CropLife Australia

February 2025

Gene Technology Bill

Select Committee Submission

Executive Summary

- **Opportunity for Modernisation**: The New Zealand Government should be commended for the rapid development of a robust regulatory proposal that will ensure New Zealand farmers, health practitioners, researchers, and the broader public have access to all of the biotechnology innovations needed to support New Zealand wellbeing and prosperity.
- **Risk-Proportionate Regulation**: CropLife supports New Zealand's proposed Gene Technology Bill 2024 (the Bill) approach to establish a science-based regulatory framework providing a tiered approach to gene technology risk-proportionate assessment, including the proposal to exempt certain organisms (such as the products of gene editing) from regulation. We would like to see this harmonised with global regulatory best practices in this field.
- **Trans-Tasman Harmonisation**: The proposed framework is closely modelled on Australia's system, which has provided over two decades of safe and effective gene technology oversight, and takes advantage of the comprehensive, but yet to be implemented, Australian review.
- **Emerging Global Leader**: By integrating Australia's experience and learnings from international systems, New Zealand has the opportunity to leap ahead globally with a modern, science-based and risk-proportionate regulatory model.
- **Subordinate Regulations**: Much of the Bill's operational detail will be in the subordinate Gene Technology Regulations (the Regulations), which are yet to be released. Improved direction from Government on how the regulatory scheme will operate and amendments that provide greater clarity to industry about the scope of the scheme will assist in reducing uncertainty and increase investment.
- **Regulator Independence**: The Bill establishes a new independent Gene Technology Regulator (the Regulator), appointed by the Minister but employed within the NZ Environmental Protection Authority (EPA), which is intended to provide independent oversight. The Bill should be further strengthened to ensure the independence of the new regulator.
- **Limits on Synthetic Nucleic Acids**: The Bill specifically regulates "synthetic nucleic acid", with no minimum size threshold. While aimed at preventing misuse, this may have unintended consequences for routine research, standard diagnostic testing, and product development, and should therefore be reconsidered.

Key Recommendations

- Amendments to the definitions of “Gene technology” and “regulated organisms” should be made to ensure technologies that result in organisms and products indistinguishable from conventional breeding are exempt.
- Duplication of risk assessments between regulatory schemes should be removed or at the very least minimised.
- Restrictive provisions on the import and use of synthetic nucleic acids should be removed from the Bill.
- Further guidance on the operation of the Regulations, should be provided as soon as possible to inform stakeholders on how the framework will operate.
- Provisions facilitating the Regulator to initiate and/or guide updates to the Gene Technology Regulations, such as exemptions of specific techniques or products, would help to ensure risk-proportionate regulatory agility.
- Further independence should be provided for the Gene Technology Regulator, including risk assessors and enforcement officers.

1. Introduction

CropLife Australia (CropLife) is the national peak industry organisation representing the plant science sector, including biotechnology, in Australia. CropLife represents the innovators, developers, manufacturers, formulators and suppliers of crop protection products (organic, synthetic and biologically based pesticides) and agricultural biotechnology innovations. CropLife's membership is made up of both large and small, patent holding and generic, companies. Accordingly, CropLife advocates for policy positions that ensure the agricultural sector that is internationally competitive through globally leading productivity and sustainability, both of which are achieved through access to world-class technological innovation and products of the plant science sector.

CropLife welcomes the opportunity to comment on the proposed Gene Technology Bill 2024 (the Bill). New Zealand (NZ) has long maintained some of the most restrictive provisions on gene technology—provisions that, while originally designed to uphold a "clean and green" reputation, now restrict research, and risk impeding innovation as well as global market access. Recent decades have seen major advancements in biotechnology, demonstrating the safe and effective use of gene technology in agriculture, healthcare, and research.

In this context, we commend the NZ Government for taking proactive steps to modernise the nation's regulatory approach. By proposing a tiered, science-based framework for assessing the potential risks of gene technology, the Bill seeks to ensure farmers, health practitioners, researchers, and the broader public have access to valuable tools and products that can advance New Zealand's wellbeing and prosperity.

