint ministers meeting

Date:	13 March 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2324-2241

Purpose

To provide you with information on the gene technology regulatory reforms to support your meeting with the Gene Technology Ministerial Group on Tuesday 19 March.

Annex 1 provides you with a list of your colleagues' legislation that will be impacted by the reforms. Annex 2 provides you with suggested talking points for the meeting.

Executive Summary

You have established a ministerial group (the Group) to discuss work to reform New Zealand's gene technology regulations. The first meeting on Tuesday 19 March is an opportunity to identify any priorities or concerns your ministerial colleagues would like considered as part of the reforms, and to develop a shared understanding with them on scope and objectives.

Our policy work is at an early stage and ministerial agreement on some initial issues would help direct our analysis. We therefore suggest the following agenda:

- What you are trying to achieve with the reform
- Scope – should the new legislation focus on gene technologies or also include other biotechnologies?
- Approach – what are your colleagues' views on the extent to which gene technologies should be permitted in New Zealand?
- Impact on other legislation – are your colleagues interested in working with you to streamline administrative processes across portfolios?

MBIE recommends focusing the scope solely on gene technologies because other biotechnologies are generally lower risk or are adequately regulated. The former is already a complex area, and we need to be disciplined on scope to deliver the reforms in a timely manner. You could also raise that work will be needed on what happens to existing HSNO provisions on new organisms that are not gene technologies, which are arguably outside your delegation from the Prime Minister.

There are several options on the regulatory approach that would influence how permissive the new regime would be for the use of gene technologies. Following Australia's example would mean adopting a 'hybrid' approach, which exempts certain lower-risk technologies from regulation. Other jurisdictions have gone further to exempt techniques that deliver similar results to conventional selective breeding in crops. Our options analysis would benefit from guidance on whether we should aim to be at the frontier of new technologies or should take a more precautionary approach to managing risks.

Your colleagues are responsible for other legislation that will be impacted by these reforms. In most cases this will be a simple updating of references to the new legislation. With your colleagues' approval, we could also work with their agencies to reduce regulatory complexity by integrating parts of the new legislation with other ministers' legislation and regulating authorities.

Recommended action

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

a **Discuss** with officials the proposed gene technology regulatory reform objectives and options regarding legislative scope and regulatory approach

Discuss

b **Agree** to forward this briefing to the Gene Technology Ministerial Group

Agree / Disagree

c **Note** that MBIE officials will work with the relevant agencies where the gene technology reforms interact with existing legislation within the portfolios of the Ministers in the Gene Technology Ministerial Group.

Noted

d **Agree** to introduction of the Gene Technology Bill into the House by December 2024, with increased targeted stakeholder consultation to inform Cabinet policy decisions in place of a full public consultation process

Agree / Disagree

Simon Rae
Policy Director, Emerging Technologies
Labour, Science and Enterprise, MBIE

14 / 03 / 2024

Hon Judith Collins KC MP
Minister of Science, Innovation and Technology

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

Background

1. You have established the Gene Technology Ministerial Group (the Ministerial Group) to discuss work to reform New Zealand's gene technology regulations. The first meeting is on Tuesday 19 March and we understand the following ministers will attend:

    - Hon Dr Shane Reti (Health)
    - Hon Tama Potaka (Conservation, Māori Crown Relations and Māori Development)
    - Hon Penny Simmonds (Environment)
    - Hon Andrew Hoggard (Biosecurity and Food Safety)

2. One member of the Ministerial Group, Hon Todd McClay (Agriculture and Forestry), has given his apologies for the meeting.

3. If we are to introduce legislation into the House this year, we have limited scope to accommodate delays to the policy process, for instance due to changes requested at Cabinet. It is important that your colleagues with relevant portfolios are engaged early and are supportive of the reform.

4. The meeting is therefore an opportunity to identify any priorities or concerns your ministerial colleagues would like considered as part of the reforms, and to develop a shared understanding with them on the reform's scope and objectives. We recommend focusing on high-level issues as we are in the early stages of policy development. Future meetings could be used to cover more concrete options.

5. We suggest the following agenda for the meeting:

    - Introductions
    - What you are trying to achieve with the reform
    - Scope – should the new legislation focus on gene technologies or also include other biotechnologies?
    - Approach – what are your colleagues' views on the extent to which gene technologies should be permitted in New Zealand?
    - Impact on other legislation – are your colleagues interested in working with you to streamline administrative processes across portfolios?

Update on policy development

6. In February 2024 you agreed that work on gene technology regulatory reform should focus on adapting and improving the Australian Gene Technology Regulatory System as a first option [Briefing 2324-1836 refers].

7. We are currently looking into improvements that could be made to the Australian legislation, including recommendations from recent reviews that have not been incorporated. These may include streamlining medical applications, incorporating Treaty of Waitangi obligations, ensuring compatibility with existing international treaties and trade agreements, and incorporating a risk-based approach for field trials and full releases.

8. We will also be investigating whether to carry over some previous decisions from the Environment Protection Authority that may be more enabling for gene technologies than equivalents under the Australian regime.

The reforms aim to enable the greater use of gene technologies in New Zealand

9. We recommend discussing your objectives for the reform with the Ministerial Group to ensure the new legislation is designed in a way that is acceptable to their portfolios.

10. The reform programme aims to address the problem of current regulatory settings for gene technology being overly restrictive and disproportionate to the risks, out of date, and inflexible to emerging science and technology.

11. New Zealand is missing out on the benefits from new gene technologies that could deliver advances in health science, respond to climate change, lift agricultural productivity, and boost exports. For example, under the current Hazardous Substances and New Organisms Act (HSNO), no gene edited or genetically modified crops are grown commercially in New Zealand.

12. We suggest the legislation would be most effective at resolving these problems if it was designed to achieve the following objectives:

    - **Risk-proportionate** – it proportionately manages the risks that gene technology poses, to protect New Zealand's environment and supporting ecosystems, and the health and safety of its people and communities.
    - **Enabling** – it enables the safe use of gene technologies to deliver better health, environmental, societal, cultural and economic outcomes for New Zealanders.
    - **Accessible** – its processes facilitate the efficient assessment and approval of safe and ethical technologies and are easy for applicants to navigate.
    - **Future focused** – it anticipates and flexibly accommodates future technological developments to benefit New Zealanders.
    - **Rights and Interests** – it appropriately reflects potential obligations to actively protect Māori rights and interests under Te Tiriti o Waitangi/The Treaty of Waitangi.

The scope of new legislation should focus on gene technologies

13. You will need to agree the scope of the legislation with the Ministerial Group as it will influence the reform's impact on their portfolios. The key decision is whether the legislation should have a narrow scope and focus on gene technologies exclusively or whether it should also cover other biotechnologies. In addition, we will need to consider what happens to existing HSNO provisions for new organisms are not gene technologies (eg biocontrol agents).

14. Gene technology generally refers to the use of modern technologies (i.e. not traditional methods such as selective breeding) to modify the genes or genetic material of organisms. This includes technologies such as gene editing. It is a subset of biotechnology, which is a broad branch of science that combines biology and technology to develop new products, methods and organisms intended to improve human health and society. It includes a wide range of fields and technologies that may or may not include genetic modification.

15. MBIE recommends proposing to the Ministerial Group that the legislation focus exclusively on gene technologies because:

    - Many biotechnologies pose low risks to human health and the environment and do not require regulation. Others, such as vaccines developed without gene technologies, are covered adequately by other legislation and regulators.

- International practice tends towards dedicated gene technology regulations, such as in Australia
- A wider scope could increase administrative complexity and costs by duplicating or clashing with existing legislation such as the Medicines Act or the Agricultural Compounds and Veterinary Medicines Act.
- A wider scope would require more policy development to deliver effective legislation, and it would be very difficult to complete this in time to introduce a bill into the House this year.

16. You have previously indicated that your intent is to put in place new dedicated legislation for gene technologies. This will likely require additional changes to ensure that the remaining aspects of HSNO (primarily new organisms) continue to function effectively. In particular, there is a prima facie case that regulation of new organisms should be moved to the Biosecurity Act. We will explore options for this with the Ministry for Primary Industries (MPI) and the Ministry for the Environment, and you may wish to raise this with colleagues. Changes to provisions for new organisms are arguably outside your current delegation from the Prime Minister to take forward gene technology regulation, and therefore would need to be either led by or jointly proposed with relevant Ministers.

17. Your colleagues may ask for the reforms to cover biotechnologies or similar technologies that face regulatory constraints outside this narrow scope, such as the importation and use of chemical compounds like methane inhibitors. Our advice is that these constraints are often due to legislation outside the scope of your delegation from the Prime Minister (e.g. the Agricultural Compounds and Veterinary Medicines Act) and, if removing these constraints is desirable, that legislation would need to be amended regardless of the scope of the gene technology bill. Changes to gene technology regulation are already a complex undertaking and we consider that we will need to take a disciplined approach to defining scope if we are to meet current timelines for enactment.

18. We will provide detailed advice, following policy development and consultation with the Technical Advisory Group, on what gene technologies could be considered within the regulatory scope of the new legislation and how to ensure it is future proofed for subsequent advancements. We will also explore mechanisms by which to exempt certain gene technologies from regulation should it be determined that their risk is low and comparable to other unregulated technologies or conventional techniques.

We could follow the Australian regime or take a more permissive approach like the European Union has proposed

19. You will have choices about the regulatory approach to gene technologies, which means how they would be assessed under the new legislation and whether some lower risk technologies should be streamlined or exempt from regulation. Our policy development of these options would benefit from a discussion with your colleagues on their preferences about the extent to which gene technologies should be permitted in New Zealand.

20. New Zealand's current regulatory approach for GMOs is referred to as 'process-based'. This means the HSNO Act focuses on the technology used to produce a GMO to determine what is and is not regulated. Process-based approaches can become outdated as technology advances unless they are regularly updated to account for these developments.

21. You have two main options to replace the process-based system, either a **hybrid approach** (e.g. Australia and England) or an **outcomes based approach** (e.g. USA and Canada).

Hybrid approach

22. You have agreed for MBIE to investigate the Australian system as a first option, which would mean taking a hybrid approach. This combines a process-based approach while specifically exempting certain lower risk gene technologies from regulation. Should we adopt this approach, a key decision will be determining which gene-editing techniques are exempted and how this would be updated as technology advances.

23. The Australian legislation exempts relatively few techniques from regulatory oversight, known as SDN-1 techniques. Other jurisdictions, such as the United States, Canada, and England, exempt a greater number of techniques. Similarly, following approval by the European Parliament's Environmental Committee in January, the European Parliament is beginning negotiations with member states on a proposal to exempt a wider range of gene-editing techniques in plants that produce results equivalent to those that could be achieved through conventional breeding techniques. Changes to EU rules in particular have the potential to set wider norms for international trade, particularly as new techniques for gene editing are difficult to detect.

24. Any technique involves a degree of risk so our advice on which gene technologies should be exempted under regulation would consider what types of organisms (humans, plants, animals, microorganisms) apply, as well as the types of gene technology applications that may still require case-by-case assessment.

Outcome-based approach

25. Outcome or trait-based approaches focus on regulating the outcome or trait produced in an organism rather than the process or technique used to obtain it. This means it is better able to address novel technologies compared to process-based or hybrid approaches.

26. While outcome-based approaches are well-regarded in the scientific community given their focus on the ultimate traits produced, it is not clear that outcome-based legislation in other jurisdictions has produced higher rates of approved applications and products compared to hybrid legislation, or a better balance of risk and opportunity.

27. One potential drawback is that, by focusing on outcomes and not technologies, there can be a lack of clear rules for research conducted within laboratories. Another drawback specific to the New Zealand context is that Māori interests in this area relating to whakapapa concern the modification of genetic material, not just the outcomes or traits ultimately produced.

The reforms will require amendments to your colleagues' legislation

28. Your colleagues are responsible for existing acts that interact with the proposed reforms (Annex 1). In several cases these acts refer to the existing HSNO regime and will need to be updated to refer to the new gene technology legislation and regulator.

29. With your colleagues' approval, we could also work with their agencies to consider options to integrate the new legislation with other ministers' legislation and regulating authorities, with the aim of reducing regulatory complexity. For example, the current system requires some gene technologies to be approved by multiple regulators before they can be used (e.g. both from the EPA and Medsafe for certain medicines). We think there is value in investigating whether these processes could be streamlined or consolidated.

30. The most relevant legislation interacting with the proposed new legislation includes:

    - *Biosecurity Act 1993* – Under New Zealand's current regulatory system for GMOs, HSNO focuses on risks from GMOs while the Biosecurity Act focuses on risks *associated* with organisms, including GMOs. Additionally, the Biosecurity Act enables the approval of containment facilities, within which research on GMOs can be conducted, as well as

enabling the importation of GMOs into New Zealand. There is an opportunity to streamline processes by working with MPI on whether specific functions under new gene technology legislation (such as compliance) could be consolidated.

- *Medicines Act 1981* – Under the current system, medicines that are, or contain, GMOs must be approved under both the HSNO Act and the Medicines Act before they can be used on people. A similar system is in place under Australian legislation, with the Office of the Gene Technology Regulator (OGTR) assessing risks to public health and the environment and the Therapeutic Goods Administration assessing risks to patients. While the Medicines Act was due to be replaced in 2026 by the Therapeutic Products Act 2023 the Government has signalled its commitment to repeal the Therapeutic Products Act.

- *Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act)* – Agricultural compounds and veterinary medicines must be approved under both the HSNO Act and the ACVM Act before they can be used in plant and animal management. A similar system is in place under Australian legislation, with the OGTR assessing risks to public health and the environment and the Australian Pesticides and Veterinary Medicines Authority assessing risks to plant, animal, and human health.

- *Animal Welfare Act 1999* determines whether animals can be manipulated. Manipulation includes the breeding or production of an animal using any breeding technique (including genetic modification) and considers the effect of genetic modification on the animal's production performance and on its progeny.

- *Food Act 2014* creates a regulatory framework for ensuring food is safe and suitable for the protection and promotion of public health. New Zealand also has a Food Treaty with Australia that enables the creation of harmonised food standards for labelling and composition and mutual recognition of food safety standards. Novel foods, including those derived from GMOs must be approved for use prior to marketing.

- *Imports and Exports (Restrictions) Act 1988* restricts the import and export of goods such as dangerous goods or hazardous waste and upholds New Zealand's international obligations in this area. This includes the Cartagena Protocol, for which countries that export GMOs that are intended to be released into the environment must give the importing country advance notice of the export, and then the importing country must agree to the export.

Science system stakeholders are positive about the reforms

31. You may wish to update your colleagues on stakeholder feedback to the proposed reforms so far. We have held targeted engagements over the last two weeks with sector experts and key stakeholders to seek feedback on their experiences of the current legislation and to identify potential opportunities, issues, and mitigations at an early stage.

32. They include universities and research institutes, industry associations, Crown Research Institutes, biotech companies, Genomics Aotearoa, Royal Society Te Apārangi, Federated Farmers and primary industry sector groups.

33. Stakeholders were generally in agreement that the current regulatory settings for gene technology are no longer fit for purpose nor delivering the strongest benefit for New Zealanders. Stakeholders felt there was a genuine opportunity to explore the New Zealand specific environmental and human health benefits from gene technologies, as well as commercial benefits.

34. Some key views that arose from the sessions were:

- New Zealand is missing out on economic opportunities and development of new technologies. For example, prohibitions on genetically modified crops mean New Zealand is missing out on crops that are more resistant to disease and the impacts of climate change or have enhanced nutritional content.
- Current compliance costs are high and, in many cases, prohibitive. This acts as a deterrent to undertaking research but also to researchers choosing a career path in biotechnology.
- General support for adapting and improving the legislative framework of another jurisdiction such as Australia, to fit New Zealand's specific context and circumstances. However, it was noted that would need to ensure that new frameworks aligned with our global markets, and that there are aspects of the Australian legislation that we should improve on.
- Gene technology is moving rapidly and there is a need to ensure any new regulatory framework is future proofed.
- Some sectors will have diverse views, for example some parts of the horticulture sector are well advanced in thinking about gene technology while others are concerned about potential impacts on organic certifications and our 'clean green' brand.
- Māori interests and expectations will be important to consider as we develop new legislation.

Next steps

35. You confirmed on 6 March 2024 that the Gene Technology Bill should be introduced into the House by December 2024 and that to achieve this deadline we would need to remove the public consultation period, leaving the Select Committee process as the main vehicle for public input. We will hold increased targeted engagements with stakeholders to inform Cabinet policy decisions, additional to those already planned, by establishing additional focus groups with Industry and Māori.

36. Our targeted engagement has been well received by research and business sectors and there is a genuine willingness to support development of fit for purpose gene technology regulation. We will continue our targeted engagement with a focus on setting up the industry focus group and Māori focus group.

37. The revised timeframe is outlined below:

Step	**Timeframe**
Policy design	March – May 2024
RIA assessment + Cabinet policy approvals	June – July 2024
Issuing of drafting instructions	August 2024
Drafting	August – October 2024
Pre-Cabinet approvals (Minister's signoff, coalition consultation, Bill of Rights review, etc.)	October – November 2024

Cabinet approval for introduction	Confidential advice to Government
Select Committee	Confidential advice to Government 2025
Second reading, Committee of the Whole, Third Reading	Confid ential 2025
Commencement	Confid ential 2025

Annexes

Annex One: Affected legislation

Annex Two: Talking Points

Annex 1: Affected legislation

Minister	Portfolio	Act	Interaction with gene technology reform
Hon Penny Simmonds	Environment	Hazardous Substances and New Organisms Act 1996 (**HSNO Act**) Resource Management Act 1991 Environmental Protection Authority Act 2011	New organisms, organisms (includes human cell), genetically modified organisms (GMO) Regional rule provisions Review of Regulator form, function, powers and duties
Hon Dr Shane Reti	Health	Therapeutic Products Act 2023 / Medicines Act 1981 Human Assisted Reproductive Technology Act 2004 Human Tissue Act 2008 Health Research Council Act 1990	Genetic means, processes and treatments Qualifying therapeutic products and new medicines Restrictions on specified biotechnical procedures. Prohibited actions. Review definition of GMO Ethics Committees
Hon Andrew Hoggard	Biosecurity	Biosecurity Act 1993 National Animal Identification and Tracing Act 2012	Unwanted organisms and pest management Genetic information
	Food Safety	Agricultural Compounds and Veterinary Medicines Act 1997 Animal Products Act 1999 Food Act 2014	Biological compounds and agricultural compounds Qualifying and restricted veterinary medicine Standards for GM of animal products and food
Hon Todd McClay	Agriculture, Forestry, Hunting and Fishing, Trade	Animal Welfare Act 1999 Plant Variety Rights Act 2022	Animal manipulation, genetic modification and biological product Plant essentially derived varieties
Hon Tama Potaka	Conservation	Conservation Act 1987 Reserves Act 1977 National Parks Act 1980 Wild Animal Control Act 1977 Wildlife Act 1953	Biological control organism to control wild animals or animal pests Genetic modification Conservation management and wild animal controls
	Māori Development		WAI 262 - Te Pae Tawhiti work programme is focussed on policy development relating to Māori cultural intellectual property and provenance

Minister outside of GE Ministers Group	Portfolio	Act	Interaction with gene technology reform
Hon David Seymour	Regulation Health (Associate Minister)	Medicines Act 1981 Pae Ora (Health Futures) Act 2022	Delegated authority for current medicines regulator, Medsafe Delegated authority for Pharmac Delegated authority for proposed Medicines Strategy
Hon Casey Costello	Health (Associate Minister)	Therapeutic Products Act 2023	Delegated authority for the repeal of the Therapeutic Products Act 2023 and potential new therapeutics policy
Hon Shane Jones	Minister for Oceans and Fisheries	Fisheries Act 1996	Fish farming Biological diversity and unwanted aquatic organisms

Annex Two: Talking points

Objectives

- New Zealand's gene technology rules are overly restrictive, out of date, and inflexible to new science and technologies. We are missing out on the benefits of new gene technologies that could deliver advances in health science, respond to climate change, and lift agricultural productivity.
- I am working to introduce new legislation that enables the safe use of gene technologies, is efficient and accessible for applicants, and is future-proof for technological advances.

Scope

- I propose that the new legislation focus on regulating gene technology, which is a type of biotechnology that focuses on modifying the genetic material of organisms.
- Other biotechnologies do not need to be regulated or are already covered by legislation in your portfolios such as the Medicines Act, which covers vaccines that were developed without gene tech.
- *[If asked about including biotechnologies that don't involve gene tech]* Getting gene technology regulation right is a high priority and already quite complex. I am keen that we make the most important changes right now and do it well, which means we need to be disciplined about scope. We can always look to make other changes in parallel through another process.

Approach

- I am interested in your thoughts on how permissive New Zealand should be on the use of gene technologies.
- While Australia is more open than New Zealand, other jurisdictions like England and Canada have gone even further to remove restrictions on gene tech that delivers similar results to conventional selective breeding. The European Commission has also proposed a more liberal approach than Australia, although that still requires approval by EU Member States.
- Should we aim to be at the frontier of new technologies, or should we take a more cautious approach like Australia so we can learn from others' experiences?

Impacts on your colleagues' portfolios

- To progress this work, we would need to make minor changes to several acts within your portfolios where they refer to the existing Hazardous Substances and New Organisms Act regime for gene technologies.
- With your approval, I would also like to commission MBIE to work with your agencies to investigate how we might streamline administrative processes between

our portfolios. For example, some gene therapies currently require approval from both the EPA and Medsafe before they can be used here.

- Streamlining these functions, which could include delegating some responsibility to agencies in your portfolios, would reduce administrative costs and enable New Zealanders to access the benefits of gene tech more quickly.
- We also need to decide what we do about new organisms that are not genetically modified such as biocontrol agents (eg insects introduced to control pest plants). We could leave them in the HSNO Act, but that runs the risk of increasing regulatory complexity when we are trying to simplify things. It might be more logical to move regulation of new organisms to the Biosecurity Act, similar to many other jurisdictions.

What stakeholders are saying

- MBIE officials are engaging with many organisations in the science and innovation sectors and have been hearing strong positive feedback on our proposed reforms.
- Stakeholders are excited by the opportunities this reform offers to use of gene tech outside of the lab, and are keen to see an effective, accessible process that keeps costs down.
- There's been support for adapting the Australian regime, but some want us to go further and align with the European Union which is proposing to open up even further to gene tech.

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of gene technology – second joint ministers meeting

Date:	1 May 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2324-3096

Action sought		
	Action sought	**Deadline**
Hon Judith Collins KC MP **Minister of Science, Innovation and Technology**	**Agree** in principle that the proposed Gene Technology Bill contains a risk-tiering approach, sets non-regulated organisms under secondary legislation, and aligns definitions with the Australian Gene Technology Act 2000. **Agree** to forward this briefing to the Gene Technology Ministerial Group.	8 May 2024

Contact for telephone discussion (if required)				
Name	**Position**	**Telephone**		**1st contact**
Simon Rae	Policy Director, Emerging Technologies		Privacy of	✓
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The following departments/agencies have been consulted
Ministry for Primary Industries, Ministry for the Environment, Treasury, Environmental Protection Authority, Ministry of Health

Minister's office to complete:

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

Comments

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of gene technology – second joint ministers meeting

Date:	1 May 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2324-3096

Purpose

To provide you with advice on issues for inclusion in the upcoming Gene Technology Bill for discussion at your meeting with the Gene Technology Ministerial Group on Wednesday 8 May.

