MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

EVENT BRIEFING

Meeting with the Environmental Protection Authority

Date:	18 June 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2324-3846

Action sought		
	Action sought	**Deadline**
Hon Judith Collins KC MP **Minister of Science, Innovation and Technology**	**Note** the contents of this briefing to support your meeting with the Environmental Protection Authority on 19 June	19 June 2024

Contact for telephone discussion (if required)			
Name	**Position**	**Telephone**	**1st contact**
Simon Rae	Policy Director, Emerging Technologies	s 9(2)(a)	ü
s 9(2)(a)			

The following departments/agencies have been consulted

Minister's office to complete:

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- ☐ Withdrawn

Comments

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Purpose

You have agreed to meet with the Environmental Protection Authority (EPA) at your office on Wednesday 19 June 2024 at 4:00 PM.

This briefing provides supporting information and key questions you may wish to ask the EPA (**Annex One**).

Recommendations

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

a **Note** the contents of this briefing to support your meeting with the Environmental Protection Authority on 19 June

Noted

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

18 / 06 / 2024

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

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Background

1. At the third meeting of the Gene Technology Ministerial Group, s 9(2)(g)(i) [redacted]

2. We understand some of s 9(2)(g)(i) [redacted]

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

The EPA has issued eleven approvals for genetically modified organisms

4. To date, the EPA has approved nine Genetically Modified Organisms (GMOs) that are medicines, and a further two GMOs that are veterinary medicines or are contained in veterinary medicines. Most recently, it approved CAR T-cells for the use in the treatment of cancer under its rapid assessment pathway (which provides a decision within ten working days).

5. The EPA and its predecessor, the Environmental Risk Management Authority, have also approved twenty field tests of GM plants, animals and microorganisms.

The EPA's ability to create a more permissive regulatory regime for advancements in gene technology has been impacted by court cases

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

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

8. As a result, products of these newly developed technologies continue to be subject to full regulatory oversight as genetically modified organisms.

If these concerns can be addressed, the EPA has some advantages as a location of the Gene Technology Regulator

9. Advantages of retaining the regulatory function with the EPA include:

   a. its existing technical capabilities,

b. relationships with the sector and with Māori,

c. relevant committees (such as Ngā Kaihautū Tikanga Taiao), and

d. complementary regulatory functions in relation to new organisms.

Genetically modified new organisms would be a rare occurrence and can be streamlined through specific legislative provisions

10. While there may be complexity in separating the regulation of GMOs and New Organisms, the majority of GMOs that are being researched and potentially released are based on host organisms that are not new to New Zealand. The EPA consider applications to release an organism into the environment that is both new and genetically modified will be a rare occurrence.

11. To mitigate any potential regulatory duplication in these rare scenarios, we can design legislative provisions that would ensure processes are streamlined. For instance, this process could be streamlined through the regulator seeking a risk assessment of an application from the EPA's New Organisms team where an unmodified GMO would be considered a new organism.

You may wish to test some challenges the EPA may face in delivering the new regime

12. This meeting is an opportunity for you to discuss s 9(2)(g)(i) around the EPA's ability to deliver the new regulatory regime. We have provided some key questions for you to test with the EPA at **Annex One**.

The new legislation will set a clear minimum for the Regulators risk tolerance

13. You have indicated a concern that a conservative regulator might regulate in a way that prevents the change in legislation achieving the change in approach desired. There are a number of design features of the legislation that make this less likely.

The new legislation will reduce what needs to be approved on a case-by-case basis

14. Our proposed changes would deregulate certain gene editing techniques that replicate what could be achieved through conventional breeding methods. Users would not need to consult or seek approval from the Regulator for release into the environment or introduction to market.

15. Low risk categories of genetically modification activity, captured by our proposed risk matrix, will not need case-by-case risk assessment or approval by the Regulator. While the risk matrix will be able to be amended by the regulator, s 9(2)(f)(iv)

16. These legislative mechanisms will work together to establish a risk proportionate regime by matching the level of regulatory oversight against the risks involved in the activity, meaning oversight increases when risks also do. This will improve regulatory efficiency for lower risk activities while providing graduated oversight of medium and high risk activities where regulatory assessment is desirable.

It will change the level of regulatory scrutiny proportionate to risk

17. Currently, the purpose of the HSNO Act is to both prevent and manage risks posed by GMOs. Under the new regime, risk assessments will be guided by the proposed **new legislative purpose**, which is to solely to manage risks posed to human health and the environment, and will include an objective to enable the safe use of gene technology.

18. We are also proposing to **remove the precautionary approach for risk assessments** under the new regulatory regime. This is based on good regulatory practice, which prompts designers of regulatory regimes to focus attention on how the operative mechanisms guide a risk management approach, rather than seeking to guide the regulator through high level values statements.

19. These components will alter the risk tolerance for assessments captured under the proposed licensed categories of gene technology activities.

The new Regulator's risk tolerance could be further influenced through additional legislative mechanisms

Call-in power

20. You have indicated that you consider a Ministerial call-in power would be a useful tool to ensure that decisions are taken in accordance with the intent of the legislation. As a call-in power functions on a case-by-case basis, this may not influence the overarching risk tolerance of the new Gene Technology Regulator. Regular use of a call-in power would be likely to create uncertainty for applicants and the regulator.

