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Options to strengthen gene technology risk management

Introduction

I have been approached by some MPs, who have sought further comment from me regarding the scheme of the Gene Technology Bill, which is currently before the Health select committee for consideration. I have been specifically asked to comment on how the proposed framework of the Bill could be improved to enhance trust and confidence in the regulatory regime having regard to the way other jurisdictions have addressed perceived risks associated with gene technology.

Key points

If Parliament wants to reduce the level of risk gene technology provides, it could consider making changes to the Bill along the following lines:

1. Ensure closer alignment between New Zealand's regime and other international regimes. New Zealand's system could become a middle ground between the Australia, European Union and United States systems.
2. Ensure that all gene technologies that are to be released into the environment are risk assessed by the regulator before release or, for low-risk ones, are at the very least required to be registered with the regulator. There could be no (or severely limited) automatic exemptions for environmental release.
3. Ensure greater independence of the regulator. The Australian system provides a potential model.
4. Allow a wider range of people and entities to request reviews of the regulator's decisions and introduce a civil liability regime.

Options for how these points could be adopted are presented below.

The current scheme of the Bill

The Bill is intended to provide a standalone regulatory regime for gene technology. It establishes a relatively complex framework for the categorisation of activities to develop genetically modified organisms (GMOs) and their regulation.

The Bill regulates GMO activities based on an approach that has been referred to as a risk matrix framework. This groups activities into different categories, depending on whether they are to be used in containment (e.g. a research laboratory), if the activity is meant for

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environmental release or if it is for a medical use. For each activity category, the Bill establishes the following risk tiers and associated authorisations:

- "Exempt" – minimal risk activities that will be unregulated under the Bill and the Regulator will not be notified of their occurrence.
- "Non-notifiable" – very low risk activities. If someone undertakes these activities, they do not need to notify the Regulator and must comply with any requirements for where or how a non-notifiable activity must be undertaken.[1]
- "Notifiable" – low risk activities, about which the Regulator must be notified, and which must comply with any prescribed requirements regarding supervision or verification of activities, and import, export, transportation, storage and disposal of modified organisms.[2]
- "Licensed" – activities involving medium-high risk or uncertain risk that will require case-by-case risk assessment before they can be authorised, to determine that all the risks of the proposed activity can be adequately managed.

The Bill gives the Regulator the power to declare activities as exempt, non-notifiable, notifiable or pre-assessed licensed activities. The Minister, by way of regulations, may further exempt organisms, gene-editing techniques or technologies from the operation of the Act.[3]

The proposed risk matrix

Containment e.g. lab	Environmental release	Medical use
Non-notifiable	**Non-notifiable**	**Non-notifiable**
Notifiable	**Notifiable**	**Notifiable**
Licensed: Expedited Assessment	**Licensed:** Permit Expedited Assessment Full Assessment	**Licensed:** Permit Expedited Assessment Full Assessment

Note: Under the 'Containment' category, release into the environment would be prohibited.

Figure 1. Modified from MBIE. [4]

1 Gene Technology Bill, cl 158(b).
2 As above, cl 159(c) and (d).
3 Noting that this is subject to the Regulator being empowered to impose conditions on any exemption, and to amend or revoke an exemption, see the Gene Technology Bill, cl 163.
4 Containment labelled "Laboratory and Industrial" in original MBIE matrix. Regulation of Gene Technologies – Policy Decisions: Proactive Release of Advice, Regulation of gene technology – second joint ministers meeting, 8 May 2024, p 13.

Activities that are exempt under the Bill and are therefore completely unregulated include:

- any activity involving unguided repair (SDN1).[5,6] This involves breaking the DNA at a targeted site and then letting the DNA randomly repair itself. This repair can introduce small random mutations (substitutions, insertions or deletions) at the targeted position in the DNA. This all happens without the addition of foreign DNA, hence the term "unguided repair"; and may include
- any activity involving guided repair (SDN2). This involves breaking the DNA at a targeted position in the DNA and introducing a template of donor DNA that is used to generate a predicted modification.[7]

These activities could be undertaken by anyone and in any plant, animal or microorganism without the knowledge of the Regulator.