Annexes 1, 2 and 3 provide you with summaries of the topics we propose for discussion at the meeting.

Executive Summary

Cabinet will need to make policy decisions around the nature of the proposed Gene Technology Bill and functions of the new regulator before drafting instructions can be issued to the Parliamentary Counsel office. This briefing focuses on key legislative questions, namely authorising genetic modification activities through risk tiering, non-regulated technologies, and definitions.

Most jurisdictions regulate some genetic modification activities differently on the basis that they are higher or lower risk ('risk tiering'). However, most activities are treated the same regardless of risks and a more graduated system, involving several risk tiers, would be more risk proportionate by matching the level of oversight against the risks involved in the activity (eg oversight increases when risks do). Australia has a graduated model we propose adapting for New Zealand.

Legislation in both Australia and New Zealand enables certain technologies to be exempted from regulation through secondary legislation. Specific exemptions do not need to be agreed at this time but, as a starting point, we propose to combine the existing non-regulated lists from both Australia and New Zealand. This would enable New Zealand researchers to use technologies that have been unregulated in Australia while not restricting current activities.

Unlike New Zealand, jurisdictions like Australia and England have been extending exemptions to lower risk gene editing techniques. We recommend a more permissive approach than Australia because it regulates some techniques (known as SDN-2) that are similar in risk to those it exempts (SDN-1). This proposal has been supported by industry and science stakeholders.

The new legislation will need to define gene technologies and genetically modified organisms to determine the regulator's remit. We propose to align our definitions with the Australian Gene Technology Act 2000 to support consistency and trans-Tasman research collaborations. We recommend some minor changes from Australia to avoid regulating human beings and some common medical therapies, and to future proof the regime for constructed organisms (ie those created from scratch using synthetic biology).

We have continued stakeholder engagements with Māori and industry. Māori views on gene technologies are diverse, but there is significant interest in the opportunities offered by the proposed legislation. They are most interested in enabling solutions to sustain the environment and protect taonga species. Industry generally supports the reforms and there is significant interest in a more permissive approach to gene editing exemptions than Australia. However, producer groups have raised that some consumers will have preferences for non-genetically modified products and the new regime would need to preserve industry's ability to supply them (eg non GM verifications).

Recommended action

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

a **Agree** to forward this briefing to the Gene Technology Ministerial Group

Agree / Disagree

b **Agree** in principle, pending further policy development, that the proposed Gene Technology Bill contain the following features:

i. A risk-tiering approach for activities, informed by the Australian non-regulated, non-notifiable, notifiable, and licensed categories.

Agree / Disagree

ii. Non-regulated organisms that can be set under secondary legislation, with the initial list made from merging the existing Australian and New Zealand exemptions.

Agree / Disagree

iii. Exemptions for the use of gene editing techniques that deliver results that are equivalent to those that could be achieved naturally.

Agree / Disagree

iv. Definitions of regulated (ie genetically modified) organisms that are aligned with the Australian Gene Technology Act 2000, with exceptions to include constructed organisms and exclude human beings and non-replicating RNA, DNA and viral vectors.

Agree / Disagree

Simon Rae
Policy Director, Emerging Technologies
Labour, Science and Enterprise, MBIE

01 / 05 / 2024

Hon Judith Collins KC MP
Minister of Science, Innovation and Technology

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

Background

1. The second meeting of the Gene Technology Ministerial Group (the Ministerial Group) is on Wednesday 8 May at 8:00-8:45pm. We understand the following ministers will attend:

    - Hon Andrew Hoggard (Biosecurity and Food Safety)
    - Hon Mark Patterson (Rural Communities and Associate Agriculture)
    - Hon Todd McClay (Agriculture) – if international travel permits

2. Ministers Reti (Health), Potaka (Conservation, Māori Crown Relations and Māori Development) and Simmonds (Environment) have sent apologies and will be represented by advisors.

3. This meeting is an opportunity to build consensus with colleagues on key aspects of the legislation in advance of seeking Cabinet agreement. We suggest the following agenda:

    - Introductions
    - Adopting a risk-tiering approach (Annex 1)
    - Approach to non-regulated technologies (Annex 2)
    - Definitions (Annex 3)

4. At the first meeting (2324-2241 refers) you agreed with colleagues that the legislation should focus on gene technologies. You raised that the Hazardous Substances and New Organisms Act 1996 (HSNO) would need to be amended to address new organisms not covered by the upcoming Gene Technology Bill. The Ministry for the Environment is preparing advice on this.

5. We also proposed the following objectives for the legislative reform which, pending ministerial feedback, will be used as criteria for our analysis:

    - **Enabling** – the legislation enables the safe use of gene technologies to deliver better health, environmental, societal, cultural and economic outcomes for New Zealanders.
    - **Risk-proportionate** – it proportionately manages the risks that gene technology poses, to protect New Zealand's environment and supporting ecosystems, and the health and safety of its people and communities.
    - **Efficient and Accessible** – its processes facilitate the efficient assessment and approval of safe and ethical technologies and are easy for applicants to navigate.
    - **Future focused** – it anticipates and flexibly accommodates future technological developments to benefit New Zealanders.
    - **Rights and Interests** – it appropriately reflects potential obligations to actively protect Māori rights and interests under Te Tiriti o Waitangi/The Treaty of Waitangi.

Cabinet will need to agree on key issues to draft the legislation

6. Cabinet will need to decide the following issues before drafting instructions can be issued to the Parliamentary Counsel Office:

   The legislation

   i. **Scope and definitions:** What is and is not being regulated? How are gene technologies and genetically modified organisms defined?

   ii. **Authorisations:** What activities should require authorisation? Should certain activities be treated differently and, if so, how (eg laboratory research, medical use, environmental release)? How should the regulator interact with international regulators?

   iii. **Legislative purpose:** Should the legislation aim to prevent risks or manage them? Should it focus solely on risks or conduct risk/benefit assessments?

   The regulator

   iv. **Form:** should the regulator be a Crown agent, departmental agency or something else? Where should it be situated?

   v. **Assessments and decision making**: What evidence should the regulator consider in its assessments?

   vi. **Compliance, monitoring and enforcement:** How should these services be provided and should there continue to be a role for other agencies like MPI?

7. This briefing focuses on the first two legislative questions, namely authorising genetic modification activities through risk tiering, non-regulated technologies, and definitions. Our next briefing in late May will cover the legislative purpose and the regulator.

8. To future proof the legislation, we note there will also be a range of issues to be resolved in secondary legislation after Cabinet's decisions, such as which specific technologies should initially be exempt from regulatory oversight. We will advise you on these where relevant.

We propose to adopt a graduated 'risk tiering' approach inspired by the Australian system

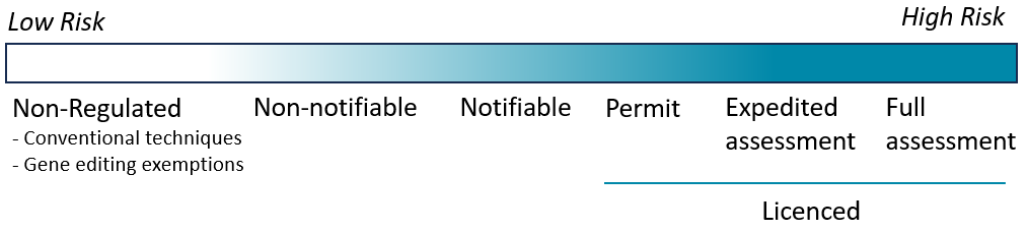
9. Due to the range of ways gene technologies can be used, most jurisdictions have some differentiation of activities based on risk so that regulatory requirements are increased or decreased depending on the risks involved.

10. Most approaches currently in use internationally, however, have few gradations of risk, meaning most activities are treated the same regardless of risks. For example, the American system provides limited tools to prevent accidental releases that could adversely impact the environment and agriculture, while the current New Zealand system is overly restrictive on laboratory-based research that is safely contained.

11. We consider that an approach, involving several graduated risk tiers, would best achieve the objectives for this reform. This would be risk proportionate by matching the level of oversight against the risks involved in the activity (eg oversight increases when risks do), and so improve regulatory efficiency for lower risk activities while providing graduated oversight of medium and high risk activities where regulatory assessment is desirable.

12. The main disadvantage of a more graduated approach is that it creates a more complex regulatory scheme and may provide less certainty about how various activities will be regulated in advance.

13. The Australian Office of the Gene Technology Regulator (OGTR) currently operates a graduated system that could be adapted for New Zealand. The below diagram shows the different authorisation categories in the Australian system as risks to people and the environment increase:



14. The categories are (from lowest to highest risk):

- **Non-regulated technologies** do not need to be conducted in containment and are not monitored by the regulator. This category includes techniques that are not gene technologies and/or organisms that are not GMOs. We propose to include low-risk gene editing techniques that are indistinguishable from natural genetic changes.

- **Non-notifiable activities** must be conducted in containment (ie must not be released into the environment) but do not need to be reported to the regulator. For example: CAR T-cell therapies, which are very low risk as they cannot persist outside of the patient they were taken from.

- **Notifiable activities** must be conducted in an approved containment facility, verified by an internal biosafety committee, and must be reported to the regulator on an annual basis (which can be after the activity is carried out). For example, modifying non-invasive plants in laboratories.

- **Licensed activities** require approval from the regulator before they can be conducted. For example: higher risk activities like most field trials and environmental releases, or laboratory modification of pathogenic organisms. Australia has proposed to add the ‘permit’ and ‘expedited’ categories to speed up approvals for medium risk applications.

If we adapt the Australian risk-tiering model, we propose some improvements

15. Our evaluation of proposed improvements to the Australian legislation and provisions in other overseas legislation have identified two improvements for the regulated technologies categories (ie non-notifiable to licensed):

- **Introducing a risk matrix** by applying the authorisation categories differently between laboratory and industrial research (ie contained), environmental release, and medical use. The Australian regulator found that treating these activities similarly was challenging to implement, especially treating medical uses as an "environmental release".

- **Introducing 'joint review', 'recognised regulator', and 'recognised approval' provisions:** These provisions would accelerate the assessment process by allowing the regulator to jointly review applications with other regulators and reuse data from previous approvals overseas. Medical gene technologies approved by recognised international regulators would be automatically approved under the gene technology legislation but would still require Medsafe approval prior to use in patients. Recognition of overseas approvals for medical use can be more automatic because there is not the same need to account for potential local environmental differences.

16. Annex 1 summarises our proposal for a risk-tiering approach.

We recommend a slightly more permissive approach to non-regulated technologies than Australia

17. Legislation in both Australia and New Zealand can exempt certain technologies and organisms through secondary legislation. In New Zealand this mechanism has primarily been used to exempt organisms that have traditionally been considered not-GM even though they otherwise meet legislative definitions. In Australia, and increasingly in other jurisdictions, these types of provisions are being used to exempt gene editing techniques that achieve effects similar to conventional techniques.

18. We propose to carry over the ability to set non-regulated technologies and organisms in secondary legislation, which will require an empowering provision in the primary legislation. This will support the new legislation to be future focused as secondary legislation is more readily made or updated to account for new technologies than primary.

19. The specific technologies on the lists would be under secondary legislation and do not need to be agreed at this time. However, as a starting point, we propose to merge the existing non-regulated lists from both Australia and New Zealand, including those deemed not regulated through statutory determinations (a primary legislation power). There are some differences in the lists, which means that both countries do not regulate some technologies and organisms that the other does. This would enable New Zealand researchers to use technologies that have been unregulated in Australia while not restricting current activities.

We propose more permissive exemptions for gene editing than Australia

20. Unlike New Zealand, jurisdictions like Australia, England and the European Union exempt some lower risk gene editing techniques from regulation. This is on the basis that such techniques involve similar risks to conventional technologies and so there is limited need for regulatory assessment.

21. Jurisdictions differ on the extent to which these techniques are exempted. England, for example, exempts techniques that deliver results that are equivalent to that which could be achieved through conventional breeding (this law has not been passed in

Scotland and Wales). Australia's approach is less permissive and is limited to techniques that it considers are comparable to other unregulated technologies. The European Union has proposed a similar approach to England for plants only, but it is uncertain if and when this would be implemented.

22. As a starting point, we recommend an approach that is more permissive than Australia's because the technical basis of Australia's exemption regulates a set of techniques (known as SDN-2) that are more predictable than those that are unregulated (known as SDN-1), and therefore is inconsistent from a risk perspective. Furthermore, it may not always be possible to identify from the organism which technique has been used. Industry and science stakeholders have supported this approach.

23. This approach would potentially still regulate some techniques that are exempt in England, and under the EU's proposal. The boundaries of the English approach, however, remain unclear and the practical scope of its definition (based on the use of "traditional processes") is largely untested. The views of industry and science stakeholders on taking a more permissive approach than that we have proposed have also been more cautious.

24. If confirmed, the EU's proposal to put in place a broad exemption for plants would have a significant impact on global norms regarding exemptions. Because exemptions would be set in secondary legislation, there would be scope to expand exemptions relatively easily in response to changing global norms.

25. Our proposal would apply to all organisms because at the level suggested, the risk profile of techniques is similar. The EU proposal applies only to plants. English legislation applies only to plants and animals.

26. Annex 2 summarises our proposals for non-regulated technologies, gene editing exemptions, and details different international approaches to exemptions.

We need to define what is a genetically modified organism

27. To determine the regulator's remit, the new legislation will need to define gene technologies and genetically modified organisms. Stakeholders have raised that some of the existing definitions in HSNO are out of date, and so we propose to align our definitions with the Australian definitions in the Gene Technology Act 2000 as there is general agreement internationally on most of its definitions. This will increase efficiency by ensuring consistency with a key trading partner and for collaborations with Australian researchers.

28. However, reviews of the Australian legislation have recommended two changes to their definitions:

    - **Excluding human beings (but not human cells):** This will ensure that someone is not classified as a GMO (and thus subject to restrictions) if they have genetically modified medical treatments like gene-therapies.

    - **Explicitly include 'construction' in the definitions for gene technology and genetically modified organism:** This will ensure that the legislation is future-proof to advances in synthetic biology which can construct an organism from scratch, rather than merely modifying an existing organism.

29. We also propose to maintain the existing exclusion in New Zealand's current definition of viral vectors, RNA and DNA that are all non-replicating (unlike Australia's definition). This would avoid unintentionally increasing the administrative burden for common medical therapies including several vaccines.

30. It may also be necessary to treat some or all native flora, fauna and taonga species as organisms requiring separate consideration. This will be the subject of further advice.

31. Annex 3 summarises our proposals for defining gene technologies and GMOs.

Industry and Māori stakeholders are generally supportive of the proposed reforms

Māori views on gene technologies are diverse, but there is significant interest in the opportunities offered by the proposed legislation

32. The Gene Technology Māori Focus Group met on 23 and 24 April. Members comprise Māori researchers, geneticists, a commercial leader, and iwi interests. The main feedback was:

- Māori positions on gene technologies are diverse, and many support the change to regulating genetic modification and view the current legislation and regime as out of date and non-enabling. Several members supported the concept of the Australian gene technology regulator regime if it is adapted for the New Zealand context.

- Māori interests around gene technologies are broad and include commercial interests especially in agriculture, milk production, farming, and land use. Whānau health and the ability of new technologies to improve quality of life is a key focus. They were most interested in enabling solutions to sustain the environment and protect taonga species.

- The Group advises that most Māori see the protection of the whakapapa belonging to taonga species as a critical component of any new legislation and noted that the Crown has agreed Treaty settlements that provide Māori with a role in the management of taonga species. Effectively managing risks to important environmental values are also a priority.

- The Group is keen for enabling legislation that allows Māori to share the benefits from new genetic technologies while providing for the science community to undertake this work with consideration for Māori interests and rights.

Industry generally supports the reforms, but there are some concerns around preserving products that continue to meet varied consumer expectations about the use of GM

33. We are continuing targeted engagements with industry stakeholders and established an industry focus group with representatives from the primary, health, manufacturing, biotechnology sectors and innovation investors. Key feedback includes:

- Industry is generally supportive of adapting and improving the legislative framework of Australia to fit New Zealand's specific context. However, it was

noted that there are some restrictive aspects of the Australian legislation (eg gene editing exemptions) that we should improve on.

- Gene technology is moving rapidly and there is a need to ensure any new regulatory framework is future proofed.
- There is a need to streamline regulatory approvals to avoid some of the complex interactions with other regulators and legislation (for example, some applications require approval under both HSNO and the Medicines Act).

34. Specific views from the primary sector included:

- There is a need to respond to changing consumer preferences, market dynamics and advances in gene technology.
- Widespread support for exempting low risk gene editing technologies that are closer aligned to our major trading partners' exemptions.
- A number of producer groups emphasised consumer expectations that products are produced without the use of genetic modification, and that any change would need to preserve the ability of producers to supply these customers.
- Concerns about gene-edited organisms entering their supply chains, and the potential inability to control contain, trace and reverse releases of some organisms into the environment.
- Releasing more GMOs into the environment may increase the cost for the organics sector to certify their products as non-GM.

Next steps

35. Officials are available to discuss this briefing with you in advance of the Ministerial Group at your officials' meeting on Tuesday 7 May.

36. In late May, we will provide a second briefing which will cover the legislative purpose and the role and functions of the regulator.

37. We suggest that the content in these two briefings, following feedback from the Ministerial Group, would form the basis of a Cabinet paper to seek agreement to begin drafting the legislation. We propose taking advice to the Cabinet Economic Policy Committee (ECO) on 24 July 2024 and Cabinet on 29 July.

Annexes

Annex 1: Graduated risk tiering approach

Annex 2: Non-regulated technologies and gene editing exemptions

Annex 3: Definition of genetically modified organisms

Annex 1: Graduated risk tiering approach

Annex 2: Non-regulated technologies and gene editing exemptions

Annex 3: Definition of genetically modified organisms

The New Regime Would be Built Around Graduated Risk Management Processes

Non-Regulated Technology

These regulations would specify those techniques and technologies that are not regulated, including certain gene editing techniques, null segregants, mutagenesis.

GMO Register

The register would specify those very low risk GMOs that aren't tied to a license and can be used by anybody.

Regulated activities under the risk matrix framework

The regulator is able to assign activities to risk tiers, with requirements graduated based on risks. Pathways would be tailored for laboratory and industrial use, environmental release, and medical use.

Laboratory and Industrial

- Non-notifiable
- Notifiable
- Licensed:
  - Expedited Assessment

Environmental Release

- Non-notifiable
- Notifiable
- Licensed:
  - Permit
  - Expedited Assessment
  - Full assessment

Medical Use

- Non-notifiable
- Notifiable
- Licensed:
  - Permit
  - Expedited Assessment
  - Full assessment

Key features and questions for Ministerial discussion

Key Features

- Regulated activities would be assigned by the regulator to a risk tier within three categories: laboratory research and industrial use, environmental release, and medical use. This would recognise that medical use is not the same as environmental release.
- While a risk-tiering framework like Australia's would more proportionately regulate these activities, a trade-off is that when compared to less graduated risk-tiering frameworks, this approach is more complex. This complexity could be mitigated through explicit guidance provided by the regulator.
- The new regulator would be given the ability to undertake joint assessments of applications with other overseas regulators, while retaining the ability to make decisions based on the joint review.
- The new regulator would also be given the ability to assess certain applications through an expedited pathway where an application has previously been assessed by a 'recognised' regulator. Additionally, medical treatments approved by 'recognised' overseas regulators would be automatically approved under the new legislation (note: Medsafe approval would still be required prior to use in patients).
- Recognition of overseas approvals for medical use can be more automatic than environmental releases because there is not the same need to account for local environmental differences.

Key Questions

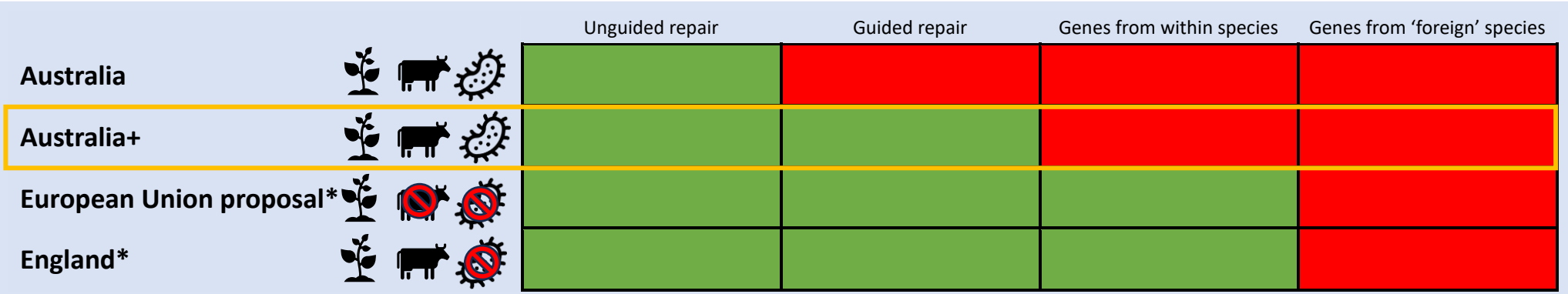
Adopting the Australian risk-tiering approach would result in a more graduated risk-tiering framework compared to New Zealand's approach or that of the United States.

Do you agree with the adoption of a risk-tiering framework like under the Australian system?

The non-notifiable and notifiable risk tiers will have lower oversight than under current legislation, both in terms of the assessments and compliance monitoring.

Do you agree with having lower oversight for very low and low risk activities?

Gene-editing techniques



*Exemptions under the EU proposal would only apply to plants (not animals and plants), while under the new English regulations they only apply to plants and animals (not microorganisms).

Non-regulated technologies and organisms

Null segregants
In vitro fertilisation
Embryo rescue
Protoplast fusion
Zygote implantation
Radiation and chemical mutagenesis
RNA interference
Epigenetics
Gene-editing exemptions (as above)

Blue = Australia and New Zealand non-regulated technologies (non-exhaustive)

Green = Additions from New Zealand statutory determinations and new exemptions (non-exhaustive)

Key considerations and questions for Ministerial discussion

Key Considerations

- There are a range of gene editing techniques and their application to different types of organisms can create different risks.
- International jurisdictions are exempting or proposing to exempt gene editing techniques based on their equivalency to unregulated techniques, the equivalency of their effect to those that could arise naturally or from conventional breeding, and the inability to detect these changes.
- According to advice from our Technical Advisory Group, unguided and guided repair gene-editing techniques have equivalent levels of risk to each other and to conventional breeding techniques.

Key Questions

We propose to, at a minimum, expand on the current Australian gene-editing exemptions and go with an Australian+ approach (highlighted above). We will investigate going further, as under the English system.

Do you agree to, as a minimum, adopt an Australia+ approach with the potential to go further?

It is proposed that the list of non-regulated technologies and organisms under Australia's and New Zealand's legislation be combined under the new legislation.

Do you agree with the combination of these two non-regulated lists?

