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Submission to the Health Committee on the Gene Technology Bill

DairyNZ welcomes the opportunity to provide feedback to the Health Committee on the Gene Technology Bill ('the Bill').

DairyNZ wishes to be heard in support of this submission and would be prepared to consider presenting alongside others making similar submissions at any hearing.

The details of our written submission and recommendations for improvements to the Bill are presented below.

The contact for matters relating to this submission is Dr Bruce Thorrold, DairyNZ Chief Science Advisor, bruce.thorrold@dairynz.co.nz.

About DairyNZ

The New Zealand dairy sector generates $25 billion per annum in export earnings, comprises one-third of all goods revenue, and employs almost 55,000 people.

DairyNZ is the industry-good organisation representing all 10,500 of New Zealand's dairy farmers. DairyNZ is funded by a levy on milk solids paid by all dairy farmers under the Commodity Levies (Milksolids) Order 2020. Our work is focused on helping build a profitable, sustainable, and resilient dairy sector through science, research, advocacy, economic analysis, and extension to farmers.

Executive Summary

DairyNZ supports the intent of the Gene Technology Bill to enable the safe testing and use of gene technologies in Aotearoa New Zealand. The Bill provides a good foundation for creating a more balanced regulatory environment for gene technologies. However, five critical issues must be addressed to mitigate risks to the pastoral sector and ensure farmers retain agency and choice. DairyNZ recommends the following amendments to the Bill:

1. **Trade and market access:** The Bill's purpose should be expanded to explicitly address trade and market access risks to safeguard the competitiveness of New Zealand's primary sector.

Greater certainty is also needed over the process by which non-notifiable, unregulated and/or exempt activities are determined and registered.

2. **Co-existence:** The Bill's definition of 'environment' should be clarified to confirm that it covers primary production systems, ensuring the Regulator can effectively address primary sector issues, in particular co-existence. There is a well-established system and practices used for production of high-grade seed crops, which provide a working example of co-existence in practice. This could serve as a useful starting point for the primary sector to lead the development of appropriate regulatory settings for co-existence.
3. **Primary sector input:** The Regulator requires greater primary sector input and advice than is currently provided for in the Bill. A dedicated primary sector sub-committee to the Technical Advisory Committee is urgently required, as well as an expansion of the skill set of the Technical Advisory Committee.
4. **Māori rights and interests:** Officials should be tasked with considering a broader range of options for protecting Māori rights and interests, including expanding the proposed functions of the Māori Advisory Committee.
5. **Transparency and trust:** A 2–5-year transitional period with greater transparency in decision-making by the Regulator or the Minister on matters relating to the primary sector is required. As an example, this would ensure that no technologies or organisms are deemed 'exempt' during that period. This approach would enable trust and confidence to be built in the new regulatory system.

DAIRYNZ SUBMISSION

1. Overview

DairyNZ supports the overall intent of the Bill to establish a new regulatory framework for gene technology and genetically modified organisms (GMOs).

The dairy sector stands to gain from streamlined access to gene technologies via beneficial plant and animal traits, including pest/disease resistance, improved nutritional value, reduced greenhouse gas emissions, improved resilience to climate change, productivity gains, and animal welfare. While the timelines for these technologies to reach the New Zealand market remain uncertain (anywhere from 5-10 years), any potential benefits must be carefully weighed against the risks. These include trade and market access challenges, co-existence issues, impacts on cultural values, and unintended consequences such as increased weediness or negative impacts on animal health/longevity.

Our submission is focused on amendments to the Bill to clarify its purpose, ensure proper protections for the primary sector and maintain agency and choice for farmers.

2. Primary sector input

At the outset, the Health Committee should be aware that the primary sector has had very limited opportunity to contribute to the Government's reform process, digest the details of the Bill and accompanying material, and engage meaningfully with farmers.

While the Ministry for Business, Innovation and Employment (MBIE) convened an Industry Focus Group, consultation was limited to just two meetings in May 2024. No further information was available to the sector to enhance understanding of the process or support farmer education or engagement until the Bill was published in December – at the start of the summer holiday period. This timing, combined with the complexity and technical nature of gene technology reform, has made it extremely challenging to gather farmer input.

Given the sector's minimal involvement in shaping the Bill, and the potential risks it poses to trade and market access, we urge the Health Committee to give careful consideration to the views of other primary sector submitters, including Fonterra and the Dairy Companies Association of New Zealand (DCANZ), and the potential changes they have identified for further consideration by the Committee.

