

Physicians & Scientists for Global Responsibility

Email: Social: Website: info@PSGR.org.nz @PSGRNZ PSGR.org.nz

November 6, 2025.

Dear New Zealand members of Parliament,

Eleven months ago, on December 17 2024, PSGR emailed you to request that the Gene Technology Bill be put on hold, pending a European Commission (EC) outcome (See appendix page 3.).

Following the Health Select Committee's decision to recommend that the Bill advance, PSGR must stress to you, an elected MP (we as a charity we hold no political affiliation) that the European Union has not settled its position. For New Zealand to pre-emptively legislate ahead of this major jurisdiction, particularly when we are a small policy-taker economy, presents a real risk of being premature and strategically unsound.

You have likely been advised that, to date, no cost–benefit, risk assessment, or economic analyses have been undertaken. As neither benefits nor costs have been verified, any claimed benefits at this stage are simply assertions.

We also remind MPs that under the Bill, responsibility for the health and environmental regulation of a technology and its emissions would be shifted from the independent statutory regulator, the NZ Environmental Protection Authority (NZEPA), to the very agency mandated to promote economic growth and the commercial uptake of new technologies, i.e., the Ministry of Business, Innovation and Employment (MBIE).

Such an arrangement runs counter to a core principle of constitutional and democratic governance: the separation of regulatory oversight from economic advocacy functions.

[1] The EC has still not finalised their legislation on this same issue, the regulation of gene edited organisms.

The EU reached a political agreement on a common position in July 2024, after prolonged negotiations but no new law is in force. Council–Parliament–Commission negotiations are converging around a compromise text. This covers:

- A new category NGT-1: plants deemed equivalent to conventional breeding → much lighter regulation
- NGT-2: modified but not deemed equivalent → more oversight, but still less than current GMO law
- Patent-related provisions: mandatory reporting of patented genetic elements; patentability questions punted to further review

Final legal processes and formal adoption have not occurred, nothing confirming final legislation has been published in Europe s Official Journal. This includes finer grained detail on how traceability, labelling and coexistence rules will apply to NGT-1 crops (the EU more transparently calls what NZ is calling "new breeding techniques" (NBTs) as new genomic techniques (NGTs); how patent disclosure and licensing obligations will be enforced, and space for individual member state approaches.

[2] The USA has recently reversed its 2020 deregulation.

A recent Op Ed by Professor Jack Heinemann in <u>The Post</u>, questions why this has not been a lead in stories promoting the Gene Technology Bill.

[3] The shift of regulatory authority into an agency primarily tasked with promoting economic growth subverts fundamental democratic principles.

In a democracy, the separation of powers is intended to prevent the concentration of powers and the abuse of authority. Historically, environmental regulation has been kept at arm s length from the very institutions that have a vested interest in advancing new technologies and the emissions and pollutants those technologies can produce.

The migration of regulatory oversight from the NZ EPA to MBIE would completely over-ride key democratic principles and embed a conflict of interest. This is because MBIE s purpose is to promote economic growth.

[4] No assessment was ever made of the feasibility of retaining the existing legislation and amending it.

The Minister in charge and Attorney General Judith Collins explicitly directed that MBIE officials/stakeholders could not consider retaining the existing Hazardous Substances and New Organisms (HSNO) Act 1996 (Regulatory Impact Statement (RIS) page 3).



[5] Claims that the HSNO Act is out of date are not supported.

The RIS (p.3) asserts that various reports over the past 15 years have found that the HSNO Act's GMO provisions are increasingly out of date. However, the cited reports are NZ government documents that do not compare domestic provisions with foreign jurisdictions. For example, current European NGT legislation explicitly requires action with full regard to the precautionary principle. In June 2024 MBIE officials discarded the precautionary principle, claiming this reflected good regulatory practice. MBIE officials provided no data to justify its removal. PSGR s Gene Technology Regulatory Reform paper (March 2025) discusses these issues in depth.

[6] Democracies should not only fund science to develop technology, but to understand their risks.

This is not currently the case in New Zealand (See PSGR s <u>2025 report on Science System Reform</u>). MBIE, the agency for promoting economic growth (MBIE) also controls science policy and hence science funding. MBIE has structured science funding policy to prioritise the development of innovations and there are no funding channels for research science to understand the adverse outcomes (to human and environmental health) from such innovations.

With this in mind, please understand that every scientist advocating for the Gene Technology Bill has a financial conflict of interest, because state funding will be directed through MBIE.

[7] MBIE in developing their policy, ignored the Government Expectations for Good Regulatory Practice.