Policy intent for the scope of the Genetically Modified Organism definition

Proposed modifications to definitions

Genetically modified organism means:

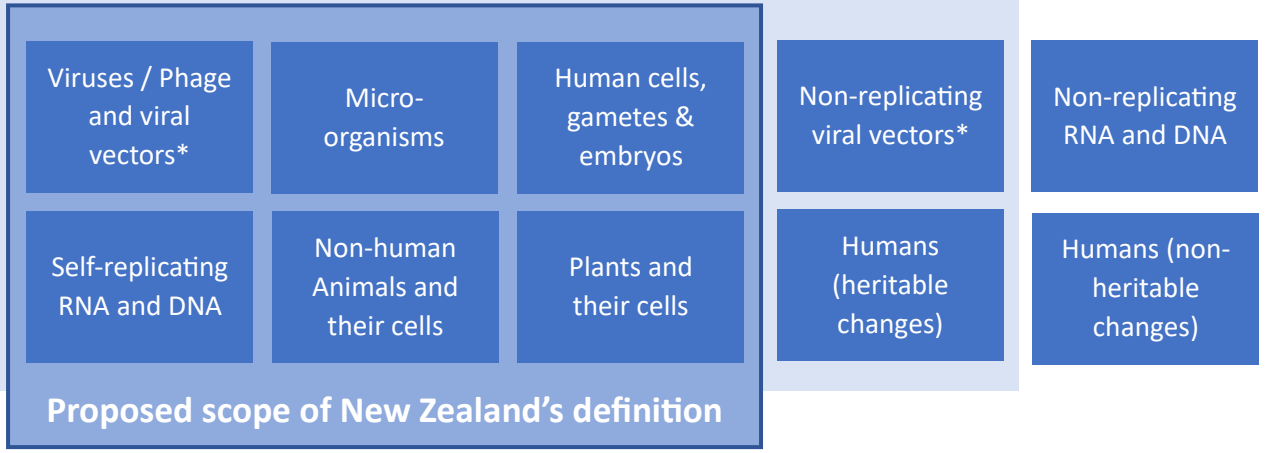
a) an organism that has been modified or ***constructed*** by gene technology; or…

Gene technology means any technique:

a) for the ***construction*** or modification of genes or other genetic material; or…

PCO will develop the technical drafting for these definitions.

Scope of Australia's GMO definition



Key features and questions for Ministerial discussion

Key Features

- 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.
- The inclusion of *constructed* and *construction* is intended to future proof the definitions given advances in synthetic biology.
- 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.
- Regulatory oversight of heritable changes to human beings is already achieved through the Human Assisted Reproductive Technology Act 2004.
- The scope will include replicating RNA and viral vectors used to make GMOs but will exclude non-replicating RNA and non-replicating viral vectors currently used in vaccines, gene therapies and cell therapies.

Key Questions

A proposed change to the Australian legislation is to fully exclude human beings from the definition of genetically modified organisms (GMOs), as is prescribed by the HSNO Act.

Do you agree that new legislation should fully exclude human beings from the definition of GMOs?

It has also been proposed that the gene technology and GMO definitions under Australian legislation includes *construction,* in addition to modification.

Do you agree that this addition is included under new legislation?

*Non-replicating viral vectors would not themselves be classed as GMOs, but their use when creating GMOs would be regulated.

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of gene technology – third joint ministers meeting

Date:	5 June 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2324-3529

Action sought		
	Action sought	**Deadline**
Hon Judith Collins KC MP **Minister of Science, Innovation and Technology**	**Agree** in principle a number of key policy settings about the basis of the gene technology regulator's decision-making, the regulator's level of independence and decision-making processes, and the form of the regulator **Agree** to forward this briefing to the Gene Technology Ministerial Group.	10 June 2024

Contact for telephone discussion (if required)				
Name	**Position**	**Telephone**		**1st contact**
Simon Rae	Policy Director, Emerging Technologies		Privacy of natural	✓
Privacy of natural	Privacy of natural persons		Privacy of natural	

The following departments/agencies have been consulted
Department of Conservation, Ministry for the Environment, Environmental Protection Authority, Ministry of Foreign Affairs and Trade, Ministry of Health, Ministry for Primary Industries, Te Puni Kōkiri, Public Service Commission, the Treasury. The Department of Prime Minister and Cabinet was informed.

Minister's office to complete:

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

Comments

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of gene technology – third joint ministers meeting

Date:	5 June 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2324-3529

Purpose

To provide you with advice on policy choices for the proposed Gene Technology Act, for discussion at your meeting with the Gene Technology Ministerial Group on 11 June 2024. We propose this meeting focuses on the gene technology regulator: the basis for its decision-making, its level of independence for decision-making processes, and its form.

Executive summary

The proposed Gene Technology Act will need to set out the matters the regulator must consider when making decisions about authorisations. The current regime sets out a wide range of matters including taking a precautionary approach, and recognising and providing for 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.

We consider the breadth of considerations in the Hazardous Substances and New Organisms (HSNO) Act unrealistic for a regulator to assess robustly, driving unnecessary cost and complexity for applicants. We propose the new regime follows Australian practice and limits its consideration to managing environmental and human health risk.

We recommend the regulator is not required to assess the benefits of applications, because it does not help to address the question of whether and how risks to human health and the environment can be managed. Similarly, we consider the recitation of the precautionary approach in the HSNO Act is a blunt tool for shaping the regulator's risk tolerance and that this is better achieved through the development of a sound decision-making methodology.

We propose to shift formal decision-making to a single statutory decision-maker rather than a committee, because this is more appropriate for technical assessment of risks, as opposed to a broader judgment about values. We also consider that the existing Ministerial call-in power is inconsistent with a technically-focused approach. We propose that public consultation should be undertaken where risk is high or the level of risk is uncertain, so that the regulator is engaging with the public in setting the overall risk tolerance of the regime at the margin.

The regulator could be established within an existing public service department or an existing Crown entity (ie the Environmental Protection Authority (EPA)). We consider that MBIE is a reasonable choice for the location of the regulator if you wish to locate it in a public service department, and that other options (eg the Ministry of Primary Industries or the Ministry of Health) are not obviously better. Advantages of retaining the regulatory function with EPA include its existing capabilities, relationships and complementary regulatory functions. However, Ministers would need to have confidence that the EPA can achieve the change in regulatory approach envisaged in new legislation. Both options assume MPI would continue to be the primary

enforcement agency for the new regime, given the overlap with MPI's responsibilities under the HSNO and Biosecurity Acts.

We will provide a further briefing in mid-June with options to ensure the new regime protects Māori rights and interests, outlines the relationship between the proposed new Act and other legislation, and raises other matters where Cabinet decisions will be needed to issue drafting instructions for the Bill.

Recommended action

The Ministry of Business, Innovation and Employment recommends you:

a **Agree** to forward this briefing to the Gene Technology Ministerial Group

Agree / Disagree

b **Agree** in principle that the proposed Gene Technology Act contain the following features:

i. The regulator's decision-making should be based on whether or not risks can be managed to an acceptable level to protect the environment and human health

Agree / Disagree

ii. The regulator should not be required to assess potential benefits of an application when making a decision

Agree / Disagree

iii. No reference to the precautionary approach

Agree / Disagree

iv. Ethics excluded from consideration on the basis that these issues are already dealt with in other specialised legislation

Agree / Disagree

v. A purpose statement that conveys that the intent is to enable the safe use of gene technologies by managing environmental and human health risk

Agree / Disagree

vi. A single, statutory decision-maker supported by advice from a technical advisory committee and other relevant agencies

Agree / Disagree

vii. No call-in power for the Minister, to maintain the independence of the Regulator's decision-making process

Agree / Disagree

viii. Public consultation requirements integrated into the risk tier framework, meaning it would be mandatory only if the activity is assigned to higher risk tier levels

Agree / Disagree

c **Agree** in principle that the regulator be located in:

i. Public service department – MBIE

Agree / Disagree

Or

ii. Crown entity – Environmental Protection Authority (EPA)

Agree / Disagree

d **Agree** in principle that the Ministry for Primary Industries (MPI) would continue to be the primary enforcement agency for the gene technology regulatory regime.

Agree / Disagree

Simon Rae
Policy Director, Emerging Technologies
Labour, Science and Enterprise, MBIE

05 / 06 / 2024

Hon Judith Collins KC MP
Minister of Science, Innovation and Technology

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

Background

1. The third meeting of the Gene Technology Ministerial Group (the ministerial group) is on Tuesday 11 June 2024 at 11:00 – 11:45 am. We understand the following ministers will attend:

    - Hon Tama Potaka (Conservation, Māori Crown Relations and Māori Development)
    - Hon Andrew Hoggard (Biosecurity and Food Safety)
    - Dr Parmjeet Parmar

2. Ministers Reti (Health), Patterson (Rural Communities and Associate Agriculture), and Simmonds (Environment) have sent apologies and will be represented by advisors. Minister McClay (Agriculture) has sent his apologies.

3. At the ministerial group's last meeting on 8 May 2024 (2324-3096 refers), Ministers agreed in principle:

    - the new regulatory regime should adopt a risk-tiering approach, incorporating three distinct risk pathways: for contained use in a laboratory or industrial process, for release into the environment, and for medical use
    - exempted gene-editing techniques should include template-guided mechanisms to direct gene repair, and officials should continue exploring the potential to go further for some host organisms
    - approvals required across multiple regulatory systems should be streamlined where possible,
    - definitions should include constructed organisms, and exclude human beings and non-replicating RNA, DNA, and viral vectors
    - international alignment is a further important objective for regulating gene technology and genetically modified organisms (GMOs).

4. We propose a new objective to reflect the importance of international alignment as:

    "**Internationally aligned** – settings are consistent with our international obligations and commitments, and are in step with New Zealand's major trading partners and other comparable jurisdictions to facilitate trade and improve New Zealand's ability to access new technologies."

This briefing is the second of three briefings we intend to provide you before we provide you with a draft Cabinet paper

5. Our previous briefing identified six issues Cabinet will need to decide on before drafting instructions can be issues to the Parliamentary counsel office:

    The legislation

    i. **Scope and definitions:** What is and is not being regulated? How are gene technologies and genetically modified organisms defined?

    ii. **Authorisations:** What activities should require authorisation? Should certain activities be treated differently and, if so, how (eg laboratory research, medical use, environmental release)? How should the regulator interact with international regulators?

iii. **Legislative purpose:** Should the legislation aim to prevent risks or manage them? Should it focus solely on risks or conduct risk/benefit assessments?

The regulator

iv. **Form:** should the regulator be a Crown agent, departmental agency or something else? Where should it be situated?

v. **Assessments and decision making**: What evidence should the regulator consider in its assessments?

vi. **Compliance, monitoring and enforcement:** How should these services be provided and should there continue to be a role for other agencies like MPI?

6. Our previous briefing provided advice on items (i) and (ii). This briefing provides advice on (iii), from the perspective of matters the regulator needs to take account of when making decisions, (iv), (v), and (vi). A summary of the advice is provided at Annex One to support discussion at the meeting.

7. A third and final briefing will address cross-cutting or additional issues not identified in the earlier list, specifically:

- options to ensure the new regime protects Māori rights and interests
- advice on whether the regulator should take into account market access issues when making decisions
- the relationship between the proposed new Act and other legislation
- whether the Minister should have a power to issue a general policy direction to the regulator
- compliance and enforcement provisions, including proposed offences and penalties.

A narrower basis for decision-making for the regime would best support the objectives

The regulator should focus on managing risks to the environment and human health

8. The current regime takes a wide range of matters into account when evaluating applications and making decisions (Hazardous Substances and New Organisms (HSNO) Act 1996, sections 4 through 9). These include taking a precautionary approach, and recognising and providing for 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.

9. We propose the new regulator approves activities where they are satisfied the risks can be managed to an acceptable level to protect the environment and human health. The narrower focus on managing risks to human health and the environment will enable a consistent, evidential, and transparent approach to evaluating applications and making decisions.

The regulator should not assess potential benefits

10. This proposed approach replicates the approach in the Australian Gene Technology Act, but represents a change from the existing process under the HSNO Act. Notably, the Australian Act does not require the Office of the Gene Technology Regulator (OGTR) to also consider

benefits when deciding whether an application should be approved. This was a deliberate choice to focus the regulator on a scientific evaluation of the risks, and to avoid making value-laden judgments about social, economic and cultural factors which are more difficult to assess and compare.

11. While omitting assessment of benefits may appear counter-intuitive, it is unnecessary if the regulator has a scientifically sound risk assessment process that is not overly precautionary and instead focuses on managing risks down to an acceptable level of tolerance. Australia, for example, has made numerous approvals despite the absence of a benefits assessment, demonstrating that it is not a requirement of an enabling regulator.

12. In contrast, 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. It 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 developed the technology (often at significant financial risk) and to make the application.

13. If Ministers wanted the regulator to consider benefits, we recommend doing so for only full environmental releases. At this stage the regulator could use data from the GMO's development in containment to provide some evidence for the benefit assessment. Benefit assessments are impractical for earlier stages such as field trials because relevant data is limited.

We should not include a specific reference to the precautionary approach in the Act

14. The current HSNO Act includes a provision requiring all actions undertaken under the Act to be undertaken with caution in the face of scientific uncertainty. This wording is significantly more conservative than the internationally agreed definition of the precautionary approach that appears in the Rio Declaration on Environment and Development of 1992. Our understanding is that this provision, and its interpretation by the courts, has encouraged a conservative approach on the part of the current regulator. The Australian Gene Technology Act restates the Rio Declaration wording.

15. We recommend not including a specific provision referring to the precautionary approach in the proposed Gene Technology Act. Good regulatory practice is to focus attention on how the operative mechanisms guide a risk management approach (for instance through setting out a risk management framework or decision methodology in secondary legislation), rather than seeking to guide the regulator through high level values statements.

16. If Ministers considered a reference to the precautionary approach necessary, we recommend using the Rio Declaration language, which refers to "serious or irreversible damage" and the "cost effectiveness" of preventative measures. This is the approach taken in Australian legislation.

Ethics considerations are appropriately addressed in other legislation

17. We do not recommend considering the ethics of activities in the decision-making process because ethics is already considered by other related regulatory systems. For instance, in respect of human-assisted reproductive technologies or medicines, ethics is given consideration by the National Ethics Advisory Committee established by and accountable to

the Minister of Health. Ethics for animals is also considered by MPI's National Animal Ethics Committee established under the Animal Welfare Act. If changes are required to ethical standards, these are best achieved through mechanisms that already deal with ethics issues, to avoid ethical principles being addressed multiple times across overlapping legislation.

We will provide separate advice on market access issues and Māori relationships with taonga species

18. We are working through whether it is desirable for the authorisation process to include considering risks to market access and trade, similar to the Agricultural Compounds and Veterinary Medicines Act 1997 (the ACVM Act). While this mechanism appears to work well in the ACVM Act, we are concerned it may present challenges similar to those encountered for benefits assessments.

19. New Zealand's context has an important difference from that of Australia, namely the Crown's duty to protect Māori interests in taonga, and taonga species in particular. This duty is reflected in the HSNO Act, and we are considering how this could be appropriately reflected in the proposed Gene Technology Act. We intend to brief you on both these issues later in June 2024.

We propose including reference to enabling the safe use of the technology in the purpose statement

20. We see value in making it explicit in the purpose statement that the intent of managing environmental and human health risks is to enable the safe use of gene technologies. Such a statement will provide an overall expectation for the regulator, but without predetermining how it decides on the use of any particular gene technology.

The regulator should be an independent decision-maker with access to relevant advice

21. Currently GMO decisions in New Zealand are either made by an expert committee appointed by the EPA under the HSNO Act, or by its Chief Executive. Applicants are required to provide evidence in their applications to support the various matters the decision-maker must consider. We understand from the research sector that applications often entail lengthy (often several years) 'pre-engagement' with the community to enable the applicant to provide the decision-maker with necessary information.

22. The EPA is required to publicly notify all applications for the outdoor field testing or release of a GMO, with the sole exception of human and veterinary medicines. It has discretion to consult publicly on other applications. EPA staff complete a risk assessment after receiving submissions. During the public submissions period it must hold hearings if a hearing is requested by a submitter. The Minister for the Environment may make decisions on an application if they consider it will have significant effects (through the HSNO Act's 'call-in' provision).

We propose a single statutory decision maker rather than a committee

23. We propose to move to a system that looks more like the Australian Gene Technology Regulator. This would involve:

    - the decision-maker being a statutory officer with a supporting office

- advice being provided to the decision-maker by a technical advisory committee, and other relevant agencies
- seeking public submissions on some risk assessments and risk management plans.

24. The Australian Office of the Gene Technology Regulator considers the single decision-maker model to work very well for its regime. If the proposed New Zealand regulator's decision-making is similarly limited to risk management, rather than a wide range of considerations, we consider it would be appropriate to have a single decision-maker, albeit one that draws on a wide range of advice. This reflects the idea that assessing gene technology risks should be a technical, science-based process.

25. A committee has the perceived advantage that it is able to draw in a wider range of perspectives in order to assess complex and ambiguous information. In practice, we consider this advantage is overstated. A single regulator will also need to draw on a wide range of information, through a range of advisory mechanisms, and this information will need to be appropriately recorded to demonstrate that the regulator has considered all relevant criteria. Decisions remain subject to judicial review, which has proved an effective check on regulatory decision making under the HSNO Act.

We recommend public consultation requirements are integrated into the risk tiering model

26. The Australian system currently requires a public consultation process for environmental releases. Under the risk tiering model we have proposed (based on reforms Australia is considering for its system), whether a public consultation process is mandatory or not would depend on how a particular application is assigned to the risk tiers. This model envisages that some environmental releases, with lower or more certain risk profiles, are allowable without a full assessment and in these cases public consultation is at the regulator's discretion. Public consultation would be mandatory when a full assessment of an application is required, at the highest level of the proposed risk tiers.

27. In a mandatory consultation process (or if the regulator chose to seek public input), the regulator would invite submissions on the draft risk assessment and management plan, which enables the public to submit on their view of the suitability of the risk management controls. This approach ensures that the public is engaged in informing the regulator's risk tolerance at the margins (ie only those applications where the desired societal outcome is most uncertain).

The Minister's call-in power should be removed

28. Similarly, we recommend removing the existing power for the Minister to call in an assessment, as this makes what should be a technical process a political one to assess what is in the national interest. It also undermines the independence of the regulator, and opens a Minister to lobbying that they should call in a particular application.

29. An intermediate solution for direct Ministerial engagement in decision-making would be to grant the Minister the power to issue a general policy direction to the regulator. We will provide further advice on this option in our next briefing.

30. As part of our next briefing we will provide further advice on a mechanism for the regulator to access advice and expertise to provide for Māori rights and interests.

There are two main options for the organisational form of the regulator

We have assessed the option of a new regulator in MBIE against PSC guidance

31. The National Party's *Harnessing Biotech* plan envisaged the Ministry for Business, Innovation and Employment (MBIE) becoming the home of the gene technology regulator, in the form of a departmental agency. To ensure you have visibility of the range of possible options for the form of the regulator, we have assessed this and other options against the Public Service Commission's (PSC) guidance and engaged with PSC.

32. PSC has indicated it supports consideration of a public service department (eg MBIE) and EPA as the options for the home for the regulator. 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.

33. In both the departmental and Crown entity options it is possible to have a statutorily independent regulatory function. The primary difference between the two options is the distance from the responsible minister:

    - In the departmental option, the minister would have a direct line to the chief executive (or their delegate) to set expectations and govern the gene technology regulator. However, a statutory officer would retain independent regulatory decision-making responsibilities.
    - In the Crown entity option, this relationship would be at arm's length, with the minister setting expectations through the relationship with the EPA board, as it does now.

Other potential agency locations are not obviously better than MBIE

34. Public service departments where the regulator could be established include MBIE, the Ministry for Primary Industries (MPI) and the Ministry of Health (MoH), all of which have existing scale and expertise as regulatory agencies. There are pros and cons of each agency, but neither MPI nor MoH present any compelling advantages over MBIE as a location.

We estimate costs as up to Confid ential **a year**

35. We are still working through the likely costs of locating the regulator in a government department, and how these should best be funded. Our current estimate is up to Confide ntial a year. While we have further work to do on costs, our working assumption is using a public service agency will be more expensive than the EPA, due to the need to establish new systems and committees duplicating some costs in a new regulator. We expect the ability to transfer funds from EPA's baseline will be limited.

There would be advantages in the EPA remaining the regulator

36. Advantages of retaining the regulatory function with the EPA include its existing technical capabilities, relationships with the sector and with Māori, relevant committees (such as Ngā Kaihautū Tikanga Taiao), and complementary regulatory functions in relation to new organisms. We anticipate this option would cost less to implement than the MBIE option given the EPA would be able to leverage existing committees and infrastructure. However, Ministers would need to have confidence that the EPA can achieve the change in regulatory approach envisaged in new legislation.

MPI would continue to provide enforcement functions

37. Both options assume that MPI would continue to be the primary enforcement agency for the gene technology regulatory regime. Many compliance functions will overlap with MPI's responsibilities under the HSNO and Biosecurity Acts. These include approving and verifying compliance of facilities which hold new organisms (including GMOs) to containment standards, and monitoring parties' compliance with conditions for GMO activities.

38. The alternative is for the gene technology regulator to establish its own embedded enforcement function and field resources, which would be duplicative. Nevertheless, the gene technology regulator will require some powers related to compliance monitoring and enforcement, such as requiring reports and information and to change controls as a result of the reports.

39. MPI provides the compliance function for new organisms under delegation from the Chief Executive of the EPA. We will provide further advice in our next briefing on whether we recommend changes to the compliance powers that currently exist in the HSNO Act, or whether these can be adopted unchanged.

Next steps

40. We will provide a further briefing in mid-June. This will include:

- options to ensure the new regime protects Māori rights and interests
- advice on whether the regulator should take into account market access issues when making decisions
- the relationship between the proposed new Act and other legislation (such as whether regional councils should retain the ability to control the use of GMOs under the Resource Management Act 1991 through regional policy statements and plans)
- whether the Minister should have a power to issue a general policy direction to the regulator
- enforcement and compliance powers, in particular proposed offences and penalties.

41. We propose to provide you with a draft Cabinet paper in late June, together with refined costing information for your proposed form of regulator to enable you to consult with the Minister of Finance before commencing ministerial consultation.

Annexes

Annex One: Summary of choices regarding regulator

Annex One: Summary of choices regarding regulator

Options	Advice
Matters for the regulator to take into account when making decisions	
1. Risk assessment and management of the gene technology and GMO activity on the environment and human health, OR 2. Comprehensive assessment including the precautionary approach, ethics and weighing economic costs, benefits and risks. Note: We will provide separate advice on market access issues and Māori relationships with taonga species.	We recommend focusing the regulator's decisions on managing risks to the environment and human health. This will enable a consistent, evidential, and transparent approach to decision-making.
Regulator independence and decision-making processes	
<u>Level of independence</u> 1. Independent decision-maker in all cases, OR 2. Provide for ministerial call-in power for decisions that require some type of national interest consideration.	If the regulator's decisions are to be focused on whether risks to the environment and health and safety of people can be managed, an independent decision-maker is best placed make the decision.
<u>Decision-making</u> 1. Decisions made by single person – either an independent statutory officer or chief executive (who may delegate to suitably qualified person) – supported with advice from a technical advisory committee, other agencies and the regulator's staff, OR 2. Decisions made by a committee of people with necessary technical expertise, supported with advice from other agencies and the regulator's staff.	A single person decision-maker is a more efficient decision making model for science-based technical matters. The single person decision maker would have access to advice from a technical committee. Consultation requirements and clear risk management procedures are sufficient to ensure a wide range of perspectives are taken into account where necessary.
<u>Public input</u> 1. Public consultation requirements are integrated into the risk tiering model, ie if the application is assigned to the highest category in the risk tier for a licence decision consultation would be mandatory. This would mean the regulator is not required to publicly consult for environmental releases that are assessed as lower risk, OR	Public consultation on applications assigned to the highest risk tier will support public trust and confidence in decisions about risk management for GMOs with high or uncertain risk.

