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Physicians & Scientists for Global Responsibility

When powerful agencies hijack democratic systems.

PART I: THE CASE OF GENE TECHNOLOGY REGULATORY REFORM

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Image: The New Coalition, Punch, 1855.

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SUMMARY

This 2-part 2025 review by the Physicians and Scientists for Global Responsibility New Zealand Charitable Trust (PSGR), documents policy process and official conduct regarding gene technology reform (part I) and science system reform (part II)[1]. The papers consider information provided in official documents that suggest that officials may be setting aside or undermining important issues and conventions that are essential to sustaining a robust, healthy, accountable democratic nation-state.

The papers highlight an apparent corruption of governance processes and conventions. In light of the information detailed in this report on gene technology reform (Part I), PSGR ask that readers contemplate whether the situation is sufficiently grave that the passing of the Gene Technology Bill would jeopardize the national interest, impacting human and environmental health, as well as productivity and trade. PSGR also ask that readers apply the 'reasonable person'. Have Ministry of Business, Innovation, and Employment (MBIE) officials and the Minister in charge, Judith Collins, acted with honesty and integrity in their carrying out of work related to gene technology regulatory reform?[2]

PSGR calls for two separate public enquiries to evaluate the actions of that Minister and officials in driving outcomes which appear to severely restrict the capacity of the new gene technology regulator, and the New Zealand science system, to conduct activities that would serve the public purpose and support constitutional and democratic government.

The papers arrive at two recommendations:

Part I: Gene Technology Reform Recommendation: That the Gene Technology Bill be placed on hold. That the Ombudsman convene an Inquiry into conduct of the Ministry of Business, Innovation, and Employment (MBIE) and the Hon. Judith Collins, Kings Counsel and Attorney-General, in regard to their work on gene technology regulatory reform over the period 2023-2025. That the Ombudsman considers evidence that this body of persons acted improperly in their duties, directly undermining public law conventions, in order to expedite policies and laws in favour of the deregulation of gene editing technology. That the terms of reference pay particular attention to the benefits of observing the principle of open justice, and require that the inquiry follows independent, impartial and fair processes. (See PSGR recommendations pages 50-51).

Part II: Science System Reform Recommendations: That a transparent and public inquiry is undertaken to evaluate the past, present and future role of New Zealand's RSI&T system. This inquiry must be independent, impartial and fair. It may be in the form of a public inquiry or a Royal Commission (Inquiries Act 2013, s.6). [1]

This inquiry is necessary because there is evidence that the current science system is inadequately resourced to meet the objectives of society at large; and that the science system reforms that are currently underway (2023-2024) have excluded any evaluation or discussion on this issue. These current reforms will further direct the RSI&T system away from optimising science and research intended to identify and address domestic problems and challenges. PSGR recommend that the RSI&T system Inquiry problem definition address:

> *'the capacity of the publicly funded RSI&T system to demonstrably contribute to public-good knowledge, and in doing so serve the public purpose and support the wellbeing of New Zealand, her people, resources and environment'.*

[1] PSGR (2025) When powerful agencies hijack democratic systems. Part II: The case of science system reform. See recommendations pages 53-56. Bruning, J.R.. Physicians & Scientists for Global Responsibility New Zealand. April 2025. ISBN 978-1-0670678-1-6. https://psgr.org.nz/component/jdownloads/send/1-root/174-science-system-reforms-hijack-democracy

[2] Crown Entities Act 2004. s54 Duty to act with honesty and integrity. https://www.legislation.govt.nz/act/public/2004/0115/latest/DLM329984.html

This report, Part I of two papers, focuses on the case of regulatory reform of gene technology in New Zealand. Throughout the policy-process, media and government messaging has assured New Zealanders that the new regulations will result in the safe 'risk-proportionate' use of gene technologies and regulated organisms; by managing the risks they present to the health and safety of people and the environment.

Members of Parliament cannot know how many gene-edited organisms would become invisible and undeclared if the current risk tiering proposal succeeds. Policymakers did not assess how many gene edited techniques and organisms would fall outside regulation and be undeclared. The legislation is optimised to reduce regulatory scrutiny, making many activities of developers invisible to the public.

There has been no scientific or economic evaluation undertaken to confirm that the new legislation, the Gene Technology Bill, will be 'risk-proportionate'. While promising that risks will be managed, no risk assessment of the technologies, organisms, and pathways of harm has been undertaken. Officials have then risk-tiered gene editing techniques and organisms by de-classifying them as a genetically modified organism, outside of regulatory oversight and monitoring. Neither the Minister nor officials concerned themselves with evaluating and receiving advice on good regulatory practice to ensure the safe regulation of genetically modified technologies and organisms. There has been no scientifically rigorous evaluation to justify this risk-tiering of techniques and organisms outside of regulation.

Return-on-investment analyses are not regularly undertaken to assess the commercial impact and financial return from biotechnology research. To date, officials have not evaluated the financial outcomes from over twenty years of publicly funded New Zealand-based biotech investment.

