MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

COVERSHEET

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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

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In Confidence

Office of the Minister of Science, Innovation and Technology

Cabinet

Regulation of gene technologies – policy decisions

Proposal

1 This paper seeks agreement to a new regime for regulating gene technologies and 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: ending the effective ban on genetic engineering (GE) and genetic modification (GM) in New Zealand, and streamlining approvals for field trials and the use of non-GE/GM biotechnology. Taking Cabinet decisions on these proposals is item 16 on the Coalition Government's Q3 Action Plan.

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has the potential to deliver enormous benefits to New Zealand, it is heavily restricted by the overly precautionary and out of date Hazardous Substances and New Organisms Act 1996 (HSNO).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. This legislative proposal aims to achieve this by:

4.1 updating definitions to account for current and potential future changes to technologies

4.2 adopting a new risk management approach and a risk tiering framework

4.3 streamlining decision making, and giving the Minister tools to ensure desired regulatory outcomes

4.4 clarifying how the regulation should address distinctive Māori rights and interests

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

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activities by the techniques used while excluding some low-risk gene editing techniques 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 accelerated by drawing on the expertise of recognised international regulators.

7 The regulator would be an independent statutory officer situated within either the Ministry of Business, Innovation and Employment (MBIE) or the Environmental Protection Authority (EPA). They would be supported by an expert Technical Advisory Committee and a Māori Advisory Committee.

8 To ensure the regulator acts consistently with reform objectives, Government would be able to influence the regulator via general policy directions. There is also an option to include an ability to call in decisions either as a means of appeal or where there is the potential for nationally 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 regional councils and territorial and unitary authorities to restrict the use of genetically modified organisms (GMOs) in 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 those in HSNO to ensure consistency with existing regimes where appropriate. The Ministry for Primary Industries (MPI) undertakes some of these functions under HSNO for new organisms and would be best placed to take on comparable functions under the new legislation.

11 With Cabinet's agreement, I estimate that the new regime would begin operation by the end of 2025. I propose to work with the Minister of Finance prior to Budget 25 on funding options for the new regulator Confidential advice to

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

6e1wa178jr 2024-08-29 14:03:09

improving health outcomes. Technologies currently being developed include:

13.1 sterile Douglas Fir to prevent wilding pines

13.2 clover with boosted condensed tannin content to reduce methane emissions and bloat

13.3 engineering a patient's own cells to fight cancer (CAR-T cells).

14 Many of our trading partners (Australia, England, the United States, Japan, Argentina and the European Union) have reduced restrictions on gene technologies or are proposing to do so. Reforming our system now positions New Zealand's 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 HSNO. It prohibits the import, development, field testing and release of GMOs unless approved by the 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 in its outcomes, or 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.

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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.

19 Some features of the regime (e.g. compliance and enforcement) will be based on HSNO for consistency but updated as necessary.

A ministerial group has developed the reforms outlined

20 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 represented the Health, Agriculture, Trade, Conservation, Māori Crown Relations, Māori Development, Environment, Biosecurity, Food Safety, and Rural Communities portfolios.

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

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

22 **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. **Appendix Two** provides a summary of the proposed regime and its primary features. **Appendix Three** compares the proposed changes with the existing HSNO system and summarises impacts.

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A new regulatory regime will ensure New Zealand benefits from gene technology

Purpose and scope of the regime

New legislation should establish an enabling, risk proportionate and efficient regime

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

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

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

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

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

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

23.6 **Internationally aligned:** the regime should be in step with our major partners to facilitate trade and improve access to new technologies.

24 The proposed regime seeks to achieve these objectives through:

24.1 Refreshed definitions that take into account emerging technologies, and lessons from past implementation

24.2 A risk management approach proven in Australian legislation and that meets modern best practice for managing novel technologies

24.3 Updating technologies exempted from regulation to take account new gene editing techniques, in line with emerging practice other countries

24.4 A risk tiering approach that ensures that the expectations on users of gene technology and applicants for licences are proportionate to risk

24.5 Using secondary legislation to ensure that exemptions from regulation and risk tiers can be kept up to date and account for changes in technology and regulatory knowledge

24.6 Streamlining decision-making with a single decision-maker and focusing public consultation on higher risk applications

6e1wa178jr 2024-08-29 14:03:09

24.7 Providing clear guidance on how the regulator should account for distinctive Māori rights and interests

24.8 Providing scope for the Minister to intervene if the regulator is not delivering on the intent of the changes.

The legislation should regulate gene technologies

25 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 some organisms that are genetically modified (for instance by radiation treatments), and definitions of GMOs vary from place to place for good regulatory reasons. For this reason I refer to "regulated organisms".

26 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.

27 I further propose a power for technologies and organisms or types of technologies and organisms to be excluded from regulation by secondary legislation. This is because the precise scope of what needs to be regulated varies as new techniques develop, and we learn more about the risks posed by existing techniques.

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

28 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.

28.1 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.

28.2 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.

29 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 legislation's purpose statement. 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.

6e1wa178jr 2024-08-29 14:03:09

Precedent from previous decisions will inform future decisions

30 The focus on risk management, and its clearly defined scope will allow for a greater use of precedent in decision-making. When similar organisms are assessed, much of the information that will be reviewed by the regulator can be re-used. This will create predictability for applicants, and reduce regulatory effort. The system is also designed so that over time lower levels of regulatory oversight can be applied when experience demonstrates that activities with types of organisms are safe.

The regulator should not assess the potential benefits of an application

31 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 increases regulator risk, and applicant costs, but it does not provide an environmental benefit.

Ethics considerations are appropriately addressed in other legislation

32 I am satisfied that a specific ethics provision should not be included in this legislation because there are adequate controls in related regulatory systems. For instance, the National Animal Ethics Committee considers the ethics of genetically modifying animals under the Animal Welfare Act 1999. In relation to the use of genetic technology in human clinical trials and research, scientific assessment is provided by the Gene Technology Advisory Committee, with ethics review undertaken by the Health and Disability Ethics Committees. There is currently no ethical oversight for clinical use of genetic technology in humans Confidential advice to Government Implantation of genetically modified embryos and gametes is prohibited by the Human Assisted Reproductive Technologies Act 2004.

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

33 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 as these can be adequately managed by implementing assurance and supply chain separation programmes that are used successfully in Australia and North America.

34 However, to support assurance processes, the legislation will enable the regulator to require regulated organism users to keep records that they have done so where necessary to ensure the reliability of trade assurance systems.

6e1wa178jr 2024-08-29 14:03:09

Assurance processes can also adequately manage risks to organic certification

35 Organic products also require certification that they do not contain GMOs or have not been contaminated by them. In overseas jurisdictions the risk of inadvertent presence of GMOs is successfully managed by segregation of organic crops and supply chain assurance measures. I am confident that similar measures can be effective in New Zealand.

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

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

36 I propose to shift New Zealand's regulatory regime from a generally "process-based" approach, focussed on the technology used to produce a product, to a "hybrid" model like that used in Australia and England (and proposed in the European Union; EU). In this 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

37 Adopting a hybrid model would enable specific gene technology activities and organism activities to be exempted via regulations. An activity or organism would be exempted because it either presents minimal risks or, if an organism, it cannot be distinguished from those achievable by conventional techniques.

38 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 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

39 In line with international practice, exempted activities and organisms would also include some low-risk gene editing techniques. This would cover organisms modified by gene editing techniques that produce specific minor changes, or were guided by template(s), 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 exemptions can be updated by regulation, in future exemptions could be extended to match English and EU rules if there is positive experience of how these regimes operate in practice.

6e1wa178jr 2024-08-29 14:03:09

Risk-proportionate authorisations framework for regulated activities

Overview of authorisations framework

40 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.

41 Australia's framework has three categories for regulating activities according to the type of activity: Contained activities; Activities involving intentional environmental release (environmental release), and clinical trials and medical applications (medical applications).

42 I propose to adopt these three categories and to proportionately regulate risk within these categories, I propose each category have three risk tiers: 'Non-notifiable', 'Notifiable' and 'Licensed'. The 'Licensed' risk tier for the environmental release and medical applications categories would also contain three assessment types: Pre-assessed activity, Expedited assessment, and Full assessment (see Appendix 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.

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

43 The 'Activities Approved for General Use' list would enable some activities to be conducted without a licence for which the regulator has decided that: any risks posed by those activities are minimal, and that it is not necessary for persons undertaking those activities to be covered by a licence to protect human health and the environment.