Options	Advice
2. Public consultation required if the licensing application is for an environmental release including field trials. This would mean that the regulator is required to consult even on lower risk applications.	
Form of the regulator	
<u>Departmental or Crown entity form</u> 1. Regulator sits within public service department as a branded business unit (eg MBIE, MPI, MoH): • Minister retains direct oversight of the functioning of the regulator (but is not involved in decisions) • rationales for each of the agencies to host regulator, but none is a perfect fit • likely to be at least marginally more expensive than the EPA OR 2. Environmental Protection Authority takes on responsibility for the proposed Gene Technology Act: • Minister at arm's length, setting expectations through the board and Crown entity accountability mechanisms • EPA has existing technical capabilities, relationships and infrastructure that can be leveraged to set up the new gene tech regulatory regime	While the EPA retains important advantages as a potential regulator, there are also benefits in setting up a new regulator to ensure the regulatory reform achieves the desired rebalancing of regulatory outcomes. While MBIE lacks some of the complementary functions of other potential locations for the regulator, the arguments for either MPI or MoH are not compelling.
<u>Primary enforcement agency</u> 1. MPI is the primary enforcement agency for the gene technology regime, OR 2. The gene technology regulator has its own embedded enforcement team and field resources.	MPI continuing as the primary enforcement agency is effective and efficient given the overlaps in required compliance monitoring and enforcement activities with its responsibilities under the HSNO and Biosecurity Acts. Establishing a team within the gene technology regulator would be duplicative.

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of gene technology – fourth joint ministers meeting

Date:	19 June 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2324-3917

Action sought		
	Action sought	**Deadline**
Hon Judith Collins KC MP **Minister of Science, Innovation and Technology**	**Agree** in principle a number of key policy settings about how the gene technology regulator will address Māori rights and interests, how trade risks should be addressed, the relationship between the new legislation and other legislation, whether the legislation should include a power to issue a general policy direction, and potential restrictions on synthetic nucleic acid screening. **Agree** to forward this briefing to the Gene Technology Ministerial Group.	27 June 2024

Contact for telephone discussion (if required)				
Name	**Position**	**Telephone**		**1st contact**
Simon Rae	Policy Director, Emerging Technologies		Privacy of natural	✓
Privacy of natural persons	Privacy of natural persons		Privacy of natural persons	

The following departments/agencies have been consulted
The Ministry for the Environment, the Ministry of Primary Industries, the Department of Conservation, Te Puni Kōkiri, the Ministry of Foreign Affairs and Trade and the Environmental Protection Authority were consulted in the preparation of this advice.

Minister's office to complete:

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

Comments

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of gene technology – fourth joint ministers meeting

Date:	19 June 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2324-3917

Purpose

To provide you with advice on policy choices for the proposed Gene Technology Bill, for discussion at your meeting with the Gene Technology Ministerial Group on 27 June 2024. We propose this meeting focuses on Māori rights and interests, trade considerations, and the interaction with other legislation. Minsters may also wish to review the overall structure of the regime as set out at Annex One, prior to finalisation of the Cabinet paper.

Executive summary

This is the final of three briefings addressing key issues for inclusion in the Cabinet paper on a new gene technology regime. It addresses cross-cutting issues and additional issues not identified in previous papers. We have also included a visual overview of key elements of the regime at Annex One taking into account all decisions made to date, including recommendations in this paper.

We recommend putting in place a statutory requirement for the regulator to consider risks to kaitiaki relationships to taonga species, and risks to cultural practice arising from the environmental release of genetically modified organisms. Ministers may also want to consider a statutory advisory committee mechanism to support these requirements.

We recommend that trade risks arising from the approval of genetically modified organisms are best addressed through improvements to agricultural assurance processes, and the legislation should not include a specific mechanism requiring the regulator to address these risks. This is the approach taken in other jurisdictions, and we understand has been successful in Australia.

We recommend removing councils' ability to restrict the use of GMOs under the Resource Management Act. The imposition of further restrictions at the local level have the potential to undermine the effectiveness of specialist regulatory decisions, and would potentially duplicate more expert assessments.

We propose to create an ability for the regulator to undertake joint regulatory assessments where organisms are regulated under multiple regimes. In the scenarios where this is most likely to occur, other regimes are charged with managing distinct risks that would be beyond the capability of the gene technology regulator to address, and therefore a single approval is not feasible.

We recommend Ministers consider including a power to issue general policy directions to the regulator in the legislation, and that this mechanism may be a more effective means to provide for Ministerial oversight of the regulator than a call-in power on individual decisions.

We propose that existing compliance and enforcement powers in the Hazardous Substances and New Organisms Act (HSNO) should be transferred over to the new Act. We judge these powers are

adequate as they are, and this will minimise complexity for MPI as the compliance and enforcement agency.

We recommend that the legislation should include the ability to put in place a requirement for producers of nucleic acid sequences to screen these for potentially dangerous sequences, should this be considered necessary in future.

Recommended action

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

a **Agree** to forward this briefing to the Gene Technology Ministerial Group

Agree / Disagree

b **Agree** in principle that the proposed Gene Technology Act contain the following features:

i. No specific consideration of trade risks in regulatory decision making

Agree / Disagree

ii. Explicitly removing councils' ability to restrict GMOs under the Resource Management Act

Agree / Disagree

iii. Joint regulatory assessments where organisms are regulated by multiple domestic regimes

Agree / Disagree

iv. An ability for the Minister to issue a general policy direction to the regulator

Agree / Disagree

v. An ability to require domestic providers to screen synthetic nucleic acid sequences

Agree / Disagree

c **Agree** in principle that the proposed Gene Technology Act:

i. Includes a statutory requirement for the regulator to consider risks to kaitiaki relationships to taonga species, and risks to Māori cultural practice arising from the environmental release of genetically modified organisms

Agree / Disagree

ii. Establishes a statutory Māori advisory committee to advise the regulator on Māori rights and interests

Agree / Disagree

OR

iii. Leaves to the regulator the choice about how it accesses appropriate expertise to manage risks to Māori rights and interests

Agree / Disagree

Simon Rae
Policy Director, Emerging Technologies
Labour, Science and Enterprise, MBIE

25 / 06 / 2024

Hon Judith Collins KC MP
Minister of Science, Innovation and Technology

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

Background

1. The fourth meeting of the Gene Technology Ministerial Group (the ministerial group) is on Thursday 27 June 2024 at 10:15 – 11:00am. At this stage we do not have information on which Ministers will attend.

2. At the ministerial group's last meeting on 11 June 2024 (2324-3529 refers), Ministers agreed in principle:

    - The regulator's decision-making should be based on whether or not risks can be managed to an acceptable level to protect the environment and human health
    - The regulator should not be required to assess potential benefits of an application when making a decision
    - The legislation should not include a reference to the precautionary approach
    - Ethics should be excluded from consideration on the basis that these issues are already dealt with in other specialised legislation
    - The legislation should include a purpose statement that conveys that the intent is to enable the safe use of gene technologies by managing environmental and human health risk
    - There should be a single statutory decision-maker supported by advice from a technical advisory committee and other relevant agencies
    - That the Ministry of Primary Industries (MPI) would continue to be the primary enforcement agency for the gene technology regulatory regime

3. Ministers deferred a decision on the location of the regulator, and expressed a strong preference to retain a call-in power, especially if the Environmental Protection Authority remained the regulator.

4. This is the final of three briefings we were to provide you in advance of the Cabinet paper. It addresses cross-cutting issues and issues not identified in our earlier briefings, specifically:

    - Options to ensure the new regime protects Māori rights and interests
    - Advice on whether the regulator should take into account trade and market access issues when making decisions
    - The relationship between the proposed new Act and other legislation
    - Whether the Minister should have a power to issue a general policy direction to the regulator
    - Compliance and enforcement provisions

5. We have included a visual overview of the main elements of the regime as agreed so far (including those recommended in this briefing) as an A3 at Annex One. We propose to use

this to support Cabinet decision-making on the regime as a whole, and would welcome feedback on its design and the overall balance of the regime it depicts.

Māori rights and interests

Māori have diverse interests in gene technologies

6. Māori perspectives on gene technologies are diverse. Māori have interests in the opportunities offered for improving healthcare, conservation, and economic aspirations. Māori authorities' investment in primary industries is particularly strong, with just over a quarter of all Māori authorities operating in primary industries. Many Māori also have concerns about the potential negative impact of gene technologies on the environment as well as on native and taonga species in particular.

There are distinctive Māori cultural interests in relationships to the environment and specific species

7. Many Māori cultural practices are inextricably linked to the New Zealand environment and its flora a 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 a number of Treaty settlements.

8. There are three main options for including a provision to protect Māori rights and interests in the regime, specifically:

    - A general provision for the regulator to act in accordance with the principles of the Treaty of Waitangi
    - Specific provisions for the regulator to take into account risks to Māori rights and interests in the assessment of risk and the development of a risk management plan
    - Specific obligations to consult with Māori on decisions, or types of decisions

    Each of these options might usefully be supported by an independent statutory Māori advisory committee.

Not including a specific mechanism may create uncertainty for applicants and increase the risk of judicial review of decisions

9. If you chose not to put specific provisions in place, this may create uncertainty for the regulator and applicants. The Courts have tended towards the practice that legislation should be interpreted consistently with the Treaty of Waitangi unless Parliament has specifically provided otherwise. As such, the Courts would be likely to consider that the Crown should make informed decisions on matters affecting the interests of Māori unless explicitly provided otherwise. In this context it seems that a regulator would be likely to set up a consultative mechanism in order to manage this risk to its decision-making even

without a specific requirement but would be doing so with less clarity for participants in that process, and potentially less confidence that the process would meet its Treaty obligations if tested in the Courts. A specific requirement will provide certainty and guidance as to the intent of Parliament in relation to Treaty obligations under the Act.

A general provision offers little to no advantage

10. Many Acts have provisions that require a regulator to "take account of" or "have regard to" the principles of the Treaty of Waitangi in exercising their functions. While these types of provisions do potentially have some symbolic value for Māori, their legal effect is largely the same as having no provisions at all, except for the fact that the express formulation of the Treaty provision matters. We do not recommend this approach.

The regulator could have a statutory obligation to consider specific Māori interests

11. We consider that it would be useful for the regulator to have a statutory obligation to consider risks to both:

    - kaitiaki relationships with taonga species, and
    - cultural practice (tikanga) resulting from the introduction of genetically modified organisms into the environment (whether through an environmental release or medical use).

    Where these risks are material, the regulator should be required to incorporate them into risk assessments, and to put in place practicable measures to mitigate them in risk management plans.

12. To maintain fidelity to the Māori interests being protected, this approach would require the regulator to make its own judgments about tikanga. This is not impossible, but it does present some challenges. In practice, we would expect the regulator to draw on external expertise on tikanga, and to consult specifically affected Iwi or hapū in the case of taonga species. Any decisions could be challenged through the courts, and we would expect the courts to consider expert Māori evidence on whether tikanga was correctly considered. On the other hand, many Māori are ambivalent about the role of the courts in determining the application of tikanga, and are likely to question the ability of a Crown regulator to make such determinations.

The regulator could be required to consult with Māori generally on some decisions

13. A third option is for the regulator to have an obligation to consult with Māori on decisions. This would need to be limited to certain circumstances in order to be practicable, as an obligation to consult Māori generally suggests a fairly wide ranging exercise. It is difficult to see how such an obligation that effectively provided for the breadth of Māori interests could be accommodated within Ministers' objective to have an efficient and enabling environment for approvals. An obligation to consult also leaves open the question as to the action the regulator must take as a result of that consultation, and in particular the extent to which the results of that consultation are binding.

A statutory advisory committee mechanism could be useful to support consideration of Māori interests

14. Advisory committees are a relatively common mechanism to support decision-making about Māori interests. If implemented well, they can add credibility to the regulator's decision-making through their ability to provide transparent and independent advice. Importantly, an advisory committee has the potential to mitigate some of the risks that exist in having a regulator attempt to interpret tikanga regarding genetic modification. While an advisory committee does represent an additional administrative step, it need not release the regulator from its obligation to meet statutory timeframes.

15. There are some important limitations to implementing an advisory committee mechanism, in particular:

    - Advisory committees are not representative of the views of Māori, and Iwi and hapū expect to have direct input into at least some decision-making

    - Advisory committees that are purely advisory are seen to have limited effect, and there needs to be some level of obligation on the regulator to implement their advice (this aspiration is in tension with the first issue)

    - Several pieces of legislation include advisory committees with functions that overlap those proposed here. This creates risks of duplication of effort, inconsistencies between the committees on similar questions, and high demand on a limited number of Māori expert advisors.

16. We believe these issues could be addressed through careful design of the committee's role and function through the legislative drafting process, and coordination with agencies that operate existing committees of similar function. If the EPA were to remain the regulator for gene technologies, it is possible that its existing committee Ngā Kaihautū Tikanga Taiao could perform this function, but we have not tested this with the EPA in providing this advice.

The legislation should not place the onus on applicants to identify risks to Māori interests

17. One of the key advantages of an advisory committee is it clearly identifies a body that is able to identify risks to Māori interests. A particular complaint of applicants under the current process is that they are required to undertake extensive efforts prior to application to identify potential risks, and this is a substantial hidden cost. In a more balanced mechanism, the applicant would 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.

Many Māori also attach particular importance to the distribution of benefits from use of genetic material from indigenous species

18. Māori we have spoken to as part of our targeted consultation have also highlighted Māori interest in the use of genes from taonga species to develop new products (also known as biodiscovery or bioprospecting), and their expectation that Māori should benefit from their use. However, attempting to address this issue in this legislation would add significant complexity to the legislation, and could not reasonably be addressed by a regulator focussed on risks to the environment and human health.

19. The ambiguous legislative environment for biodiscovery in New Zealand does potentially create a barrier for investment in New Zealand biotechnology companies relying on genetic material isolated from indigenous species. This is because many offshore investors expect to see evidence that material has been collected in accordance with international norms. A biodiscovery system would provide a clearer pathway for this type of innovation, including international collaborations. Most New Zealand researchers working in this area make efforts to establish strong relationships with relevant Iwi and hapū, in part to mitigate this risk.

20. Ministers may wish to give further thought to the relative priority accorded to the development of a biodiscovery regime as part of efforts to support the biotechnology industry in New Zealand and to address wider Māori interests in gene technology. Te Puni Kōkiri has undertaken some initial work in this area, and MBIE is supportive of it leading further work to explore the potential for a biodiscovery regime to strengthen the biotechnology value chain.

Market access and trade

The trade risks from GMOs would be best managed by improvements to agricultural assurance processes

21. In our last briefing (2324-3529), we advised that the regulator should only consider risks to human health and the environment, and not other issues such as ethical or economic impacts. This narrower focus is to enable a more consistent, evidence-based and transparent approach to evaluating applications and making decisions.

22. Some stakeholders have asked for the regulator to consider trade impacts as well as risk to human health and the environment as an exception to that approach. GMO reform involves trade risks because trading partners may not accept exports that have been 'contaminated' by GMOs, incidentally or otherwise.

23. We recognise these risks are real but consider they can be adequately managed without a specific requirement for consideration in the Act. This is because:

    - It is not uncommon for GMO and non-GMO supply chains to coexist in the same country. Implementing assurance and supply chain separation programmes can prevent unintentional crossover and help manage trade risks. 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

    - Most trade risks are due to failures in the assurance process which, beyond user error, are typically due to the unintentional spread of GMOs to non-GMO production systems. We expect that any controls and limits imposed by the regulator to manage environmental risks will also manage these risks. For example, under the Resource Management Act (RMA) the risk of non-organic sprays drifting to organic farms is managed currently by controls on the user at time of spraying

    - Considering market access and trade risks would complicate the assessment process. Trade risks must be considered in the context of the GMO's benefits because 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.

24. Our recommended approach mirrors the Australian Gene Technology Act, which does not require the Office of the Gene Technology Regulator (OGTR) to consider risks to market access and trade when assessing applications. It is important to note, however, that New Zealand exports a greater proportion of its primary produce than Australia. The Ministry of Foreign Affairs and Trade has indicated it would prefer that the regulator had at least some mechanism to account for trade risks.

25. The Ministry of Foreign Affairs and Trade is analysing New Zealand's trade and international agreements to identify additional obligations resulting from GMO reform. We will provide you with this information as part of our advice accompanying the Cabinet paper. Our initial assessment is that such obligations are primarily around notifying trading partners whether an export contains GMO products and so would not restrict the wider reform programme.

Interaction with other legislation

We recommend removing councils' ability to restrict GMOs under the Resource Management Act (RMA)

26. The RMA allows regional councils, territorial and unitary authorities to set restrictions on the use of GMOs under regional policy statements and plans. Several councils have done so, including Hastings District Council, Northland Regional Council and Auckland Council. This has had little practical impact under HSNO as there have been no agricultural releases of GMOs in New Zealand. However, under the new regime this could create a dual approval process where councils could restrict the use of GMOs despite being approved by the gene technology regulator.

27. In our view, regional concerns would be best assessed by the regulator and managed through the risk management plans it develops for each GMO release. We recommend removing the RMA's ability to set restrictions on GMO use because:

- An RMA decision effectively duplicates the approval processes because an expert regulator would have already managed GMO risks through a dedicated risk management plan
- RMA restrictions are unlikely to be risk proportionate as they are typically used to restrict any environmental release of a GMO, instead of managing the specific risks from each application
- Removing the power would ensure a more predictable and enabling regulatory environment for GMOs, instead of creating a patchwork of different requirements across the country
- Unlike the gene technology regulation, the RMA process is based on a balancing of interests rather than a technical risk assessment, and restrictions can be significantly influenced by ideological opposition to GMOs (often driven by national interest groups) and the economic interests of incumbent groups.

28. Additionally, some regional councils have told us that GMOs and non-GMO zones were no longer a significant issue for their constituents. They supported national-level decision-making if the role of councils was clear and acknowledged councils do not have the relevant in-house expertise or capacity for this issue.

The most effective way to streamline GMO approvals is through joint regulatory assessments

29. MBIE has been working with other agencies to identify opportunities to streamline the GMO approval process where organisms also require approval under other legislation, such as by reducing the number of approvals required.

30. The most common dual approvals are likely to be between the new gene technology legislation and either the Medicines Act or the Agricultural Compounds and Veterinary Medicines Act. We consider it possible but unlikely that approvals would be sought simultaneously under the gene technology legislation and the new organisms part of HSNO. Approvals under the gene technology legislation and the hazardous substances part of HSNO are also foreseeable.

31. Our advice is that a single approval by a single regulator (ie by the gene technology regulator) is not practical because each regulator assesses important risks to fulfil the purposes of their regimes that are outside of the expertise of the others. For example, Medsafe assesses complex medical efficacy data to ensure patient safety that the gene technology regulator would not be able to assess without significantly expanding its resourcing and duplicating the capability of Medsafe. We doubt that this would be possible in practice, and it would certainly be expensive. Veterinary approvals are similar.

32. Our expectation is that a significant number of medical treatments will fall into either the non-notifiable or notifiable categories under the proposed risk tiering framework and therefore will not require separate gene technology regulator approval. The inclusion of internationally recognised regulator approvals for medicines should further reduce medicines that require additional oversight by the gene technology regulator (2324-3096 refers). Veterinary medicines are likely to be similar, although because of the way they are sometimes used (for instance given to flocks or herds in feed), risks of entry into the environment may be greater.

33. We assess that overlaps with the remaining parts of HSNO are less likely. For the new organisms part of HSNO, we consider that in general, introducing new organisms into the environment is a higher risk activity than introducing new genes into already existing organisms. As a general principle we would recommend that the weight of regulatory activity should sit with the higher risk activity.

34. While we do not consider a single approval by a single regulator an achievable goal, we do think it is possible to streamline assessments through a combination of statutory and administrative measures. We consider the most effective way to streamline the approval processes is through the ability to undertake a joint assessment. This model would ideally see regulators consider a single application that addressed the requirements of each regulator, and allowed the gene technology regulator to recognise as equivalent assessments made under other Acts (for instance the ACVM Act also assesses risks to public health, but not risks to the environment). While approval from each regulator would still be required, this would align timeframes and would reduce the administrative burden on

applicants by using a single application, where possible. It would also avoid the risk that different regulators would reach different decisions about the same risk on the basis of the same information.

35. The simplest way of streamlining approvals will generally be for the gene technology regulator to accept assessments by other domestic regulators of broadly equivalent risks. Achieving a high degree of two-way integration between the gene technology legislation and the Medicines Act and/or ACVM Act is likely to be legislatively complex, and would require us to undertake further policy work on how this might be achieved. For instance we are conscious that there are significant limitations on proprietary information in medicines applications, and this is likely to prove a challenging barrier to overcome.

General policy directions

The responsible minister should be able to guide the regulator through general policy directions

36. In our last briefing we advised that the new legislation should not include HSNO's ministerial 'call-in' power. Joint ministers noted that removing this power would reduce government's ability to intervene without legislative change should the regulator act contrary to the policy objectives (eg becoming too permissive or precautionary).

37. We consider that enabling the responsible minister to provide general directions to the regulator may provide a better mechanism to provide the type of control we understand Ministers are seeking.

38. A call in power has three main weaknesses in achieving this goal:

- The potential to call in decisions will create uncertainty for applicants about the regulatory process, and therefore operate against your objectives for the regime
- Ministerial decisions will still be bound by the decision-making processes of the new legislation and would require the same information of applicants. Because unlike some other environmental legislation in New Zealand, decisions made under the regime are a risk management decision rather than a balancing of interests, there is not the same scope for Ministers to reach a different decision to the regulator
- A call-in power would operate on a case-by-case basis, and therefore may not have the broad impact on the regulator's risk tolerance we understand Ministers are seeking.

39. We have identified a number of potential uses of a general policy direction that would appear to meet your needs:

- 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 (eg joint assessment provisions)

40. The ability to issue a general policy direction still carries risks of perceived interference with the regulator's independence. However, we consider that the policy direction option involves fewer risks than a call-in power because it could not countermand individual decisions and could not override the decision-making process set in the primary legislation.

Compliance, monitoring and enforcement provisions

Carrying over HSNO's enforcement provisions will reduce administrative complexity

41. In our last briefing (2324-3529) we recommended that the Ministry of Primary Industries (MPI) should manage compliance, monitoring and enforcement for the new gene technology legislation.

42. MPI advises that it would be most effective in this role if the compliance, monitoring and enforcement provisions were based on the existing HSNO regime as much as possible. MPI is responsible for enforcing multiple related Acts, such as HSNO, the Agricultural Compounds and Veterinary Medicines Act and the Biosecurity Act. The combined system is already administratively complex and a unique enforcement regime for gene technology would further increase it.