Awkward 'truths' have been downplayed in media and in official documents. These include that (a) genetically modified technologies and organisms released into the environment can be heritable and persist into the future; and (b) that gene editing technology processes can also be used to kill or sterilise.

MBIE is the government agency for economic development and growth that also controls science policy and funding, and in the process directs millions to developers of genetically modified organisms (GMOs).

The political call for removing the Hazardous Substances and New Organisms Act 1996 (HSNO Act) has been pursued primarily by MBIE, MBIE funded scientists and biotech industry lobbyists. Minister Judith Collins explicitly directed officials that policy consultations would not consider reform of the HSNO Act.

MBIE has effectively secured oversight and control of the development of policy and legislation to regulate the very technologies that it funds, which MBIE believes will promote economic growth. MBIE's pursuit of deregulation has occurred regardless of the political party in power.

MBIE's claims that the legislation will be risk-proportionate, are derived from Royal Society Te Apārangi 2016-2019 campaign papers which recommended legal reform[3] and through quasi-harmonisation with Australian legislation, which also exempts some gene editing techniques. No evaluation was undertaken to establish whether the Australian legislation has 'stood the test of time'.

A cross-agency Ministerial group was established in 2017. Since that time, the scientific advice that has informed Ministers has primarily come from the MBIE-funded Royal Society. The Royal Society campaign was funded by MBIE, with the goal of raising awareness of the potential of gene editing technologies and encouraging social acceptance of new GM technologies via the provision of case studies. The Royal Society was not funded to scientifically evaluate risks from gene editing technologies and organisms to human or environmental health, including evaluation of unanticipated non-target and off-target risks.

[3] Royal Society Te Apārangi (August 2019) Gene Editing Legal and Regulatory Implications. Pages 140-150. https://www.royalsociety.org.nz/assets/Uploads/Gene-Editing-FINAL-COMPILATION-compressed.pdf

Despite not conducting any risk assessment, the Royal Society made suggestions for legal reform.

The current form of the Gene Technology Bill will result in legislation that is even more deregulated than Australia's. New Zealand people would be entirely unaware of the undeclared gene-edited foods, techniques and organisms that could be released.

MBIE strategically selected organisations with biotech investments, industry lobbyists and medical and biotech scientists working in institutions funded by MBIE to undertake biotech research as the 'stakeholders' and 'technical experts' to provide advice on the adequate regulation of the technologies that they hope to commercially release. Groups that MBIE would have been well-aware of, that had submitted for example, to a 2023 consultation, were excluded from key policy development processes.

Independent experts in the regulation of these technologies, without conflicts of interest, were not invited into consultations.

This case study shows considers the role of MBIE driving regulatory reform for the very technologies it funds. However, the case of gene technology reform is reflective of a broader, systemic problem.

As Part II outlines, the science system has been decoupled from its potential to support broader public interest goals and is not sufficiently adequately resourced to meet the objectives of society at large. The 2023-2025 science system reform promises more of the same. MBIE's innovation and commercialisation focus effectively prohibits funding for science and research that might identify and research New Zealand's biggest challenges, which involve overlapping socio-political, environmental and economic drivers.

Economic growth is but one subset of factors that contributes to a thriving nation. The gene technology and science system consultation processes suggest that the responsible Ministers and Ministries consider the 'public interest' to be a nebulous and superfluous construct, with no real purpose.

The democratic dilemma that PSGR present here, is that the control of scientific research is held by the agency for economic growth, that this is the same agency that funds biotechnology scientists, and who is now developing the laws to reduce regulatory controls over the very technologies that they fund.

PSGR urges officials schooled in democracy, governance and public law to take time to investigate the robustness of MBIEs claims that their policy is 'risk-proportionate'. PSGR suggest that Judith Collins and MBIE's activities have undermined administrative and constitutional conventions via corrupted policy and consultation processes. PSGR highlight the manifold ways that the Gene Technology Bill binds the regulators hands. The Bill cannot assure the protection of human and environmental health. This review suggests that democratic norms have been perverted.

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[1] GETTING SOME CONTEXT – HAS GOOD-PROCESS HAS BEEN SUBVERTED?

The justification for the Gene Technology Bill 2024[4] is published in a Regulatory Impact Statement.[5] The Bill was introduced on December 10, 2024, just before the summer recess.

For a government official or legal scholar, PSGR's concerns and recommendations may appear to be over-stated. Unfortunately, media coverage of GMOs, regulation and risk has for many years been distorted. Much of the media coverage has been dominated by MBIE funded scientists or biotech investors who have promoted the possible benefits of newer gene editing techniques and organisms.[6]

Elected members, government officials, and the general public may suspect something is amiss, but untangling drivers of complex problems is rarely straightforward. The public has reason to be sceptical.

There is evidence that both MBIE and the Honourable Judith Collins KC have demonstrated their inappropriateness for taking on gene technology regulatory reform, and their bias to deregulating the very technologies that they imagine will lead to economic growth, in manifold ways:

a. MBIE directs science policy and science funding. Most funding streams demand that scientists pursue 'excellent' science with high 'impact', and where outcomes support economic growth.