CropLife is proud to be the Trans-Tasman Industry Partner of BIOTechNZ. Moreover, we have a long history of working with a diverse group of New Zealand stakeholders. CropLife is supportive of the proposed framework but has included several refinements and critiques herein. We look forward to working with policymakers and stakeholders to refine and implement a framework that supports science-led innovation, safeguards public trust, and positions New Zealand as a leader in the responsible beneficial application of modern gene technologies.

2. The Framework

The New Zealand Government was elected with a commitment to modernise their gene technology regulatory framework. The release of the Bill is a major step in this process. As noted, the proposed framework is heavily influenced by the Australian National Gene Technology Scheme which takes advantage of an effective and established regulatory system. In addition, along with the Bill, the NZ Government released a Regulatory Impact Statement (RIS) that provides guidance on the intention of the new framework.

The New Zealand framework will also heavily rely on subordinate legislation in the form of the Gene Technology Regulations (the Regulations). However, to date, these regulations have not been released. Although their absence limits stakeholder feedback and engagement in this process, CropLife appreciates that the RIS does provide some guidance as to the exceptions. For example, the removal of regulation from "certain gene editing techniques that are indistinguishable from conventional developed techniques".[1]

The proposed regulatory model, a hybrid-based approach, would focus on a regulatory trigger for regulation of the risk to human health or the environment regardless of whether that risk stems from the process itself or the outcome.[2] This is an intermediate position between a purely process-based approach, where all of a given technology or technique is regulated regardless of the final product, or a purely outcome-based approach, where regulation focuses on the final organism or product (i.e. does this product contain novel DNA).

With the correct settings, the proposed hybrid model holds promise to deliver on the Government's elected mandate. If the regulatory trigger is to be a specified process, it is important for this hybrid model to incorporate appropriate measures to ensure risk proportionate regulatory assessment/data requirements in order to avoid unnecessary regulatory burden. This will ensure the flexibility to quickly address new scientific consensus and international regulatory approaches.

2.1 The Australian System

The proposed NZ framework mirrors many aspects of the Australian system, which is lauded for its science-based approach and risk-tiered regulatory structure, however, the Australian National Gene Technology Scheme is over two decades old. It is important to note that the Third Review of the National Gene Technology Scheme was commenced in 2017, with the final report released 2018.[3] Even if implemented in full, this review is now almost seven years old.

By following the Australian system too closely, NZ risks remaining behind more progressive jurisdictions. Whereas, by contrast, the adoption of a more outcome-based and flexible system, supported by decades of empirical data, would allow NZ to emerge as a leader in innovation.

2.2 Rejection of An Outcome-Based System

Although the proposed model marks a considerable improvement, dismissing a purely outcome-based approach was a missed opportunity to establish a genuine future

[1] Ministry of Business, Innovation and Employment, 'Regulatory Impact Statement: Reform of Gene Technology Regulation', 2024, para 171 ('MBIE RIS').
[2] Ibid.
[3] Commonwealth of Australia, *The National Gene Technology Scheme* (Website, Accessed January 2025).

proofed regulatory system and ensuring the benefits of biotechnology to NZ. While this aligns with the Australian position, it does not reflect more modern approaches such as those in Brazil, Canada, Chile, or the UK.

The justification for rejecting an outcome-based approach remains unclear. It is not evident why this system would be "unable to regulate any high-risk gene technology processes that may develop in the future"[4] or how it would have the effect of "inhibiting established innovative research and development"[5]. On the face of it, one might expect that an outcome-based approach would be agnostic to new gene technology processes and focusing on actual risk and reducing overregulation. Greater clarity from regulators is essential to understand these assertions and ensure the most effective model is adopted.

Adopting an outcome-based framework would position NZ as a global leader in biotechnology and reflect a risk-proportionate regulatory system. However, we acknowledge that at this point in time such an approach would add complexity and time to the development of a new framework. Appropriate formulation of the Regulations can support a risk-proportionate approach that is comparably agnostic of the processes used.

3. Regulatory Impact Statement

3.1 Risk Assessment

It is concerning that even after four decades of GM-derived insulin, three decades of GM crop cultivation, billions of GM vaccine doses, and a rapidly emerging wealth of novel therapeutics, the RIS overstates the risks of gene technology.[6] All actions, processes, and technologies pose potential risks and, when appropriate, these risks are mitigated by robust science-based regulatory frameworks. Using inflammatory language in the RIS adds little to the discourse other than to encourage the ongoing spread of misinformation.