43. We support this advice as we have not identified any significant improvements to HSNO's enforcement provisions that would outweigh the resulting administrative costs.

Synthetic nucleic acid screening

There is growing awareness internationally of national security risk arising from synthetic nucleic acids

44. Advances in gene technologies have enabled nucleic acids (DNA and RNA) to be chemically synthesised and acquired without needing to be derived from an existing organism. Called "synthetic nucleic acids", these are important for research but could also enable someone to engineer a highly pathogenic organism for malicious purposes.

45. Several key national security partners are either implementing or looking to implement requirements for producers of synthetic nucleic acids to screen customer orders, to help ensure that only those with a legitimate peaceful use case are supplied nucleic acids with potentially harmful applications. These include the United States, which has recently announced screening requirements for companies receiving federal funding and the United Kingdom, which is looking to implement legislative requirements on relevant companies.

This is not an immediate risk in New Zealand, but if it becomes one, we should have tools to address it

46. Agencies consulted as part of this process have generally expressed some scepticism about the benefits of implementing a screening process when there are no companies currently providing this service in New Zealand and have questioned whether it is a good fit for this legislation. Exports of potentially harmful synthetic nucleic acids are controlled by export

controls on strategic goods operated by the Ministry of Foreign Affairs and Trade, but this would not control domestic supply.

47. Despite the limited need to include these provisions in legislation now, and the potential inconsistency with the primary purpose of the Act, we are concerned that screening these sequences could become an international norm, or at least an expectation of security partners, and in those circumstances, we are unlikely to be presented with a more suitable legislative opportunity. We therefore consider there would be value putting a mechanism in the legislation that would allow the gene technology regulator to require domestic producers of synthetic nucleic acids to screen them if this becomes a necessity in future.

48. Any screening process would be designed to minimise any administrative burden on producers, and we would align our requirements with those of the United States and United Kingdom. Given the trend of countries implementing similar measures, most offshore providers have similar screening requirements in place already or would look to implement them in the near future, and therefore imported sequences are increasingly screened at source.

Next steps

49. We propose to provide you with a draft Cabinet paper in late June, together with refined costing information for your proposed form of regulator to enable you to consult with the Minister of Finance before commencing ministerial consultation.

Annex

Annex One: Visual overview of the Gene Technology Regime

Annex One: Visual overview of the Gene Technology Regime

Gene Technology – Proposed Regulatory Regime

- The legislation is intended to enable New Zealand to safely benefit from gene technologies by managing risks to human health and the environment.
- It will achieve this by managing the risks that genetically modified organisms pose, proportionate to their impact to the environment and public health.

KEY FEATURES OF THE REGULATORY REGIME

- Risk-proportionate
- Internationally-aligned
- Retains public participation
- Allows greater use of gene editing
- Focuses on the management of risk
- Leverages overseas expertise
- Streamlined, efficient and transparent processes

NON-REGULATED TECHNOLOGIES AND ORGANISMS

GENE EDITING TECHNIQUES

- Organisms modified using unguided and template guided repair would be unregulated. Example applications include:

- STERILE WILDING PINES
- GRASS ENDOPHYTES
- GABA TOMATOES
- NON-BROWNING MUSHROOMS
- DISEASE-RESISTANT MAIZE
- DISEASE-RESISTANT POTATOES

CONVENTIONAL TECHNIQUES

- Techniques commonly regarded as not creating a GMO would remain unregulated, including:

- NULL SEGREGANTS
- RNA INTERFERENCE
- REPLICANT-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 laboratory and industrial use, environmental release, and medical use.

LABORATORY / INDUSTRIAL	ENVIRONMENTAL RELEASE	MEDICAL USE
Non-notifiable	Non-notifiable	Non-notifiable
Notifiable	Notifiable	Notifiable
Licensed: Expedited assessment	Licensed: Permit Expedited assessment Full assessment	Licensed: Permit Expedited assessment 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 and plants.
- **Licensed activities** 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 unique 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 staff, a technical advisory committee, and a Māori advisory committee.
- Their responsibilities will include the assessment and management of the risks of GMOs, providing advice on technical matters to Ministers, and providing information to the public and guidance to regulated parties.

STREAMLINED DUAL ASSESSMENT PROCESSES

- Where appropriate, approvals required under multiple legislation will be streamlined through joint assessments.
- Given the overlap of factors considered in their assessments, where a new organism has been genetically modified, a joint assessment by the EPA and the regulator for new organisms would be mandated.

LEVERAGING THE EXPERTISE OF OVERSEAS REGULATORS

- Joint review provisions will enable the regulator to undertake joint assessments with other overseas regulators. After completion of the assessment, the regulator would make their own independent decision on the application.
- Automatic approval of medicines under the gene technology legislation would apply to GM medicines approved by overseas regulators previously recognised by the New Zealand gene technology regulator.
- Expedited assessments would apply to GMO activities approved by overseas regulators previously recognised by the New Zealand gene technology regulator.

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of gene technology – draft Cabinet paper

Date:	3 July 2024	**Priority:**	Medium
Security classification:	Budget - Sensitive	**Tracking number:**	2324-4026

Action sought		
	Action sought	**Deadline**
Hon Judith Collins KC MP **Minister of Science, Innovation and Technology**	**Note** you are meeting the Finance Minister on 4 July to secure required agreement to consult on the draft Cabinet paper attached **Provide** officials with feedback on the draft Cabinet paper **Agree** to initiate Ministerial consultation with all relevant Ministers on the Cabinet paper as soon as practicable, subject to receiving pre-approval to do so from the Minister of Finance.	

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

The following departments/agencies have been consulted
The Treasury, Department for the Prime Minister and Cabinet, the Ministry for the Environment, the Ministry for Primary Industries, the Department of Conservation, the Ministry of Health, the Ministry for the Environment, Te Puni Kōkiri, the Ministry of Foreign Affairs and Trade, and the Environmental Protection Authority were consulted on the Cabinet paper.

Minister's office to complete:

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

Comments

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of gene technology – draft Cabinet paper

Date:	3 July 2024	**Priority:**	Medium
Security classification:	Budget - Sensitive	**Tracking number:**	2324-4026

Purpose

To provide you with a draft paper seeking Cabinet agreement to the proposed Gene Technology Regulatory Regime, so that you can initiate Ministerial consultation following pre-approval from the Minister of Finance.

Recommendations

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

a **Note** that the attached draft Cabinet paper has been developed in line with the decisions of the Gene Technology Ministers Group and in consultation with relevant agencies

Noted

b **Note** the draft Cabinet paper recommends Cabinet delegate decision-making authority to the Minister of Science, Innovation and Technology (and other Ministers as relevant) to develop technical or specific aspects of the regime

Noted

c **Note** that policy development has been expedited to enable introduction of a Bill to the House before the end of 2024, resulting in a stakeholder and agency consultation process that may have excluded some key perspectives

Noted

d Confidential advice to Government

[redacted]

h **Note** that to meet the target date of ECO consideration on 7 August 2024, the minimum Ministerial consultation of 5 working days needs to begin by 15 July and completed by 19 July

Noted

i **Either**:

i. **Provide** officials with feedback on the draft Cabinet paper

Agree / Disagree

Or:

ii. **Agree** to initiate Ministerial consultation with all relevant Ministers on the Cabinet paper as soon as practicable, subject to receiving pre-approval to do so from the Minister of Finance.

Agree / Disagree

Tony de Jong
Manager, Biotech Policy & Regulation
MBIE

03 / 07 / 2024

Hon Judith Collins KC MP
Minister of Science, Innovation and Technology

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

Background

1. The draft paper attached as **Annex One** seeks Cabinet agreement to the proposed Gene Technology Regulatory Regime and the issuing of drafting instructions for the legislation.
2. To improve the accessibility of a complex regime, mirroring a recent approach taken for similar decisions for the Offshore Renewable Energy Regulatory Regime, the main paper summarises the proposals and policy rationale, while the technical detail of the regime is set out for Cabinet agreement in the paper's Appendix One. The paper also includes two additional appendices summarising the proposed regime:
    i. Appendix Two – a visual summary of the regime, and
    ii. Appendix Three – a comparison between new regime and status quo (Hazardous Substances and New Organisms Act)
3. You have committed to introducing a Bill before the end of 2024. To meet this timeframe, you will need Cabinet agreement to your proposal in early August 2024, and your office has requested targeting Cabinet's ECO Committee on Wednesday 7 August 2024.

The draft Cabinet paper is based on Gene Technology Ministers' decisions

Cabinet's agreement is sought to policy necessary to begin drafting the legislation

4. The draft Cabinet paper seeks Cabinet agreement to:
    a. The high-level design of the proposed regime.
    b. Delegate specific technical decisions to yourself and joint ministers.
    c. Issue drafting instructions to the Parliamentary Counsel Office
5. The paper includes the following sections, based on decisions by joint ministers:
    a. **Purpose and Scope:** the legislation will seek to manage risks to the environment and human health and safety from gene technologies and regulated genetically modified organisms.
    b. **Regulatory approach:** it will be based on international 'hybrid' regimes which exclude low-risk gene editing techniques from regulation.
    c. **Authorisations:** it will adapt Australia's authorisation framework which regulates activities against several risk tiers.
    d. **Decision making:** the regulator will be a single decision maker advised by technical staff and expert committees.
    e. **Ministerial involvement:** there will be ministerial policy directions and call-in powers to intervene if the regulator acts contrary to its policy objectives.
    f. **Interaction with other legislation:** Councils' power under the Resource Management Act to restrict gene technologies should be removed. Applications involving multiple regulators (e.g. Medsafe) will be streamlined through joint assessments.

g. **Compliance, monitoring and enforcement:** MPI will provide these functions, which will be updated to reflect modern legislative design standards since the existing HSNO regime was introduced.

h. **Implementation:** The paper provides options on whether the regulator should be within MBIE or the Environmental Protection Authority (EPA).

It also addresses key settings discussed at the 27 June joint ministers meeting

6. As agreed at the 27 June Gene Technology Ministers meeting:

Māori rights and interests would be considered through a 'kaitiaki relationship' approach adapted from the Plant Variety Rights Act 2022 (PVR):

a. In response to Ministers request, we have including provisions for Māori rights and interests based on the PVR regime. This has the following features:

i. The provisions are triggered when there may be adverse impacts to kaitiaki (guardianship) relationships with indigenous species and non—indigenous species of significance (e.g. those brought by Māori settlers).

ii. A Māori advisory committee will provide advice to the regulator on adverse effects to those species and recommend potential mitigations. It will also issue engagement guidelines and provide advice to applicants and kaitiaki.

iii. The regulator, on advice from the committee, may change or revoke a previous approval on the basis that the applicant has breached conditions or that a kaitiaki relationship was damaged at the time of the approval.

b. Ministers asked for one substantive change to the model by making the committee an advisory body, whereas in the PVR regime it has decision making powers to decline applications where there are significant adverse effects. This change will not reduce the information considered during the regulatory process but may be criticised for reducing Māori decision making over significant species.

The paper provides options on whether the regulator should be hosted by MBIE or the EPA

c. The paper provides the rationale and costings to support a Cabinet discussion on hosting the regulator in either MBIE or the EPA. In summary:

Host	Advantages	Risks	Estimated 4-year cost
MBIE	Broad range of experience with demonstrated ability to house independent regulators Stronger connection to technology and innovation functions	No complementary regulatory functions More costly to set up new regulator and greater risk of delays	Confidential advice to
EPA	Reduces regulatory complexity by avoiding a new regulator	Risk EPA would be seen as the 'status quo' and lack stakeholder confidence	Confidential advice to

	Existing technical capabilities and complementary regulatory functions (new organisms)	More distant from ministerial control (partially mitigated by ministerial policy direction)	

d. The paper also provides for:

i. A Ministerial call-in for applications, 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.

ii. The streamlining of approval processes, where there is overlap with other legislation, through a joint approval process. This will allow the regulator to recognise and/or share approvals relating to the same or equivalent risks, and to share protected information for efficiency and to reduce duplication.

Cabinet delegation of decision-making authority is sought for further policy decisions

7. Further work is required to develop technical or specific aspects of the regime, and Cabinet is asked to delegate decision-making where these can reasonably be made by a Minister (or Ministers). Areas for further advice and decisions include on offences, defences, and penalties, detailed design of the decision-making advisory process, and specific screening processes for synthetic nucleic acids.

Key agencies have been consulted on the proposal

8. A group of agencies have been regularly engaged on the GTRR proposal to develop policy settings and understand risks and opportunities in relation to other government initiatives. Relevant agencies were also formally consulted on the draft Cabinet paper between 26 June and 2 July. A summary of feedback and any resulting changes to the draft Cabinet paper is included in Annex Two.

Tight timeframes have expedited the policy development process, creating some potential risks

9. The tight timeframes requested to develop the regime and enable the introduction of a Bill to the House in 2024 has required policy to be developed at pace. This has resulted in a targeted consultation process across government and key stakeholders which has:

a. Limited officials' ability to consider a wide range of perspectives, potentially compromising the quality of the proposal developed.

b. Free and frank opinions

10. Through the agency consultation process we have also identified a limited number of policy issues that require further clarification before drafting instructions can be issued. These are not central to the design of the regime, but we propose to try and resolve them before the

paper is lodged so that necessary changes can be included in the final version of the Cabinet paper if you agree.

The Finance Minister must pre-approve ministerial consultation

You are meeting the Minister of Finance on 4 July Confidential advice to Government

Confidential advice to Government

Confidential advice to Government

Confidential advice to Government

Next steps

August 2024 policy approval will keep you on track to introduce a Bill to the House in 2024

17. Your office has requested we target submitting the paper for consideration by the ECO Committee on 7 August, which requires lodgement on 1 August. To meet this deadline:
    a. As outlined, Minister of Finance approval is required to begin consultation.
    b. We need your feedback or approval on the paper prior to consultation.
    c. A minimum of five working days consultation is required with relevant Ministers:
        i. We consider it necessary for consultation to conclude no later than 19 July to allow us to address feedback and seek your final approval to lodge

18. The current milestones and timeline up until the Bill is introduced to the House is as follows:

Milestone	**Timing**
Confidential advice to Government	
Feedback on Cabinet paper	4 July-9 July
Update and signout paper	10-12 July
Ministerial consultation starts by	15 July 2024
Ministerial consultation ends	19 July 2024
Lodge Cabinet paper	1 August 2024
ECO considers paper	7 August 2024
Cabinet considers paper	12 August 2024
PCO drafts legislation	August to December 2024
Bill introduced to the House	December 2024

19. We are also considering our approach to developing further advice on delegated matters. We will update you on the expected timeframe for this advice in due course.

Annexes

Annex One: Draft Cabinet paper

Annex Two: Key agency feedback on the Cabinet paper

Annex Three: Letter to Minister of Finance Confidential advice to Government

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

Annex One – Draft Cabinet paper

Attached separately

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

Annex Two – key agency feedback on the Cabinet paper

Agency	Key feedback	Our response
The Treasury	• Agreed with the general direction of the Cabinet paper and the key outcomes proposed. • Confidential advice to Government [redacted]	A small proportion of cost recovery occurs under the existing regime through the charging of application fees, and we agree that this will be appropriate under the new regime. Confidential advice to Government [redacted]
Department of the Prime Minister and Cabinet	• Fiscal implications should consider the potential for cost recovery from applicants (even if partial). Free and frank opinions [redacted] The power to cost-recover should be included in the drafting decisions.	Agree that the Gene Technology Act should include a power to establish fees and levies for cost recovery and this is now reflected in the Cabinet paper.
Ministry for Primary Industries	Legal professional privilege [redacted] Other feedback included: • Paper should have more mention of impact on specific acts (Biosecurity, Animal Welfare, Food, Organics Products). • That the regulator being accountable to a Chief Executive seems inconsistent with it being independent. • Concerns that a ministerial call-in power may create political interference and affect the independence of the regulator. • Request that Biosecurity New Zealand be part of the emergency authorisation process. • Clarify who is responsible for what during joint assessments.	Offences and penalties require further development and will be addressed in a supplementary Regulatory Impact Statement (RIS) in consultation with the Ministry of Justice. Agree that wording should be altered to clarify our intention to base compliance provisions on current system rather than copying and pasting the provisions of the HSNO Act. Agree to define "environment" under the legislation. Many of the impacts on legislation and sectors are covered in our RIS and not detailed in the Cabinet paper. Agree that responsibilities in joint assessments will need to be further developed and clarified, but will not be detailed in the Cabinet paper. Agree to add a requirement that the Minister of Biosecurity is consulted as part of the emergency authorisation process.
Department of Conservation	• Cabinet should also be provided with information about the advantages of EPA being the regulator, noting that costings for the EPA option are estimated to be lower.	The Cabinet paper includes the EPA as an option for where to locate the new regulator, for Cabinet to discuss and decide, including an outline of the advantages and disadvantages of either MBIE or the EPA.
Ministry of Health	• Supportive of the direction proposed in the Cabinet paper. • Emergency use authorisations: add a requirement that the Minister also consult the Minister of Health or the Minister of Agriculture (depending on whether the emergency use relates to humans or agriculture) before making a decision. • A question of the option of call-ins [for health products] – would this be better delegated to the DG of Health • Other minor and technical points related to clarity that gene therapies require dual approval as medicines and gene technologies.	Agree to add requirement that Minister of Health is consulted when declaring emergencies. Agree that responsibilities in joint reviews will need to be further clarified but these are not detailed in the cabinet paper, will be subject to further development. MedSafe approval will still be required to administer the medicine, so ministerial call in power on GMO applications is unnecessary. Considering Māori interests through the PVR Act model will focus on the impact to kaitiaki relationships instead of a general tikanga consideration.
Ministry for the Environment	• No issues raised	N/A

Environmental Protection Authority	• Raised concerns with the proposed Ministerial direction provision; that it may affect the independence of regulator by making the regulator and its decision-making subject to swings in policy objectives when governments change. • The EPA also provided useful technical feedback to help the new regime run more smoothly, based on their experience with the (at times frustrating) provisions of the HSNO Act.	Agree with the concerns about a Ministerial direction provision. To mitigate the potential for changes in government to affect the independence of the regulator and its decision-making, we consider that it will be important to carefully prescribe the scope of the Ministerial direction to achieve the aims of the provision without it resulting in unintended consequences.
Te Puni Kōkiri	• Generally comfortable with the proposal for a Māori Committee as it is largely modelled on the Plant Variety Rights (PVR) Act approach. However, there is a substantive difference in that the gene tech regulator is proposed to be the decision-maker rather than the committee in respect of an application that may have adverse effects on a kaitiaki relationship. Preference would be for the Māori Committee to have the power to stop a gene technology application proceeding if it determines the proposal would have adverse effects on a kaitiaki relationship. As an alternative, suggested that regulator could be required when making a decision to not read down Māori rights and interests identified by the Māori Committee. • Seeks a recommendation that Cabinet note that biodiscovery/bioprospecting policy work will be developed and this would consider benefits and also assist in providing the pathways for Māori rights and interests.	We agree that careful consideration will need to be given to how the regulator's obligations to consider the advice from the Māori Advisory Committee are drafted in legislation. The proposal that TPK undertakes biodiscovery policy work could be noted in the Cabinet paper if this is agreed by the Minister for Māori Development.
Ministry of Foreign Affairs and Trade	• Concerned that decisions may be made without consideration being given to the impacts of the proposed new regime on trade. MFAT has not had time to undertake an assessment. • Proposes that trade and market access considerations should be reflected in the new regime. • Requested inclusion of a legislative requirement for products to be self-identified as Genetically Modified via product labelling. This will be crucial for ensuring that trade risks can be mitigated through the assurance process, by allowing New Zealand to prove to trade partners International relations that, where applicable, exported products are not GMO.	MFAT's support for an assessment of trade impacts was requested but was not possible in the timeframes. However, we have considered trade and market access impacts and how these could be addressed in discussion with MPI, given its lead role advising on the primary sector and related market access assurance programmes. It is expected that the new regime will have impacts for the organics / non-GMO primary sector once GMO products begin to be released into the environment. There will need to be new supply chain management systems implemented to account for both GMO and non-GMO production, and additional assurance processes to enable organic / non-GMO products to meet market requirements. We have included a requirement for record-keeping to support this. We note that the export of genetically modified organisms is not currently regulated by HSNO but by the Imports and Exports (Living Modified Organisms) Prohibition Order 2005.

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

Annex Three - Letter to Minister of Finance Confidential advice to Government

Attached separately – includes:

- Letter to Minister of Finance
- Confidential advice to Government

In Confidence

Office of the Minister of Science, Innovation and Technology

Cabinet Economic Policy Committee

Regulation of gene technologies – policy decisions

Proposal

1 This paper seeks:

1.1 agreement to key features of a new regime for regulating gene technologies

1.2 authority to issue drafting instructions to the Parliamentary Counsel Office to draft primary legislation for the new regime.

Relation to government priorities

2 The proposals in this paper support the Government's coalition agreement commitments to enable the greater use of gene technologies that would provide benefits to New Zealand, specifically:

2.1 Ending the effective ban on genetic engineering (GE) and genetic modification (GM) in New Zealand

2.2 Streamlining approvals for trials and the use of non-GE/GM biotechnology.

Executive Summary

3 While gene technology has the potential to deliver enormous benefits to New Zealand, it is heavily restricted by the overly precautionary and out of date Hazardous Substances and New Organisms Act 1996 (HSNO). The research community and industry consider HSNO to be fundamentally not fit for purpose and in need of fundamental change.

4 We need new legislation to regulate gene technology. This should have the intention of enabling New Zealand to safely benefit from these technologies by managing risks to the environment and the health and safety of people.

5 The proposed regime is primarily based on Australia's Gene Technology Act 2000. This means it would take a 'hybrid approach' by regulating higher risk activities by the techniques used while excluding some low-risk gene editing activities from regulation.

6 Activities regulated by the regime would be assessed under a risk proportionate authorisations framework where conditions are applied to activities based on their anticipated risks, with riskier activities having greater

requirements placed on them. The assessment process may be expedited by drawing on the expertise of recognised international regulators.

7 The regulator would be a single independent statutory officer situated within the Ministry of Business, Innovation and Employment. They would be supported by an expert Technical Advisory Committee and a Māori Advisory Committee.

8 To ensure the regulator acts consistently with the reform objectives, the Government would be able to influence the regulator via general policy directions and the ability to call in decisions that have the potential for significant effects..

9 Gene technology activities are regulated by a range of legislation and regulators, so the approval process will be streamlined using joint assessment processes and information sharing. The ability for territorial authorities to restrict the use of GMOs in their regional and district plans under the Resource Management Act 1991 will also be removed to ensure a nationally consistent approach to decisions.

10 The compliance, monitoring and enforcement functions and powers will be based on HSNO to ensure consistency with existing regimes where appropriate. The Ministry of Primary Industries (MPI) undertakes some of these functions under HSNO for new organisms and would continue in this role under the new legislation.

11 With Cabinet's agreement, I estimate that the new regime would begin operation by the end of 2025. Confidential advice to Government

Background

Gene technology can deliver enormous benefits for New Zealand

12 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%. Even under current restrictive rules, New Zealand's biotech sector generated $2.7 billion in revenue in 2020, and underpins a bioeconomy worth over $50 billion.