General Direction

21. You may wish to consider having a power to issue a general policy direction instead of a call-in power. This could allow the government to influence the Regulator's risk tolerance without legislative change should the regulator act contrary to policy objectives (eg becoming too permissive or too precautionary).

22. This mechanism could also influence the assessment process by providing guidance on risk tolerance (the level of risk at which an application can still be approved) and how environmental and human health risks should be interpreted. It could also be used to set operational expectations, such as approval timeframes and consultation requirements.

Annexes

Annex One: One pager to support meeting with the EPA

Annex One: One pager to support meeting with the EPA

Dr Allan Freeth

Dr Allan Freeth has been the Chief Executive of the EPA since September 2015.

He has previously held Chief Executive positions at TelstraClear and Wrightson Limited. Prior to that he held senior management roles in Wrightson Rural and at Trust Bank New Zealand Limited.

He is a Director of Crimestoppers and he also acts as an advisor for multiple charities associated with child and youth organisations.

He holds a Doctorate in Philosophy in Population Genetics and an MBA.

Key questions

- What do you consider to be the key barriers to you approving environmental releases in the past?
- Should these be addressed through a more permissive regime, how comfortable would you be in approving these applications, including in an agricultural context?
- What does the EPA have in place to ensure you can successfully deliver the new regime?
- How comfortable would you be functioning under increased Ministerial Direction?
- How comfortable would you be in delivering a risk tiered regulatory regime that would include some activities having no oversight from the regulator?

[25 June 2024]

MBIE's capability to take on the role of the gene technology regulator

Your office has asked us to put together a brief assessment of MBIE's capability to take on the role of the gene technology regulator in order to support your decision-making about the location of the regulator. This paper does not address systemic issues that were addressed in our formal advice on this topic.

Setting up a regulator from scratch is an uncommon activity, and comes with significant uncertainty

Agencies are asked to set up completely new regulators infrequently. While it is not unusual to set up a new regulator in form, otherwise "new" regulators will typically transfer a significant core of staff and systems from a previous regulator with similar or overlapping responsibilities. In the case of the gene technology regulator there is likely to be limited scope to transfer capability from the EPA because the EPA will still be required to regulate new organisms, and we understand there is significant overlap in the regulatory capabilities required.

Setting up a new regulator will require us to identify suitably qualified staff, develop new operational policies and processes, and provide for the infrastructure for the regulator to operate. This will necessarily take time and entails operational risks, and we are likely to be limited in how much we are able to do before legislation is enacted by Parliament.

The gene technology regulator will be reliant on specialised capability likely to be in short supply

Our most recent experience in setting up a wholly new regulator is the regulator for the Outer Space and High-altitude Activities Act 2017. For key aspects of safety relating to the launch of rockets, this regulatory recognises authorisations from U.S. authorities rather than relying on internal capability (which it currently does not have and that would be hard to establish).

Even for technical assessments that are done in house, the Space regulator has had trouble hiring technical staff as these are not readily available in New Zealand – only within the last 2-3 years bringing on staff with direct space expertise (as opposed to aviation). There are similar challenges with the establishment of a gene technology regulator. While staff with relevant technical qualifications should be reasonably easy to hire, as well as staff with regulatory experience, it is uncertain how easy it will be to identify individuals with a combination of relevant technical qualifications and appropriate regulatory experience. In our experience, this is particularly important for senior roles. A lack of practical knowledge is a regular complaint of industry across many regulatory regimes. Consequently, technical and regulatory competence are at the core of establishing the credibility and efficiency of the new gene technology regulator.

While MBIE has broad expertise in operating regulatory systems, it has few complementary functions

MBIE does have broad expertise in operating regulatory systems, and we are fortunate in having a dedicated team to support the development of systems and processes for our regulatory functions. This allows us to apply lessons from multiple regulatory systems to the setup of a new regulator. We also have a strong regulatory policy culture that means that we are well equipped to understand Ministers' intent in the development of the new legislation at an organisational level.

Where we are less well-placed is in having complementary regulatory capability, which is important for achieving economies of scale for specialist expertise and breadth of practical regulatory experience. We do not currently have responsibility for any environmental management functions, nor do we have significant capability in understanding biological systems. There are some potential overlaps in technical expertise with IPONZ's role with regard to the Plant Variety Rights Act, but these are probably at the margins.

MBIE does have strong relationships with the science and innovation sector that we would expect to be important users of the regulatory system. Our relationships with other important stakeholders, such as Iwi, are generally in economic rather than environmentally focused areas. We would need to invest significant effort in building the trusted relationships with Māori in this area that will be critical to the smooth operation of the new gene technology regime.

A new regulatory regime in MBIE will require some underlying infrastructure costs and risks

The new regulatory regime will require new application processes and a register of GMOs. This will require the development of new IT infrastructure that provides an appropriate level of record-keeping, oversight and audit functions for the regime. Because we operate other regulatory systems that also require applications and registers we expect that we will be able to use some of the same core infrastructure. But because the regime is quite different to anything we currently administer, some customisation will be inevitable. This inevitably comes with accompanying cost and risk.

Timetable for the Gene Technology Bill

Context

The timetable set out below for preparing and enacting the Gene Technology Bill was put together by PCO and MBIE. PCO and MBIE are committed to resourcing this project at the required level to achieve these targets.

The timetable has been prepared on the understanding that:

- the Bill is to be introduced and have a first reading this year:
- the Bill is to be referred to a select committee for 6 months.