44 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

45 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:

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

6e1wa178jr 2024-08-29 14:03:09

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

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

Provision of an emergency authorisation power to address imminent threats

46 I also recommend that the legislation also include powers for the Minister to issue an emergency authorisation to respond to an actual or imminent threat to the health and safety of people or the environment (for example, to enable use of a GM medicine in response to a pandemic).

Decision making

There will be a single decision maker (regulator) advised by technical staff, a technical advisory committee, and a Māori advisory committee

47 I propose appointing an independent statutory officer (ISO) as the regulator, supported by an office. The regulator's role will include:

47.1 Assessing applications for licensed activities.

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

48 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 ISO would be appointed by the responsible Minister.

The regulator will be well supported in their decisions by a technical advisory committee

49 Under the new regime, I propose that in making decisions, the regulator be required to consider advice from a ministerially-appointed technical advisory committee (TAC). The TAC will advise the regulator on technical matters relating the gene technologies and the management of their risks. The TAC is advisory only, and its advice would not be binding on the regulator.

Public consultation will only be required for full assessments

50 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

6e1wa178jr 2024-08-29 14:03:09

uncertain risk). The regulator would invite submissions from the public on the draft Risk Assessment and Risk Management Plan to consult on the suitability of the risk management controls, with a 30 day minimum consultation period.

51 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 risks to human health and safety and the environment are less known.

52 In addition, the regulator would also be required to publicly consult on proposed changes to secondary legislation, including changes to those activities categorised as non-notifiable, notifiable, and eligible for a pre-assessed activity licence.

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

53 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.

54 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 regulator must have particular regard to the advice but it is not binding on the regulator. The Committee will also issue engagement guidelines and provide advice to applicants and Māori on the application process. The Committee would be appointed by the Minister.

Ministerial involvement

55 Government needs a mechanism to intervene if the regulator acts contrary to its policy objectives (e.g. becoming too permissive or too conservative). I propose including a power in the legislation to issue 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.

56 If Cabinet wanted to grant stronger powers for the Minister to intervene in specific decisions, the legislation could also include:

6e1wa178jr 2024-08-29 14:03:09

56.1 A ministerial appeal process, whereby an applicant can appeal to the Minister to have a decision reconsidered, or

56.2 A ministerial ability to call-in applications 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

57 Gene technologies may require dual regulatory approvals where there is overlap with other legislation, most commonly with either the Medicines Act 1981 or the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM). Organisms requiring approvals under gene technology legislation and the new organisms part of HSNO are also possible, but less likely. A single approval (ie by the gene technology regulator) is not practical because each regulator assesses different risks to fulfil the purposes of their regimes that are outside of the expertise of the others (for instance Medsafe assesses medical efficacy, safety and quality of medicines, but not the environmental risks of new medicines).

58 I consider we can make the process simpler for applicants, although this requires some complexity “under the hood”. The legislation should include provisions that enable applicants to make single applications where possible, and that ensure that regulators are not assessing the same risk twice. Achieving this requires the legislation to provide for a range of situations that can accommodate the differing scopes of the regimes in question, and to provide some flexibility for regulators to implement administrative mechanisms (eg information sharing, application for rapid assessments, or potentially joint forms) to make the system work.

59 I therefore propose that the regulator be given the power to:

59.1 Undertake rapid assessments of regulated organisms that are also medicines, therapeutics or veterinary medicines, where these present lower risks to the environment and public health

59.2 Undertake joint assessments or joint decision-making where there are overlaps in the risks addressed by the other regulator (for instance under the ACVM or the HSNO Act)

59.3 Deem approvals of new organisms under the HSNO Act as approvals under the Gene Technology Act, if the regulator is satisfied that the HSNO Act adequately addresses the risks to the environment and human health and safety

60 I further propose to make changes to ACVM and HSNO to support joint assessments and joint decision-making. Because there will be almost no overlap in regulatory scope between the Medicines Act and the Gene Technology Act, and the vast majority of medicines and therapeutics will be

6e1wa178jr 2024-08-29 14:03:09

able to progress through the rapid assessment pathway, joint assessments will not create efficiencies for applicants.

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

61 The RMA allows regional councils and 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, Northland Regional, and Auckland). This creates a dual approval system where councils could restrict the use of GMOs despite being approved by the regulator.

62 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.

The approval path for agricultural products review is complementary to this work

63 Cabinet has recently agreed to a regulatory review into the agricultural products approval path focussing on issues with regulatory approvals for agricultural and horticultural products not genetically modified. This is complementary to my proposed changes, and, when implemented, should ensure a streamlined pathway for the approval of both genetically modified and non-genetically modified agricultural products.

International agreements

64 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 is working to ensure the proposed regime will be consistent with the text of the Convention and the Protocol.

65 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.

66 New Zealand also has binding international obligations under the Comprehensive Progressive Trans-Pacific Partnership Agreement, including article 2.27 regarding 'Trade of Products of Modern Biotechnology'. These place no limitations or requirements on domestic legislation of gene technology except for basic transparency and information sharing requirements.

6e1wa178jr 2024-08-29 14:03:09

National security or defence

Synthetic nucleic acids should be subject to specific screening processes

67 National security or defence

68 I propose that legislation provide the ability for regulations to be made requiring any domestic providers of nucleic acids and manufacturers of benchtop nucleic acid synthesisers to comply with a customer screening framework and be approved by the regulator before they can operate in New Zealand. 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

69 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 (e.g. statutory determinations):

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

69.2 Compliance, monitoring and enforcement provisions, including offences, defences, and penalties

69.3 MPI's role as the compliance, monitoring and enforcement agency.

Implementation of the new regulatory regime for gene technology

70 If Cabinet agrees with the recommendations in this paper, MBIE 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

71 Establishing the regulator within MBIE would locate the regulator next to the technology and innovation functions we are seeking to support through

6e1wa178jr 2024-08-29 14:03:09

legislative reform. MBIE has a broad range of regulatory experience, and has demonstrated an ability to house effective independent regulators.

72 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

73 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 is that it would avoid introducing a new regulator into an already complex regulatory environment. Initial costings suggest this option will be less expensive.

74 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.

75 If Cabinet decides to locate the regulator in the EPA it would be required to operate differently to the current regime. The legislation itself provides a different decision-making framework. Decisions are also not taken by the EPA itself or its decision-making committee, but rather by the SO, who would be appointed by the Minister. Advisory committees set up by the legislation do not make decisions but only advise the regulator.

I seek authority to approve further detail of the regime

76 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 regime scope.

The regime could be in place by the end of 2025

77 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 Bill drafting and House time.

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

79 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

6e1wa178jr 2024-08-29 14:03:09

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 – September 2024
Drafting of Bill	August – December 2024
Bill introduced and first reading	Confiden r 2024
Select Committee (six months)	Confidential 2025
2nd reading, Committee of the whole House, 3rd reading, Royal assent, Act commences	Confidential 2025
Secondary legislation in force	Confid 2025
Establishment phase	Confidential 2025
Regulator operational	Confidenti 2025

Cost-of-living Implications

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

Financial Implications

81 The new regime will establish a new regulator to make decisions in accordance with primary and secondary legislation on gene technologies. Depending on regulator location, from establishment to the end of 2028/29:

81.1 the cost for MBIE to set up and operate the regulator is estimated at Confidential advice to Government

81.2 the comparable cost for the EPA is Confidential advice to Government

82 Whether located at MBIE or the EPA, the expected steady state cost from the third year of operation is approximately Confidentia l advice to per year. Each option also includes approximately Confidential advice to over the same period for MPI to undertake compliance, monitoring and enforcement of the new regime.

83 This new function will require appropriate funding to adequately equip the regulator to perform its role effectively from the outset, and proper resourcing to enable the regulator to adequately respond to increased demand is a critical success factor.

84 I intend to work with the Minister of Finance to identify the most appropriate funding mechanism for the new regulator. Confidential advice to Government

6e1wa178jr 2024-08-29 14:03:09

Confidential advice to Government

85 I also propose the new legislation include provisions enabling regulations to allow for cost recovery and to set fees and charges. These may offset a small proportion of costs in future years.

Legislative Implications

86 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 1993, ACVM, and the RMA.

87 Confidential advice to Government

88 The proposed Act would bind the Crown.

Impact Analysis

Regulatory Impact Statement

89 A joint MBIE, MfE and MPI Regulatory Impact Analysis Review Panel has reviewed the attached Impact Statement prepared by MBIE. The Panel considers that the information and analysis summarised in the Impact Statement partially meets the criteria necessary for Ministers to make informed decisions on the proposals in this paper.