A clear understanding of outcomes and benefits has not been demonstrated. The NZ government requires agencies to:

- clearly identify the nature and underlying cause of the policy or operational problem it needs to address, drawing on operational intelligence and available monitoring or review information
- undertake systematic impact and risk analysis, including assessing alternative legislative and non-legislative policy options, and how the proposed change might interact or align with existing domestic and international requirements within this or related regulatory systems.
- make genuine effort to identify, understand, and estimate the various categories of cost and benefit associated with the options for change.

At no stage has MBIE transparently evaluated, acknowledged or discussed the risks that could arise from deregulation of gene editing techniques and organisms, to identify the operational problem that regulatory agencies are faced with when GMOs (including gene editing techniques and organisms) are released into biological environments.

The Gene Technology Bill would set in place a framework for long term regulation, yet no risk assessment has been carried out for legislation that would be responsible for carrying out risk assessment. MBIE papers discussing newer gene edited organisms presume that they present an equal (equivalent) threat to conventionally bred organisms.

However, MBIE did not adhere to the <u>Good Regulatory Practice</u> document expectations and conduct systemic impact and risk analysis. Earlier papers, including by the <u>Royal Society Te Apārangi</u> did not conduct any scientifically rigorous risk analysis (see PSGR s review in the PSGR s <u>Gene Technology Regulatory Reform</u> paper).

In <u>The Post</u> article discussed above, Prof. Heinemann highlighted the problem that when officials conflate an outcome as being indistinguishable (in the same category of risk) with the potential of risk and hazard from an activity.

[8] Following the Minister's direction officials have not consulted with the public on these reforms . (RIS page 13.)

The Productivity Commissioner has explicitly recommended that the public and especially Māori would be consulted with prior to developing draft legislation.

PSGR ask that you, as an elected MP, take into account the current status of the European Commission's deliberations and the constitutional concerns arising from transferring regulatory oversight to MBIE. We ask that you reflect on the fact that without a cost-benefit or risk analysis, you cannot make a responsible decision. We therefore urge you to reject the Bill in its present form, or at minimum defer its progression until the European Union's legislative position is known and independent cost-benefit and risk assessments are undertaken.

Yours sincerely,

The members and trustees of the

Physicians & Scientists for Global Responsibility Charitable Trust New Zealand.



APPENDIX

Tue, 17 Dec 2024, 10:47

Dear Members of Parliament,

Please put the Gene Technology Bill on hold, pending a European Commission outcome.

Why?

- 1. Proposed European legislation has stalled' (see attached April 12, 2024 draft).
- 2. In Europe, deregulation exclusively concerns plants, while in New Zealand deregulation would encompass plants, animals, and microbes.
- 3. New Zealand would deregulate techniques of gene editing that have not been deregulated anywhere else. However, this 'point of difference' is not clearly disclosed.
- 4. The European Commission has drafted significant caveats, including transparency provisions and protections for non-GMO breeders into their proposed legislation.
- 5. MBIE claims that the Precautionary Principle approach is outdated. Precaution with newly created gene edited organisms is never outdated, due to new compounds being produced.
- 6. Note that in the European Commission legislation, the Precautionary Principle text is included. The Precautionary Principle must be inserted in any legislation claiming to steward GMOs which include gene editing techniques and gene edited organisms.
- 7. The current Bill must be thoroughly understood by MP's in light of proposed FSANZ changes in regulation current proposals could result in 94% of gene edited foods avoiding premarket assessment (and traceability). Food safety of these GE foods is very unlikely to have been assessed.

In New Zealand it is claimed that the legislation will be 'evidence based' and 'risk proportionate', but it cannot be:

- If these claims for 'evidence' and 'risk' are exclusively based on Australian legislation.
- If the technical experts are a small group of people who may work for organisations that receive funding for biotechnology research and where their scope of feedback is restricted.
- Neither Biosecurity nor the Ministry for the Environment have conducted an assessment or impact analysis on how the resulting legislation will impact them.
- No economic analysis has been undertaken.
- Assessment of global consumer willingness to pay a premium for GMO-free food has not been included.

Please find attached:

- <u>PSGR October 2024 Fact Check 101</u> which discusses these issues, and provides links to the European Commission document.
- European Commission draft document.
- Article by trustee Jodie Bruning (B.Bus.Agribus., M.A.) <u>which discusses policy papers</u> that were released this week.



Kind regards| Ngā mihi

Elvira Dommisse

BSc(Hons), PhD (Biotechnology)

For the Trustees of

Physicians and Scientists for Global Responsibility