To achieve this, we assume that—

- the usual timeframes required for Ministerial and coalition party consultation can be shortened from standard requirements:
- time will be made available for the Bill to have a first reading in the last sitting week of the year.

The timetable has been significantly compressed to provide for the Bill to be introduced this year. s 9(2)(f)(iv) [redacted]

We note that the timetable will likely be unachievable if—

- Cabinet policy approval for this Bill is not obtained in full on 12 August:
- there are delays in delegated policy decisions being made:
- there are any shifts in policy direction once drafting is underway.

To help mitigate these risks, we recommend providing you with regular joint agency updates on the Bill's progress and providing you with briefings to seek your decision on matters as required.

s 9(2)(h) [redacted]

Proposed timetable

12 August 2024	Cabinet policy approval
12 August 2024	MBIE provides PCO with Tranche 1 drafting instructions based on Cabinet decisions
12 August 2024	Iterative drafting process begins on Tranche 1 instructions. PCO prepares multiple draft versions of the Bill, MBIE and others provide feedback on each version and address queries

	and gaps. Bill likely to be very large (200 + clauses) and likely to require 10 or more drafts
9 September 2024	Ministers make policy decisions for matters not determined by Cabinet, including in relation to: • establishment of regulator • reviews and appeals • enforcement, offences, and penalties • joint assessments with international regulators • the synthetic nucleic acid (SNA) customer screening regime • the containment facility standards regime • amendments to other Acts • transitional and savings provisions
16 September 2024	MBIE provides PCO with Tranche 2 drafting instructions in relation to policy decisions made by Ministers
16 August – 1 November 2024	Iterative drafting process continues, including in response to Tranche 2 instructions
s 9(2)(f)(iv)	

Appendix Two: 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 and evidence-based
- Internationally-aligned
- Leverages overseas expertise
- Retains public participation
- Streamlined, efficient and transparent processes
- Allows greater use of gene editing
- Focuses on the management of risk

NON-REGULATED TECHNOLOGIES AND ORGANISMS

GENE EDITING TECHNIQUES

- Techniques producing results indistinguishable from those achievable with conventional breeding would be exempt. Example applications include:

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

EXEMPT TECHNOLOGIES AND ORGANISMS

- Technologies and organisms commonly regarded as not creating or being a GMO would be exempt, including:

- NULL SEGREGANTS
- RNA INTERFERENCE
- REPLICATION-DEFICIENT VIRAL VECTORS
- EPIGENETICS
- MUTAGENESIS
- PROTOPLAST FUSION

RISK MATRIX FRAMEWORK

The regulator would assign activities to non-notifiable and notifiable risk tiers, the requirements of which will be graduated based on risk. Categories would be tailored for contained activities, activities involving intentional environmental release, and clinical trials and medical applications.

CONTAINED ACTIVITIES	ENVIRONMENTAL RELEASE	MEDICAL APPLICATIONS
Non-notifiable	Non-notifiable	Non-notifiable
Notifiable	Notifiable	Notifiable
Licensed - Expedited assessment	Permit Licensed - Expedited assessment Licensed - Full assessment	Permit Licensed - Expedited assessment Licensed - Full assessment

- **Non-notifiable activities** would be very low risk and would include CAR T-cell therapies and routine laboratory research.
- **Notifiable activities** would be low risk and would include research with laboratory animals.
- **Permits and licences** would cover field trials, clinical trials, and commercial releases.

ASSESSMENTS AND APPROVALS

Licensed activities would require assessment and approval by the regulator. Permits would not require a Risks Assessment and Risk Management Plan and only full assessments would require public consultation.

Application is received → Regulator prepares a Risk Assessment and Risk Management Plan → Public consultation → If satisfied risks can be managed, regulator issues license

GENE TECHNOLOGY REGULATOR

- The regulator will be a single decision-maker, supported in their functions by an office, a technical advisory committee, and a Māori advisory committee.
- Their responsibilities will include 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

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MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Gene Technology regime – offences, defences, and penalties

Date:	28 August 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2425-0835

Action sought		
	Action sought	**Deadline**
Hon Judith Collins KC **Minister of Science, Innovation and Technology**	**Agree** to the proposed offences, defences, and penalties regime for the Gene Technology Bill to inform drafting instructions to the Parliamentary Counsel Office.	2 September 2024

Contact for telephone discussion (if required)			
Name	**Position**	**Telephone**	**1st contact**
Tony de Jong	Manager, Biotech Policy & Regulation	s 9(2)(a)	✓
s 9(2)(a)			

The following departments/agencies have been consulted
Ministry of Justice, Ministry for Primary Industries

Minister's office to complete:

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

Comments

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Gene Technology regime – offences, defences and penalties

Date:	28 August 2024	**Priority:**	Medium
Security classification:	In Confidence	**Tracking number:**	2425-0835

Purpose

To seek decisions on the offences, defences, and penalties settings for the Gene Technology (GT) regime in line with the delegated authority agreed by Cabinet, necessary to inform drafting instructions for the GT Bill.