Climate Implications of Policy Assessment

90 MfE has confirmed that a climate implications assessment is not required for the proposed regime.

Population Implications

91 The proposals would not disproportionately impact distinct population groups.

Human Rights

92 There are no human rights implications arising from these proposals. 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 drafting.

Use of External Resources

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

6e1wa178jr 2024-08-29 14:03:09

Consultation

94 MBIE consulted with the following agencies in the development of the proposals outlined in this paper: The Treasury, Department for the Prime Minister and Cabinet, MfE, MPI, the Public Service Commission, the Department of Conservation, the Ministry of Health, Te Puni Kōkiri, the Ministry of Foreign Affairs and Trade, and the EPA.

95 MBIE conducted targeted engagement with industry and research stakeholders most likely to be affected by the proposals including: universities and research institutes, iwi and Māori groups, industry associations, Crown Research Institutes, biotech companies, and primary industry and export groups. A Technical Advisory Group and Industry and Māori Focus Group were also established. The proposals have not been publicly consulted.

96 MfE provided expertise and an analysis of the submissions 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.

Communications

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

Proactive Release

98 I plan to proactively release this paper, with 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** that Coalition Agreements commit to enabling the greater use of gene technologies that would provide benefits to New Zealand, specifically: ending the effective ban on genetic engineering and modification in New Zealand, and 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;

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;

6e1wa178jr 2024-08-29 14:03:09

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

5 **Note** that the risk management approach will allow for greater re-use of assessments, increase predictability for applicants, and that the overall design of the regime allows for lower levels of regulatory oversight to be applied when experience demonstrates that types of organisms are safe over time;

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

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

8 **Agree** that regulated organisms will be those that have been modified or constructed by gene technology including human cells, but excluding human beings;

9 **Agree** that the legislation will apply to specified activities in relation to an organism modified or constructed by gene technology unless the gene technology or organism is exempted;

Hybrid, risk-tiered regulatory approach, with clear exemptions

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

11 **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 techniques from regulation;

12 **Agree** the legislation include provisions to enable secondary legislation to exempt technologies or organisms from regulation, where these either involve minimal risks, or if organisms, cannot be distinguished from those achievable by conventional techniques;

13 **Agree** that from establishment the regulator 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;

14 **Agree** that organisms modified by gene editing techniques that produce specific minor changes, *or* were modified by template(s), and do not introduce new genetic material would also be excluded from regulation;

15 **Agree** that the legislation provide a statutory determination power to enable the regulator to determine the status of an organism or technology;

6e1wa178jr 2024-08-29 14:03:09

A risk-proportionate authorisations framework

16 **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: Contained activities; Environmental release; and Medical applications; and

16.1 each of these categories to have three tiers reflecting level of likely risk: 'Non-notifiable', 'Notifiable' and 'Licensed', and

16.2 the 'licensed' risk tier for the environmental release and medical applications categories to then contain three types of licence process based again on risk: Pre-assessed activity, Expedited assessment, and Full assessment;

16.3 the 'licensed' risk tier for the contained activities category to contain one type of licence process: Expedited assessment;

17 **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;

Decision making

18 **Agree** decisions be made by an independent statutory decision-maker;

19 **Agree** the independent statutory decision-maker be appointed by the Minister;

20 **Agree** Technical Advisory Committee and Māori Advisory Committee members be appointed by the Minister;

21 **Agree** that consistent with an enabling and risk proportionate approach, public consultation be:

21.1 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 Risk Management Plan regarding the suitability of the risk management controls.

21.2 be at the regulator's discretion for Risk Assessment and Risk Management Plans for any expedited assessments;

22 **Agree**, that in making decisions consistent with the purpose of the legislation, the regulator focus only on managing risks to the health and safety of people and the environment, approving activities where it is satisfied the risks can be managed to a level that protects human health and safety of people and the environment;

23 **Agree** that the regulator should consider relevant impacts on Māori kaitiaki relationships with native and non-native species of significance in its decision making, where relevant to the purpose;

6e1wa178jr 2024-08-29 14:03:09

24 **Agree** that the regulator will be supported by a Māori Advisory Committee when considering adverse impacts on kaitiaki relationships, which will be modelled off the Plant Variety Rights Act 2022 but in an advisory role;

25 **Agree,** *Either*

25.1 applicants be given the ability to appeal a decision by the regulator to the Minister

Or

25.2 the legislation does not include a call-in power or an ability to appeal to the Minister

Or

25.3 the Minister be given the power to call-in applications if the Minister considers that the application would have nationally significant effects on the health and safety of people or the environment;

26 **Agree** the Minister be empowered to issue temporary emergency authorisations to respond to an actual or imminent threat to health and safety of people or the environment;

27 **Agree** to include a provision in the legislation for the responsible minister to issue general policy directions to the regulator;

28 **Agree**, regarding reviews and appeals of decisions, that an applicant or licensee may request a review of the regulator's decision and will have the right of appeal;

29 **Authorise** the Minister of Science, Innovation and Technology to take further decisions on the details of the review and appeals process;

Interaction with other legislation

30 **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;

31 **Agree** that the regulator be given the power to:

31.1 Undertake rapid assessments of regulated organisms that are also medicines or veterinary medicines, where these present lower risks to human health and safety and the environment

31.2 Undertake joint assessments or joint decision-making where there are overlaps in the risks addressed by the other regulator

31.3 Deem approvals of new organisms under the HSNO Act as approvals under the Gene Technology Act, if the regulator is satisfied that the

6e1wa178jr 2024-08-29 14:03:09

HSNO Act adequately addresses the risks to human health and safety and the environment;

32 **Agree** to amend the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM) to create the necessary powers to support joint assessments or joint decision-making;

33 **Authorise** the Minister of Science, Innovation and Technology, in consultation with the Minister of Food Safety, to take further decisions on detailed ACVM changes to implement recommendation 32;

34 **Agree** to remove from the Resource Management Act 1991 the ability for regional councils and territorial and unitary authorities to restrict the use of GMOs, to remove duplication and provide a nationally-consistent and predicable regulatory environment for gene technology;

35 **Agree** that the proposed consequential changes to the Hazardous Substances and New Organisms Act 1996 (HSNO) include: Removal of GMOs; Aligning definitions; Ways for the regulators to share information and work together; Application pathways in HSNO updated to allow for joint applications; Transitional provisions, and Other consequential amendments;

36 **Authorise** the Minister of Science, Innovation and Technology, in consultation with the Environment Minister, to take further decisions on detailed HSNO changes;

37 **Authorise** the Minister of Science, Innovation and Technology, in consultation with relevant Ministers, to take further decisions on changes required to the following Acts and associated secondary legislation: Agricultural Compounds and Veterinary Medicines Act 1997, Food Act 2014, Biosecurity Act 1993, Animal Products Act 1999, Medicines Act 1981, Human Assisted Reproductive Technologies Act 2004, Human Tissue Act 2008, Animal Welfare Act 1999, Imports and Exports (Restrictions) Act 1988, and Conservation Act 1987, and the Imports, and Exports (Living Modified Organisms) Prohibition Order 2005, Resource Management Act 1991, Reserves Act 1970 and National Parks Act 1980;

38 **Note** that Cabinet recently agreed to a regulatory review into the approval path for agricultural and horticultural products and that this review will address approval pathways for non-GM agricultural products;

Compliance monitoring and enforcement, and offences, defences, and penalties

39 **Agree** that the compliance, monitoring and enforcement, and offences, defences, and penalties regime (including pecuniary penalties and civil liability) from HSNO carry over where practicable, and subject to modifications to reflect current legislative best practice;

40 **Authorise** 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 compliance,

6e1wa178jr 2024-08-29 14:03:09

monitoring, and enforcement provisions, and offences, defences, and penalties introduced by the regime;

41 **Agree** that the Ministry for Primary Industries will be responsible for compliance, monitoring, and enforcement activities;

42 **Agree** that legislation provide for regulations to be made to require domestic commercial providers of synthetic nucleic acids and manufacturers of bench-top nucleic acid synthesiser equipment to comply with a customer screening framework and be approved by the regulator before they can operate in New Zealand;

Agreement to regime as outlined in Appendix One

43 **Agree** to the detailed design of the regime**, described in Appendix One**;

Financial implications

44 **Note** that depending on regulator location, from establishment to the end of 2028/29:

44.1 the cost for MBIE to set up and operate the regulator is estimated at Confidential advice to Government

44.2 the comparable cost for the EPA is Confidential advice to Government

44.3 the expected steady state cost from the third year of operation is approximately Confidentia per year, and each option also includes approximately Confidential advice to over the same period for MPI to undertake compliance, monitoring and enforcement of the new regime.

