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Committee Secretariat
Health Committee
Parliament Buildings
Wellington

Submission to the Health Committee on the Gene Technology Bill 2024

Tēnā koe,

Scion is a Crown Research Institute specialising in forestry, industrial biotechnology and advanced manufacturing. Our role within New Zealand uniquely positions us to assess the critical opportunities this legislation enables and the adequacy of its safeguards. We currently host New Zealand's only plant GMO field trial and serve as the key research provider for many of New Zealand's biotechnology companies.

It is our view that the modernisation of the gene technology regulations is essential, as existing regulations have stifled research, innovation and commercialisation in New Zealand. We welcome change.

Forestry

Forestry plays a crucial role in New Zealand's bioeconomy, providing renewable resources and environmental benefits while replacing fossil-based materials. However, it is increasingly challenged by climate change, increased biosecurity threats and changing environments. We share the United Nations Food and Agriculture Organization's perspective that gene technologies are a key tool in addressing these challenges¹. Scion is actively working with New Zealand industry to develop trees with enhanced carbon capture capabilities and improved resilience. Our work includes trees that do not produce seeds to help stop the spread of tree weeds such as wilding conifers, enhancing pest and disease resistance, and improving wood properties for construction and biomaterials. However, progress under existing HSNO regulations has been limited, as it has not been possible to grow trees past sexual maturity.

Industrial biotechnology

New Zealand's emerging synthetic biology industry shows significant promise but requires appropriate regulatory frameworks for commercial-scale operations. Commercialisation depends on large-scale fermentation facilities that can produce at economically viable volumes. Current research includes biofuels, bioplastics and specialty chemicals. However, the current regulatory framework's restrictive interpretation of containment severely constrains scaling from a laboratory environment. Without the ability to operate industrial-scale fermentation facilities like those found in Europe or the United States, New Zealand risks losing synthetic biology opportunities to other countries with more enabling regulatory environments.

Scion supports the Bill

Scion strongly supports the modernisation of New Zealand's gene technology regulation. The Bill reflects modern scientific understanding and regulatory approaches developed through over 30 years of international experience with gene technologies, recognising that historical concerns about gene technologies have not materialised and that an enabling, evidence-based approach is more appropriate than blanket restrictions. Recent assessments from The Royal Society (UK)², European Academies' Science Advisory Council (EU)³, and notably, the National Gene Technology Scheme (AU)⁴ all endorse a hybrid risk-proportionate approach to regulation. The Australian review is particularly relevant, having successfully managed a similar framework for over two decades in an economy and environment comparable to New Zealand's.

We strongly support several key aspects of the Bill. The risk-proportionate approach to regulation aligns with international best practice while maintaining appropriate safeguards. The establishment of an independent regulator with clear authority to make determinations about gene technology applications and adapt to emerging technologies is crucial for effective implementation. The creation of technical and Māori advisory committees will provide essential expertise and cultural guidance.

Key point for consideration

Our experience has often demonstrated that physical containment measures can create significant practical barriers to implementation. To ensure the Bill achieves its enabling intent while maintaining appropriate safeguards, containment requirements must reflect current technological capabilities and practical operational realities.

There are multiple effective mechanisms that can be employed to prevent the unwanted movement, release, or spread of a regulated organism. Biological containment methods, such as reproductive sterility in trees, can provide more reliable containment than physical barriers. This approach enables region-specific evaluation of trees under varied environmental conditions, including exposure to local pests and diseases, while eliminating the need for costly containment infrastructure. Similarly, across the world, industrial-scale fermentation operates under controlled process containment using standard manufacturing practices, rather than the stringent laboratory containment standards that have limited adoption in New Zealand.

As technologies and international best practices continue to evolve, the regulatory frameworks must be flexible enough to enable innovation while maintaining public confidence. To achieve this, we recommend adopting an outcome-based definition modifying Section 7(1) to define containment as:

"Containment means employing biological characteristics, process controls, physical barriers or any combination thereof to confine a regulated organism and prevent its unintended release or spread."

Rather than providing an indicative list of containment methods in the Bill, we propose these be addressed in secondary legislation, which can be more readily updated as technology develops. Possible methods include:

- Biological containment: Organisms unable to survive or reproduce outside controlled conditions
- Process containment: Sealed fermentation vessels and associated systems designed for industrial-scale production
- Physical containment: Structures appropriate to the organism and scale of operation

Implementation requirements

Successful implementation of the Bill requires careful consideration of key elements. The regulatory body must be adequately resourced with appropriate staffing, expertise and clear guidance to fulfil the Bill's enabling intent.

While the Ministry for Primary Industries will enforce the HSNO Act, Biosecurity Act and new Gene Technology Act should the Bill pass into law, its traditional emphasis on precaution and risk minimisation will require an evolution to balance safety with the Bill's objectives to enable innovation.

Summary

The framework established by the Bill will support New Zealand's existing forestry industry and enable the growth of new industries in industrial biotechnology and sustainable manufacturing. With the suggested amendment and considerations around implementation, this legislation will enable New

Zealand to address critical environmental challenges and compete globally in sustainable manufacturing whilst ensuring robust protection for human health and safety and the environment.

Ngā mihi nui, na



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References

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3. European Academies' Science Advisory Council. (2017). Genome editing: scientific opportunities, public interests and policy options in the European Union. ISBN: 978-3-8047-3727-3
4. Commonwealth Government of Australia. (2018). The Third Review of the National Gene Technology Scheme, Final Report.