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June 16, 2025.

Letter to Councillors of regional councils and territorial authorities (TLAs). Re: Gene Technology Bill.

Dear Councillor,

By now, elected members and staff at TLAs will be reading articles in local agricultural papers and in the accredited media, discussing the benefits to New Zealand of the Gene Technology Bill, currently at the select committee stage. Public submissions closed in February, yet the report to the Select Committee remains unpublished.

We urge elected members to be circumspect. Few articles have frankly addressed the deficiencies in the policy formulation. This was highlighted by both scientists and legal experts in their Select Committee submissions. As elected members you recognise the importance of step-by-step processes that follow transparent and accountable stages, as per the Good Regulatory Practice guidelines. End-stage policy and law must be of high quality.

The Ministry for Business, Innovation and Employment and the Minister in charge, the Hon Judith Collins, advised all that they were pushing the policy and Bill through at a fast pace. Unfortunately, it shows. Neither a scientific case nor an economic case was made for the reforms. The evidence base in the Regulatory Impact Statement does not demonstrate that gene edited technologies and organisms can or will be safely and rigorously regulated by the proposed legislation, now and for future generations. Yet the proposed regulatory framework would radically place unknown quantities of genetically modified organisms (GMO) outside of any form of regulation.

If the Bill is passed, government officials and New Zealand exporters will be flying blind with a regulator that has no regulatory control because large numbers of gene edited technologies and organisms will escape any regulation.

With the Gene Technology Reform process, the failures in due diligence are numerable:

MBIE's legislation promises to *'enable the safe use of gene technologies and regulated organisms by managing their risks'*. The new framework shifts (risk-tiers) many gene edited techniques and organisms (which are non-controversially accepted by scientists as processes of genetic modification) outside of any regulatory oversight. They would be considered as not-GMO for the purposes of regulation, and not declared, assessed or monitored.

94% of gene edited plants could be outside regulation. Unlike Europe, New Zealand would not just deregulate plants, but would deregulate microorganisms, fungi and animals as well. A European study estimated that 94% of GMO plants under the proposed 'non-GMO' class, which in Europe is more rigorous than New Zealand, could escape all regulation. No such evaluation has taken place in New Zealand.

No risk assessment. The Good Regulatory Practice guidelines require that systematic impact and risk analysis be undertaken. This did not occur, yet the legislation promises to *manage risks*. It is, of course, not possible to manage risks, if you do not even know what risks may arise from the GMOs that would be *inside* the legislative framework, but also those GMOs that would be risk-tiered *outside* of the legislation and regulatory oversight. Any DNA manipulations can involve risks. MBIE did not commission independent scientists to assess if the legislation was fit-for-purpose, even though risk tiering of gene edited technologies and organisms *outside* of regulatory oversight is a novel regulatory approach. MBIE frankly do not know whether the bill could prevent harm and protect human or environmental health.

No cost-benefit analysis. The Good Regulatory Practice guidelines require cost benefit analysis to be undertaken and that any outcome should be achieved in the least-cost way. No cost benefit analysis was undertaken of the set-up costs of new legislation versus simply amending the existing HSNO Act. Instead, the Minister-in-charge directed officials not to include reform of the HSNO Act as a policy option during early stage consultation (Regulatory Impact Statement page 3).

No economic analysis. The guidelines require impact analysis on how the proposed change might align with international requirements. No systemic analysis of trade implications was undertaken. New Zealand will be vastly less regulated than the European Union, for example, should the Bill proceed.

No trade analysis. MBIE misled people by claiming that the legislation would bring New Zealand into line with our major trading partners, without undertaking a comprehensive analysis. However, the proposed changes would not align us with trading partners. The Centre for Integrated Research in Biosafety (INBI) (page 7) stated that *'in at least one significant way, New Zealand proposes to accept risks to human health and the environment unacceptable to any other country.'*

Removing the public right to know due to the risk-tiering outside the legislation. GMO-free food status is highly desired by premium markets, with a much higher market growth rate than conventional food. In our submission to the select committee, PSGR cited multiple studies (page 14) which show that consumers actively pay a premium for GMO-free food. The Regulatory Impact Statement acknowledges no research had been undertaken to estimate the value of this market.