45 **Note** that it will not be practical or desirable to fully recover the costs of regulation from applicants and other regulated parties;

46 Confidential advice to Government

Location of the regulator

47 **Agree** the regulator will be located in the EPA;

48 **Agree** that constraints will be added to the process for appointing the independent statutory officer that reinforce its independence from EPA decision-making processes;

Legislative implications

49 **Agree** that the proposals will be given effect through the Gene Technology Bill (the Bill)Confidential advice to Government

6e1wa178jr 2024-08-29 14:03:09

50 **Agree** that the Bill will include a provision stating the Act will bind the Crown;

51 **Agree** that the Bill will include regulation-making powers, including the ability to make regulations to prescribe cost recovery, fees and charges;

52 **Agree** that the Minister of Science, Innovation and Technology is authorised to further clarify and develop policy matters relating to this paper's proposals in a manner not inconsistent with the policy recommendations outlined;

53 **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 of Science, Innovation and Technology

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Appendix One: Design of the Gene 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 organisms modified by gene technologies, and

1.2 Managing the risks to the health and safety of people and the environment 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 likely be used in legislation and are expected to evolve through the drafting process.

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. This will include human cells but will not include human beings.

5 ‘Organism’ and ‘genetically modified organism’ are referred to across a number of New Zealand Acts and the implications of adopting current definitions or making any changes will need to be worked through.

6 The legislation will regulate activities that relate to regulated organisms. ‘Activity’, in relation to a regulated organism, will include:

6.1 Making, developing, producing, breeding, propagating, manufacturing, growing, raising, or culturing, a regulated organism,

6.2 Supplying, importing, storing, or transporting, a regulated organism,

6.3 Using, conducting experiments with, releasing, or disposing of, a regulated organism.

7 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 ‘new organism’, as well as removing and modifying relevant provisions and references from the HSNO Act.

8 The legislation will be based on Australia’s Gene Technology Act 2000, with modifications made to adapt it to the New Zealand context.

Regulatory approach

9 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.

10 The Act will include provisions to enable the creation of secondary legislation to exempt techniques and organisms from regulation that either present minimal risks or, if an organism, cannot be distinguished from those achievable by conventional techniques.

11 The Act will include provisions to enable organisms modified by gene editing techniques that produce specific minor changes, *or* were modified by template(s), and do not introduce new genetic material to also be excluded from regulation.

12 Organisms and technologies that are currently exempt and not regulated under the gene technology legislation of either New Zealand or Australia will also be exempt. These exemptions will include, but may not be limited to:

12.1 Relevant statutory determinations made by the Environmental Protection Authority (EPA) under section 26 of the HSNO Act,

12.2 Organisms listed under the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998,

12.3 Organisms listed under Schedule 1 of Australia's Gene Technology Regulations 2001,

12.4 Technologies listed under Schedule 1A of Australia's Gene Technology Regulations 2001.

13 The Act will provide the ability for the regulator to make a statutory determination as to whether a technology meets the definition of gene technology, or whether an organism has been modified or constructed by gene technology, or whether an organism meets the definition of a regulated organism.

14 When making a statutory determination the regulator will take into account any previous statutory determinations made under the Act and any relevant information provided by the applicant or held by the regulator or another government agency.

Risk-proportionate authorisations framework for GMO activities

15 It will be an offence for any person to undertake an activity in relation to a regulated organism (an activity), unless authorised to do so under the new Gene Technology Act.

16 There will be five 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.

17 A risk matrix will form the authorisation framework for non-notifiable, notifiable, licensed authorisations. This matrix will be divided into three categories of activities:

17.1 Contained activities,

17.2 Activities involving intentional environmental release, and

17.3 Clinical trials and medical applications.

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 indicative risk they correspond to, their requirements, and the sorts of activities that they are likely to include.

Risk tier + assessment type	**Indicative gene technology risk**	**Regulator role**	**Requirements**	**Examples or type of activities**
Non-notifiable	Very low risk	No approval needed and no active monitoring	Activity must correspond to category (i.e. activities under the Contained activities category must not be released into the environment)	Administration of CAR T-cell therapies (under the Clinical trials and medical applications category)
Notifiable	Low risk, provided specific conditions are met	No approval needed and no active monitoring. Regulator must be notified of activity.	Persons undertaking the activity to notify the regulator about their activities	Laboratory research with animals

Risk tier + assessment type	Indicative gene technology risk	Regulator role	Requirements	Examples or type of activities
Licensed – Pre-assessed activity	Medium indicative risk	Verify that the activity and applicant are eligible for a pre-assesses activity licence (no case-by-case risk assessment)	Applicants will apply to the regulator for a pre-assessed activity licence before commencing an activity. Activities must correspond to an activity listed as eligible for a pre-assessed activity licence. Pre-assessed activity licence holders must comply with prescribed conditions.	Where the regulator has extensive regulatory knowledge and the risks of activities have been decided as manageable through risk management conditions previously found to be effective.
Licensed - 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 managed. Public consultation would be undertaken if the regulator considers there are issues warranting consultation.	Tailored licence conditions.	Where some of the risks of the activity are well understood by the regulator, or where GMOs have been approved by recognised regulators (see paragraphs 73-77).
Licensed - 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. Public consultation.	Tailored licence conditions.	For activities with which the regulator has no or limited regulatory knowledge.

20 For licences under the ‘Contained activities’ category, only the Expedited assessment pathway will be available. The Pre-assessed activity pathway and the Full assessment pathway will be available for the other two categories, ‘Activities involving intentional environmental release’ and ‘Clinical trials and medical applications’.

21 For contained activities, any intentional release of a regulated organism into the environment is prohibited. The person undertaking the activity must notify

the regulator of any unintentional release of a regulated organism into the environment.

Non-notifiable

22 The non-notifiable risk tiers across the three categories will cover activities that present a very low risk to health and safety of people 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.

23 The Act would specify the main requirements of the non-notifiable risk tier. The Act would also specify that non-notifiable activities, under any of the categories, would also be subject to any requirements that may be set under regulations for non-notifiable risk tiers.

24 The Act would empower the regulator to specify the activities that it can assign to non-notifiable risk tiers via a notice and the regulator may attach conditions to the activity for it to be considered non-notifiable. The Act will also empower regulations to be made specifying the criteria the regulator must be satisfied an activity meets, in order for that activity to be included under a non-notifiable risk tier.

Notifiable

25 The notifiable risk tiers across the three categories will cover activities that present a low risk to the health and safety of people and the environment, provided certain requirements are met by those undertaking those activities.

26 The Act would provide the ability for regulations to be made that specify requirements to undertake a notifiable activity. These may include requirements relating to:

27 Containment facility requirements (which may include complying with standards issued by the regulator),

27.1 Notifications to the regulator,

27.2 Supervision or verification of notifiable activities by a compliance body within or accessible to the person undertaking the activity, such as an Institutional Biosafety Committee that meets certain requirements, or

27.3 Transportation, storage and disposal requirements.

28 The Act would provide the ability for the regulator to specify the activities that it can assign to notifiable risk tiers via a notice and the regulator may attach conditions to the activity for it to be considered a notifiable activity. The Act will also empower regulations to be made specifying the criteria the regulator must be satisfied an activity meets, in order for that activity to be included under a notifiable risk tier.

Licensed activities

29 A licence may be issued by the regulator for activities under one of three pathways:

29.1 A ‘Pre-assessed activity’ pathway,

29.2 An ‘Expedited assessment’ pathway, or

29.3 A ‘Full assessment’ pathway.

30 The regulator may only issue a licence if satisfied the applicant is fit and proper, and able meet any conditions that would be associated with the licence.

Licensed – Pre-assessed activity

31 Applicants can apply to the regulator for a licence to undertake a pre-assessed activity. The Act will specify that a licence must be issued by the regulator to an applicant if the regulator is satisfied that the activity corresponds to a type of activity listed as eligible for a pre-assessed activity licence.

32 The application process for a pre-assessed activity licence would be:

32.1 An application is received,

32.2 The regulator decides whether the proposed activity is eligible,

32.3 The regulator decides whether the applicant is a fit and proper person to carry out the activity and meet any conditions,

32.4 If the regulator is satisfied that the proposed activity and applicant meet the criteria for a pre-assessed activity licence, the regulator must issue a licence for that activity.