DairyNZ engagement with farmers

DairyNZ has been working to raise awareness of gene technology and the reform process with farmers and other stakeholders over the past eight months. However, as noted above, this has been very challenging due to the lack of detailed information from the Government on the proposed new regulatory framework. DairyNZ farmer engagement has included creation of a dedicated web page on the DairyNZ website, a Talking Dairy podcast, articles in general and rural media, regular email communication to farmers, and a small number of webinars and targeted meetings with levy payers (both pre- and post-publication of the Bill).

This limited farmer engagement has shown that a diversity of views exists within the dairy sector, from strong support through to strong opposition. Some farmers see significant potential in gene technology to enhance productivity, sustainability and resilience, while others have concerns about market acceptance, trade implications, ethical considerations, and potential risks to the environment or livestock. This diversity of views underscores the importance of dialogue with the primary sector to ensure that the new regulatory framework aligns with its needs and values.

3. Critical issues for the dairy sector

The benefits of enabling greater use of gene technologies are dependent on the quality of the new regulatory system that is introduced. DairyNZ has identified five critical issues with the Bill that must be addressed:

1. Trade and market access risks
2. Co-existence considerations
3. Primary sector expertise to support the Regulator
4. Māori rights and interests
5. Transparency of decision-making, especially in the initial years of implementation

These are explained in further detail in sections 3.1-3.7 below, with a table summarising change to key elements of the Bill in section 3.8.

3.1 Trade and market access risks

New Zealand dairy exports are highly regarded for their quality, safety and sustainability. This reputation underpins access to high value markets, supports trade agreements, and differentiates New Zealand products in competitive global markets. Maintaining this status is crucial for economic successes, therefore the benefits of gene technology must be carefully balanced against potential market risks.

Adjust the Purpose of the Bill

DairyNZ, along with many others across the dairy sector and wider primary industry, is concerned that the Bill does not provide for trade and market access risks. We understand that these considerations were deliberately excluded from the Bill as an 'on balance' decision by Cabinet.

Like others in the primary sector (see also submissions from Fonterra and DCANZ), we do not agree with MPI's assertion that trade and market access risks can be managed through existing, improved assurance processes under the Animal Products Act.[1] We agree with the advice from the Ministry of Foreign Affairs and Trade (MFAT)[2] that the Regulator should be required to consider these risks in assessing applications to use gene technologies and GMOs. We seek amendment to the purpose of the Bill to achieve this.

Tighter provisions relating to exempt and non-notifiable technologies and organisms

While we support the criteria in the Bill for determining whether very low-risk organisms are exempt from regulatory risk assessment, we recognise that some exempt and non-notifiable technologies and organisms in the primary sector context may still pose trade and market access risks, including SDN-1 techniques.

Currently, the Bill does not require exempt or non-notifiable technologies and organisms to be registered with the Regulator nor trigger public consultation processes. This creates potential trade and market access risks due to the lack of certainty about which of these technologies and organisms may be present in New Zealand. It also means the Regulator is unable to undertake procedural steps that would otherwise allow it to receive relevant information from affected sectors. Like others in the primary sector, we seek a process of registration to manage this risk.

In addition to a more comprehensive register, DairyNZ believes that robust traceability will be important for managing trade and market access risks. We recommend that the list of conditions that the Regulator may impose on a licence be strengthened to include requirements to enable product identification and tracing.

Lastly, to build trust in the system, we seek a two-five year transitional period whereby no technologies or organisms can be fully exempted from the regulation. This addresses a sequencing

[1] See Regulation of Gene Technologies – Policy Decisions
[2] See Regulation of Gene Technologies – Policy Decisions and Regulatory Impact Statement - Reform of Gene Technology Regulation

issue in the Bill whereby declarations on non-notified activities can currently be made before underpinning regulations have been created that would prescribe the criteria and requirements relating to non-notifiable activities (see also section 3.5).

Further analysis of these issues can be found in the Fonterra and DCANZ submissions.

Recognised overseas authority

We support the Regulator's ability to recognise risk assessments conducted in other jurisdictions; this will help streamline the application and decision-making process. However, given the critical role of the pastoral sector and trade in New Zealand's economy, these overseas assessments may need to be supplemented with additional assessments to ensure they are fit for purpose here.