Recommended action

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

a **Agree** to consult with the Minister of Justice on the recommendations in this paper consistent with Cabinet's delegation on these matters;

Agree / Disagree

b **Agree** to the offences, defences, and penalties policy decisions as set out in **Annex One** and other relevant decisions as set out in **Annex Two**;

Agree / Disagree

c **Note** that:

i. penalties set out in Annex One account for the most severe instance of each offence and/or, where relevant, where an offence is done knowingly or recklessly

ii. should you agree to the decisions in this briefing, we will, as part of the drafting process, establish graduated penalties under each maximum penalty to account for less serious instances of each offence, and

iii. each provision is subject to wording refinement through the legislation drafting process but will maintain the intent of your decisions in this briefing;

Noted

d **Note** Annex Three sets out a high-level comparison of proposed offences and penalties against those of the Australian Gene Technology regime;

Noted

e **Note** the Ministry for Primary Industries proposed including a power of arrest for enforcement officers and we have considered but discounted this proposal.

Noted

Tony de Jong
Manager, Biotech Policy and Regulation
MBIE

28 / 08 / 2024

Hon Judith Collins KC
Minister of Science, Innovation and Technology

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

Background

Cabinet has confirmed the detailed design of the Gene Technology (GT) regime…

1. On 12 August 2024 Cabinet confirmed the detailed design of the GT regime agreed to by the Cabinet's Expenditure and Regulatory Review Committee (EXP-24-MIN-0041 and CAB-24-MIN-0296 refer). Following this, we have provided an initial set of drafting instructions to the Parliamentary Council Office (PCO).

***…**but there are a range of outstanding policy matters to resolve, including the GT regime's offences, defences and penalties, and your agreement is sought on these matters*

2. In agreeing the design of the GT regime, Cabinet:

    a. agreed that where practicable, HSNO Act's offences, defences, and penalties provisions (including pecuniary penalties and civil liability) carry over to the new GT regime, subject to modifications to reflect current legislative best practice, and

    b. authorised you as the Minister of Science, Innovation and Technology, in consultation with the Minister of Justice as relevant, to take further decisions in line with the policy decisions agreed by Cabinet on the details of offences, defences, and penalties introduced by the GT regime.

3. Advice and further decisions necessary to instruct PCO on these matters is set out below.

Proposed offences, defences and penalties for the Gene Technology Bill

We developed the proposed offences, defences, and penalties settings following consultation with the Ministry of Justice and accounting for Legislation Design and Advisory Committee guidelines

4. **Annex One** sets out offences listed alongside associated penalties, the recommended liability (*mens rea* versus strict liability), whether a defence is applicable, and brief rationale.

5. **Annex Two** sets out a series of further settings that are relevant to offences, defences and penalties, including remedies, mitigations and destruction of organisms, infringement offences, attribution of liability, defences details, and statutory timeframes.

6. We note that:

    a. the penalties specified in Annex One account for the most severe instance of each offence and/or, where relevant, where an offence is done knowingly or recklessly

    b. should you agree to the decisions in this briefing, we will, as part of the legislation drafting process, establish graduated penalties under each maximum penalty to account for less serious instances of each offence, and

    c. each provision may be subject necessary further refinement through the legislation drafting process but will maintain the intent of your decisions in this briefing.

The proposed offences, defences, and penalties settings are largely modelled off the HSNO Act, except where there are good reasons to depart or reflect contemporary legislative design[1]

7. The offences, defences and penalties design principles reflect the GT regime's purpose and objectives. The proposed provisions are more specific to gene technology and activities than the HSNO Act's equivalent provisions, which manage a broader range of issues.

8. Compared to the HSNO Act, we consider that the proposed GT penalties are more proportionate to the misconduct, the potential impact on New Zealand, and in line with modern legislative practice. The purpose of this approach is to deter participants, particularly body corporates, from breaching the GT regime. The proposed provisions clearly distinguish between the penalties applicable to both individuals and body corporates, something the HSNO Act does not do.

9. We consider that establishing more severe penalties will create greater confidence for the public that the regime is being enforced appropriately to mitigate potential risks.

10. We note the risk that a more punitive regime may discourage research and innovation, particularly by smaller entities. To help mitigate this potential impact we propose that penalties are proportionally set to account for the severity of misconduct, as well as intent or recklessness.

We provide a comparison against the Australian GT regime (although direct comparison may be challenging)

11. **Annex Three** provides a comparison of the proposed offences and penalties against comparable provisions in the Australian GT Act. While this comparison provides a high-level indication of the regimes trans-national operators are likely to be exposed to, this approach does not necessarily provide like-for-like reference due to different contexts and legislative and regulatory environments (including New Zealand's biosecurity and new organisms regimes).

12. Overall, we consider the proposed offences and penalties to be similar to those in Australia's regime, although there are instances where each regime would be more punitive than the other. We note:

    a. Australia does not distinguish punishments between 'individuals' and other persons (e.g. body corporates).

    b. Unlike New Zealand where fines are fixed in primary legislation and remain at a set level until legislation is amended, Australia uses 'penalty units' to determine penalties (with one unit currently valued at $313 AUD). The value of penalty units is indexed and regularly updated[2], which will partially close or expand differences in penalties in these regimes over time.

    c. There are some provisions from the HSNO Act carried over that do not reflect any comparable provisions in Australia's GT Act, but we did not consider there was a

[1] For example, we considered the approaches taken in the *Organic Products and Production Act 2023* and the *Therapeutic Products Act 2023*.

[2] For example, between mid 2020 and mid-2023 the value of a penalty unit rose in increments from $210 AUD to its current rate.

strong policy rationale to remove these from New Zealand's new GT regime, or considered that the offences will likely be covered by other Australian legislation.