13 Beyond the potential economic benefits, gene technologies offer potential solutions to pressing national challenges such as climate change and improving health outcomes. Recent beneficial advances include:

13.1 new therapies for hard-to-treat genetic diseases and cancers

13.2 agricultural feed grasses able to reduce animal emissions, and

13.3 better heat and drought resistant crops.

14 Many of our trading partners (Australia, England, the United States, Japan, Argentina and the European Union) are reducinge restrictions on gene

technologies or proposing to do so. Reforming our system now positions New Zealand scientists and businesses well to take advantage of significant opportunities in future.

The current regulatory regime inhibits the development and use of safe gene technologies and products

15 While gene technologies have been used in New Zealand laboratories since the 1970s, research outside containment (such as laboratories) has been heavily restricted since the introduction of the Hazardous Substances and New Organisms Act 1996 (HSNO). It prohibits the import, development, field testing and release of genetically modified organisms (GMOs) unless approved by the Environmental Protection Authority (EPA).

16 HSNO was developed when genetic modification was relatively new and not well understood and it is now regarded as one of the most stringent regimes in the OECD. This has had a chilling effect on the research, development and application of gene technologies in New Zealand, because it is:

16.1 an effective ban on non-medical GMOs, which has not approved environmental releases in practice, even though it is possible in theory

16.2 not risk proportionate either in its outcomes, or in its requirements of applicants

16.3 administratively burdensome, to the extent that it is limiting domestic R&D and forcing New Zealand researchers to go offshore

16.4 out of date and its settings do not reflect modern GM techniques, leading to some activities being either under or over regulated.

17 While amendments to HSNO could technically address the issues identified, I consider that new legislation is required because:

17.1 New dedicated legislation gives the opportunity to build on overseas models that have demonstrable track records for enabling the safe use of gene technology.

17.2 HSNO has a broad remit beyond gene technology, and the extensive changes needed would require significant additional work to ensure the wider regime continues to function. This would delay the reform and increase costs.

17.3 We need to communicate a clear departure from the previous restrictive approach to encourage innovation. The research community and industry consider HSNO to be fundamentally not fit for purpose and amending HSNO would risk the appearance of business-as-usual.

The proposed new regulatory regime has been developed at pace

18 In developing proposals officials have sought to either 'borrow the best' from other mature regimes, and adapt it to New Zealand's settings, or carry over relevant New Zealand settings for consistency. In particular:

18.1 The proposed regime is primarily adapted from Australia's federal *Gene Technology Act 2000*, which is well regarded as an enabling regime that appropriately manages the risks from gene technology. This approach will ensure alignment with a close trading partner and research collaborator, and it is a system with which many New Zealand researchers will already be familiar with.

18.2 Some administrative features will be based on HSNO for consistency (e.g. monitoring, compliance and enforcement).

A ministerial group has developed the reforms outlined

19 Gene technologies impact a range of portfolios and legislation in addition to the Science, Innovation and Technology portfolio. I convened the Gene Technology Ministerial Group in early 2024 to develop and test proposals and ensure portfolio perspectives were considered. Ministers involved were:

19.1 Hon Dr Shane Reti (Health)

19.2 Hon Todd McClay (Agriculture, Trade)

19.3 Hon Tama Potaka (Conservation, Māori Crown Relations and Māori Development)

19.4 Hon Penny Simmonds (Environment)

19.5 Hon Andrew Hoggard (Biosecurity and Food Safety)

19.6 Hon Mark Patterson (Rural Communities and Associate Agriculture).

The appendices provide a summary of the proposed regime and detail its technical design and changes from the status quo

20 As gene technology legislation involves significant technical detail, I have included three appendices to support Cabinet's discussion of the regime:

21 **Appendix One** covers the technical and detailed design of the regime. I seek Cabinet agreement to its contents to direct the Parliamentary Counsel Office in drafting the legislation.

21.1 **Appendix Two** provides a summary of the proposed regime and its primary features.

21.2 **Appendix Three** compares the proposed changes with the existing HSNO system and summarises their impacts.

A new regulatory regime will ensure New Zealand can benefit from gene technology

Purpose and scope of the regime

The new legislation should establish an enabling, risk proportionate and efficient regime

22 To ensure New Zealand can benefit from gene technology opportunities, we need legislation focused on achieving the following outcomes:

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

22.2 **Risk-proportionate:** restrictions on gene technology and GMOs should be proportionate to the risks that each application poses.

22.3 **Efficient:** Applications should be efficiently assessed, and the process should be easy for applicants to navigate.

22.4 **Future focused**: the legislation should accommodate future technological developments without needing frequent amendments.

22.5 **Rights and interests:** the regime should appropriately consider Māori rights and interests under the Treaty of Waitangi.

22.6 **Internationally aligned:** the regime should be in step with New Zealand's major partners to facilitate trade and improve access to new technologies.

The legislation should regulate gene technologies

23 I propose that this legislation focus solely on gene technology (as in Australia). In practice gene technology is regulated through the organisms it is applied to. While these are sometimes referred to as "genetically modified organisms" (GMOs) this often leads to confusion because definitions (including those in HSNO) typically exclude organisms that are intuitively genetically modified, and definitions of GMOs vary from place to place for good regulatory reasons. For this reason I refer to "regulated organisms".

24 The full scope of the legislation would be broad and encompass any technique for the construction or modification of genes or other genetic material that is not used for traditional breeding or natural selection. Regulated organisms would be limited to organisms that have been modified or constructed by gene technology but would explicitly exclude human beings.

25 Because the precise scope of what needs to be regulated varies with the development of new techniques, the existence of traditional techniques that fall within the definitions of gene technology but that have been shown to pose limited risk, and experience managing the risks of existing techniques, I

further propose a power for organisms or types of organisms to be excluded from regulation by secondary legislation.

The legislation's scope should be focused on assessing risks to the environment and the human health

26 I propose that the legislation's regulatory scope is adapted from Australia's federal regime, which has a narrow scope focused on managing risks to the health and safety of people ('human health') and the environment. This has two main advantages.

26.1 The focus on managing risks leads to a more enabling regulator because it is required to consider options to reduce an application's risks (e.g. conditions) as part of its decision-making process.

26.2 Risks to the environment and human health can be objectively assessed, which enables a more consistent, evidential, and transparent approach to evaluating applications and making decisions.

27 The effect of the legislation, however, must be to *enable* the safe use of gene technologies and the design of the regime is intended to create that rebalancing. This should be clearly expressed in the purpose statement of the legislation.

28 This purpose means that, like Australia, the legislation would not consider the potential benefits of an application, ethics considerations, or trade and market access risks.

The regulator should not assess the potential benefits of an application

29 Applicants do not invest time and effort in the development of a gene technology unless they believe it presents some benefits. In practice requiring benefits to be assessed leads to the regulator seeking additional information from the applicant that, particularly in the case of innovative products, may not be available. It provides avenues for legal challenge by incumbents that increase risks for the regulator, and costs for the applicant, but it does not provide an environmental benefit. It also suggests that counter-intuitive result that we should accept lower environmental standards if the economic benefit is great enough.

The trade and market access risks from New Zealand's use of GMOs would be best managed by improvements to agricultural assurance processes

30 Some stakeholders have called for the regulator to consider the international trade impacts of applications because of a perceived risk that trading partners may not accept exports that have been 'contaminated' by GMOs, incidentally or otherwise. I consider that the regulator should not consider trade and market access risks when deciding an approval application because these risks can be adequately managed by implementing assurance and supply chain separation programmes that are used successfully in Australia and North America.

31 In order to support assurance processes, however, the legislation will enable the regulator to require users of regulated organisms to keep records that they have done so where this is necessary to ensure the reliability of trade assurance systems.

A hybrid, risk-tiered regulatory approach, with clear exemptions

New Zealand should adopt a hybrid, risk-tiered approach (like Australia)

32 I propose to shift New Zealand's regulatory regime from a generally "process-based" approach, which focuses on the technology used to produce a product, to a "hybrid" model like that used in Australia and England, and has been proposed in the European Union. Under a hybrid model, the scope of the regulation is determined by the process, but lower risk activities are either exempt from regulation, or assigned to categories that do not require case-by-case licensing.

A hybrid approach means specific gene technologies can be exempted from regulation

33 Adopting a hybrid model would enable specific gene technology activities to be exempted via regulations. An activity would be exempted because it either involves minimal risks or its products cannot be distinguished from those achievable by conventional breeding techniques.

34 I propose to set out an initial list of non-regulated activities to provide certainty to researchers, assist the transition from HSNO and to enable relevant research to begin as soon as the regime comes into effect. This list would include all organisms modified by gene techniques that are currently considered to not be genetically modified organisms in either New Zealand or Australia (including those listed in the EPA's relevant statutory determinations).

Low risk gene editing techniques should be exempt from regulation

35 In line with international practice, the list of non-regulated activities would also include some low-risk gene editing techniques. I propose to exempt techniques that produce specific minor changes, and do not introduce new genetic material. This would be more permissive than Australian rules, which counter-intuitively allow for random gene changes, but not guided ones. It would be less permissive than English and proposed EU rules for plants, which seek to set the standard at changes achievable by conventional breeding. This is because England and the EU set an uncertain boundary as to what is and is not regulated and may therefore be difficult to implement in practice. Because I proposed that further activities can be exempted, in future exemptions could be extended to match English and EU rules if there is positive experience of how these regimes operate in practice.

Risk-proportionate authorisations framework for regulated activities

Overview of authorisations framework

36 The new regime must be risk proportionate, ensuring that the regulatory burden on applicants is proportionate to the risk of the activity they are proposing to undertake. To this end, I propose to adopt and improve on Australia's current GMO authorised activities framework, incorporating proposed changes to their regime which seeks to regulate medicines containing GMOs more appropriately.

37 Australia's framework has three categories for regulating activities according to the type of activity:

37.1 Laboratory and Industrial Use,

37.2 Environmental Release, and

37.3 Medical and Veterinary Use.

38 I propose to adopt these three categories and to proportionately regulate within these three categories, I propose each category have three risk tiers: 'Non-notifiable', 'Notifiable' and 'Licensed'. The 'Licensed' risk tier for the environmental release and medical and veterinary use categories would also contain three assessment types: Permit, Expedited assessment, and Full assessment (see Annex Two for a visual overview of the regime including the proposed risk matrix). Appendix One includes a table which sets out the risk matrix in greater detail, including examples of the types of activities that could fall into each category.**Error! Reference source not found.Error! Reference source not found.**

The regulator may issue 'general approvals' for activities involving minimal risks

39 The 'Activities Approved for General Use' list would enable some activities to be conducted without a license for which the regulator has decided that:

39.1 any risks posed by those activities are minimal

39.2 it is not necessary for persons undertaking those activities to be covered by a licence to protect public health and the environment.

40 This would mean that any specific organism included on this list (for instance, a GM ornamental flower) would be able to be imported and used by anybody, provided any conditions attached to the listing are complied with and other legislative requirements are met (eg biosecurity).

The regulator would leverage international expertise to accelerate assessments

41 To ensure the regime is internationally aligned and New Zealand can benefit from international expertise, I recommend three approval pathways be

included to accelerate assessment processes and approvals where possible. These are:

42 **Joint assessments** of licensed activities with other international regulators ('joint international assessments') to enable applicants to apply for an environmental release or medical use licence under multiple jurisdictions simultaneously

42.1 **Automatic gene technology approvals** of GM human medicines approved by at least two 'recognised regulators' that assess gene technologies in a manner comparable to New Zealand; medicines would still need to be approved under the Medicines Act

42.2 **Expedited assessments** for organisms approved by recognised regulators so international data and assessments can be used by the regulator in New Zealand

The responsible minister can grant an emergency authorisation to address imminent threats to human health and the environment

43 The legislation would also include:

43.1 powers for the Minister to issue an emergency authorisation to respond to an actual or imminent threat to human health or the environment

43.2 the ability for the regulator to issue a temporary licence for inadvertent possession of a regulated organism so that the organism can be disposed of safely.

Decision making

There will be a single decision maker (regulator) advised by technical staff and expert committees

44 I propose appointing an independent statutory officer (ISO) as the Regulator, supported by an office. The Regulator's role will be to:

44.1 Assess applications for licensed activities.

44.2 Determine which activities and new characteristics of organisms (traits) are non-notifiable and notifiable activities, meaning a licence is not required .

45 Appointing a single decision maker is a departure from HSNO, under which decisions are typically made by an expert committee appointed by the EPA. This reflects the idea that assessing gene technology activity risks should be a technical, science-based process, and removes the challenges that come with committee-based decision making, such as the length of time required to make decisions.

The regulator will be well supported in their decisions by advisory committees

46 Under the new regime, I propose that in making decisions, the Regulator be required to consider advice from a technical advisory committee (TAC). The TAC will be responsible for advising the regulator on technical matters relating the gene technologies and the management of their risks.

Public consultation will only be required for full assessments

47 I propose that public consultation would only be required for licences that require a *full assessment* by the regulator (i.e. activities that have a high or uncertain risk). The regulator would invite submissions from the public on the draft risk assessment and management plan to consult on the suitability of the risk management controls.

48 For *expedited assessments*, the regulator would have discretion to publicly consult on its Risk Assessment and Risk Management Plan, only if it deems it necessary. This approach allows for the public to be consulted to inform the regulator's risk tolerance for those applications where the desired societal outcome is most uncertain.

49 In addition, the regulator would also be required to publicly consult on proposed changes to secondary legislation, including changes to the list of exempted technologies and organisms, and those activities categorised as non-notifiable, notifiable, and eligible for a permit.

The regulator should consider adverse effects on kaitiaki relationships with taonga species

50 The Crown has recognised in multiple Treaty settlements that Māori have rights and interests in certain species of flora and fauna. Recognising these rights through a specific process in the legislation will honour the Crown's obligations under the Treaty of Waitangi and provide certainty to the regulator, applicants, and the courts on how parliament intends for these rights to be protected.

51 I propose to adapt the process from the Plant Variety Rights Act 2022, which I consider provides a good model for considering these rights in an enabling legislative framework. This would involve a Māori advisory committee advising 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 Committee will also issue engagement guidelines and provide advice to applicants and Māori on the application process.

Ministerial involvement

52 Government needs a mechanism to intervene if the regulator acts contrary to its policy objectives (eg becoming too permissive or cautionary). I propose two provisions:

52.1 General policy directions, which will give the Minister the ability to set general parameters for the regulator such as guidance on risk tolerance, or increasing use of discretionary powers

52.2 Ministerial call-in for applications, 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.

Interaction with other legislation

The regulatory process can be streamlined through joint assessments

53 Gene technologies may require dual regulatory approvals where there is overlap with other legislation, most commonly with either the Medicines Act or the Agricultural Compounds and Veterinary Medicines Act.

54 A single approval (ie by the gene technology regulator) is not practical because each regulator assesses important risks to fulfil the purposes of their regimes that are outside of the expertise of the others. For example, Medsafe assesses the safety, efficacy and quality of medicines that the gene technology regulator could not assess without significantly expanding its resourcing and duplicating the capability of Medsafe.

55 Nevertheless, I consider it is possible to streamline applications so that they are required to submit the minimum amount of information to satisfy both regulators, and to ensure that regulators are not duplicating decision-making about the same risks. I propose to put in place joint approval process, which would allow the regulator to recognise and/or share approvals relating to the same or equivalent risks, and powers to share protected information to achieve a high level of efficiency.

The Resource Management Act 1991 (RMA) should be amended to remove councils' powers to restrict GMOs

56 The RMA allows regional councils, territorial and unitary authorities to set restrictions on the use of GMOs under regional policy statements and plans. Several councils have done so, including Hastings District Council, Northland Regional Council and Auckland Council. This creates a dual approval system where councils could restrict the use of GMOs despite being approved by the gene technology regulator.

57 I propose removing councils' powers to set restrictions on organisms regulated by this Bill because Councils lack the specialised expertise to manage gene technology risks, and unnecessarily duplicate national level

assessments. Removing the power would ensure a more predictable and enabling regulatory environment for GMOs, instead of creating a patchwork of different requirements across the country.

International agreements

58 New Zealand has binding international obligations under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity in respect of the transboundary movement of living modified organisms. This, and the parent Convention on Biological Diversity also place obligations to manage risks to the conservation and sustainable use of biodiversity arising from genetically modified organisms. MBIE has reviewed the proposals for this new legislation and consider it is consistent with the text of the Convention and the Protocol.

59 New Zealand primarily implements its Cartagena Protocol obligations through the Imports and Exports (Living Modified Organisms) Prohibition Order 2005. The definition of Living Modified Organisms under the Protocol and the Order differ from the definition of GMOs in HSNO, and will continue to differ from definitions used in this legislation.

60 New Zealand also has binding international obligations under the Comprehensive Progressive Trans-Pacific Partnership Agreement (CPTPP). This includes article 2.27 regarding 'Trade of Products of Modern Biotechnology' but these place no limitations or requirements on domestic legislation of gene technology except for basic transparency and information sharing requirements.

National security or defence

Synthetic nucleic acids should be subject to specific screening processes

61 National security or defence

62 I propose that legislation provide the ability for regulations to be made requiring any domestic suppliers of nucleic acids to screen customer orders. While there are no companies currently providing this service in New Zealand, these requirements may become expected by close security partners and we are unlikely to be presented with a more suitable legislative opportunity.

Some functions and powers will be based on HSNO

The regime will be based on some of the functions and powers in HSNO

63 While many of the substantive provisions of HSNO require overhaul, some of the functions and powers are relevant to the new regime. Basing these on HSNO will support the smooth integration of the regime into the wider

regulatory context. I therefore propose to base the following powers and functions on HSNO, amended where necessary to modernise approaches that are now considered out of date legislative practice (eg the use of continuing offences) or where more recent examples elsewhere in legislation improve on the same tool (eg statutory determinations):

63.1 The ability of the regulator to make statutory determinations if there is potential ambiguity about the technical scope of legislative definitions

63.2 Compliance and enforcement provisions, including penalties

63.3 MPI's role as the compliance and enforcement agency.

Implementation of the new regulatory regime for gene technology

64 If Cabinet agrees with the recommendations in this paper, MBIE officials will work with the Parliamentary Counsel Office to prepare legislation to give effect to the proposals. MBIE will be responsible for the administration of the legislation. There are two options for the location of the regulator, MBIE or the EPA.

Option one: the regulator is located in MBIE

65 Establishing the regulator within MBIE would locate the regulator next to the technology and innovation functions we are seeking to support through legislative reform. MBIE has a broad range of regulatory experience, and has demonstrated an ability to house effective independent regulators.

66 Because it would be a new regulatory function for MBIE, this option is likely to be more costly. MBIE does not have significant complementary regulatory functions, and there is some additional risk in expecting MBIE to set up a new regulator from scratch.

Option two: the EPA remains the regulator

67 The EPA already has the technical capabilities to perform the gene technology regulatory role, and has complementary regulatory functions. The main advantage of locating the new regulator with the EPA, however, would be that it would avoid introducing a new regulator into an already complex regulatory environment. Initial costings suggest this option will be less expensive.

68 Free and frank opinions As a Crown Entity, the EPA is more distant from Ministerial control than a public service department, although this would be mitigated somewhat by the powers of general policy direction proposed for the legislation.

I seek authority to approve further detail of the regime

69 Further policy details will need to be decided during the development of the legislation. I seek Cabinet agreement to delegate authority to the Minister of Science, Innovation and Technology, in consultation with other Ministers as relevant, to make further policy decisions in line with the proposals set out here, so long as they are not contrary to the objectives and scope of the regime.

The regime could be in place by the end of 2025

70 I am proposing to deliver this regime by the end of 2025 to enable the regulator to be established and approve its first applications in this term of government. This requires the prioritisation of the drafting of this Bill and in the House.

71 Alongside primary legislation, secondary legislation that sets out the detail of administrative processes will need to be developed. MBIE will lead the development of the necessary secondary legislation. Some of this is intended to be in place shortly after the Bill is passed to enable the regulator to begin operation.

72 I intend to introduce the Bill in December 2024. This would enable the first applications to be assessed in early 2026, per the milestones in the table below. To enable these timelines, MBIE has prepared drafting instructions based on the proposals in this paper to enable PCO to begin drafting the Bill immediately following Cabinet decisions. If there are significant changes to the policy proposals, timelines will need to be revised.

Milestone/Activity	**Timeframe**
Cabinet decisions on regime	August 2024
MBIE prepares drafting instructions	August 2024-September
Drafting of Bill	August – December 2024
Bill introduced and first reading	Confidenti 2024
Select Committee (six months)	Confidential 2025
2nd reading, Committee of the whole House, 3rd reading, Royal assent, Act commences	Confid 2025
Secondary legislation in force	tbc
Establishment phase	Confidential 2025
Regulator operational	Confidential advice to 2025

Cost-of-living Implications

73 There are no immediate or direct cost-of-living implications arising from the proposals in this paper. The proposals would have an indirect impact over time by enabling the development of new consumer products using gene technologies.

Financial Implications

74 The new regime will establish a Gene Technology Regulator to make decisions in accordance with primary and secondary legislation on gene technologies. Ensuring a properly resourced regulator that can adequately respond to increased demand is a critical success factor for the new regime.

75 Officials estimate the costs for establishing and operating this new regulatory function in the first two to three years as Confid annually, reducing to Confid annually from Year 4. The ongoing operational costs for the Regulator housed within MBIE are estimated at Confid per annum, with higher costs in Year 1 (Confidential advice to Government) and Year 2 (Confid). These estimated costs include staffing, specialist and external advice, and ICT and systems. Cost recovery will be provided for in legislation, meaning a small proportion of costs could be offset in future years.

76 Locating the new regulator in the EPA will be significantly cheaper at only Confiden over the four year period (compared to Confid at MBIE – both totals include costs for compliance, monitoring and enforcement). While the EPA already regulates genetically modified organisms, it currently has only two positions allocated to this work. It expects the new regime to generate a significant increase in applications and regulated gene technology activity, requiring a more substantial regulatory capacity.

77 I am proposing that compliance monitoring and enforcement of the new regime is undertaken by MPI, as with the HSNO regime. Officials estimate costs of up to Confi across the first two years associated with developing and delivering training material on requirements of the new regime to compliance staff. Costs beyond the first two years would depend on the volume of applications received.

78 This new function will require appropriate funding to adequately equip the Regulator to perform their role effectively from the outset. Officials do not anticipate being able to “lift and shift” funding from EPA’s baseline as the EPA’s responsibilities will not significantly reduce with the introduction of the new gene technology regime. Confidential advice to Government

79 I propose the new legislation include provisions enabling regulations to allow for cost recovery and set fees and charges, but these are not a practical means of funding the regulator. The new regulatory system moves regulation away from case-by-case licenses, meaning that much of the cost of the regulator will be in maintaining the integrity of a broader public good system.

Some cost recovery will be possible in licence applications, but the need to seek a licence is not intended to be a disincentive, and it will take time for this revenue to come on stream. Most countries, including Australia, do not seek to recover costs from licensing, and we need to be careful to maintain New Zealand's competitiveness as a location for biotechnology innovation.

Legislative Implications

80 New primary and secondary legislation is needed to implement the proposals. The proposed regime will be given effect through the Gene Technology Bill, supporting secondary legislation, and consequential amendments to other legislation including HSNO, the Biosecurity Act, and the RMA.