Removing the Precautionary Approach. MBIE claims that precaution is outdated, and cites government papers to justify their claim. None of the cited papers stated that a precautionary approach was outdated. The claim seems to have come out of thin air.

The August 2024 Regulatory Impact Analysis (RIS) shows that MBIE did not undertake risk assessment, cost-benefit, economic analysis, or an analysis of the impact on New Zealand exporters. The RIS states plainly that there would be unquantified costs to non-GMO exporters, and that they were unable to quantify the expected benefits. The RIS acknowledges that MBIE did not engage broadly with Māori. (page 7)

MBIE-funded scientists are big proponents. The Productivity Commissioner had recommended wide-ranging consultation to review whether the legislation needed to be updated, with the general public and Māori. The Minister directed officials not to engage with the general public (page 13). MBIE carefully selected scientists and organisations to consult with, and excluded knowledgeable scientists who understood the nature of the risks of such DNA technologies. Most of the stakeholders chosen by MBIE had science funding from MBIE for gene editing research or were engaged in partnerships with MBIE-funded scientists. Most of these stakeholders had science funding from MBIE for gene editing research or were engaged in partnerships with MBIE-funded scientists.

Media has been biased towards deregulation. Assoc Professor Valentina Dinica reviewed media representations. Dinica confirmed that the vast majority of media articles were pro-genome editing, and did not undertake any critical analysis.

Consultation with Māori was not transparent. It mostly occurred under a MBIE-funded Plant and Food grant (no.C11X1602) that focussed on the benefits of new gene editing technologies and organisms and of the attitudes of Māori. Māori were not advised that no risk assessment had been undertaken. Māori were not advised that a considerable number of techniques and organisms would be exempt from any form of regulation.

No powers for the regulator to freely monitor and assess risks. The regulator lacks inquisitorial powers and cannot turn around and reassess the organisms outside the legislation.

Regulators are normally at arm's length from political agencies. This new legislation gives the power of administration of the law, and development of secondary legislation (where guidelines and rules would be contained), to MBIE. Unfortunately, MBIE, New Zealand's economic growth agency, controls the science budget and funds the scientists to develop GMOs. There is no independent funding set aside for scientists to study the risks from GMOs, including newer gene editing technologies. This is because MBIE's science policy is focussed on innovation and economic growth.

The policy and legislative deficits which underlie gene technology reform, deserve a far more critical eye than has so far occurred.

While much of the discussion by scientists about what gene editing technologies and organisms may do in future sounds exciting, much of it remains theoretical and speculative at best.

Laboratory development using biotechnology is not the concern of this communication to elected officials, rather it is the problem of uncontrolled and unmonitored releases of genetically modified organisms (GMOs) into New Zealand's environment.

The references below further outline further the scientific issues, which include the non-controversial fact that all gene editors, including the technologies that would be risk tiered outside of regulation, are *powerful mutagens*. It's very evident that gene flow into the environment, and contamination (e.g. seed and pollen) from GM grasses under development is expected by the developers. The extent to which off-target, and non-target effects could occur, should the Gene Technology Bill be enacted is simply unknown. At this stage the potential for such risks has not even been estimated, because MBIE failed to request a scientifically rigorous analysis for proof of concept.

REFERENCES

- Centre for Integrated Research in Biosafety (INBI) (2025). Submission to the Parliament Health Committee on the Gene Technology Bill 2024. Supplementary Submission.
- PSGR (2025). Submission to the Parliament Health Committee on the Gene Technology Bill.
- PSGR (2025) When powerful agencies hijack democratic systems. Part I: The case of gene technology regulatory reform. Bruning, J.R., Dommisse, E.. ISBN 978-1-0670678-0-9