32.5 If the regulator is not satisfied that the proposed activity or applicant meets the criteria, the regulator must not issue a licence for that activity.

33 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. The applicant may also withdraw the application at any time in the process.

34 The Act will enable regulations to be made setting out the criteria the regulator must follow to list types of activities, and their associated risk management conditions, as eligible for a pre-assessed activity. These criteria would include:

34.1 Types of activities for which the regulator has extensive regulatory knowledge, the risks of which the regulator is satisfied could be

managed through a or specific set of defined management conditions that have previously been shown to be effective in managing risks.

34.2 Types of activities with risks the regulator is satisfied could be managed by a standard set of management conditions that have previously been shown to be effective in managing risks.

35 The regulator would be required to seek advice from its Technical Advisory Committee and Māori Advisory Committee, and publicly consult, on the types of activities proposed to be listed as eligible for a pre-assessed activity licence and the relevant risk management conditions attached to those activities.

36 Activities eligible for a pre-assessed activity licence and any conditions would be published by the regulator in a notice.

Licensed - Expedited assessments

37 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.

38 The regulator must prepare a risk assessment and risk management plan. It would be at the regulator's discretion as to whether public consultation is required for an expedited assessment.

39 If the regulator considers that another assessment pathway is more appropriate for the application, the regulator may allocate the application to a pre-assessed activity or full assessment pathway, with the agreement of the applicant. If the applicant does not agree, their application will be declined. The applicant may also withdraw the application at any time in the process.

Licensed - Full assessments

40 Applicants can apply to the regulator for a licence via a full assessment pathway.

41 Public consultation would be mandatory requirement for a full assessment.

42 If the regulator considers that another assessment pathway is more appropriate for the application, the regulator may allocate the application to a pre-assessed activity licence or expedited assessment pathway, with the agreement of the applicant. If the applicant does not agree their application will be declined. The applicant may also withdraw the application at any time in the process.

Assessment processes – Expedited assessments and Full assessments

43 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.

44 The process for expedited assessments and full assessments will be:

44.1 An application is received,

44.2 The regulator notifies its Māori Advisory Committee of the application, to provide the Committee an opportunity to advise on whether there might exist any kaitiaki relationship that might be affected by the proposed activity,

44.3 The regulator undertakes a risk analysis of the application, including preparing a Risk Assessment and Risk Management Plan (RARMP) taking into account the matters prescribed in regulations and containing conditions to manage any identified risks (as prescribed in regulations),

44.4 The regulator would then be required to seek the advice of its Technical Advisory Committee and specified agencies on its RARMP,

45 The regulator must take into account advice it has received from its Technical Advisory Committee and specified agencies, on its RARMP. The regulator must also have particular regard to the advice of the Māori Advisory Committee.

45.1 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 on the RARMP for a minimum period of 30 working days,

45.2 Should the regulator decide that the proposed activities pose a high risk the health and safety of people or the environment, the regulator would invite public submissions on the RARMP for a minimum of 50 working days.

45.3 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.

46 If the regulator is satisfied that risks to the health and safety of people and the environment from the proposed activities are able to be managed, the applicant is fit and proper and able to comply with any conditions, the regulator must issue a licence.

47 If the regulator is not satisfied with the criteria above, the regulator must not issue a licence.

48 A licence may either be issued by the regulator with conditions or issued without conditions.

49 The regulator may seek advice on any aspect of an application with, relevant agencies, and any other organisation or person the regulator considers appropriate.

Activities Approved for General Use

50 The Act will enable regulations to be made setting out the criteria that the regulator must follow to specify ‘activities approved for general use’. These will be added via notice and may be undertaken by anybody without a specific licence.

51 The Act will specify the criteria for those activities that can be added to the ‘Activities Approved for General Use’ list. These criteria will be that the regulator is satisfied that:

51.1 Any risks posed by those activities are minimal, and

51.2 It is not necessary for persons undertaking those activities to be covered by a licence for any risks to the health and safety of people or risks to the environment to be managed.

52 The regulator would be able to add to this list previously licensed activities and activities not previously authorised.

53 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

54 The Act 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.

55 The Minister may make an emergency authorisation if they have received advice from relevant ministers that an actual or imminent threat to the health and safety of people or the environment, and that the proposed authorisation would, or would be likely to, adequately address the threat.

56 Relevant Ministers would include, but are not limited to, those Ministers that are responsible for the administration of the following Acts (and other Acts as required):

56.1 Agricultural Compounds and Veterinary Medicines Act 1997.

56.2 Biosecurity Act 1993.

56.3 Conservation Act 1987.

56.4 Fisheries Act 1996

56.5 Resource Management Act 1991.

56.6 Hazardous Substances and New Organisms Act 1996.

56.7 Health Act 1956.

56.8 Medicines Act 1981.

56.9 Civil Defence Emergency Management Act 2002.

57 The responsible Minister would be able to issue an emergency authorisation if:

57.1 They are satisfied that there was an actual or imminent threat to the health and safety of people or the environment.

57.2 They are satisfied that the activity proposed in the authorisation would, or would be likely to, adequately address the threat.

57.3 They have received advice from the regulator that any risks to the health and safety of people, and the environment posed by the activity are able to be managed.

57.4 The Minister is satisfied that any risks to the health and safety of people, and the environment posed by the activity are able to be managed.

58 The Minister may include conditions in the emergency authorisation – for example, that only certain persons may carry out the activity subject to the authorisation.

59 The authorisation process would not require public consultation or the development of a risk assessment and risk management plan, however the regulator could recommend conditions to the responsible Minister.

60 The authorisation and the Minister's reasons for the authorisation will be publicly notified.

61 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 authorisation only if:

61.1 The Minister has received advice from the original advisor that the threat still exists, and

61.2 The Minister is satisfied the threat still exists.

62 The Minister may extend the period of effect of an emergency authorisation more than once if the threat remains, but each extension must not exceed six months.

63 The Minister may vary any conditions and may suspend or revoke an emergency authorisation.

Suspension, cancellation, variation and transfer of licences

64 The regulator will have the authority to suspend, cancel, transfer or vary a licence as prescribed in primary legislation.

Suspension and cancellation of licences

65 The regulator may suspend or cancel a licence, by written notice to the holder of that licence, if:

65.1 The regulator believes on reasonable grounds that a condition of the licence has been breached, whether by the licence holder or by a person covered by the licence,

65.2 The regulator believes on reasonable grounds that the licence holder, or a person covered by the licence, has committed an offence against the proposed Gene Technology Act or its regulations,

65.3 The licence was obtained improperly,

65.4 The regulator becomes aware of risks associated with the continuation of the activity authorised by the licence, and is satisfied that the licence holder has not proposed, or is not in a position to implement, adequate measures to manage those risks.

65.5 The regulator is satisfied that the licence holder is no longer a fit and proper person to hold the licence.

Surrender of a licence

66 The holder of a licence may, with the consent of the regulator, surrender the licence.

Transfer of licences

67 A holder of a licence, and another person (the *transferee*), may jointly apply to the regulator for the licence to be transferred from the licence holder to the transferee.

68 The regulator must not transfer the licence unless the regulator is satisfied that, if the licence is transferred, any risks to the health and safety of people and the environment posed by the activity authorised by the licence will continue to be able to be managed.

69 The regulator must not transfer the licence unless the regulator is satisfied that the transferee is a fit and proper person to hold the licence.

Variation of licence

70 The regulator may vary a licence, by notice in writing given to the licence holder, either:

70.1 At any time, on the regulator's own initiative, or

70.2 On application by the licence holder.

71 Variations to a licence may include, but are not limited to:

71.1 Imposing licence conditions or additional licence conditions,

71.2 Removing or varying licence conditions that were imposed by the regulator.

72 The regulator must not vary a licence unless the regulator is satisfied that any risks to the health and safety of people and the environment posed by the activity authorised by the licence as varied will continue to be able to be managed.

Provisions to leverage international expertise

73 Provisions will enable the use of international expertise to accelerate assessments and approvals through the use of the following mechanisms:

74 Joint assessments with international regulators,

75 Deemed authorisations under the proposed Gene Technology Act of human medicines approved by two 'recognised gene technology regulators', and

75.1 Expedited assessments for activities approved by a 'recognised gene technology regulator'.

Recognised regulators

76 The Act will enable the regulator to establish other international regulators as 'recognised gene technology regulators' by notice.