"Non-notifiable" activities will be regulated in the sense that those activities may be required to comply with any requirements for where or how they must be undertaken. However, as there is no requirement to notify them, the Regulator may not receive any information about them and therefore will not have any effective way to ensure that any requirements are being met.

Alignment with other jurisdictions

There are several ways in which the proposed framework is more permissive than other jurisdictions, particularly with respect to exemptions, and the scope of GMO activities for which there will be no regulatory oversight. A table which compares international regimes, previously provided to the select committee, is provided in the Appendix.

Exemptions

As I understand it, exempted techniques (those that are not regulated by the Bill) may modify plants, animals and microorganisms, and could be released into the environment. This is in contrast to other jurisdictions:[8]

- Australia allows exemptions to apply to plants, animals and microorganism (like New Zealand is proposing) but only allows unguided repair (SDN1) modifications to be exempt from regulation. [9] In Australia, guided repair (SDN2) is covered by regulation.
- The United States and England only allow exemptions for plants and animals.
- The European Union is proposing to only allow exemptions to apply to plants. However, they are proposing to allow exempt modifications to include unguided (SND1), guided (SDN2) and genes from within species (SDN3 without foreign DNA) repair. This is similar to Canada.

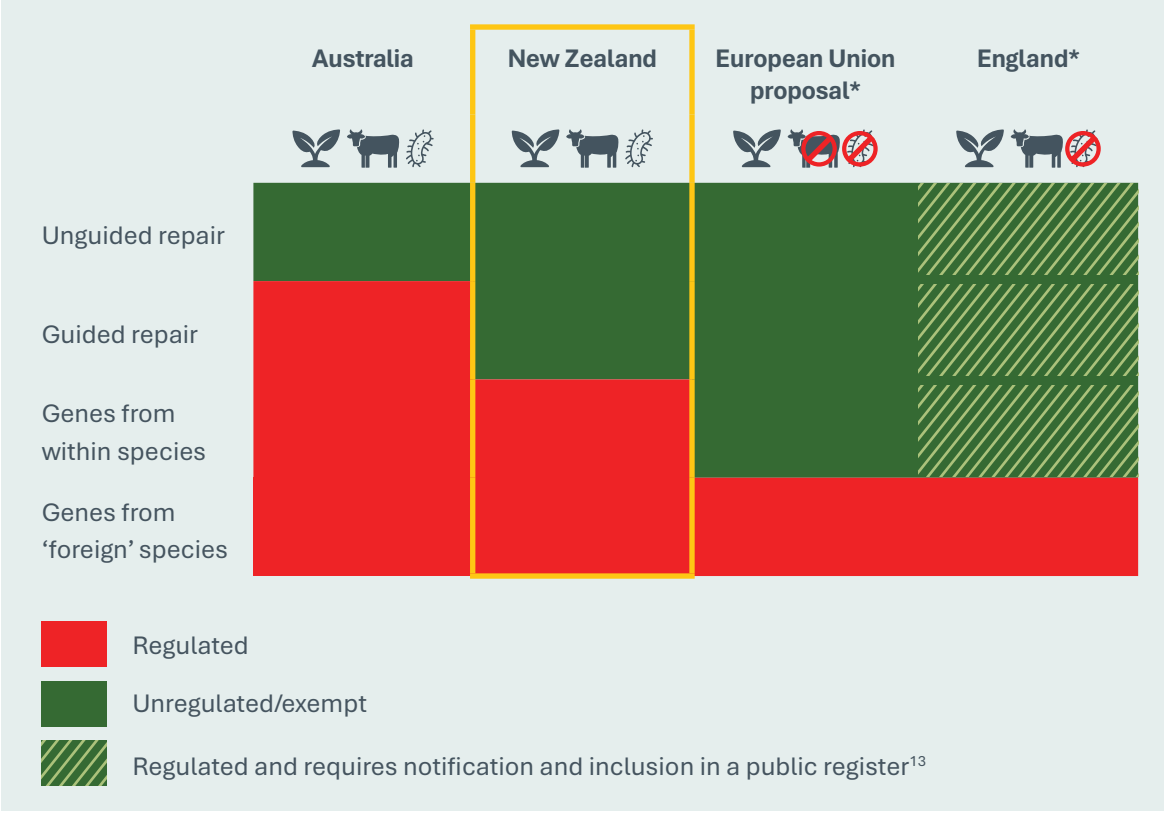
5 See item 4, Schedule 1 of the Gene Technology Regulations 2001 (Aust) as incorporated by cl 163(4)(c)(i).
6 Site directed nucleases (SDN). An enzyme creates site-specific double-strand breaks (DSBs) in the DNA at a defined sequence. Depending on the approach (SDN-1, 2 or 3) different outcomes are possible. SDN-1: following the DSBs, the DNA undergoes spontaneous repair, introducing random mutations (substitutions, insertions or deletions) at the target site, without the addition of foreign DNA (hence 'unguided' repair). SDN-2: following the DSBs, DNA is repaired with template DNA to generate a predicted modification (hence 'guided' repair). SDN-3: following the DSBs, DNA is repaired with the addition of a large stretch of template DNA (can be entire genes). This template DNA could be from within species (cisgenic), or from a 'foreign' species (transgenic).
7 Regulation of Gene Technologies: Policy Decisions, CAB-24-MIN-0296, 12 August 2024, paragraph 14. https://www.mbie.govt.nz/dmsdocument/29939-regulation-of-gene-technologies-policy-decisions-minute-of-decision-proactiverelease-pdf
8 See Appendix 1.
9 See item 4, Schedule 1 of the Gene Technology Regulations 2001 (Aust).