3.2 Proposed Exemptions

Annex A of the RIS outlines the operation, including examples of excluded technologies, of the proposed regulatory framework.[7] Non-regulated technologies include gene editing techniques producing results indistinguishable from those achievable through conventional breeding[8], null segregants, RNA interference, mutagenesis and protoplast fusion. Although a purely outcome-based regulatory system better reflects a risk-proportional framework, the exemption of these technologies will support innovation in the NZ's biotechnology sector. It will be important that these are appropriately captured

[4] MBIE RIS, para 156.
[5] Ibid, para 155.
[6] Ibid, paras 50-53.
[7] Ibid, Annex A.
[8] Listed examples include non-browning mushrooms, GABA tomatoes, and disease-resistant crops.

in the Regulations to reflect the reality of modern breeding practices introducing genetic variation into our food crops.

4. The Bill

4.1 Proposed Definitions

Recommendation: The definitions outlining the scope of the regulatory framework should exempt technologies and organisms that are indistinguishable from those developed through conventional breeding.

The NZ Bill proposes broad and undiscerning definitions for "gene technology" and "regulated organisms" that will capture many low-risk gene technologies. The proposed definitions omit exemptions for mutagenesis, gene editing indistinguishable from conventional breeding, and null segregants. Although the framework permits lower-risk technologies with verified safety outcomes to be exempt in the future, it still imposes strict requirements on organisms that neither present any greater risk than conventional breeding nor can be distinguished from conventionally bred counterparts. These should be excluded from regulation at the scheme's outset.

As such, the approach will not deliver a risk-proportionate regulatory system and could impact the investment certainty that will support the full benefit of gene technology to NZ. A preferred approach would be to follow the regulatory posture developed by Food Standards Australia and New Zealand as part of proposal P1055. We would recommend that the definitions be altered to reflect this. For example (underlining denotes addition):

> ***gene technology***—
>
> *(a) means any technology used to modify or construct genes or other genetic material; but*
>
> *(b) does not include—*
>
> *(i) conventional processes; or*
>
> *(ii) induced mutagenesis wherein genetic changes are cause by*
>
> *a. radiation; or*
>
> *b. chemical exposure; or*
>
> *c. directed nuclease where nucleic acid template was not added to guide homology.; or*
>
> *(iii) introduction of RNA into an organism, if:*
>
> *a. the RNA cannot be translated into a polypeptide; and*
>
> *b. the introduction of the RNA cannot result in an alteration of the organism's genome sequence; and*
>
> *c. the introduction of the RNA cannot give rise to an infectious agent.; or*
>
> *(iv) any other technology specified in the regulations for the purposes of this paragraph*[9]

[9] Gene Technology Bill 2024 (NZ), s 7 ('GT Bill').

regulated organism—

(a) means—

(i) an organism that has been modified or constructed by gene technology; or

(ii) an organism that has inherited (from the host organism) genes or genetic material that occurred in the host organism because of gene technology; or

(iii) an organism or a category of organisms declared by regulations to be regulated organisms; but

(b) does not include—

(i) an organism that is descended from a genetically modified organism (the initial organism), if none of the traits it has inherited from the initial organism are traits that occurred in the initial organism because of gene technology; or

(ii) an organism that was modified by gene technology but in which the modification, and any traits that occurred because of gene technology, are no longer present; or

(iii) an organism or a category of organisms declared by regulations not to be regulated organisms; or

(iv) a human being[10]

The Bill's definition of 'conventional processes' includes 'natural homologous recombination', but the word natural is undefined and is not included in the Australian context. Reference to natural in this context should be removed.

The use of 'regulated organism' potentially misleads the reader into assuming uncaptured organisms will be unregulated. Even if a given product is not capture within the scope of the Bill, New Zealand has a comprehensive regulatory environment, including frameworks that regulation medical treatments, food safety, chemical use, and environmental impact. Thus, actions and organisms will always be regulated. A better term might be 'designated organism' or 'scheduled organism'.

4.2 The Bill Supports NZ's International Obligations

Recommendation: The adherence to international agreements, requiring individual interpretation, should be removed. If a provision is needed, formulation should reflect that used for the Treaty of Waitangi (section 4).