81 Confidential advice to Government [redacted]

82 The proposed Act would bind the Crown.

Impact Analysis

Regulatory Impact Statement

83 Cabinet's impact analysis regimes apply to the proposals in this Cabinet paper. AGENCY'S Regulatory Impact Analysis Review Panel has reviewed the attached Regulatory Impact Statement "NAME" produced by MBIE.

84 The Panel considers that it partially meets the quality assurance criteria. It stated FEEDBACK. To fully meet the quality assurance criteria, it would be necessary to:

84.1 IMPROVEMENTS

Climate Implications of Policy Assessment

85 The Ministry for the Environment has confirmed that a climate implications assessment is not required for the proposed regime.

Population Implications

86 The proposed regime would not disproportionately impact distinct population groups.

Human Rights

87 There are no human rights implications arising from the proposals in this paper. Consistency with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993 will be discussed with the Ministry of Justice during the drafting process.

Use of External Resources

88 These proposals have been developed without the use of external resources.

Consultation

89 MBIE consulted with the following agencies in the development of the proposals outlined in this paper: LIST OF AGENCIES

90 MBIE has conducted targeted consultation with industry and research stakeholders most likely to be affected by the proposals including: Confidentialit [redacted] A Technical Advisory Group and Industry and Māori focus groups were also established. The proposals have not been consulted publicly.

91 To support this reform, the Ministry for the Environment has provided expertise and an analysis of the submissions it received last year on proposals to improve the regulations for laboratory and biomedical research using GMOs. Where possible, insights from this consultation have and will be incorporated into this reform to further improve regulations for New Zealand researchers.

Communications

92 I propose to issue a media release announcing the design of the regulatory regime and expected timeframes for introducing legislation and implementing the regime.

Proactive Release

93 I plan to proactively release this paper, with any redactions consistent with the Official Information Act 1982 Confidential advice to Government [redacted]

Recommendations

The Minister of Science, Innovation and Technology recommends that the Committee:

Background

1 **Note** the Governing coalition agreements commit to enabling the greater use of gene technologies that would provide benefits to New Zealand, by

1.1 Ending the effective ban on genetic engineering and modification in New Zealand, and

1.2 Streamlining approvals for trials and the use of non-GE/GM biotech.

2 **Note** that the Gene Technology Ministerial Group, comprising a range of portfolios and parties, have developed the reform proposals outlined in this paper;

Purpose and scope of the regime

3 **Note** that the proposed regime is based on Australia's Gene Technology Act 2000 with relevant updates and adaptations where required for the New Zealand context.

4 **Agree** that the scope of the legislation will be focused on managing risks to health and safety of people and the environment

5 **Agree** that the aim of the legislation is to enable to the safe use of gene technologies, and this should be reflected in the legislation's purpose

6 **Agree** that the legislation will include all gene technologies within its broad scope, where gene technologies are any technique for the construction or modification of genes or other genetic material that is not used for traditional breeding or natural selection

7 **Agree** that regulated organisms will be those that have been modified or constructed by gene technology but exclude human beings.

Hybrid, risk-tiered regulatory approach, with clear exemptions

8 **Note** that key recommendations on the regime's design are set out below, a full design of the regime is described in **Appendix One**

9 **Agree** that the legislation take a hybrid approach to regulation of gene technologies, combining a process-based approach to higher risk activities while specifically exempting lower risk activities and traits from regulation;

10 **Agree** that from establishment the regulator will exclude from regulation all techniques and organisms that are explicitly and currently excluded from the definition of a genetically modified organism in either New Zealand or Australia

11 **Agree** that gene editing techniques that that produce specific minor changes, and do not introduce new genetic material would also be excluded from regulation

12 **Agree** that the legislation include a provision to exclude further technologies from regulation, where they either involve minimal risks or their products cannot be distinguished from those achievable by conventional breeding techniques;

13 **Agree** that the legislation provide a statutory determination power to enable the regulator to determine the status of an organism or technology;

A risk-proportionate authorisations framework

14 **Agree** that the regime take a risk-proportionate approach where conditions are applied based on the anticipated risks of the activities, with three primary categories through which activities can be regulated in a way most suitable to their use: Laboratory and Industrial; Environmental Release; and Medical Use; and

14.1 each of these categories to have three tiers reflecting level of likely risk: 'Non-notifiable', 'Notifiable' and 'Licensed', and

14.2 the 'licensed' risk tier for the environmental release and medical use categories to then contain three types of licence process based again on risk: Permit, Expedited assessment, and Full assessment;

14.3 the 'licensed' risk tier for laboratory and industrial category to contain one type of licence process: Expedited assessment.**Error! Reference source not found.**

15 **Note** that under the risk proportionate approach proposed for the non-notifiable and notifiable risk tiers, which will encompass very low risk and low risk activities, the regulator would have minimal operational oversight:

16 **Agree** that members of the Technical Advisory Committee be appointed by *[Minister/Regulator/CE]* / *[in consultation with]..*

17 **Agree** that consistent with an enabling and risk proportionate approach, public consultation be:

17.1 required for licences that require a *full assessment* by the regulator (i.e. assigned to higher risk tier levels), with submissions invited on the draft risk assessment and management plan regarding the suitability of the risk management controls.

17.2 be at the regulator's discretion for Risk Assessment and Risk Management Plans for any expedited assessments;

18 **Agree**, that in making decisions consistent with the purpose of the legislation, the Regulator focus only on managing risks to the environment and health and safety of people, approving activities where it is satisfied the risks can be managed to a level that protects the environment and human health and safety;

19 **Agree** to include a provision in the legislation for the responsible minister to issue general directions to the regulator.

Interaction with other legislation

20 **Note** that in certain instances gene technologies will require approval under more than one regulatory system, and it is not practicable to implement a single approval due to complexity and specialisation of expertise;

21 **Agree** that in such instances a joint assessment processes between relevant regulators be undertaken where possible, and data and information can readily be shared between agencies to facilitate assessment;

22 **Agree** to remove from the Resource Management Act 1991 the ability for regional councils, territorial authorities and unitary authorities to set restrictions on the use of GMOs to remove duplication and provide a nationally-consistent and predicable regulatory environment for gene technology;

Compliance, enforcement, and penalties

23 **Agree** that the compliance, enforcement and penalties regime from HSNO carry over where practicable, and subject to modifications to reflect current legislative best practice;

24 **Agree** that the Ministry for Primary Industries is responsible for the legislation's compliance and enforcement provisions;

25 **Agree** that legislation provide for regulations to be made to require domestic commercial suppliers of nucleic acids to screen customer orders;

Agreement to regime as outlined in Appendix One

26 **Agree** to the detailed design of the regime**, described in Appendix One**;

Financial implications

27 **Note** that a new regulator located in MBIE is expected to cost Confid over the next four years, and that a new regulator located in the EPA is expected to cost Confid over four years.

28 **Note** that it will not be practical or desirable to fully recover the costs of regulation from applicants and other regulated parties

Location of the regulator

29 **Agree** that

Either

29.1 The regulator will be located in MBIE

Or

29.2 The regulator will be located in the EPA

Legislative implications

30 **Agree** that the proposals will be given effect through the Gene Technology Bill (the Bill)Confidential advice to Government

Confidential advice to Government

31 **Agree** that the Bill will include a provision stating that the Act will bind the Crown.

32 **Agree** that the proposed regime will require amendments to other legislation, including the Hazardous Substances and New Organisms Act 1996, and the Resource Management Act 1991

33 **Agree** that the Bill will include regulation-making powers including the ability to make regulations to prescribe:

33.1 Cost recovery, fees and charges

33.2

34 **Agree** that the Minister of Science, Innovation and Technology is authorised to further clarify and develop policy matters relating to the proposals in this Cabinet paper in a manner not inconsistent with the policy recommendations contained in the paper

35 **Invite** the Minister of Science, Innovation and Technology to issue drafting instructions to the Parliamentary Counsel Office for the Gene Technology Bill and associated secondary legislation.

Authorised for lodgement

Hon Judith Collins KC MP

Minister for Science, Innovation and Technology

Appendix One: Design of the Genetic Technology Regulatory Regime

Purpose and scope of the regime

1 The purpose of the regime will be to enable the safe use of gene technologies. The regime will do this by:

1.1 Regulating gene technologies and genetically modified organisms, and

1.2 Managing the risks to the environment and risks to the health and safety of people from organisms modified by gene technology.

2 The scope of the legislation will encompass gene technology and organisms modified by gene technology. The terms ‘gene technology’, ‘genetically modified organism’, ‘organism’ and ‘regulated organism’ will be defined in legislation and expected to evolve through the drafting process. An overview of the terms follows:

3 ‘Gene technology’ will include techniques used for the modification or construction of genes or other genetic material but will not include traditional breeding techniques or natural selection.

4 ‘Regulated organisms’ will include organisms that have been modified or constructed by gene technology, including human cells but not including human beings.

5 Regulation of genetically modified organisms will be removed from the Hazardous Substances and New Organisms (HSNO) Act 1996 by removing genetically modified organisms from the definition of a ‘new organism’, as well as removing and modifying relevant provisions and references.

6 The legislation will be based on Australia’s Gene Technology Act 2000, with modifications made to adapt it to a New Zealand context.

Regulatory approach

7 Legislation will take a hybrid approach to the regulation of gene technology, combining a process-based approach to higher-risk activities while exempting lower-risk activities from regulation.

8 The legislation will include a provision to enable the creation of regulations that would outline those techniques and organisms that would be exempt from regulation.

9 At its establishment, organisms that have been modified with gene editing techniques that are indistinguishable to outcomes produced using conventional breeding techniques (and other relevant criteria) and do not

involve the insertion of genetic material, will be classified as not regulated organisms.

10 Public consultation will be required as part of the regulatory process for classifying technologies and organisms as not regulated. These not regulated technologies and organisms may be set under a schedule of the Act or secondary legislation and will require an Order in Council to modify.

11 At its establishment, the new legislation will also exempt organisms and technologies that are currently declared to be exempt and not regulated in either New Zealand or Australia. These organisms and technologies will be included under the not regulated organisms and technologies list under secondary legislation.

12 These exemptions will also include relevant statutory determinations made by New Zealand's Environmental Protection Authority.

13 New organisms, under the HSNO Act, will require separate consideration when transitioning to the new regime.

14 The new legislation will provide the ability for the regulator to make a statutory determination as to whether a technology is a gene technology, or whether an organism has been modified by gene technology, or whether an organism is a regulated organism.

Risk-proportionate authorisations framework for GMO activities

15 It will be an offence for any person to undertake an activity with a regulated organism (an activity), including, but not limited to, making, importing, developing, manufacturing, or releasing a regulated organism, unless authorised to do so under the new Gene Technology Act.

16 There will be six means by which activities could be authorised under the Gene Technology Act. That would be by:

16.1 Meeting the criteria of a non-notifiable risk tier,

16.2 Meeting the criteria of a notifiable risk tier,

16.3 Being issued a licence,

16.4 Being included under the 'Activities Approved for General Use' list,

16.5 Receiving an emergency authorisation, and

16.6 Being issued an inadvertent activities licence.

17 A risk matrix will form the authorisation framework for non-notifiable, notifiable and licensed authorisations. This matrix will be divided into three categories of activities:

17.1 Laboratory and Industrial,

17.2 Environmental Release, and

17.3 Medical and veterinary use.

18 Each category will have three risk tiers:

18.1 Non-notifiable,

18.2 Notifiable, and

18.3 Licensed.

19 The following table provides an overview of the risk tiers and assessment types, the indicate risk they correspond to, their conditions or requirements, and the sorts of activities that they are likely to include.

Risk tier + *assessment type*	**Indicative gene technology risk**	**Regulator role**	**Conditions or requirements**	**Examples or type of activities**
Non-notifiable	Very low risk	Nil	Activity must correspond to category (i.e. activities under the Laboratory category must not be released into the environment)	Administration of CAR T-cell therapies (under the Medical and veterinary use category)
Notifiable	Low risk, provided specific requirements are met	Nil (except being notified annually)	Research organisations to notify the regulator about their activities	Laboratory research with animals and higher risk organisms
Licensed				
Permit	Medium indicative risk	Verify that the activity and applicant are eligible for a permit (no case-by-case assessment)	Applicants will apply to the regulator for a permit before commencing an activity. Activities must correspond to a list. Permit holders must comply with defined licence conditions.	Where the regulator has extensive regulatory knowledge and the risks of activities have been decided as manageable through licence conditions previously found to be effective.
Expedited Assessment	Medium to high indicative risk	Undertake risk assessment and develop risk management plan to determine whether the risks of an activity can be	Tailored licence conditions.	Where some of the risks of the activity are well understood by the regulator, or

		managed to an acceptable level of tolerance. Public consultation at regulator's discretion		where GMOS have been approved by recognised regulators.
Full assessment	High indicative risk or substantial uncertainty as to risk	Undertake risk assessment and develop risk management plan to determine whether the risks of an activity can be managed to an acceptable level of tolerance. Public consultation.	Tailored licence conditions.	For activities with which the regulator has no or limited regulatory experience.

Non-notifiable

20 Non-notifiable risk tiers will cover activities that present a very low risk to human health and safety and the environment. Like notifiable activities, activities meeting the criteria for a non-notifiable risk tier could be commenced without receiving prior approval from the regulator. Notification to the regulator would also not be required prior to a non-notifiable activity commencing.

21 Requirements would be placed on non-notifiable activities under the Laboratory and Industrial category. The core requirements of the non-notifiable risk tier under the Laboratory and Industrial category would be that:

21.1 any intentional release of a regulated organism into the environment is prohibited,

21.2 the regulator must be notified of the unintentional release of a regulated organism into the environment.

Notifiable

22 Notifiable risk tiers will cover activities that present a low risk to public health and the environment, provided certain requirements are met by those undertaking those activities.

23 Primary legislation would provide the ability for regulations to be made that may specify requirements to undertake a notifiable activity. These may include requirements relating to:

23.1 Containment facility requirements,

23.2 Notifying the regulator of a notifiable activity,

23.3 Supervision or verification of notifiable activities by an internal compliance body within or accessible by an institution, such as an Institutional Biosafety Committee, or

23.4 Transportation, storage and disposal requirements.

Licensed activities

24 Licences may be issued for activities after assessment under either of three different assessment pathways: permit, expedited assessment, and full assessment.

25 The regulator will have the authority to vary, suspend, transfer or cancel licences, as under the Australian Gene Technology Act 2000.

Permits

26 Applicants can apply to the regulator for a permit to undertake an activity. A permit may be issued by the regulator to an applicant if the regulator is satisfied that:

26.1 the activity is eligible for a permit, and

26.2 the applicant is suitable to carry out the activity.

27 If the regulator considers that another assessment pathway is more appropriate for the application, the regulator may allocate the application to an expedited or full assessment pathway, with the agreement of the applicant.

28 Primary legislation will enable the regulator to list activities as eligible for a permit if the activities meet the criteria listed under secondary legislation. These criteria would include:

28.1 Activities for which the regulator has extensive regulatory knowledge, the risks of which the regulator is satisfied could be managed through a set of defined licence conditions that have previously been shown to be effective.

28.2 Activities with risks the regulator is satisfied could be managed by a ‘universal’ set of licence conditions that have previously been shown to be effective.

29 The regulator would be required to publicly consult on the activities proposed to be listed as eligible for a permit and the relevant risk management conditions attached to those activities.

30 Activities eligible for a permit would be published by the regulator in a notice.

Expedited assessments

31 Applicants can apply to the regulator for a licence via an expedited assessment pathway. The regulator may undertake an expedited assessment if the regulator is satisfied that the activity involves risks well understood by the regulator and as such only some components of the activity require assessment.

32 It would be at the regulator’s discretion as to whether public consultation is required for an expedited assessment.

33 If the regulator considers that another assessment pathway is more appropriate for the application, the regulator may allocate the application to a permit or full assessment pathway, with the agreement of the applicant.

Full assessments

34 Applicants can apply to the regulator for a licence via a full assessment pathway.

35 Public consultation would be mandatory requirement for a full assessment pathway.

36 If the regulator considers that another assessment pathway is more appropriate for the application, the regulator may allocate the application to a permit or expedited assessment pathway, with the agreement of the applicant.

Assessment processes – Expedited assessments and Full assessments

37 The process for an expedited assessment will be the same as for a full assessment, except for the public consultation requirement being mandatory for full assessments and at the regulator's discretion for expedited assessments.

38 The process of expedited assessments and full assessments will be:

38.1 An application is received,

38.2 The regulator decides whether an application meets the criteria for an expedited assessment or a full assessment,

38.3 The regulator seeks the advice of its Māori Advisory Committee on whether there might exist any kaitiaki relationship that might be affected by the proposed activity,

38.4 The regulator undertakes a risk analysis of the application, including preparing a Risk Assessment and Risk Management Plan (RARMP),

38.5 The regulator consults its Technical Advisory Committee on the RARMP,

38.6 Based on advice from the Technical Advisory Committee, the regulator makes any amendments to the RARMP it deems necessary,

38.7 If a public consultation is required (as for full assessments) or the regulator determines that a public consultation is necessary for an expedited assessment, the regulator will notify the public and other parties of the application and invite submissions for a minimum period of 30 working days,

38.8 Based on the RARMP and, if applicable, any submissions received during the public consultation period, the regulator will decide to issue

a licence or not. The regulator must decide whether to issue a licence or refuse to issue a licence.

39 If the regulator is satisfied that the risks posed by the activities proposed to be authorised are able to be managed in such a way as to protect the health and safety of people and the environment, the regulator may issue a licence, with or without conditions.

40 If the regulator is not satisfied that the risks posed by the activities proposed to be authorised are able to be managed in such a way as to protect the health and safety of people and the environment, the regulator must not issue a licence.

Activities Approved for General Use

41 The primary legislation will enable the regulator to add activities that may be undertaken by anybody without a specific licence, to an 'Activities Approved for General Use' list.

42 The criteria for this 'Activities Approved for General Use' list, set under secondary legislation, will include:

42.1 any risks posed by those activities are minimal, and

42.2 it is not necessary for persons undertaking those activities to be covered by a licence to protect public health and the environment.

43 The regulator would be able to add to this list both previously licensed activities and activities not previously authorised.

44 The regulator would be required to publicly consult on any additions, modifications, or removals to this list. Changes to this list would be published via a notice.

Emergency authorisations

45 Primary legislation will enable the responsible Minister to temporarily authorise an activity that is needed to respond to an actual or imminent threat to health and safety of people or the environment. This would be similar to the emergency authorisation provisions of the Australian Gene Technology Act.

46 The Minister may make an emergency authorisation having sought advice and consulted with relevant Ministers and agencies.

47 The responsible minister would be able to issue an emergency authorisation if they were satisfied that:

47.1 there was an actual or imminent threat to human health or the environment, and

47.2 the activity proposed in the authorisation would, or would be likely to, adequately address the threat.

48 The authorisation process would not require public consultation or the development of a risk management plan, however the Regulator could recommend conditions to the responsible Minister.

49 The Minister would be able to make an emergency authorisation if:

50 They have received advice from the regulator that any risks posed by the activity are able to be managed in a way to protect health and safety of people, and the environment.

50.1 They are satisfied that any risks posed by the activity are able to be managed in such a way as to protect health and safety of people, and the environment.

51 The authorisation and the Minister's reasons for the authorisation will be publicly notified.

52 An emergency authorisation would last for a period of up to six months from the point at which the authorisation starts. The Minister may extend the period of effect of an emergency authorisation more than once, but each single such extension must not exceed six months.

Inadvertent activities

53 Persons can apply to the regulator for an 'inadvertent activity' licence, in instances where that person has come into possession of a regulated organism without realising or intending to.

54 The regulator would have the ability to issue this licence for a specified period of time so that the regulated organism can be disposed of safely.

Provisions to leverage international expertise

55 Provisions will enable the use of international expertise to accelerate assessments and approvals through the use of the following mechanisms:

55.1 Joint assessments with international regulators,

55.2 Automatic authorisations under the Gene Technology Act of human medicines approved by two 'recognised gene technology regulators', and

55.3 Expedited assessments for activities approved by a 'recognised gene technology regulator'.

Joint assessments

56 Primary legislation will enable the regulator to undertake joint assessments of licence applications with other international regulators. Eligible applications

would be those that are being assessed via a full assessment pathway. The joint assessments would be done to inform the regulator's Risk Assessment and Risk Management Plan and prior to public consultation.

57 The legislation will enable the regulator to enter into agreements with other international regulators for the purposes of undertaking these joint assessments. These agreements would be required prior to any joint assessments being undertaken.

58 While the Minister may direct the regulator to consider and explore potential joint assessment agreements, the regulator would not be obligated to enter into an agreement with another international regulator if it is not satisfied the international regulator would offer the standard of assessment required.

59 Following public consultation, the regulator would make its own decision as to whether to issue a licence, independent of the decision of the other international regulator(s) of which it has conducted the joint assessment.

Recognised regulators

60 Primary legislation will enable the regulator to establish other international regulators as 'recognised gene technology regulators'. The criteria for an international regulator to be a 'recognised gene technology regulator' would be that a regulator must:

61 Assess activities in a manner comparable to the New Zealand regulator, and

61.1 Operate under a legislative framework comparable to the New Zealand gene technology legislation.

62 The regulator would be required to publicly consult on regulators it proposes to establish as 'recognised gene technology regulators'. The list of recognised regulators would be published via a notice.

63 The regulator will be required to regularly monitor 'recognised gene technology regulators' to ensure they continue to meet the criteria above.

Automatic authorisations of human medicines

64 Once a human medicine that is or contains a regulated organism has been approved by at least two 'recognised gene technology regulators' it will be automatically authorised under the Gene Technology Act.

65 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.

66 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.

67 Approval by Medsafe will continue to be required before any clinical use.

Expedited assessments for activities approved by 'recognised gene technology *regulators'*

68 Activities that have been previously approved by one or more 'recognised gene technology regulators' will be eligible for the expedited assessment pathway for a licence.

69 It would be a requirement that the activity has been approved by a 'recognised gene technology regulator' that publishes their data and assessments, in a way that is readily accessible to the New Zealand regulator.

70 This provision would be similar to the 'recognised international regulators' provision under the HSNO Act, the purpose of which is to expedite the assessment of hazardous substances through the better use of international data and assessments.

71 The regulator will make its own independent decision, based on its Risk Assessment and Risk Management Plan and feedback from relevant persons and agencies.

Assessments and decision-making

72 The regulator will license an activity if it is satisfied risks to the environment and risks to the health and safety of people can be managed.

73 The regulator's assessment of an application will not include assessment of the following:

73.1 Potential benefits (economic or otherwise),

73.2 Ethical considerations,

73.3 Trade, international agreements and market access risks, or

73.4 Cultural, social or spiritual matters.

74 The regulator will be required to seek advice on expedited and full assessment licence applications from its Technical Advisory Committee, its Māori Advisory Committee, the responsible Minister, the Ministry for Primary Industries, Department of Conservation, and any other agency or person it considers appropriate.

Ministerial call-in provision

75 Legislation will provide the power for the responsible Minister to 'call-in' and decide an application if the Minister considers that the application would have nationally significant effects on the environment or the health and safety of

people. Applications eligible to be called-in would be those that are being assessed via a full assessment pathway.