Additionally, the Bill does not limit the number of modifications that can be made with the proposed exempt techniques. Multiple modifications could be made to the genome of plants, animals or microorganisms without them being regulated using techniques, such as multiplexing or serial modifications.

- Multiplexing involves simultaneous modifications of multiple target sites within the genome using techniques such as CRISPR.[10]
- Serial modifications involve performing multiple rounds of editing in the same cells.

In the United States, to be eligible for exemption from regulation, limits are applied to the number of modifications and their distribution in plants.[11] The European Union is proposing similar limits.[12]

Gene-editing techniques



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

Figure 2. Modified from MBIE.[13]

10 Clustered regularly interspaced short palindromic repeats.

11 For example, up to 12 simultaneous (multiplex) or sequential modifications if each modification individually qualifies the plant for exemption and occurs in a different gene. https://www.govinfo.gov/content/pkg/FR-2024-11-13/pdf/2024-26232.pdf

12 https://food.ec.europa.eu/document/download/5a994ff5-153a-4886-a3cc-794512dce27a_en?filename=gmo_biotech_ngt_proposal_2023-411_annex_en.pdf

13 Regulation of Gene Technologies – Policy Decisions: Proactive Release of Advice, Regulation of gene technology – second joint ministers meeting, 8 May 2024, p 14. https://www.mbie.govt.nz/dmsdocument/29940-regulation-of-gene-technologies-policy-decisions-proactive-release-of-advice-proactiverelease-pdf

Modifying the Bill

Based on the above comparison with international regimes, I set out an inexhaustive range of options below for how the Bill might be modified to bring it into closer alignment with other jurisdictions.

Require notification of all activities

Many industry submitters have raised concerns about the inability to trace exempt activities.[14] As the Bill is currently written, it appears that exempt and non-notifiable techniques (and the resulting GMOs) would not need to be recorded in a register maintained by the Regulator. This means that the Regulator will have no oversight of their use, for example, how many GMOs using these techniques are made, and where they are being used. This would include exempt and non-notifiable GMOs that are released into the environment.