Section 5 of the Bill requires that:

Decision makers must have regard to Convention on Biological Diversity including Cartagena Convention

The Regulator and every other person who carries out a function or duty or exercises a power under this Act, must when doing so, have regard to the provisions of—

(a) the Convention on Biological Diversity; and

(b) the Cartagena Protocol.[11]

[10] Ibid.

[11] Ibid, s 5.

New Zealand is a party to the Convention on Biological Diversity and the Cartagena Protocol and as such will follow their provisions. While the NZ gene technology regulatory framework will no doubt reflect their obligations, the formulation of this provision is too broad. The RIS rightly notes that the current restrictive application of the precautionary principle in existing system is no longer fit for purpose.[12] Every aspect of the Rio Declaration formulation of the precautionary approach, and referred to in the Cartagena Protocol, is very widely interpreted.[13] Requiring that anyone operating under this proposed Act regard these international instruments potentially leaves their interpretation to individuals, and subsequently the courts if decisions are challenged. Importantly, the Regulator's obligations to ensure compliance with the Convention on Biological Diversity and the Cartagena Protocol are covered elsewhere in the Bill.[14]

Removing this section would provide stakeholders with greater clarity and avoid arbitrary or evolving interpretations of these instruments. Failing the removal of the section, we would suggest that it be reworded to read:

> *This Act recognizes and respects the Crown's obligations under the principals of the Convention on Biological Diversity including Cartagena Convention.*

This formulation would align with those provisions in section 4 of the Bill.

4.3 Synthetic Nucleic Acid

Recommendation: The synthetic nucleic acid provisions should be removed from the primary legislation. If a clear need is identified, and their effectiveness demonstrated, their inclusion would be more appropriate in secondary legislation.

Although partially redacted, the RIS outlines a potential risk arising from synthetic nucleotides.[15] As synthesis technology improved, the cost per nucleotide decreased and the maximum length increased. This led to recognition that a pathogen could be potentially assembled via the combining of numerous pieces of synthetic nucleic acid. It is critical to acknowledge that the synthesis of nucleic acid, especially in the form of oligonucleotide primers for polymerase chain reaction (PCR), is the backbone of molecular biology. Its global importance was seen recently in the ability to rapidly test for (and sequence) SARS-CoV-2 (COVID-19) which maintained ongoing accuracy via the development of new oligonucleotide primers as the virus mutated.[16] These PCR-based diagnostic tests are used in highly diverse human/animal health, conservation, and

[12] MBIE RIS, paras 35-36.
[13] See, eg, Jacqueline Peel, '*Precaution - A Matter of Principle, Approach or Process?*' (2004) 5(2) *The Melbourne Journal of International Law*.
[14] GT Bill, s 110(e).
[15] MBIE RIS, paras 241-255.
[16] For a brief overview from early in the pandemic see Park, M., Won, J., Choi, B.Y. et al. *Optimization of primer sets and detection protocols for SARS-CoV-2 of coronavirus disease 2019 (COVID-19) using PCR and real-time PCR*. *Exp Mol Med* 52, 963–977 (2020). 'https://doi.org/10.1038/s12276-020-0452-7'

biotechnology applications. As such, the health and wellbeing of New Zealand depends on the ability to rapidly import synthetic nucleic acids.

The prominent discussion of this issue in the RIS is not risk proportionate. The risks posed by this application of technology are limited and any restrictions are unlikely to be effective in their mitigation while adding a potentially dangerous burden to NZ health workers, conservationists and researchers.

The Bill designates synthetic nucleic acid as a control point, with provisions throughout facilitating limitations and enforcement on their creation, importation, and use.[17] It is defined broadly as (underlining emphasis added):

> ***synthetic nucleic acid***—
>
> *(a) means molecules, <u>of any sequence length,</u> that have been constructed outside living cells by joining nucleic acid molecules; and*
>
> *(b) includes—*
>
> *(i) DNA and RNA, whether single- or double-stranded; and*
>
> *(ii) whole-organism genomes (for example, viruses or bacteria)*[18]

Without a size limit, this definition may inadvertently capture all synthetic oligo primers used in PCR screening, creating significant barriers for research and diagnostics. Unfortunately, the Bill provides little guidance on the operation of these synthetic nucleotide provisions. The RIS notes that any supplier requirements would align with those of the US or UK to minimise administrative burden.[19] However, it is unclear what this would entail.