76 The authorisation and the Minister's reasons for the authorisation will be publicly notified.

Advisory committees

77 Primary legislation will establish advisory committees that will support the regulator to carry out its functions and will include:

77.1 Technical Advisory Committee, and

77.2 Māori Advisory Committee.

78 Legislation will enable the regulator to establish subcommittees if it deems it necessary.

79 Members of the Technical Advisory Committee and the Māori Advisory Committee will be appointed by the responsible Minister on the advice of the regulator.

80 The Technical Advisory Committee will advise the regulator on technical matters relating to regulated organisms and the management of their risks, including, but not limited to, advising on:

80.1 Risk Assessment and Risk Management Plans,

80.2 Guidance documents and risk analysis frameworks,

80.3 Proposed updates to the non-notifiable and notifiable risk tiers, and

81 Proposed activities eligible for permits.

Māori Advisory Committee

82 The regulator will be required to consider relevant adverse effects to Māori kaitiaki relationships with indigenous species and non-indigenous species of significance (kaitiaki relationship) in its decision making. The process will be modelled on the Plant Variety Rights Act 2022.

83 The Māori Advisory Committee will advise the regulator on these adverse effects. It will have the following functions:

83.1 Issue engagement guidelines and provide advice to applicants and kaitiaki.

84 Consider applications referred to it by the regulator and advise whether the application should proceed, including whether an adverse effect could be mitigated by conditions imposed by the regulator or an agreement between the applicant and kaitiaki.

84.1 Advise the regulator whether the use or approval of a proposed activity is likely to be offensive to Māori.

84.2 Advise the regulator, upon application by any person, whether a previous approval should be changed or cancelled if:

84.2.1 It determines that there was an adverse effect on a relevant kaitiaki relationship at the time of the approval.

85 A license holder has breached a condition or undertaking made as part of the approval to manage adverse effects on kaitiaki relationships.

Statutory timelines for decision making

86 The regulator will be required to set statutory timelines, through secondary legislation, for processing applications, consultation and deciding an application.

Risk assessment and risk management

87 Primary legislation will require that in preparing its risk assessment the regulator must take into account risks posed by those activities, including any risks to the health and safety of people or risks to the environment, having regard to matters prescribed under regulations.

88 The matters for the regulator to take into account, may include:

88.1 The properties of the host organism,

88.2 The effect, or expected effect, of the intended genetic modification on the host organism,

88.3 The effects or expected effects of the regulated organism,

88.4 The potential for spread or persistence of the regulated organism in the environment,

88.5 Provisions for limiting spread and persistence of the regulated organism or its genetic material in the environment,

88.6 The extent or scale of the proposed activity,

88.7 Any likely impacts of the proposed activity on the health and safety of people, the environment, or kaitiaki relationships with a specific species,

88.8 The short and long-term impacts of the regulated organism,

88.9 Any previous domestic or international assessments relating to the activity, and

88.10 The potential for the regulated organism to be harmful to other organisms, adversely impact the ecosystem, transfer genetic material to another organism, have an advantage relative to other organisms in the environment, be toxic, allergenic, or pathogenic to other organisms.

Risk assessment and the Cartagena Protocol

89 New Zealand is required to ensure risk assessments are conducted to meet the requirements of the Cartagena Protocol. New Zealand has an obligation to ensure that the development, use, movement, and release of Living Modified Organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking into account human health risks.

Appealing decisions

90 Provisions that enable an applicant to appeal a decision made by the regulator will be updated and broadly aligned with Part 8 of the HSNO Act, where applicable.

Review of decisions

91 Primary legislation will include a provision to enable an applicant to seek a review of a licence decision made by the regulator, similar to the Australian Gene Technology Act 2000.

Reassessments

92 The legislation will provide the regulator the authority to undertake reassessments, or partial reassessments, of decisions. These will be undertaken at the discretion of the regulator if it deems it appropriate.

93 These reassessments may be initiated by any person, including the regulator.

94 Reassessment provisions will be updated and aligned with those under section 62 of the HSNO Act. Partial reassessment provisions will be updated and broadly aligned with those for hazardous substances under the HSNO Act.

95 Based on the outcomes of a reassessment, the regulator will have the authority to amend, vary, suspend and cancel licenses.

96 Legislation will also provide the ability for the regulator to make amendments to licences to correct minor or technical errors without needing to undertake a full or partial reassessment.

Delegation

97 Legislation will enable the regulator to delegate to relevant regulatory agencies the power to assess and issue a licence for an activity. These provisions will be updated and broadly aligned with the section 19 delegation provisions of the HSNO Act.

The Gene Technology Regulator

98 The regulator will be an independent statutory officer, supported by an office and an operational budget.

99 The focus of the regulator will be to enable the safe use of gene technology through managing the risks of regulated organisms to the environment and to the health and safety of people.

Functions and powers of the regulator

100 The functions and powers of the regulator will include, but will not be limited to:

100.1 Assessing applications for licensed activities.

100.2 Authorising licensed activities.

100.3 Determining those activities that are covered by non-notifiable and notifiable risk tiers.

100.4 Providing information and advice about the regulation of gene technology and regulated organisms to:

100.4.1 The responsible Minister.

100.4.2 Other regulatory agencies.

100.4.3 The public.

100.5 Issuing technical and procedural guidelines in relation to gene technology and regulated organisms.

100.6 Providing advice to the responsible Minister on the effectiveness of the legislative framework and possible amendments to achieve the purpose of the legislation.

100.7 Monitoring international practice in relation to the regulation of gene technology and regulated organisms.

101 In the performance of its functions, the Regulator may take advice from:

101.1 The Technical Advisory Committee,

101.2 The Māori Advisory Committee,

101.3 Other government agencies,

101.4 Regional, territorial and unitary authorities (Councils),

101.5 Any other person the regulator considers appropriate.

Public consultation and notification

102 The regulator will be required to carry out public consultation for:

103 Proposed changes to the list of technologies and organisms classified as not regulated,

103.1 Proposed changes to the ‘Activities Approved for General Use’ list,

103.2 Proposed changes to the activities covered by non-notifiable and notifiable risk tiers,

103.3 Proposed changes to those activities eligible for a permit.

103.4 Licences applied for via the full assessment pathway,

103.5 All licence decisions, changes to non-notifiable and notifiable risk tiers, changes to technologies and organisms classified as not regulated, and statutory determinations, will be required to be publicly notified.

104 Legislation will require the regulator to maintain a publicly accessible register of applications and licence decisions.

Compliance, monitoring and enforcement

105 Provisions for compliance, monitoring and enforcement under primary legislation will be updated and will broadly align with the relevant compliance, monitoring and enforcement provisions of the HSNO Act.

106 These provisions will include, but will not be limited to, the:

106.1 Approval of containment facilities to standards relevant to regulated organisms,

106.2 Power to inspect approved containment facilities,

106.3 Ability to issue compliance orders, infringements and prosecute for an offence or offences.

107 Primary legislation will establish a delegation power to enable the regulator to delegate compliance, monitoring and enforcement functions to another agency, such as the Ministry for Primary Industries.

108 Primary legislation will also provide the regulator with a standard set of compliance, monitoring and enforcement powers.

109 The regulator will also be empowered to develop and approve standards for containment facilities for regulated organisms.

110 Primary legislation will also enable the sharing of compliance, monitoring and enforcement information between relevant agencies.

Offences and penalties

111 Offences and penalties will be updated and broadly aligned with the existing offences and penalties regime for GMOs under the HSNO Act.

Additional components

Ministerial direction

112 Legislation will provide the ability for the responsible Minister to issue general policy directions to the regulator, the scope of which would be designed to be consistent with the purpose of the regime.

Cost recovery

113 Legislation will provide the ability for the regulator to partially recover costs from administering the regime through licence application fees and any other means it deems appropriate.

114 Cost recovery provisions under the new legislation would be updated and aligned with section 21 of the HSNO Act.

Requirements for the screening of synthetic nucleic acid

115 The legislation will enable regulations to be made via an Order in Council which would require:

116 Companies that provide synthetic nucleic acids that are based in New Zealand to screen customer orders.

117 Manufacturers of benchtop nucleic acids synthesisers that are based in New Zealand to integrate into their equipment the ability to screen nucleic acid sequences.

Interactions with other legislation

118 Consequential amendments to other legislation will include:

119 The regulatory definition of ‘organism’ will be amended to achieve consistency across the new Gene Technology Act, the Hazardous Substances and New Organisms Act 1996, and the Biosecurity Act 1993, should it be deemed necessary to remove inconsistencies and complexity between statutes.

120 Other Acts that refer to definitions in the HSNO Act relating to gene technologies, will require updating for the new legislation and definitions.

121 The Resource Management Act 1991 will be amended to remove the ability for Councils to restrict GMO use through regional policy statements and regional plans.

122 The legislation will allow information and data to be shared between the regulator and other agencies for the purposes of streamlining and facilitating

the assessment of activities that require approval from multiple New Zealand regulators.

Implementation and transitional provisions

123 The regulator will require the ability to access criminal and company register information to determine the suitability of a person to hold a licence.

124 The regulator may provide and receive information from other government agencies where that information:

124.1 is held for the performance or exercise of either the regulator or the specified entity's functions, duties or powers, and

124.2 would assist the regulator or the specified agencies in the performance or exercise of their functions, duties or powers – including the assessment of licence applications.

125 Transitional provisions will allow for relevant approvals under the HSNO Act to be transferred from the Environmental Protection Authority to the new gene technology regulator.

126 Transitional provisions will also allow for the transfer of existing and previous applications and assessments under the HSNO Act from the Environmental Protection Authority to the new gene technology regulator.

127 The new legislation and secondary regulations will include the relevant organisms and techniques that are currently declared to be exempt and not regulated in either New Zealand or Australia. This will include relevant statutory determinations made by the Environmental Protection Authority.

Gene Technology – 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
- Internationally-aligned
- Retains public participation
- Allows greater use of gene editing
- Focuses on the management of risk
- Leverages overseas expertise
- Streamlined, efficient and transparent processes

NON-REGULATED TECHNOLOGIES AND ORGANISMS

GENE EDITING TECHNIQUES

- Organisms modified using unguided and template guided repair would be unregulated. Example applications include:

- STERILE WILDING PINES
- GRASS ENDOPHYTES
- GABA TOMATOES
- NON-BROWNING MUSHROOMS
- DISEASE-RESISTANT MAIZE
- DISEASE-RESISTANT POTATOES

CONVENTIONAL TECHNIQUES

- Techniques commonly regarded as not creating a GMO would remain unregulated, including:

- NULL SEGREGANTS
- RNA INTERFERENCE
- REPLICANT-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 laboratory and industrial use, environmental release, and medical use.

LABORATORY / INDUSTRIAL	ENVIRONMENTAL RELEASE	MEDICAL AND VETERINARY USE
Non-notifiable	Non-notifiable	Non-notifiable
Notifiable	Notifiable	Notifiable
Licensed: Expedited assessment	Licensed: Permit Expedited assessment Full assessment	Licensed: Permit Expedited assessment 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 and plants.
- **Licensed activities** 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 unique 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 the 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 DUAL ASSESSMENT PROCESSES

- Where appropriate, approvals required under multiple legislation will be streamlined through greater information and data sharing.
- Given the overlap of factors considered in their assessments, where a new organism has been genetically modified, a joint assessment by the EPA and the regulator for new organisms would be possible.

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.

Comparison between HSNO and proposed Gene Technology Bill

	HSNO	Gene Technology Bill	Impact of change
Purpose	Manage or prevent adverse effects Considers benefits and risks to five factors: Environment, health and safety of people, economy, public health, and Māori culture	Manage risks Focused on risks to environment and health and safety of people	Enables a more consistent, evidence-based and transparent approach to evaluating applications and making decisions
Scope	Genetically modified organisms	Gene technologies and regulated organisms	Ensures new technologies are covered, and simplifies the exemption process
Regulatory Approach	Process-based, all activities regulated based on techniques used	Hybrid approach: Exempts from regulation low-risk gene editing techniques (producing changes indistinguishable from conventional breeding)	Will encourage greater use of safe gene editing techniques Improves alignment with other jurisdictions with similar exemptions (England, Australia, Japan, proposed in European Union)
Authorisation framework	Two possible approvals – licenses (full assessment) and rapid assessments	Adapts Australia's authorisation process, providing more assessment pathways and lowering regulatory requirements for very low and low risk activities	Improves risk proportionality of regime and reduces administrative burden for laboratory-based and medical research
Decision making	Decision-making committees	Single regulator supported by office and expert committees	Increases efficiency of assessments and reduces costs
Ministerial involvement	Call-in power	Call-in power and ministerial policy directions	Allows ministers to signal expectations to regulator as well as intervene in individual decisions where necessary
Interaction with other legislation	RMA enables councils to restrict use of GMOs	RMA power to restrict GMOs removed	Removes complexity for applicants and unnecessary duplication of national-level assessments
Compliance, monitoring and enforcement	Primarily undertaken by MPI	Similar, with enforcement provisions updated to modern regulatory practice	Existing provisions appear to be functional so minor updates will provide consistency for researchers
Implementation	Implemented by the Environmental Protection Authority (EPA)	Option 1: Statutory Officer within MBIE	Builds connections with MBIE's technology and innovation functions to support biotechnology sector May encourage innovation as seen as departure from conversative status quo
		Option 2: New business unit within the EPA	Reduces administrative complexity as new regulator not required New business unit could support more enabling approach

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of gene technology – draft Cabinet paper for Ministerial consultation

Date:	11 July 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2425-0261

Action sought		
	Action sought	**Deadline**
Hon Judith Collins KC MP **Minister of Science, Innovation and Technology**	**Agree** to begin Ministerial consultation by 15 July 2024 on the draft Cabinet paper attached, incorporating feedback received **Note** that there are a number of policy areas not central to the design of the regime that require further development and decisions Confidential advice to Government **Agree** to discuss drafting timelines	15 July 2024

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

The following departments/agencies have been consulted
The Treasury, Department for the Prime Minister and Cabinet, the Ministry for the Environment, the Ministry for Primary Industries, the Department of Conservation, the Ministry of Health, the Ministry for the Environment, Te Puni Kōkiri, the Ministry of Foreign Affairs and Trade, and the Environmental Protection Authority were consulted on the Cabinet paper.

Minister's office to complete:

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

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Regulation of gene technology – draft Cabinet paper for Ministerial consultation

Date:	11 July 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2425-0261

Purpose

To seek your agreement to initiate Ministerial consultation by 15 July 2024 on a draft paper seeking Cabinet agreement to the proposed Gene Technology Regulatory Regime.

Recommendations

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

a. **Note** that the attached draft Cabinet paper has been developed in line with feedback received from your office;

Noted

b. **Agree** to begin Ministerial consultation on the draft Cabinet paper on 15 July 2024 to meet the target 7 August 2024 ECO Committee date;

Agree / Disagree

c. **Note**:
   a. there are a number of policy issues not central to the core policy design of the regime that require further development and clarification before drafting instructions can be issued but that officials were not able to progress for this Cabinet paper;

Noted

   b. these are expected to require further decisions either by delegated Minister(s) or potentially Cabinet;

Noted

   c. the drafting process is expected to raise additional matters that require further decisions;

Noted

Confidential advice to Government

e. **Agree** to discuss drafting timelines with officials;

Agree / Disagree

Tony de Jong
Manager, Biotech Policy & Regulation
MBIE

11 / 07 / 2024

Hon Judith Collins KC MP
Minister of Science, Innovation and Technology

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

Background

1. The draft paper attached as **Annex One** seeks Cabinet agreement to the proposed Gene Technology Regulatory Regime and the issuing of drafting instructions for the legislation. To meet the timeframe agreed, you need Cabinet agreement in early August 2024, and your office has requested targeting Cabinet's 7 August 2024 ECO Committee.

The draft Cabinet paper is ready for Ministerial consultation

The draft Cabinet paper reflects changes made in response to feedback received

2. We have incorporated all feedback received on the draft Cabinet paper follow briefing 2324-4026 and further discussions with your office. A tracked change version highlighting key changes in detail has been provided to your office if you required further detail of these.

Confidential advice to Government

Ministerial consultation should begin 15 July 2024 to maintain current timelines

4. ECO Committee consideration of the paper on 7 August 2024 requires lodgement on 1 August 2024. To meet this deadline a minimum of five working days consultation is required with relevant Ministers. To allow us to address feedback and seek your final approval to lodge, consultation should conclude no later than 19 July 2024.

5. Due to a House recess, the next available chance for ECO consideration after 7 August 2024 would be 21 August 2024, which would cause a two-week delay to the current timeline.

August 2024 policy approval will keep you on track to introduce a Bill to the House in 2024

6. The current milestones and timeline up until the Bill is introduced to the House is as follows:

Milestone	**Timing**
Ministerial consultation starts by	15 July 2024
Ministerial consultation ends	19 July 2024
Lodge Cabinet paper	1 August 2024
ECO considers paper	7 August 2024
Cabinet considers paper	12 August 2024
PCO drafts legislation	Confidential advice to Government (see next section)
Bill introduced to the House	Confidential advice 2024

Drafting timing

We understand PCO will recommend a revised drafting timeframe

Further work is required on provisions necessary for regime completeness and functionality

7. As outlined in previous advice, we have developed these proposals in a fast paced and ambitious timeframe. We have focused our efforts on developing the core regime for Cabinet consideration. As currently drafted the attached paper allows you to seek Cabinet decisions on the core elements of the proposed regime.

8. However, we still need to develop necessary advice for a number of policy issues that while not central to the core policy of the regime, require further development and clarification before drafting instructions can be issued. Examples include provisions on:

    a. Emergency use

    b. Statutory determinations by the new regulator

    c. Reviews and appeals of decisions by the regulator

    d. Cost recovery

    e. Offences and penalties, and

    f. Subject to Cabinet decisions, options to provide for decision making independence if regulator is located in the EPA

9. In many of these areas, we have either found there is complexity in adopting Australian provisions in the New Zealand context (e.g. emergency use provisions), or we are unable to carry over existing HSNO provisions as initially expected (e.g. for reviews and appeals, and offences and penalties).

10. Delegated Minister(s) (if delegation is approved), or potentially Cabinet will need to make decision on these matters after necessary work is completed. We also expect the drafting process to raise further unexpected matters that will also require further decisions by either Ministers or Cabinet.

Confidential advice to Government

Confidential advice to Government [redacted]

[redacted]

[redacted]

Next steps

14. We recommend you begin Ministerial consultation on 15 July 2024 to ensure we reach the target lodging the Cabinet paper for ECO Committee consideration on 7 August 2024.

15. We recommend discussing drafting timelines with officials.

Annexes

Annex One: Draft Cabinet paper

Ministerial call-in provisions, directions, and appeals

[16 July 2024]

Options for Ministerial involvement in regulatory regimes (where the Minister is not the primary decision-maker) are:

1. **Power to make directions**, which will give the minister the ability to direct the regulator in relation to a range of matters specified in their primary legislation, for example, to set general parameters for the regulator such as guidance on risk tolerance.
2. **Provision for a ministerial call-in power for applications**, 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.
3. **Power to investigate and make recommendations**, which provides the minister with the ability to investigate the performance of an regulator and its functions, powers, and duties, and make recommendations to address any issues.
4. **Review a decision,** where a minister can review a decision the regulator has made.

Provisions for ministerial involvement are specified in primary legislation, these provisions may have thresholds or specific criteria that must be met before a minister can intervene and will specify what powers the minister can use and how. The appropriate power depends on the relevant regime and is set out in legislation.

Ministerial directions *(agreed by Minister for inclusion in Gene technology legislation)*

Ministerial directions are used in Acts where a regulator may need to align the exercise and performance of its functions and powers to the policies of the government. An example of a ministerial direction is the minister directing all Crown Entities to support a whole of government approach to procurement to achieve efficiencies of scale, under the Crown Entities Act 2004. The scope of this the ministerial direction power varies and is specified in the specific legislation.

Ministerial call-in *(agreed by Minister for inclusion in Gene technology legislation)*

Provision for a ministerial call-in power is present in several Acts, including the Hazardous Substances and New Organisms Act 1996 (the HSNO Act). Under the HSNO Act, the power to call-in a decision is limited to decisions deemed nationally significant. Under the HSNO Act the minister must, when giving their decision, provide their reasons for using their call-in power, and gazetted the determination within 30 working days.

Power to investigate and make recommendations *(not yet considered by Minister, Ministerial Group, or Cabinet)*

This empowers a minister to investigate the performance of a regulator in exercising its powers and functions (or omitting to) and to make recommendations based on that investigation. The Resource Management Act 1991 (see 24A) provides these powers to Minister for the Environment for local authorities.

Review a decision *(not yet considered by Minister, Ministerial Group, or Cabinet)*

There are only limited circumstances where the subject of a decision can be reviewed by the minister. For example, in the Immigration Act 2009, an applicant for a Temporary Visa can ask to have their decision reassessed within a 14-day window. However, the decision is typically reviewed by an immigration officer. There is no right for a direct review by the minister. For other decisions, appeals are made to a tribunal or to the court.

Ministerial intervention	**+**	**-**	**Example Acts**
Directions	Can serve as a backstop to ensure a regime's operating in accordance with: • its policy intent • current government policy. Enables the minister to set operational expectations (e.g., timeframes for assessment).	Changes in Government may create uncertainty for applicants regarding how a regime will operate. Transfers liability associated with the decision from the Regulator to the minister (when the power is used). Creates reputational risk for the minister.	Agricultural Compounds and Veterinary Medicines Act 1997 (s38) Resource Management Act 1991 (s80L)

	A minister can issue a statement of expectations regarding the number of decisions considered in a given timeframe. The minister can provide guidance on risk tolerance or the interpretation of risk.	Depending on the scope of the minister's power to direct the regulator, there is potential to undermine the regulator's independence and public trust in the regulator.	
Call-in	Can serve as a backstop to ensure a regime's operating in accordance with: • its policy intent • current government policy. Enables the minister to intervene in instances of nationally significant effects on human health and the environment.	Changes in Government may create uncertainty for applicants regarding how a regime will operate. Transfers liability associated with the decision from the Regulator to the minister (when the power is used). Creates reputational risk for the minister. Potential to undermine the regulator's independence and public trust in the regulator.	Hazardous Substances and New Organisms Act 1996 (s68) Agricultural Compounds and Veterinary Medicines Act 1997 (s39) Resource Management Act 1991 (s142)
Investigation and recommendation	Can serve as a backstop to ensure a regime's operating in accordance with: • its policy intent • current government policy. Enables the minister to intervene when there is a regulator failure or the potential for one. External oversight can increase public trust in the regulator. Can help to enable continuous improvement of a regime.	Can be resource intensive. Potential to undermine the regulator's independence. This power relates to local authorities and is not necessarily appropriate for a regulatory regime like the proposed Gene Tech regime.	Resource Management Act 1991 (s24A)
Reviews	Enables a minister to intervene when there has been a specific incorrect or disputed decision.	Transfers liability associated with the decision from the Regulator to the minister (when the power is used). Creates reputational risk for the minister. Provides an avenue for applicants to lobby the minister and may risk public perceptions of influence on ministers. Can be resource intensive for the minister.	Immigration Act 2009 (s185)