77 Primary legislation will outline the factors the New Zealand regulator must consider before recognising an international regulator as a 'recognised gene technology regulator'. These factors would be whether the international regulator:

77.1 Operates in a manner comparable to the New Zealand regulator in regulating gene technology, and

77.2 Operates under a legislative framework comparable to New Zealand gene technology legislation.

78 Information from the regulator is readily accessible by the regulator.

79 The regulator would be required to publicly consult on regulators it proposes to establish as 'recognised gene technology regulators'.

80 The regulator would have the ability to declare, via a notice, that a regulator was no longer a 'recognised gene technology regulator' if it no longer meets

the relevant criteria. The regulator would be required to consult on the revocation of a regulator as a 'recognised gene technology regulator'.

81 An amendment to a notice will not require public consultation if the regulator considers that the amendment is minor in effect or corrects a minor or technical error.

Joint assessments

82 The Act will enable the regulator to undertake joint assessments of licence applications with other international regulators. Eligible applications would be those that are required to be assessed via an expedited or full assessment pathway. The joint assessments are to inform the regulator's Risk Assessment and Risk Management Plan and prior to public consultation (if applicable).

83 The legislation will enable the regulator to enter into agreements with other international regulators for the purposes of undertaking these joint assessments. An agreement between the New Zealand regulator and another international regulator, or international regulators, would be required prior to any joint assessments being undertaken by the New Zealand regulator and the international regulator or regulators.

84 While the Minister may suggest the regulator 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.

85 After undertaking a joint assessment of an application and 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).

Deemed authorisations for human medicines

86 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 deemed authorised under the proposed Gene Technology Act.

87 The deemed authorisation of the human medicine will be publicly notified along with any conditions. If there are 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.

88 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.

89 Approval by Medsafe will continue to be required before any clinical use.

Expedited assessments for activities approved by 'recognised gene technology regulators'

90 Activities that would otherwise be required to undergo a full assessment, that have been previously approved by one or more 'recognised gene technology regulators', will be eligible for the expedited assessment pathway for a licence.

91 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.

92 This provision would be similar to the 'recognised international regulators' provision under the HSNO Act, the purpose of which is to accelerate the assessment of hazardous substances through the better use of international data and assessments.

93 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

94 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.

95 The regulator's assessment of an application will not include assessment of the following:

95.1 Potential benefits (economic or otherwise),

95.2 Ethical considerations,

95.3 Trade, international agreements and market access risks, or

95.4 Cultural, social or spiritual matters.

96 The regulator will be required to seek advice on expedited and full assessment licence applications from its Technical Advisory Committee, its Māori Advisory Committee, and agencies it considers relevant to the application in question.

Ministerial call-in provision

97 The Act 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 health and safety of people or the environment. Applications eligible to be called-in would be those that are being assessed via a full assessment pathway.

98 Authorisations made under the ‘call-in’ power must be consistent the purpose of the Act. The authorisation and the Minister’s reasons for the authorisation will be publicly notified.

Advisory committees

99 The Act will establish advisory committees that will support the regulator to carry out its functions and will include:

99.1 Technical Advisory Committee, and

99.2 Māori Advisory Committee.

100 The Act will enable the regulator to establish subcommittees, made up of Technical Advisory Committee and Māori Advisory Committee members, and any additional persons if it deems it necessary for the purpose of performing the regulator’s functions under the Act.

101 Members of the Technical Advisory Committee and the Māori Advisory Committee will be appointed by the responsible Minister on the advice of the regulator.

102 The regulator must have regard to, but is not bound by, the advice of the Technical Advisory Committee or the Māori Advisory Committee or any subcommittee.

103 Requirements for committees will be specified in the Act and at a minimum will include membership requirements and appointment procedures, with further detail on tenure duration, committee procedures and recording proceedings to be described in secondary legislation.

104 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:

104.1 Risk Assessment and Risk Management Plans,

104.2 Guidance documents and risk analysis frameworks,

104.3 Proposed updates to the non-notifiable and notifiable risk tiers, and

104.4 Proposed activities eligible for pre-assessed activities licenses.

Māori Advisory Committee

105 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.

106 The Māori Advisory Committee will advise the regulator on these adverse effects. It will have the following functions:

106.1 Issue engagement guidelines and provide advice to applicants and kaitiaki.

106.2 Providing advice to the responsible Minister on proposals to exempt certain organisms or technologies.

106.3 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.

106.4 Advise the regulator on the suspension, cancellation, variation or reassessments of licenses where there are adverse effects on relevant kaitiaki relationships.

106.5 Advise the regulator whether the use or approval of a proposed activity is likely to be offensive to Māori.

Statutory timelines for decision making

107 Regulations may set statutory timeframes for the regulator to process applications, consult on applications, and decide an application. The regulator will be able to extend these timeframes on reasonable grounds.

Risk assessment and risk management

108 The Act 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.

109 The matters for the regulator to take into account, will be provided for in regulations and may include:

109.1 The properties of the host organism,

109.2 The effect, or expected effect, of the intended genetic modification on the host organism,

109.3 The effects or expected effects of the regulated organism,

109.4 The potential for spread or persistence of the regulated organism in the environment,

109.5 Provisions for limiting spread and persistence of the regulated organism or its genetic material in the environment,

109.6 The extent or scale of the proposed activity,

109.7 Any likely impacts of the proposed activity on the health and safety of people, the environment, or kaitiaki relationships with a specific species,

109.8 The short and long-term impacts of the regulated organism,

109.9 Any previous domestic or international assessments relating to the activity, and

109.10 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.

Joint assessments with domestic regulators

110 Dual regulatory approvals may be required where there is overlap with other legislation. The Act will enable the regulator to undertake joint assessments with other domestic regulators, where appropriate, to streamline processes to the extent possible

111 The Act will provide the regulator with the power to:

111.1 Undertake assessments of regulated organisms that are also medicines, therapeutics, or veterinary medicines, where these present low risks to the environment and the health and safety of people, via a 'rapid assessment' pathway (similar to the EPA's current approach for 'qualifying medicines' under the HSNO Act).

111.2 Undertake joint assessments or joint decision-making where there are overlaps in the risks addressed by the other regulator (e.g. under the Agricultural Compounds and Veterinary Medicines Act or the HSNO Act)

111.3 Deem approvals of new organisms under the HSNO Act as approvals under the Gene Technology Act if the regulator is satisfied that the HSNO Act adequately addresses the risks to the environment and health and safety of people.

112 In aid of joint assessments and streamlining processes, the Act will empower the regulator to work with other regulators to implement administrative mechanisms to make the systems work well together, including but not limited to information sharing.

113 The Act will amend other legislation to enable joint assessments with other regulators including the Agricultural Compounds and Veterinary Medicines Act or the HSNO Act.

Risk assessment and the Cartagena Protocol

114 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. The proposed

regime must be consistent with New Zealand's obligations under the Cartagena Protocol and the Imports and Exports (Living Modified Organisms) Prohibition Order 2005.

Review of decisions

115 The Act will include provisions to enable an applicant and other relevant persons to seek an internal review of a licence decision made by the regulator, similar to the Australian Gene Technology Act 2000.

Reassessments

116 The Act will provide the regulator the authority to undertake reassessments, or partial reassessments, of certain decisions. These will be undertaken at the discretion of the regulator if it deems it appropriate.

117 These reassessments may be initiated by any person, including the regulator.

118 Reassessment provisions will be updated and broadly aligned with the HSNO Act. Partial reassessment provisions will be updated and broadly aligned with those for hazardous substances under the HSNO Act.

119 Based on the outcomes of a reassessment, the regulator will have the authority to suspend, cancel, or vary a licence.

120 The Act will also empower the regulator to make amendments to licences to correct minor or technical errors without needing to undertake a full or partial reassessment.

Appealing decisions

121 Applicants will be able to appeal decisions made by the regulator generally in line with Part 8 of the HSNO Act, where applicable.

Delegation

122 The Act 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

123 The regulator will be an independent statutory officer, appointed by the Minister, supported by an office and an operational budget.

124 The focus of the regulator will be to enable the safe use of gene technology through managing the risks of regulated organisms to the health and safety of people and the environment.

Functions and powers of the regulator

125 The functions and powers of the regulator will include, but will not be limited to:

125.1 Determining the types of activities that fall within the different risk tiers.

125.2 Assessing applications for licensed activities.

125.3 Authorising licensed activities.

125.4 Determining those activities that are covered by non-notifiable and notifiable risk tiers and activities on the list of 'activities approved for general use'.