New Zealand is a participant in a multilateral export control regime, The Australia Group, that regulates dual-use biological equipment, technology and software.[20] It should also be noted that the International Gene Synthesis Consortium serves as an industry-led organisation ensuring the screening and safety of DNA synthesis and developed the Harmonized Screening Protocol.[21] Additionally, the iGEM Responsibility program provides a framework, education and meetings to address risks associated with synthetic nucleotides.[22]

It would be better if the provisions relating to synthetic nucleic acids were removed from the Bill. If greater oversight is required, this should be undertaken through international mechanism such as the Australia Group.

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[17] GT Bill, ss 65, 69, 83, 100, 112, 149, & 157.
[18] Ibid, s 7.
[19] MBIE RIS, para 247.
[20] Government of Australia, *The Australia Group* (Website, accessed February 2025) 'https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/index.html'
[21] International Gene Synthesis Consortium, *Harmonized Screening Protocol v2*.0 (Protocol, 2017) 'https://genesynthesisconsortium.org/wp-content/uploads/IGSCHarmonizedProtocol11-21-17.pdf'
[22] iGEM Foundation, iGEM Responsibility (Website, Accessed February 2025) 'https://responsibility.igem.org/'

4.4 Reducing Duplication

Recommendation: The framework should support the removal of inter-agency regulatory duplication and facilitate domestic collaboration.

Recommendation: Further strengthen the provisions around international collaboration on risk assessments.

Regulatory duplication serves as a significant barrier to an efficient and cost-effective regulatory framework. Section 20 of the Bill permits joint applications to the Gene Technology Regulator, for applications under this proposed Act, and the EPA, for applications under the *Hazards Substances and New Organisms Act 1996* (the HSNO Act). This acknowledgement should be extended to other potential regulatory intersections ensuring that assessments are not duplicated and undertaken by the most appropriate agency. An example of this collaboration was seen recently in Australia between the Office of the Gene Technology Regulator (OGTR) and Food Standards Australia New Zealand (FSANZ) on the first genetically modified banana.[23]

Although there may be NZ-specific risks relating to environmental assessment for a given application, there remains considerable potential for international collaboration on risk assessment. A successful trial of this has been undertaken between FSANZ and Health Canada for foods derived from gene technology.[24] Moreover, given the similarities to the Australian system, and building on the success of FSANZ as a multi-jurisdictional agency, there is considerable scope for highly integrated Trans-Tasman gene technology assessments.

Critically, the Bill supports international collaboration and the possibility of sharing risk assessments.[25] Strengthening of these provisions has the potential to streamline product approvals by allowing a single application for multiple countries.

4.6 The Regulator

Recommendation: Support the independence of the regulator by providing dedicated staff (including enforcement officers), support, and funding.

Recommendation: Provide additional guidance and oversight on Ministerial policy directions.

It is paramount that the operation of any regulator be independent and free from politicisation. Although the provisions in the Bill establishing the regulator are

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[23] Office of the Gene Technology Regulator, *DIR 199: Commercial release of banana genetically modified for resistance to Fusarium wilt tropical race 4 (TR4*) (Website, Accessed January 2025)
[24] Food Standards Australia New Zealand, *Health Canada-FSANZ Shared Assessment Process: Information for Applicants* (Website, Accessed January 2025) 'https://www.foodstandards.gov.au/consumer/gmfood/health-canada-fsanz-shared-assessment-process'
[25] GT Bill, ss 57, 153 & S28(b)(i).

somewhat similar to those of the Australian Gene Technology Regulator, it appears that rather than an independent office with their own federal budget allocation, they will be supported by the NZ Environmental Protection Agency (EPA).[26] The Bill requires the Regulator to act independently from the EPA and the Minister[27]. However, the Bill also requires that "[t]he person appointed must be an employee of the EPA"[28] and that they are also subject to general Ministerial policy directions[29].