Compliance and enforcement

We engaged with the enforcement agency in the design of the offences, defences and penalties settings and on compliance and enforcement settings

13. The Ministry for Primary Industries (MPI) will be the GT regime's enforcement agency, as agreed by Cabinet. MPI has accounted for greater training and upskilling requirements in its forecasts, particularly for the 12–24-month establishment phase of the new regime, in order to meet the regime's enforcement demands.

14. MPI proposed including a power of arrest under the GT Bill to empower enforcement officers to arrest individuals for obstruction when executing a search warrant (consistent with a previous proposal for such a power considered for a Biosecurity Act Amendment Bill). We have considered and discounted this because:

    a. the Ministry of Justice advise against adding this power (and also recently advised against adding it to the Biosecurity Act 1993)

    b. the risks posed by gene technologies are not sufficient to justify such a power and can be mitigated through conditions and controls

    c. this power is only present for MPI under the Fisheries Act 1996, which is not a sufficiently comparable regulatory environment, and

    d. enforcement officers will be able to execute search warrants with police present who can use the power of arrest if required.

15. Instructions on the broader range of compliance, monitoring and enforcement settings have otherwise been provided to PCO based on Cabinet decisions.

Next steps

16. We will provide further drafting instructions to PCO based on your decisions in this briefing. We are also developing further advice on other outstanding policy decisions and will work with your office on the timing of this advice.

Annexes

Annex One – Recommended Gene Technology regime offences, defences, and penalties

Annex Two – Other proposed provisions associated with offences, defences, and penalties for the Gene Technology regime

Annex Three – Proposed offences and penalties in comparison to the Australian Gene Technology regime

Annex One – Recommended Gene Technology regime offences, defences and penalties

#	Offence provision policy	***Mens rea* element –** offences with knowledge or recklessness?	**Strict liability element** – offences without knowledge or recklessness?	**Statutory defence**	**Rationale**	**Decision**
1.	A person commits an offence if the person undertakes an activity without being authorised or in contravention of the Act / its regulations.	**Yes -** *Knowingly or recklessly* *Offence in relation to a regulated organism requiring a licence* If the person is an individual – up to 5 years imprisonment, fine not exceeding $200,000, or both. Otherwise – fine not exceeding $1 million. *Offence in relation to a notifiable regulated organism* If the person is an individual – fine not exceeding $50,000. Otherwise – fine not exceeding $250,000. *Offence in relation to an activity approved for general use* If the person is an individual – fine not exceeding $40,000. Otherwise – fine not exceeding $200,000. *Offence in relation to a non-notifiable regulated organism* If the person is an individual – fine not exceeding $10,000. Otherwise – fine not exceeding $50,000.	**Yes** *Offence in relation to a regulated organism requiring a licence* If the person is an individual – fine not exceeding $100,000. Otherwise – fine not exceeding $500,000. *Offence in relation to a notifiable regulated organism* If the person is an individual – fine not exceeding $20,000. Otherwise – fine not exceeding $100,000. *Offence in relation to an activity approved for general use* If the person is an individual – fine not exceeding $15,000. Otherwise – fine not exceeding $75,000. *Offence in relation to a non-notifiable regulated organism* If the person is an individual – fine not exceeding $5,000. Otherwise – fine not exceeding $25,000.	**Yes** – for strict liability offences only, in line with the defences laid out in Annex Two.	Similar to existing Hazardous Substances and New Organisms (HSNO) Act provision (s109(1)(b-d) but captures all 'activities' as will be defined in the Act and already agreed by Cabinet (CAB-24-MIN-0296 refers). Separate offences against each risk tier will be a new feature in comparison to the HSNO Act, but is necessary to capture the GT regime's regulatory approach. Penalties align with modern legislation, and account for the fact that breaches could result in severe damages to New Zealand's environment or the general public. The inclusion of a strict liability element here differs from the HSNO regime. Under the new regime, there is likely to be greater prevalence of regulated organisms and related activities in New Zealand. Defences for strict liability offences can be created, including for instances of 'inadvertent' offences, for example a person importing a regulated organism that was otherwise labelled as 'non-GMO' but later discovered to be a regulated organism by the authorities. Inclusion of a strict liability element here also provides an incentive for people who undertake those activities to adopt appropriate precautions to prevent breaches. Given the lower risk tier activities will be more frequently used by the sector, the regulations should also establish infringement penalties for offences against the non-notifiable regulated organisms category so that there is an additional enforcement tool available.	Agree/Discuss further
2.	A person commits an offence if the person breaches conditions of a licence or the Act's regulations.	**Yes** *Knowingly or recklessly* If the person is an individual – up to 5 years imprisonment, fine not exceeding $200,000, or both. Otherwise – fine not exceeding $1 million.	**Yes** If the person is an individual – fine not exceeding $100,000. Otherwise – fine not exceeding $500,000.	**Yes** – for strict liability offences only, in line with the defences laid out in Annex Two.	Similar to existing HSNO provision (s109(1)(e)), while incorporating reference to emergency authorisations, which is new to the regime (not part of HSNO). Penalty aligns with modern legislation and accounts for the fact that breaches, particularly those with intent to cause harm, could result in severe damages to New Zealand's environment or the general public. Most instances of a person holding a licence to conduct an activity mean that the person is aware of their obligations under the Act and the conditions of licence, and the defendant should therefore have to prove that they had taken all reasonable steps to comply (or any other defence).	Agree/Discuss further
3.	A person commits an offence if the person fails to comply with directions from the regulator (including a compliance order).	**No**	**Yes** If the person is an individual – fine not exceeding $100,000. Otherwise – fine not exceeding $500,000.	**Yes** – for strict liability offences only, in line with the defences laid out in Annex Two.	Offence carried over from HSNO (s109(1)(f)). Penalty aligns with modern legislation and accounts for the fact that some breaches could result in damaging consequences to New Zealand, although the risk is likely to be lower than breaches under offences 1 and 4 (offenders are likely to already be operating within regulations i.e. hold a licence). Any breaches of greater severity are likely to be captured as part of offence 1.	Agree/Discuss further