For example, the Bill currently allows the Regulator to withhold draft risk assessments and risk management plans from public consultation if a recognised overseas authority has already authorised the activity and provided the relevant information to the Regulator (clause 28(2)(b)). However, by not seeking input on draft risk documents, critical New Zealand-specific context could be excluded in identifying, assessing and managing risks posed by gene technologies and organisms.

Building on the above example, we note the Bill automatically excludes gene technologies listed in the schedules of the *Australian Gene Technology Regulations 2001* from regulation in New Zealand (clause 163(4)(c)). This means that a classification system developed through Australia's democratic process is directly applied to New Zealand's regulatory framework. While we acknowledge that some of these technologies may warrant exclusion in New Zealand, a more appropriate approach would be to enable a New Zealand assessment process to determine their suitability.

3.2 Co-existence

While farmers expressed a wide range of views on gene technology during our engagement, we consistently heard that they want the new regulatory system to enable co-existence and support farmer choice. However, the Bill does not currently provide for this. We note that one of the main impacts identified in the Regulatory Impact Statement is the cost to farmers who choose not to use gene technologies.[3]

In the primary sector, co-existence refers to the ability of different production systems – such as conventional and organic farming – to operate near each other with minimal mutual impact. Co-existence is critical for the successful integration of gene technologies, particularly in the pastoral sector where open production systems and supply chain complexities make interactions between different farming systems unavoidable.

The gene technologies most likely to be first used in the pastoral sector involve ryegrass and white clover, New Zealand's two most commonly used pasture species. Both are 'outcrossing species', meaning their pollen is transferred by wind or insects, increasing the likelihood of gene flow between farms. Additionally, of the gene technologies in the pipeline for the primary sector, several are also

[3] See Regulatory Impact Statement - Reform of Gene Technology Regulation

perennial plants, persisting across multiple growing seasons, further complicating co-existence management. Effective containment will be practically impossible and without appropriate regulation, the risks of unintended gene transfer, trade disruptions and economic consequences for non-GM producers are increased.

There are three levels of co-existence that require attention to support the pastoral sector's use of gene technology:

a) **Co-existence with wild or weed populations:** The risk of transgenes spreading to wild or closely related weed species must be carefully managed to preserve biodiversity and avoid creating 'superweeds' that could threaten farm productivity and survival of native species.

b) **Co-existence with neighbouring farms:** Gene flow between farms (e.g. via seed or pollen) should be minimised to protect farmers' production choices, although it is important to note that zero tolerance for gene flow is not feasible given New Zealand's relatively small-scale and diverse farms.

c) **Co-existence within the supply chain:** Supply chains within the pastoral sector must be able to limit contamination of non-GM products (e.g. seeds, milk or meat) during harvest, transport, cleaning, processing, or retail. This is crucial to maintaining market confidence and protecting product integrity.

While the Bill's proposed risk assessment process (clauses 25-32) may address gene flow to wild species, it does not adequately account for farm or supply chain risks. To close this gap, DairyNZ recommends:

- **Clarifying the Bill's definition of 'environment'** to confirm that it includes primary production systems, ensuring that co-existence can be considered in development of underpinning regulations, and in risk assessment and risk management processes.
- **Establishing a primary sector sub-committee** to the Technical Advisory Committee (see also section 3.3 below). Such a grouping could lead the development of a regulatory framework within which the sector can then develop co-existence plans. Potential regulatory settings could include:
    - Comprehensive risk assessments to evaluate the likelihood of transgene flow from farm-to-farm, the risk of contamination and the potential economic impacts caused by such events. This ensures that the broader impacts on farming are considered.
    - Risk management plans requiring gene technology users to implement crop management plans that minimise gene flow beyond property boundaries.
    - Contamination thresholds based on detectable and biologically achievable limits for contamination of non-GM crops, reducing financial risk for non-GM producers.

- Requirements on technology developers to supply readily available testing methodologies to detect GM traits in products or environments. This will support transparency and enable farmers to verify compliance.

Co-existence in practice: Consider a ryegrass pasture on a dairy farm next to an arable farm producing ryegrass seed. One farm may adopt GM ryegrass, while the other could be organic or non-GM. Effective co-existence would require the GM user to actively manage those plants (either in their dairy pasture or their arable seed production crop), minimising the risk of gene flow to the neighbouring ryegrass. In both cases, a zero tolerance for any contamination is not biologically possible. However, a comprehensive risk management plan that includes requirements such as reducing GM-ryegrass flowering within a specified distance of the farm boundary will reduce the risk of contamination to a biologically realistic level.