The RIS explored where to house the Regulator, primarily a choice between establishing it as part of the EPA or as a separate unit within the Ministry of Business, Industry & Employment (MBIE). Concluding that within the EPA poses the best cost-benefit. Assuming independence can be assured, either decision may be acceptable. The EPA, as the current administrator of the HSNO Act, has the best expertise and stakeholder relationships to support the Regulator. Moreover, the EPA has previously attempted to further risk-proportionate regulation under the HSNO Act.

However, the Bill's failure to prescribe dedicated staff or budgetary allocation[30] to the Regulator undermines any true independence between the Regulator and the EPA. In fact, the Bill requires the EPA to provide administrative support to the Regulator. Given these provisions it is difficult to see how effective independence will be maintained.

Although delimitation between these general directions and specific matters are drawn within the Bill[31], interference that removes independence can extend well beyond single matters. In addition, it should be noted that under the Australian system such policy directions come from the Ministerial Council[32], but before issuing a policy principle, appropriate consultation needs to be undertaken.[33]

[26] Ibid, s 108(5).
[27] Ibid, s 111(1)(a).
[28] Ibid, s 150(4).
[29] Ibid, s 111(1)(b).
[30] Once again, it should be clearly noted that within Australia the OGTR has a dedicated appropriation account within the Department of Health and Aged care budget papers.
[31] GT Bill, s 111(2).
[32] Although referred to as the Ministerial Council in existing legislation, this body has been replaced by the Gene Technology Minister's Meeting – 'https://www.genetechnology.gov.au/about-the-national-scheme/how-it-works/ministers-meeting'.
[33] *Gene Technology Act 2000* (AU), ss 21 & 22.

4.7 Enforcement

Recommendation: Enforcement should be primarily undertaken by dedicated personnel under the supervision of the Regulator.

Recommendation: Enforcement triggers or oversight should come from the Regulator.

Under the Bill, gene technology enforcement is tied to the same agency and officers responsible for enforcement under the Biosecurity Act 1993. [34] However, this arrangement raises potential concerns:

- Existing Burdens on Biosecurity Officers: Biosecurity officers already manage significant responsibilities, including quarantine, pest control, and border security. Adding gene technology enforcement could stretch resources thin and delay responses.
- Specialist Expertise: Gene technology regulation requires a high level of scientific and technical knowledge. Without specialised training or dedicated personnel, enforcement actions may lack consistency and rigour.
- Ongoing Coordination: Effective enforcement depends on continuous communication between investigators and the Regulator. If enforcement remains separate from the Regulator's office, vital information-sharing could be slow or inconsistent, undermining the system's integrity.

Under the Australian system, the Regulator holds primary authority for enforcing compliance. Although broad provisions exist, generally inspectors operate under the Regulator's supervision, ensuring a clear and consistent chain of command, receive specialised training in gene technology, enabling them to handle technical assessments and nuanced compliance issues, and work in close coordination with the OGTR, streamlining investigative processes and maintaining a science-led approach to enforcement. This model facilitates a risk-proportionate, agile, and robust enforcement system. By contrast, merging gene technology with existing biosecurity enforcement in New Zealand could dilute both focus and expertise. Moreover, it potentially conflates GMOs with biosecurity risks.

The NZ Regulator needs to be supported for appropriate enforcement. To achieve this, adequate funding and training for enforcement personnel should be provided to the Regulator. In addition, greater clarification is needed relating to enforcement triggers. The enforcement should be guided by the Regulator, based on monitoring, reports, and risk assessments. Finally, reviewing any overlaps with biosecurity enforcement would help prevent delays, confusion, or under-resourcing.

[34] GT Bill, s7.

4.8 Supporting Committees

Recommendation: With respect to both committees, clarification regarding their size, the extent of their powers, and how their advice interacts with the Regulator's final decisions is needed.

The Bill establishes the Technical Advisory Committee[35] and Māori Advisory Committee[36]. In both cases the Regulator must have regard to the advice given by these committees. However, the extent of that obligation is unclear. Specifically, guidance should be provided on:

- Committee Powers and Procedures
    - Size: How many members will each committee have?
    - Decision-Making Authority: Do the committees only advise, or can they effectively direct certain outcomes?
- Interaction with the Regulator's Decisions
    - Binding vs. Non-Binding: Does the Regulator retain ultimate discretion, or can a committee's recommendations override a draft decision?
    - Conflict Resolution: What happens if the committees' advice conflicts with each other or with the Regulator's assessment?
    - Public Transparency: Will the Regulator be required to publicly respond to committee advice, and if so, how? Will committee advice be publicly released?