4.	A person covered by a licence commits an offence by failing to report any new significant information of any adverse effect of that regulated organism.	**Yes** *Knowingly:* If the person is an individual – up to 5 years imprisonment, fine not exceeding $200,000, or both. Otherwise – fine not exceeding $1 million. *Recklessly* If the person is an individual – fine not exceeding $50,000. Otherwise – fine not exceeding $250,000.	**No**	**No**	Carried over from HSNO (s109(1)(i)), although terminology has been updated to account for the new regime. Penalty more closely aligns with modern legislation – such as Organic Products and Production Act 2023, s102.	Agree/Discuss further
5.	A person commits an offence by providing false or misleading information to the regulator and/or enforcement officers.	**Yes** *Knowingly:* If the person is an individual – up to 5 years imprisonment, fine not exceeding $200,000, or both. Otherwise – fine not exceeding $1 million. *Recklessly:* If the person is an individual – fine not exceeding $50,000. Otherwise – fine not exceeding $250,000.	**Yes** If the person is an individual – fine not exceeding $50,000. Otherwise – fine not exceeding $250,000.	**Yes** – for strict liability offences only, in line with the defences laid out in Annex Two.	New provision (no similar provision in HSNO). This aligns with modern legislation – such as the Therapeutic Products Act 2023 s259 and s269. The penalty levels account for the fact that the most egregious offences could result in significant impacts on New Zealand's environment and/or the general public. The strict liability clause allows for defences to be available to a defendant, particularly when providing false or misleading information without knowledge in instances of significance (e.g. saving or protecting life).	Agree/Discuss further
6.	A person commits an offence if the person personates an enforcement officer.	**Yes** *Knowingly* If the person is an individual – fine not exceeding $100,000. Otherwise – fine not exceeding $500,000.	**No**	**No**	Carried over from HSNO (s109(1)(j)). Penalty aligns with modern legislation – such as the Organic Products and Production Act 2023 (ss 103).	Agree/Discuss further
7.	A person commits an offence if the person obstructs an enforcement officer in the course of their duties.	**Yes** *With intent to obstruct:* If the person is an individual – fine not exceeding $100,000. Otherwise – fine not exceeding $500,000.	**Yes** If the person is an individual – fine not exceeding $20,000. Otherwise – fine not exceeding $100,000.	**Yes** – for strict liability offences only, in line with the defences laid out in Annex Two.	Carried over from HSNO (s109(1)(k)). Penalty structure aligns with modern legislation – such as the Therapeutic Products Act 2023 (s 261) The strict liability provision accounts for instances where the person had in place processes or practices that did not deliberately intend to obstruct an enforcement officer but unreasonably prevented the officer from the process of inspection.	Agree/Discuss further
8.	A person commits an offence if they provide/manufacture synthetic nucleic acids (or equipment) without approval or in breach of the SNA screening framework requirement.	**Yes** *Knowingly or recklessly,* If the person is an individual – up to 5 years imprisonment, fine not exceeding $200,000, or both. Otherwise – fine not exceeding $1 million.	**No**	**No**	New provision (there is not currently a similar provision in HSNO). This provision is focused on preventing severe offences, such as the proliferation of biological weapons.	Agree/Discuss further

Annex Two – Other recommended settings associated with offences, defences and penalties for the Gene Technology regime