New Zealand's arable sector already employs co-existence strategies, such as minimum isolation distances and registering of crops, to prevent contamination in high-grade seed production from other nearby seed crops. This system is managed by seed retailers and only applies to plants grown for seed production. It does not require any management or rules for plants grown in pastures for grazing, such as ryegrass or clover. These current and proven practices, including the MPI Seed Field Production Standards,[4] should be the starting point for the regulatory framework for gene technology use in the pastoral sector.

By embedding co-existence requirements in the Bill, New Zealand can enable innovation while safeguarding market access and farmers' production choices.

3.3 Primary sector input

DairyNZ believes that strong primary sector expertise and input is essential to enable the Regulator to maximise the benefits of gene technology use while addressing sector-specific risks. To this end, we seek the establishment of a dedicated primary sector sub-committee to the Technical Advisory Committee. This could sit alongside other specialist sub-committees and provide support and advice on primary sector issues to both the Technical Advisory Committee and the Regulator.

We also seek that the Technical Advisory Committee itself be strengthened to ensure that there are at least 1-2 members with agricultural and trade/market access skills, knowledge and experience. It will also be vital that the Regulator have sufficient internal staff with experience in pastoral production systems.

DairyNZ also queries that the Bill only requires the Regulator to "have regard" to the advice of the Technical Advisory Committee. This should be strengthened to ensure the Regulator and the Minister are actively taking the recommendations of the Committee into consideration.

[4] Export Certification Standard - Appendix 1 Seed Field Production Standards

3.4 Māori rights and interests

Māori levy payer views on the reform process varied from supportive to strongly opposed. However, a commonly raised concern in our discussions with Māori levy payers was whether the new framework would provide for Māori relationships with both indigenous and non-indigenous species and receiving environments.

As acknowledged in the Regulatory Impact Statement (RIS), the use of gene technology engages Māori rights and interests under Te Tiriti o Waitangi, including rights to exercise kaitiakitanga for specific species and places. However, the RIS goes on to acknowledge that, due to time and scope constraints, officials were not able to analyse a wide range of options on how to best protect Māori rights and interests. Instead, Ministers decided to proceed with a modified, narrower version of the Plant Variety Rights Act 2022 in the Gene Technology Bill. The Bill also states that the proposed arrangement for a Māori Advisory Committee is how the draft legislation meets the Crown's obligations under the principles of the Treaty of Waitangi.

Given the feedback from our Māori levy payers, DairyNZ urges the Health Committee to take the time to consider a wider range of options for protecting Māori rights and interests and more meaningfully enabling Māori involvement. It will also be vital that the Regulator have sufficient internal capability in Māori rights and interests as they relate to gene technologies and organisms.

3.5 Transparency

The credibility of the Gene Technology Regulator is essential for public and industry confidence. To strengthen this, DairyNZ recommends:

- Defining key concepts such as 'low risk' and 'no more than medium risk' so their intent is clear, and a shared understanding of their application can be achieved.
- Publishing details such as Ministerial policy direction to the Regulator, which would enhance transparency and trust in the decision-making process.
- Establishing an independent process for reviewing decisions, rather than leaving this to the Regulator.
- Introducing an independent review process to audit the Regulator's performance. Regular external reviews, for example five-yearly, would provide accountability and identify areas for improvement.
- Mandating regular public reporting on regulatory activities and outcomes. Clear and accessible reporting would help maintain confidence in the regulatory framework.
- Developing a sector-specific compliance framework to address the unique needs and risks of the agricultural sector and providing sufficient resources for MPI to manage enforcement effectively. Under-resourcing and non-applicable compliance regulations could undermine the credibility of the framework.

As noted above in section 3.1, there is merit in considering a 2–5-year transitional period during which decisions made by the Regulator and/or Minister affecting the primary sector are subject to greater transparency, helping to build trust and confidence in the new system. This transitional period should also ensure an appropriate sequencing of the provisions of the Bill. For example, time should be taken to develop regulations relating to exempt and non-notified activities well ahead of the Regulator making any declarations exempting certain technologies or organisms from regulation.