Submitters raised specific concerns about the trade and primary industry implications where there is a lack of knowledge about what GMOs will be present in the environment.

Fonterra, DairyNZ and Horticulture New Zealand all suggested that activities that are currently categorised as exempt and non-notifiable should be registered with the Regulator to increase transparency and awareness of the GMO activities that are being undertaken in New Zealand.

Notification, recorded in a public register, of all GMOs increases the available knowledge about the activities being undertaken, and what may be introduced to the New Zealand environment. This would allow the Regulator to follow what modifications are being made and where, and make changes to the regulatory settings where necessary. It would also improve the transparency with which GMO activities are being pursued, thereby reinforcing the confidence of trade, primary industry and public audiences.

The current drafting of clause 58 raises interpretation issues regarding what information is required to be provided for non-notifiable activities, and what is being recorded in the register by the Regulator. Unlike notifiable activities (clause 159), regulations are not empowered to prescribe the information that is to be supplied to the Regulator (clause 158). But clause 58 requires the Regulator to maintain a register with details of all non-notifiable activities (clause 58(1)(e)).[15] It is unclear if the register was intended to just reflect the declarations under clause 47. If all activities were required to notify the Regulator, and be recorded in a register, the information requirements for non-notifiable activities would need to be prescribed.

Restrict exempt status to activities involving SDN1 modifications

Currently both unguided repair (SDN1) and guided repair (SDN2) modifications in plants, animals and microorganisms are exempt from being regulated by the Bill. This would be more permissive than even Australia, where only unguided (SDN1) modifications are exempt.

The exemptions from the Bill's regime could be aligned with Australia and limited to unguided repair (SDN1). This would still permit an unlimited number of those modifications to be made, and remain exempt and unregulated.

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14 Fonterra, DairyNZ, Horticulture New Zealand, Beef + Lamb New Zealand, Federated Farmers, Organics NZ.
15 The declarations are already subject to publications requirements, see Part 3 of the Legislation Act 2019.

Limit the number of modifications allowed if an activity is to be "exempt"

For exempted modifications (unguided SDN1 and guided SDN2 repair), there is an opportunity to use these techniques multiple times to create many small modifications (multiplex and serial modifications). If this was a concern, the Bill could limit the number of these modifications that can be made. This could be along the lines of the limits the United States imposes to be eligible for an exemption from regulation or the proposed EU limits.[16]

Prohibit exempt status for any organisms designed for environmental release

If there is concern regarding environmental risk, and interest in all environmental releases being regulated, the Bill could be changed so that no GMOs intended for environmental release could be eligible for exemption. This could be extended to non-notifiable activities also. It would mean that any environmental release of a GMO was subject to some form of individual risk assessment, dependent on the type of modification activity being undertaken. In my submission on the Bill, I recommended that any risk assessment for release include consideration of New Zealand's unique biota and environment, and any trade implications of the proposed modification.[17]

I note that Fonterra suggested something similar in its submission, suggesting that the select committee should "consider whether it is appropriate to limit non-notifiable activities associated with the agricultural sector to those conducted in containment...".[18] Making environmental releases ineligible for exemption would mirror Australia's current regime, which does not allow exempt dealings to be released into the environment (e.g. cannot involve field trials or commercial releases).[19] This may be changed under Australia's recently proposed amendments.

A trusted gene technology framework

In relation to the broad question of how the regulatory framework of the Bill could be changed to increase trust and confidence in the regulatory regime, MPs were particularly interested in the difference in risk profile between contained modifications and environmental release. In my submission, I discussed several aspects that also influence how the regulatory framework manages risk, which I set out again for Members.