Providing explicit details on the size, composition, authority, and procedural protocols of both the Technical Advisory Committee and Māori Advisory Committee will reinforce confidence in the Bill. Ideally, their advisory role should be clearly delineated, allowing the Regulator final decision-making authority while ensuring key stakeholder and cultural perspectives are respected.

4.9 The Regulations

Recommendation: Further guidance on the operation of the subordinate legislation, the Gene Technology Regulations, should be provided as soon as possible to inform stakeholders on how the framework will operate.

Recommendation: Provisions facilitating the Gene Technology Regulator to initiate and/or guide updates to the Gene Technology Regulations, such as exemptions of specific techniques or products, would help to ensure risk-proportionate regulatory agility.

Sections 155 – 167 of the Bill outline the purpose, operation, and development of the subordinate Gene Technology Regulations (Regulations). These Regulations will supply

[35] Ibid, s 113.
[36] Ibid, s 120.

the practical details that shape day-to-day compliance obligations, licence requirements, and any exemptions for low-risk technologies.

CropLife welcomes the Bill's recognition that not all updates to the Regulations warrant full public consultation.[37] By allowing a more flexible approach—where substantial changes would still undergo consultation, but minor or technical adjustments may proceed faster—the Bill supports regulatory agility.

Despite this flexibility, clarity is needed on how and by whom regulatory updates can be initiated. A mechanism allowing the Regulator to recommend or trigger amendments would help ensure the scheme remains current with scientific advances. If the Regulator lacks this power, necessary improvements or exemptions could be stalled by bureaucratic hurdles or ministerial backlog.

CropLife appreciates the indicative guidance provided so far, such as the reference in Annex A of the Regulatory Impact Statement (RIS) to exempt certain technologies (e.g., gene editing techniques producing results indistinguishable from those achievable through conventional breeding[38], null sergeants, RNA interference, mutagenesis and protoplast fusion) from regulation as a GMO in NZ.[39] This indicates a move toward exempting genuinely low-risk activities, aligning with international best practices.

In should be considered if the Regulations should be disallowable. Although such restrictions are uncommon, achieving a stable regulatory framework must be a priority. Parliamentary concerns with the gene technology framework, can be addressed at the legislative level.

However, without the full text of the Regulations, stakeholders cannot form a comprehensive assessment of the Bill's practical impacts. Thus, further clarity on the subordinate Gene Technology Regulations is essential to understanding the Bill's real-world implications.

4.10 Cost Recovery

Recommendation: Suspend implementation of cost recovery until the effective operation of the framework is demonstrated and the impact of any such provisions can be assessed.

Cost recovery provisions can help ensure sustainability of regulatory administration, but they must also support innovation, avoid imposing excessive burdens on the biotechnology sector, and be commensurate with the level of activity that is undertaken. In addition, risk assessment duplication needs to be addressed prior to the implementation of cost recovery. The NZ biotechnology sector is still comparably small

[37] Ibid, s 167.
[38] Listed examples include non-browning mushrooms, GABA tomatoes, and disease-resistant crops.
[39] MBIE RIS, Annex A.

and lacking diverse international investment. While NZ presents many attractive prospects for biotechnology, there is strong global competition for investment. Just as overregulation limits investment, so does a high cost of operation. As such, a careful balance must be achieved.

The Bill states that the direct and indirect costs, NOT funded by the Crown, will be recovered through fees, charges and levies.[40] The Bill also outlines guiding principles on the matter that, amongst other things, establish that any costs be commensurate with the benefit derived from a given service.[41] This is an incredibly difficult to determine and may not be apparent at time of application. Moreover, this might serve to discourage innovative products or pilot studies.

It is important to note that even after two decades of operation in Australia, cost recovery has not been undertaken. Frequently, the negative impact of such provisions on innovation, the introduction of novel products, and domestic research has been highlighted.

It is critical that adequate funding be provided for the administration of the Act, especially early on, to help support the growth of the biotechnology sector and foster innovation. CropLife recommends that clear guidance be provided, indicating that cost recovery will not be implemented until the framework is operating efficiently and the impacts of any such provisions can be assessed.