#	Category	Provision policy	Rationale	Decision
1.	Pecuniary penalty orders	**Offence** The GT Bill will establish a provision that the enforcement agency may apply to the court for a pecuniary penalty order that a person pay to the Crown if a person undertakes an activity without being authorised or in contravention of the Act's requirements / licence conditions. This will generally be in the case of the offence being committed: • in the course of business, or • to make a commercial gain or avoid a commercial loss. These orders are subject to the standard of proof that applies in civil proceedings i.e. 'the balance of probabilities'. **Penalty** If the person is an individual – penalty not exceeding $500,000 Body corporate – the greater of: • $10,000,000, or • 3 times the value of any commercial gain, or • 10% of the turnover of the body corporate (if commercial gain from the offence cannot be ascertained) **Defence:** There will be defence against civil liability similar to the HSNO Act in the following scenarios: • the action was necessary for the purposes of saving or protecting life or health, or preventing serious damage to property or avoiding an adverse effect on the environment • the action was due to an event beyond the control of the defendant (e.g. natural disaster, sabotage), • the defendant did not know, and could not reasonably have known, of the breach. Other provisions from the HSNO Act pertaining to administrative matters for civil pecuniary penalty orders will carry over here, subject to appropriate modifications to reflect more modern pecuniary penalty regimes.	The HSNO Act allows for pecuniary penalty orders (Part 7A). The GT Bill provision should align to HSNO provisions while reflecting more modern legislative practice (such as the Therapeutic Products Act 2023 s272).	Agree/Discuss further
2.	Remedies, mitigations and destruction of organisms	The court may also order a person who commits an offence to mitigate or remedy (or pay the costs of doing so) any adverse effects on people, the environment or land. The court may also order the destruction of any associated organism that resulted from the breach.	Aligned to HSNO provision s114(6) and s124D.	Agree/Discuss further
3.	Statutory civil liability	The regime will include a provision based on the approach that a person is liable in damages for any loss or damage caused by committing an offence. This is in addition to any other cause of action determined through proceedings. **Defences to civil liability:** In line with defences set out for pecuniary penalty orders.	Aligned to HSNO provisions (s124G and s124H), although wording updated to account for adaptations made for the new GT regime.	Agree/Discuss further
4.	Infringement offences/penalties	The GT Bill will establish legislation that enables infringement offences and associated penalties (on-the-spot fines) to be set in regulations. Legislation will be set in line with standard clauses, for example the Therapeutic Products Act 2023 sets a maximum penalty of $5000 (and other maximum penalties). This will include associated provisions necessary for implementing an infringement regime.	The enforcement agency describes infringement penalties as a useful tool to mitigate behaviours that are more serious than those addressed through directive responses, but do not necessarily warrant prosecution. This approach is aligned to HSNO provisions (s110-113). However, the legislation should enable differing infringement fees to be set for individuals versus persons otherwise – see Health and Safety at Work Act 2015 s211(1)(u).	Agree/Discuss further

5.	Attribution of liability	The GT Bill will establish liability attribution provisions, based on the following approaches:
		
		• The GT Bill will establish that every director and person concerned in the management of a convicted body corporate shall be guilty of the like offence if it is proved—
		  ○ that the offence took place with their authority, permission, or consent, and
		  ○ that they knew or could reasonably be expected to have known that the offence was being committed and failed to take steps to prevent it.
		
		• The GT Bill will also establish that an offence committed by an employee of another person will be treated as being committed by both, whether or not it was done with that other person's knowledge or approval.
		• An offence committed by a person acting as the agent of another person will be treated as being committed by the principal unless it is done without the principal's authority.
		• It will be a defence for someone whose employee commits an offence if they can prove
		  ○ that—
		  ▪ they did not know nor could reasonably be expected to have known that the offence was being committed, or
		  ▪ they took steps to prevent the commission of the offence; and
		  ○ that they took steps to remedy any effects of the offence.
			This approach is aligned to the relevant HSNO provisions (s115 and s116) and will reflect more modern legislation through the drafting process.	Agree/Discuss further

6.	Statutory timeframes	The GT Bill will establish a limitation period for filing a charging document of 2 years after the offence first came to the knowledge of the authorities.	This approach aligns with the approach taken under the hazardous substances component of the HSNO Act (109a(1)), rather than the new organisms component. We consider that this approach is more appropriate for the GT regime as it accounts for the fact that the effects from contraventions (impacts on the environment from genetic modifications) could take many years to be detected, for example due to long breeding cycles through multiple generations of an animal. The relevant HSNO provision is only 6 months, which does not align with contemporary legislation, and the enforcement agency has advised this is not sufficient.	Agree/Discuss further
7.	Defences	The GT Bill will establish defences in the following scenarios similar to the HSNO Act and the Biosecurity Act: • the action was necessary for the purposes of saving or protecting life or health, or preventing serious damage to property or avoiding an adverse effect on the environment, • the action was due to an event beyond the control of the defendant (e.g. natural disaster, sabotage) • that the offence was within the defendant's control; but the defendant tried to prevent the offence and took steps to mitigate or remedy the effects • the offence was due to the action of another person.	This approach is aligned to HSNO provisions (s117), although does not include provision relating to 'codes of practice' as they are not relevant to the new GT regime. Defences only apply to strict liability offences under the HSNO Act. A further addition has been made, which aligns with a provision from the Biosecurity Act 1993 (s154N) relating to an offence taking place outside of the control of a person (or due to the action of someone else). We consider this is appropriate given there could be an increase in instances of 'inadvertent' offences taking place by the general public.	Agree/Discuss further
8.	Synthetic Nucleic Acids (SNA)	The GT regime will include a provision that enables other SNA offences to be established through regulations.	There are likely to be emerging factors and behaviours that will influence the nature of legislation required for SNA regulation.	Agree/Discuss further

Annex Three – Proposed offences and penalties in comparison to the Australian Gene Technology regime