Containment vs. environmental release

Environmental releases of GMOs are likely to be irreversible once released. This suggests a different approach to risk assessment and different risk management from modifications that are made in containment (medical and laboratory). If the differences can be identified, these could be specified in the Bill, establishing two pathways for risk assessment for, and management of, GMO activities. This legislative design could also incorporate prescribed

16 United States: For example, up to 12 simultaneous (multiplex) or sequential modifications if each modification individually qualifies the plant for exemption and occurs in a different gene. https://www.govinfo.gov/content/pkg/FR-2024-11-13/pdf/2024-26232.pdf. European Union: https://food.ec.europa.eu/document/download/5a994ff5-153a-4886-a3cc-794512dce27a_en?filename=gmo_biotech_ngt_proposal_2023-411_annex_en.pdf

17 PCE, Submission on the Gene Technology Bill, 17 February 2025, page 5-6. https://pce.parliament.nz/media/utlfviyc/submission-on-the-gene-technology-bill_final-17-feb.pdf

18 Fonterra Gene Technology Bill Submission, paragraph 38(a). https://view.publitas.com/fonterra-comms/fonterra-submission-gene-technology-bill/page/6–7

19 https://www.ogtr.gov.au/work-gmos/about-approval-process/types-gmo-dealings#dealings-involving-intentional-release-of-a-gmo

criteria that must be applied in the approach to risk assessment and management. As currently drafted, the Bill leaves these matters to secondary legislation.

As I have noted above, undertaking an assessment of biota and environments unique to New Zealand as well as any trade implications of environmental releases would be key criteria for determining whether the risks of those releases can be appropriately managed. I suggest that reliance on 'recognised overseas authorities' might also be limited for environmental releases. Overseas regulators will not be looking at the impact a genetic alteration might have directly or indirectly on New Zealand's indigenous species or those biological products we export. While international assessments may be informative, they should not be the sole source of information relied on for a release into New Zealand's environment. I discuss this in further detail in my submission and note that other submitters have also made this point.[20]

In contrast, specific assessment of impacts to the environment or trade may not be required to be as detailed for any GMO activities in contained facilities (laboratory uses) or medical uses as their likelihood of release into the environment is much more limited.

Another option is to require an assessment of modifications made in an organism prior to environmental release. This would impose an obligation for modifications to be first made and tested within contained facilities to determine that the desired modification has in fact been made, and that no unexpected and deleterious off-target modifications have been made elsewhere in the genome. It is beyond the expertise of my office to determine whether this is biologically feasible for all modifications.

Other aspects that relate to risk management

I address the following points in detail in my submission, but as elements of the Bill that could be changed to improve trust and confidence in the regulatory regime, I briefly set them out again here.

Ministerial influence. For the independence of the gene technology regulator to be credible, the ability for the Minister to impose general policy directions should be removed, and matters on which the Regulator cannot be directed should be specified. In contrast, the Australian regime provides only a very narrow power for the Ministerial Council (combining Federal and State Ministers) to issue policy principles. [21] As I understand it, only one has ever been issued. The Australian Regulator is also truly independent, unlike New Zealand's proposed regime where the Regulator is accountable to the Minister.

Review of the Regulator's decisions. In addition to those persons identified in Schedule 3, any person who has an interest in the decision, that is greater than that of the general public, should also be able to request a review of the Regulator's decision.[22]

Civil liability. Provisions to address civil liability, similar to those in the Hazardous Substances and New Organisms Act, could be added to the Bill.

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20 Fonterra, DairyNZ and Horticulture New Zealand all stated that, taking into account the New Zealand context (unique environmental biodiversity, social and cultural fabric, economic context, importance of primary industries and related trade, and economy), are all risks that should be specifically addressed.

21 Gene Technology Act 2000 (Cth), ss 21–23. The Ministerial Council consists of one member of the Federal government, and one member from each State and Territory governments.