125.5 Determining those activities that are eligible for a pre-assessed activity licence.

125.6 Undertaking statutory determinations.

125.7 Providing information and advice to the responsible Minister on those organisms and gene technologies that should be deemed not regulated.

125.8 Providing information and advice about the regulation of gene technology and regulated organisms to:

125.8.1 The responsible Minister.

125.8.2 Other regulatory agencies.

125.8.3 The public.

125.9 Issuing technical and procedural guidelines in relation to gene technology and regulated organisms.

125.10 Providing advice to the responsible Minister on the effectiveness of the legislative framework and possible amendments to achieve the purpose of the legislation.

125.11 Monitoring international practice in relation to the regulation of gene technology and regulated organisms.

126 In the performance of its functions, the Regulator may take advice from:

126.1 The Technical Advisory Committee,

126.2 The Māori Advisory Committee,

126.3 Other government agencies,

126.4 Any other person the regulator considers appropriate.

Public consultation and notification

127 Any proposed regulations or amendments to regulations will require either public consultation or consultation with those persons the Minister considers likely to be affected by the proposals, including iwi and Māori.

128 The regulator will be required to carry out public consultation for a minimum of 30 working days on:

129 the 'Activities Approved for General Use' list (General Use list),

129.1 the activities covered by non-notifiable and notifiable risk tiers,

129.2 the list for pre-assessed activity licenses,

129.3 Licences applied for via the full assessment pathway.

129.4 Licences applied for via the expedited pathway where the regulator deems public consultation necessary.

130 Should the regulator decide that the proposed activities that are being assessed under the full assessment pathway pose a significant risk, the regulator would be required to invite public submissions on the RARMP for a minimum of 50 working days.

131 All licence decisions and their associated conditions and RARMPs, changes made to non-notifiable and notifiable risk tiers, changes made to technologies and organisms classified as exempt, statutory determinations, automatic authorisations, activities added to the General Use list, variations to licences will be required to be publicly notified.

132 The regulator will be required to publicly notify the membership of advisory committees, subcommittees and recognised gene technology regulators.

133 Legislation will require the regulator to maintain a publicly accessible register of applications, licence decisions, conditions (if any), and statutory determinations.

Compliance, monitoring and enforcement

134 The Act will contain compliance, monitoring and enforcement provisions and will broadly align with the relevant compliance, monitoring and enforcement provisions of the HSNO Act.

135 These provisions will include, and will not be limited to:

135.1 Power to inspect properties to check compliance,

135.2 Ability to issue compliance orders, infringement notices and prosecute offences.

136 The Act will enable the Ministry for Primary Industries to be an enforcement agency. This means the Ministry for Primary Industries will undertake compliance, monitoring and enforcement functions in regard to this regime. These powers may also be held by another agency in certain circumstances.

137 Primary legislation will also provide the regulator with a standard set of compliance, monitoring and enforcement powers.

138 The Act will also enable the sharing of information obtained during the exercise of compliance, monitoring and enforcement functions and powers between relevant agencies.

Additional components

Offences and penalties

139 Offences and penalties will be updated and broadly aligned with the existing offences, defences and penalties regime for GMOs under the HSNO Act, including civil liability and pecuniary penalties.

Ministerial direction

140 The Act 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

141 The Act 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.

142 Cost recovery provisions under the new Act's will enable regulations set fees and charges.

Applicant suitability

143 In deciding whether a person is a fit and proper person to hold a licence, the matters the regulator must have regard to will include, but will not be limited to:

143.1 Any conviction of the person for:

143.1.1 An offence against a relevant law (defined below), or

143.1.2 A crime involving dishonesty (as defined in section 2 of the Crimes Act 1961).

143.2 Any civil penalty order made against the person under a relevant law.

143.3 If the person holds or has held a licence, approval, registration, exemption, or other authorisation under a relevant law (an authority):

143.3.1 Any suspension or revocation of the authority,

143.3.2 Any enforcement or disciplinary action taken against the person in relation to the authority,

143.3.3 Any disqualification from holding the authority,

143.3.4 Any contravention by the person of:

143.3.4.1 The authority, or

143.3.4.2 A provision of a relevant law that applied to the person as the holder of the authority.

143.4 Whether there are other reasonable grounds to believe that the person is likely to contravene a provision of the Act.

143.5 Whether the person is or has been:

143.5.1 Bankrupt, or

143.5.2 Subject to an insolvency event (as defined in section 6 of the Financial Markets Conduct Act 2013) or to an equivalent event under a law of another country.

143.6 Whether the person is of good character.

143.7 Any other matters that the regulator thinks are relevant.

144 For the purposes of assessing whether a person is fit and proper, ‘relevant laws’ means any of the following Acts (or secondary legislation made under them):

145 The Gene Technology Act, the Agricultural Compounds and Veterinary Medicines Act 1997, the Animal Products Act 1999, the Animal Welfare Act 1999, the Biosecurity Act 1993, the Customs and Excise Act 2018, , the Food Act 2014, the Hazardous Substances and New Organisms Act 1996, the Human Assisted Reproductive Technology Act 2004, the Human Tissue Act 2008, the Medicines Act 1981, the Misuse of Drugs Act 1975, and the Psychoactive Substances Act 2013.

145.1 Any other New Zealand legislation that the regulations say is a relevant law.

145.2 A law in another country that:

145.2.1 The regulations say is a relevant law, or

145.2.2 Corresponds to all or part of a law referred to as a relevant New Zealand law.

145.3 A law that was replaced by a law referred to as a relevant New Zealand law.

Requirements for the screening of synthetic nucleic acid

146 The Act will enable regulations to be made which would require:

146.1 Providers of synthetic nucleic acids that are based in New Zealand to comply with a customer screening framework customer.

146.2 Manufacturers of benchtop nucleic acids synthesisers that are based in New Zealand to screen customer orders and integrate into their equipment the ability to screen nucleic acid sequences.

146.3 Providers and manufacturers to be approved by the regulator (or a delegated decision maker) before they can operate in New Zealand.

147 It would be an offence for a relevant provider or manufacturer to not meet the requirements set out in those regulations, from the point at which these regulations come into force. The monitoring, compliance and enforcement powers will also apply.

Containment facilities

148 The Act will authorise the regulator to develop and approve standards for containment facilities for regulated organisms, and to approve containment facilities to standards relevant to regulated organisms.

149 The Act will also enable the regulator to delegate the power to approve containment facilities.

Interactions with other legislation

150 Consequential amendments to other legislation will include:

150.1 Hazardous Substances and New Organisms (HSNO) Act 1996 will be amended to remove genetically modified organisms from the definition of a ‘new organism’ and broadly align with this regime. This will include aligning definitions, sharing information, enabling joint applications, administering transitional provisions and modifying other relevant provisions and references.

150.2 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.

150.3 Other Acts that refer to definitions in the HSNO Act relating to genetically modified organisms and gene technologies, will require updating for the new legislation and definitions.

150.4 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.

150.5 Amendments if required to enable the new Gene Technology Act to operate and interact with the Imports and Exports (Living Modified Organisms) Prohibition Order 2005 to give effect to the Cartagena Protocol.

151 The Act 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. The legislation will include, but will not be limited:

151.1 Agricultural Compounds and Veterinary Medicines Act 1997,

151.2 Hazardous Substances and New Organisms Act 1996,

151.3 The Biosecurity Act 1993, and

151.4 Medicines Act 1981.

Implementation and transitional provisions

152 The regulator will require the ability to access other agencies' records such as criminal records and Companies Office registers information to determine whether a person is fit and proper to hold a licence.

153 The regulator may provide and receive information from other government agencies where that information:

153.1 Is held for the performance or exercise of either the regulator or the specified entity's functions, duties or powers, and

153.2 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.

154 Transitional provisions will allow for relevant approvals, decisions, and statutory determinations under the HSNO Act to be transferred from the Environmental Protection Authority to the new gene technology regulator.

155 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.

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 using traditional processes or natural mutations 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	Licensed Pre-assessed activities Expedited assessment Full assessment	Licensed Pre-assessed activities 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.
- **Licences** would cover field trials, clinical trials, and commercial releases.

ASSESSMENTS AND APPROVALS

Licensed activities would require assessment and approval by the regulator. The pre-assessed activity pathway would not require a Risks Assessment and Risk Management Plan and only full assessments would require public consultation.

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

GENE TECHNOLOGY REGULATOR

- The regulator will be a single decision-maker, supported in their functions by an office, a technical advisory committee, and a Māori advisory committee.
- Their responsibilities will include assessing and authorising activities, developing regulations, providing advice on technical matters to Ministers and other agencies, and providing information and guidance to the public and regulated parties.