5. New Zealand Biotechnology Policy

Ongoing policy discussions in NZ are often clouded by misinformation. Notably, some anti-biotechnology claims date back to the 1990s and, despite being widely debunked, continue to persist in activist rhetoric.[42]

5.1 Market Segregation

An ongoing concern for NZ's biotechnology policy is the potential for market segregation resulting from the coexistence of conventional, organic, and GM products. While some stakeholders maintain an unsupported argument that maintaining a GM-free status ensures access to certain niche markets, this approach hinders broader agricultural innovation and competitiveness.

Global examples demonstrate that effective coexistence strategies—such as buffer zones and labelling—can mitigate risks and enable producers to cater to diverse markets.[43] Implementing these measures would help NZ balance market access

[40] GT Bill, s 175.
[41] Ibid, s 177(a).
[42] This includes such statements as '*GM crops may cause antibiotic resistance*', '*time studies have been too short to prove that GMO foods are in fact safe for human consumption through human clinical trials*', and '*if genes are privately owned, then independent research is often not allowed*'.
[43] See, eg, Grain Trade Australia, *Delivering market choice with GM crops* (Report, April 2019).

concerns, foster innovation, and allow farmers to choose technologies that best suit their needs.

It is also worth noting that rigid adherence to GM-free status may inadvertently restrict export opportunities to markets (such as the EU) that require sustainability measures, where biotechnology can be used to address climate change, food security, and environmental degradation.[44] Moreover, GM can open novel markets for NZ farmers.[45] A flexible regulatory approach would better support New Zealand's long-term economic and environmental goals.

5.2 Perceived Market Premium

There is a persistent claim that remaining free of GMOs allows New Zealand to command a market premium for its agricultural products. While this notion has been influential in shaping public opinion and policy, evidence supporting these claims is limited. Several independent Australian market analyses have found this not to be the case.[46,47,48]

GM-free products may attract a premium; however, global consumer trends increasingly value sustainability, reduced environmental impact, and enhanced nutritional qualities—outcomes achievable through GM technologies. Additionally, major exporting countries such as Argentina, Brazil Canada, and the US have embraced GM crops without sacrificing market access or premium opportunities.

Relying solely on the perception of a GM-free advantage risks stagnation in NZ's agricultural sector. By adopting a risk-proportionate regulatory framework that supports both GM and non-GM production, New Zealand can diversify its agricultural offerings and strengthen its global market competitiveness. A strategic approach focused on product differentiation and innovation will ultimately provide more robust and sustainable market opportunities.

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[44] See, eg, Jacinta Bowler, *Australian canola maintains EU emissions accreditation* (Article in COSMOS, September 2023) 'https://cosmosmagazine.com/earth/australian-canola-csiro-biofuels'.
[45] ISAAA, *Norway Approves Plant-derived Omega-3 Oil for Aquafeed* (Article, July 2023) 'https://www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=20287'
[46] Kym Anderson, *Independent Review of the South Australian GM Food Crop Moratorium* (Report prepared for SA Minister for Primary Industries and Regional Development, March 2019) 'https://www.adelaide.edu.au/saces/ua/media/388/Independent_Review_0319.pdf'
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6. Conclusion

The Gene Technology Bill presents NZ with an opportunity to modernise its approach to biotechnology and embrace a framework that aligns with international best practices and foster innovation. The hybrid model proposed in the Bill has potential, but its success depends on risk-proportionate implementation, clear guidelines, and an ability to adapt to emerging technologies.

NZ stands at a crossroads: maintaining a rigid GM-free stance may appeal to a narrow segment of consumers but risks isolating the nation from the benefits of biotechnological advancements. Conversely, a science-based, risk-proportionate system could position NZ as a global leader in sustainable agriculture and biotechnology innovation.

To achieve this vision, it is essential that:

- Stakeholders have transparency through the timely release of subordinate regulations.
- Policymakers ensure that low-risk technologies are excluded from burdensome oversight.
- The regulatory framework remains agile to address future challenges without stifling innovation.

By balancing innovation, market access, and environmental responsibility, New Zealand can develop a robust gene technology framework that benefits its people, environment, and economy.