3.7 Biosecurity

It is vital that the powers under the Biosecurity Act 1993 to manage the risks to primary industry from incursions of pests are not in any way undermined by the Gene Technology Bill or subsequent regulations.

3.8 Clause-by-clause summary of amendments sought

Clause	DairyNZ amendments sought
3 – Purpose	Add reference to trade and market access risks *The purpose of this Act is to enable the safe use of gene technologies and regulated organisms by managing their risks to (a) human health and safety; (b) the environment <u>and (c) trade and market access</u>.* We note that amendments will need to be made to other parts of the Bill to ensure trade and market access risks are addressed, for example clause 150 – Regulator may issue or approve standards for minimising risks to health and safety.
4 – Treaty of Waitangi	Request officials to review provisions relating to Māori rights and interests and identify other options that more meaningfully enable Māori participation in the new regulatory framework.
7 – Interpretation	Clarify that the definition of 'environment' encompasses primary production systems. Also, include definitions for key terms such as 'low risk' and 'no more than medium risk'.
11 - Interpretation	Add trade and market access risks
12 – Regulator may determine what constitutes regulated organism or gene technology	Clarify provisions relating to licensed, regulated and unregulated organisms in order to address trade and market access risks.
15 – Conditions that may be imposed in relation to authorisation	Add "requirements and practices to enable product identification and tracing" to the list of conditions.
28 – Public consultation on draft risk assessment and draft risk management plan	Adjust cl 28(2)(b) to ensure public release of draft risk assessments and risk management plans even if a recognised overseas authority has been involved.

58 – Regulator to maintain register	Adjust to ensure that exempt technologies are included in the register
106 – Functions of Minister	Ensure that 'general policy directions' issued by the Minister to the Regulator are published.
114 – Appointment and membership of Technical Advisory Committee	Add trade and market expertise to the list of skills, knowledge and experience a member of the Technical Advisory Committee must possess and remove the 'or' in cl 114(3)(f) so that agricultural skills are required, not optional. *A person must not be appointed as a member of the committee unless the Minister is satisfied that the person has skills, knowledge, or experience in 1 or more of the following areas:* *(f) agricultural ~~or aquacultural~~ systems* *(s) trade and market access* *(t) aquacultural systems*
116 – Regulator must have regard to advice from Technical Advisory Committee	Strengthen to ensure advice from the Technical Advisory Committee is actively considered by the Regulator rather than simply "given regard to".
123 – Advice given under section 122(b) and (c)	In keeping with the approach taken in the Plant Variety Rights Act 2022, strengthen to ensure advice from the Māori Advisory Committee is actively considered by the Regulator rather than simply "given regard to".
132 – Establishment of subcommittees	Consideration must be given to the urgent establishment of a primary sector advisory subcommittee of the Technical Advisory Committee (per clause 132) to ensure that the Regulator is well-supported with agricultural skills, knowledge and expertise.
135 – Procedure for review of decision by Regulator	An independent process should be established for reviewing decisions by the Regulator, rather than the Regulator doing this itself.
163 – Power to make further exemptions from operation of Act and non-regulated activities	Clarify provisions relating to licensed, regulated and unregulated organisms in order to address trade and market access risks, including deleting cl 163(4)(c).
Schedule 1 – Transitional, savings, and related provisions	Introduce transitional provisions to ensure full transparency of all decisions by the Regulator and/or Minister relating to primary production systems, including trade and market access, for at least 2-5 years. Also ensure correct sequencing of provisions, for example creation of regulations before declarations are made regarding exempt or non-notifiable technologies.

Our analysis identified other concerns relating to the drafting of clauses and their interpretation. However, the short period available for submissions restricted our ability to fully analyse and provide constructive recommendations on how these concerns could be addressed. We urge the Health Committee to thoroughly review the Bill to remove ambiguity and ensure the intent of law is clear.

4. Conclusion

DairyNZ supports the Gene Technology Bill 2024 as a significant step forward in modernising New Zealand's gene technology regulations. Addressing the critical issues and implementing the recommendations outlined in this submission will strengthen the Bill, ensuring the new regulatory framework more effectively supports the dairy sector in developing, testing and adopting innovations that drive sustainability, productivity, and global competitiveness. DairyNZ looks forward to working with the Government to refine and implement this legislation.

Nāku noa, nā

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