STREAMLINED ASSESSMENT PROCESSES

- Overlapping processes with other domestic regulators will be streamlined through information sharing, cooperation, and delegation, where appropriate.
- This will apply where gene technologies considered by the regulator are also new organisms, medicines, agricultural compounds, and veterinary medicines.

LEVERAGING THE EXPERTISE OF OVERSEAS REGULATORS

- Joint review provisions will enable the regulator to undertake joint assessments with other overseas regulators. Following the joint assessment, the regulator would make their own independent decision.
- Automatic authorisation of human medicines under the gene technology legislation would apply to medicines approved by at least two overseas gene technology regulators recognised by the New Zealand gene technology regulator.
- Expedited assessments would apply to activities approved by overseas gene technology regulators previously recognised by the New Zealand gene technology regulator.

Appendix Three: 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

Regulation of gene technology – Questions and Answers

Could we have a Ministerial call-in power for nationally significant trade risks?

- Investment in new technologies in New Zealand requires an environment that is predictable for innovators. The choice to exclude trade risks in favour of a simple technical assessment of risk contributes significantly to providing that certainty. We need to be careful not to create additional complications or mechanisms that start to undermine that certainty and predictability.
- Overstating trade risks is an argument that opponents of gene technology will advance to say why we shouldn't make these changes. That would also be an ongoing pressure on Ministers to intervene in decision-making.

The call-in power is asymmetrical and should allow for applications to be called in if there are significant economic benefits

- This scenario is unlikely in practice because it envisages a situation where a product has environmental risks that cannot be managed, yet it has economic benefits that outweigh these. An applicant is highly unlikely to design a product with these characteristics, as it will have a very limited market and will face regulatory risk globally. This is not a good product, and we shouldn't create incentives for firms to take this approach.
- This would also introduce a weighing of benefits into the legislation, which we have sought to avoid because it creates complexity and uncertainty about outcomes of the regulatory regime. Benefits are often speculative and can be difficult to demonstrate robustly, especially for innovative products.

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That the Minister be required to consult the Minister of Health where the product is intended for use in humans

- I would expect the responsible Minister to consult the Minister of Health as a matter of course in these circumstances.

Free and frank opinions

Free and frank opinions

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How have you ensured the new regime will be more enabling than HSNO?

- The legislation's purpose is explicitly to enable the safe use of gene technologies.
- In addition, to ensure that the regime is more enabling:
    - The ministerial policy direction and call-in powers will provide Government with the lever to ensure the regulator operates in an enabling manner.
    - The legislation will include other enabling features including:
        - The narrow, scientific scope will prevent applications being declined for subjective or speculative reasons.
        - The regulator will have a greater focus on risk management conditions, which will reduce the likelihood of an application being declined outright.
        - HSNO's restrictions on field trials will be replaced with case-by-case risk assessments.

Why new legislation? Why not update the existing HSNO Act?

- The HSNO Act is out of date and would need to be extensively rewritten to accommodate the necessary changes. In addition, industry and stakeholders do not consider it to be fit for purpose and amending it risks being seen as "business as usual".

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What are the likely economic benefits from gene technologies?

- It's hard to predict the economic benefits of future technological development. However, 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.

Why did you choose to adapt Australia's legislation and not other countries'?

- Stakeholders consider that the Australian Act has operated well for over twenty years and would work well in New Zealand with only minor updates. Adapting the regime will support alignment with our nearest trading partner and encourage research collaborations.
- Australia's model is consistent with countries such as England and an updated approach proposed for the European Union. The main alternative internationally is the "outcome based" model used in the United States and Canada. Officials' advised against that model because it hasn't led to greater approval rates and is more burdensome for low risk research and start-ups.

What will be the likely response from the public?

- Recent research has indicated that public attitudes towards gene technologies have been becoming more favourable, although there remain many "undecideds".

6e1wa178jr 2024-09-05 10:04:49

- For example, research from Primary Purpose this year found 34% of respondents were generally supportive of gene technology, while 29% wanted to keep New Zealand “GE-Free”. This was consistent with other recent surveys.

Why was there no public consultation?

- My proposals are consistent with those the National Party campaigned on in the 2023 election and in the Government’s coalition agreements. Officials have directly engaged with relevant stakeholders in their advice on these proposals, and the public will be able to share their views at select committee next year.

Why are you aiming to introduce new legislation at such pace?

- This Government is committed to rebuilding New Zealand’s economy. The status quo has effectively banned gene technologies, which is driving researchers and investment overseas. We need to reverse this as soon as possible so New Zealand can access and capitalise on the potential benefits of these technologies.

Why are your proposed gene editing exemptions less permissive than England or the EU?

- I’m proposing to expand on Australia’s relatively narrow exemptions to include techniques with similar risk profiles that are well understood scientifically.
- England’s more permissive approach, based on exempting gene edited organisms that are indistinguishable from non-GMOs, was only introduced last year and there are some uncertainties on how it would operate in practice. The EU has proposed a similar process for plants only, but that is yet to be confirmed.

6e1wa178jr 2024-09-05 10:04:49

- I propose taking a “wait and see” approach for now to learn from international experience, as the legislation will enable Government to expand exemptions in the future relatively easily.

- **What are the possible trade implications?**

- MFAT has registered concerns that the regime proposed would not enable regulatory decision makers to take international trade considerations into account in the assessment of applications.

- MFAT notes that international precedent for including trade considerations in Gene Technology regulations, including in the Australian Model which enables consideration of trade and market access impacts at the state-level of Government (e.g., Tasmania does not allow GM use in its state on the basis of potential impact on marketing of its goods; other Australian states have applied certain restrictions and mitigation measures as an overlay to the federal permissive legislation).

- MFAT’s preference was for Trade and Market Access to be considered by the Regulator alongside Environment and Health factors. However, MFAT has explored other ways for significant trade impacts to be factored into the process.

Response:

- This is an “on balance” decision.
- MFAT’s description of Australian rules differs from our own understanding.
- States such as Tasmania have put in place moratoria on GM cultivation. Where these moratoria have been lifted, they have generally been lifted in their entirety or remain in place for limited geographical areas and primarily because the prevailing

6e1wa178jr 2024-09-05 10:04:49

view was that earlier concerns about market access, economic impact and segregation had largely been overcome.

- The 2008 Gene Technology Agreement between the States and the Commonwealth Government explicitly prevents States from adopting a different risk scope for gene technology applications.
- Including trade and market access issues in the risk assessment will shift the balance of the regulatory regime towards a balancing of interests and away from the scientific management of risk.
- It is likely to favour incumbents in the market (who have existing and known costs and benefits) and deter innovation (where costs and benefits are more uncertain). It is highly likely to provide a mechanism for opponents of gene technology to contest approvals.
- Trade and Market Access considerations do present a risk. MPI have advised that they consider this risk can be managed through improved assurance processes, as it is successfully in other jurisdictions.

Question: Is there any guidance from existing practice or case law about what the 'national significance' threshold for the ministerial call-in power (para 53.2) is likely to mean in practice? Free and frank opinions

Response:

- There is no existing guidance or case law regarding what "national significance" could mean in practice.

6e1wa178jr 2024-09-05 10:04:49

- Free and frank opinions [redacted]
- Any decisions would still need to use the decision-making framework of the Act, and therefore could not introduce new considerations.

Question: The paper suggests that some administrative features will continue from HSNO (para. 18.2). We have heard that compliance with HSNO is particularly difficult for field trials, imposing almost-impossible monitoring conditions on scientists. Will those be removed with the new regime?

Response:

- The main source of these issues is the “field test in containment” category under HSNO, which requires organisms to be contained. This category will not exist under the new legislation.
- Administrative measures continuing from HSNO are more generic – penalties and offences, appeals etc.

- **Feedback**
  - The role for public consultation is unclear. If the regulator has determined that a product has determined that a product has ‘high or uncertain risk’, then the predictable result of public consultation will simply be unscientific calls for prohibition.

6e1wa178jr 2024-09-05 10:04:49

- I am not sure on how this should be implemented, but clarification that the ‘public’ being consulted will mostly consist of would-be users and external scientists would probably make this more useful.

Response:

- The public consultation process allows the regulator to ensure they have considered the full range of risks, and that the proposed risk management plan is appropriate and effective for managing those risks.
- The regulator is not able to take into account unscientific calls for prohibition, because they are outside the scope of the regulatory decision-making framework.

6e1wa178jr 2024-09-05 10:04:49