22 As above, s 30.

Appendix 1. Table from the PCE Gene Technology Submission[23]

Country	Regulatory approach	Terminology	Exemptions for some techniques/ pre-market assessment?	Criteria for exemption	Applies to
New Zealand (proposed)	Hybrid – with risk matrix framework	Regulated organism	Yes	Unguided (SDN-1) and guided repair (SDN-2)	Animals, plants, microorganisms 
Australia (current)	Hybrid – with contained dealings and dealing involving intentional release	GMO[24]	Yes	Unguided repair only (SDN1). Exempt dealings cannot be released into the environment (e.g. cannot involve field trials or commercial releases)	Animals, plants, microorganisms 
Australia (proposed)	Hybrid – risk tier framework. No categorisation of dealings as 'contained' 'involving intentional release' or 'clinical trials and medical applications'	GMO[25]	Yes	Unguided repair (SDN1)	Animals, plants, microorganisms 
European Union (current)	Process based	GMO[26]	No	N/A	GMO assessment framework applies to all organisms or food products
European Union (proposed)	Hybrid	GMO	Yes	Unguided (SDN-1), guided (SDN-2) and genes from within species repair (SDN-3 without foreign DNA); specified maximum number of genetic modifications compared to parent plant (proposed no more than 20 genetic modification)[27]	Plants 

23 Adapted from https://www.mbie.govt.nz/dmsdocument/29940-regulation-of-gene-technologies-policy-decisions-proactive-release-of-advice-proactiverelease-pdf ; https://www.foodstandards.gov.au/sites/default/files/2024-07/P1055%20Supporting%20document%201%20Updated%20compilation%20of%20regulatory%20approaches.pdf ; https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/P1055%20SD3%20Regulatory%20approaches%20and%20definitions.pdf

24 https://www.legislation.gov.au/C2004A00762/2016-07-01/text

25 https://consultations.health.gov.au/best-practice-regulation/amendments-to-the-gene-technology-act-200/supporting_documents/Gene%20Technology%20Act%202000%20future%20law%20compilation%20taking%20into%20account%20the%20Gene%20Technology%20Amendment%20Bill%202024.pdf

26 Directive 2001/18/

27 https://food.ec.europa.eu/document/download/5a994ff5-153a-4886-a3cc-794512dce27a_en?filename=gmo_biotech_ngt_proposal_2023-411_annex_en.pdf

Country	Regulatory approach	Terminology	Exemptions for some techniques/ pre-market assessment?	Criteria for exemption	Applies to
England	Hybrid	Precision bred organism[28]	Yes	Unguided (SDN-1), guided (SDN-2) and genes from within species repair (SND-3 without foreign DNA)	Plants, vertebrate animals 
United States	Product based	GMO, bioengineered	Yes	Specific criteria (see[29]); for example, unguided repair (SDN-1), single base pair substitution, introduces gene known to occur in plant's gene pool, up to 12 simultaneous (multiplex) or sequential modifications if each modification individually qualifies the plant for exemption and occurs in a different gene	Plants, animals 
Canada	Product based	Novel foods/ plants with novel traits	Yes[30]	Absence of foreign DNA in final plant product; no new or increase in toxins, allergens, and antinutrients; no compositional changes; no new food use	Plants 
China	Unknown	Gene-edited[31]	Unclear how rules will apply	Techniques classified into risk categories, unsure as to further detail	Plants 
Argentina	Product based	GMO[32]	Yes	Absence of new combination of genetic material in NBT organism/final product free of transgenes	Animals, plants, microorganisms 

28 https://www.legislation.gov.uk/ukpga/2023/6/pdfs/ukpga_20230006_en.pdf.
29 https://www.govinfo.gov/content/pkg/FR-2024-11-13/pdf/2024-26232.pdf
30 Exclusion from regulation as "novel foods", not GMOs.
31 From unofficial translation: https://www.fas.usda.gov/data/china-mara-issues-first-ever-gene-editing-guideline.
32 https://www.food.gov.uk/sites/default/files/media/document/comparing-international-approaches-to-food-safety-regulation-of-gm-and-novel-foods_0.pdf