#	Offence provision policy	***Mens rea* element –** offences with knowledge or recklessness?	**Strict liability element** – offences without knowledge or recklessness?	**Australian GT regime comparable offences / penalties (*in $AUD*)**	
				Offence – knows or is reckless	**Strict liability offence**
1.	A person commits an offence if the person undertakes an activity without being authorised or in contravention of the Act / its regulations.	**Yes -** *Knowingly or recklessly* *Offence in relation to a regulated organism requiring a licence* If the person is an individual – up to 5 years imprisonment, fine not exceeding $200,000, or both. Otherwise – fine not exceeding $1 million. *Offence in relation to a notifiable regulated organism* If the person is an individual – fine not exceeding $50,000. Otherwise – fine not exceeding $250,000. *Offence in relation to an activity approved for general use* If the person is an individual – fine not exceeding $40,000. Otherwise – fine not exceeding $200,000. *Offence in relation to a non-notifiable regulated organism* If the person is an individual – fine not exceeding $10,000. Otherwise – fine not exceeding $50,000.	**Yes** *Offence in relation to a regulated organism requiring a licence* If the person is an individual – fine not exceeding $100,000. Otherwise – fine not exceeding $500,000. *Offence in relation to a notifiable regulated organism* If the person is an individual – fine not exceeding $20,000. Otherwise – fine not exceeding $100,000. *Offence in relation to an activity approved for general use* If the person is an individual – fine not exceeding $15,000. Otherwise – fine not exceeding $75,000. *Offence in relation to a non-notifiable regulated organism* If the person is an individual – fine not exceeding $5,000. Otherwise – fine not exceeding $25,000.	*Person not to deal with a GMO without a licence – and knows or is reckless as to that fact* Aggravated offence[3] – 5 years imprisonment or 2000 penalty units[4] ($626,000) Any other case – imprisonment for 2 years or 500 penalty units ($156,000) N/A N/A N/A	*Person not to deal with a GMO without a license – strict liability* Aggravated offence – 200 penalty units ($62,600) Any other case – 50 penalty units ($15,650) *Offence relating to notifiable low risk dealings.* Maximum penalty – 50 penalty units ($15,650) *Person must not breach conditions on GMO register (strict liability).* Maximum penalty – 50 penalty units ($15,650) N/A
2.	A person commits an offence if the person breaches conditions of a licence or the Act's regulations.	**Yes** *Knowingly or recklessly* If the person is an individual – up to 5 years imprisonment, fine not exceeding $200,000, or both. Otherwise – fine not exceeding $1 million.	**Yes** If the person is an individual – fine not exceeding $100,000. Otherwise – fine not exceeding $500,000.	*Person must not breach conditions of a GMO licence – and knows or is reckless to that fact* Aggravated offence – 5 years imprisonment or 2000 penalty units ($626,000) Any other case – imprisonment for 2 years or 500 penalty units ($156,000)	*Person must not breach conditions of a GMO licence – strict liability.* Aggravated offence – 200 penalty units ($62,600) Any other case – 50 penalty units ($15,650)
3.	A person commits an offence if the person fails to comply with directions from the regulator (including a compliance order).	**No**	**Yes** If the person is an individual – fine not exceeding $100,000. Otherwise – fine not exceeding $500,000.	Aggravated offence – 200 penalty units ($62,600) Any other case – 50 penalty units ($15,650)	N/A

[3] Where the commission of the offence causes significant damage, or is likely to cause significant damage, to the health and safety of people or to the environment.
[4] A penalty unit in Australia is a standard amount used to determine penalties for breaches of the law, with one penalty unit currently valued at $313 AUD.

4.	A person covered by a licence commits an offence by failing to report any new significant information of any adverse effect of that regulated organism.	**Yes** *Knowingly:* If the person is an individual – up to 5 years imprisonment, fine not exceeding $200,000, or both. Otherwise – fine not exceeding $1 million. *Recklessly* If the person is an individual – fine not exceeding $50,000. Otherwise – fine not exceeding $250,000.	**No**	N/A – offence not explicitly set out in the Australian GT Act, although would likely be captured by offences under #2 in this table (breaching conditions of licence).	N/A – offence not explicitly set out in the Australian GT Act, although would likely be captured by offences under #2 in this table (breaching conditions of licence).
5.	A person commits an offence by providing false or misleading information to the regulator and/or enforcement officers.	**Yes** *Knowingly:* If the person is an individual – up to 5 years imprisonment, fine not exceeding $200,000, or both. Otherwise – fine not exceeding $1 million. *Recklessly:* If the person is an individual – fine not exceeding $50,000. Otherwise – fine not exceeding $250,000.	**Yes** If the person is an individual – fine not exceeding $50,000. Otherwise – fine not exceeding $250,000.	2 years imprisonment or 60 penalty units ($18,780)	N/A
6.	A person commits an offence if the person personates an enforcement officer.	**Yes** *Knowingly* If the person is an individual – fine not exceeding $100,000. Otherwise – fine not exceeding $500,000.	**No**	N/A – offence not set out in the Australian GT Act	N/A – offence not set out in the Australian GT Act
7.	A person commits an offence if the person obstructs an enforcement officer in the course of their duties.	**Yes** *With intent to obstruct:* If the person is an individual – fine not exceeding $100,000. Otherwise – fine not exceeding $500,000.	**Yes** If the person is an individual – fine not exceeding $20,000. Otherwise – fine not exceeding $100,000.	N/A – offence not set out in the Australian GT Act	N/A – offence not set out in the Australian GT Act
8.	A person commits an offence if they provide/manufacture synthetic nucleic acids (or equipment) without approval or in breach of the SNA screening framework requirement.	**Yes** *Knowingly or recklessly,* If the person is an individual – up to 5 years imprisonment, fine not exceeding $200,000, or both. Otherwise – fine not exceeding $1 million.	**No**	N/A – offence not set out in the Australian GT Act	N/A – offence not set out in the Australian GT Act