   - Failing to be open and honest in declaring that MBIE controls the science, research and development funding budgets, and that MBIE's own policy advantages commercial biotechnology research while creating barriers to biotechnology-related scientific research that carries no commercial potential.
   - MBIE directs responsibility for administration of the Marsden Fund to the Royal Society. The Marsden Fund is a major funding channel for gene editing research. The Royal Society shapes scientific communications through its control of the Science Media Centre. The Royal Society also administers the Catalyst Fund.
   - Many scientists use gene editing technologies to produce innovative science outcomes, but scientists are unable to research risk from gene editing techniques as there is no research funding available.

b. Government policy documents show the outsize influence of the Royal Society Te Apārangi. The Royal Society was funded by the Marsden Fund when conducting their Gene Editing series.

c. Most research on Māori views and opinions has been funded by MBIE, either through the Royal Society or Plant and Food Research, a Crown Research Institute focussed on developing gene edited products and patents. Conversations with Māori tend to infer that the Royal Society is an authority. The Royal Society focussed itself on educating people about gene editing prospects and benefits. Evaluating and educating on their risks was not part of the 2016-2019 programme.

[4] Gene Technology Bill 2024. https://bills.parliament.nz/v/6/22059628-b0cc-4931-5e07-08dd18a12bfb
[5] Ministry for Regulation. Issue date: December 20, 2024. Regulatory Impact Statement: Reform of Gene Technology Regulation. Document (signed) date: Wednesday 31 July 2024 https://www.regulation.govt.nz/our-work/regulatory-impact-statements/regulatory-impact-statement-reform-of-gene-technology-regulation/
[6] Dinica, V (February 15, 2025). Conference paper presentation. Representations of genome-engineering biotechnologies in New Zealand - Political and science communications". Conference paper presented at the Australian Political Studies Association Conference 'State of Democracy and Politics: Local, regional and global. University of Western Australia, Perth, 28 - 29 November 2024,

d. Failing to construct a Problem Definition that includes at the highest level, a requirement to ensure that human, environmental and economic health would be safeguarded by any future gene technology legislation, and that the legislation would be best practice.

    - An inappropriate Problem Definition, constructed by MBIE, was based on the hypothetical potential for gene technologies to prove instrumental for strengthening the resilience of 'the four capitals' human, social, natural, and financial/physical. No commensurate economic assessment was undertaken to verify the extent to which biotechnology has or has not achieved these outcomes in less regulated economies, as New Zealand would become.

e. Failing to secure policy-based, technical experts in the development of hazardous substances and new organisms regulation, and failing to identify or define global best practice in the regulation of GMOs and newer gene edited techniques and organisms.

f. Allocating the Health Select Committee to oversee public consultation for prospective legislation that is designed to remove regulatory barriers to so-called economic growth, rather than a Regulations Committee or the Economic Development, Science and Innovation Committee.

g. Risk-tiering (placing) entire classes of gene-editing techniques and gene-edited organisms outside of any regulation. The basis for exemptions may come from Royal Society claims that certain outcomes and organisms will be 'indistinguishable' from conventionally bred organisms.[7]

h. Eliminating the opportunity for experts, stakeholders, the general public and elected members to consider, as a policy option, retaining process-based assessment (the status quo, as per the HSNO Act) and reforming the HSNO Act, following direction from the Minister of Science, Innovation and Technology, Judith Collins. The National Party *Harnessing Biotech* manifesto document advised a shift away from the current legislative focus on the process used, and drew directly from the Royal Society 2019 papers.

i. Misleading the public to claim that important principles and ethic-based language in the Hazardous Substances and New Organisms Act are out-dated, while citing government white papers to justify their claims, when the white papers claim nothing of the sort (e.g. Europe retains the precautionary principle).[8]

j. Expressly ignoring Productivity Commissioner recommendations to conduct a broad public inquiry to firstly view if regulatory changes to current genetically modified organisms (GMOs) regulations are desirable and necessary.

k. Weighting stakeholder consultations and advisory committees to people who are either: undertaking gene-editing related research; or working directly for institutions with investments in biotechnology research and development.

    - Policy-related stakeholder consultation predominantly restricted to industries and employees of institutions who have biotech-related political and financial conflicts of interest.

[7] Royal Society Te Apārangi (August 2019) Gene Editing Legal and Regulatory Implications. Pages 140-150. https://www.royalsociety.org.nz/assets/Uploads/Gene-Editing-FINAL-COMPILATION-compressed.pdf

[8] Ministry for Regulation. Issue date: December 20, 2024. Regulatory Impact Statement: Reform of Gene Technology Regulation. Document (signed) date: Wednesday 31 July 2024 https://www.regulation.govt.nz/our-work/regulatory-impact-statements/regulatory-impact-statement-reform-of-gene-technology-regulation/

- Science System Advisory Group weighted to members who have a long-term interest in molecular genetics and the deregulation of biotechnology due to their institutional and professional affiliations.
- Technical advisory group members weight to experts in biotechnology and gene editing who are involved with institutions that are commercialising biotechnology, or directly involved in research and development for products that their (e.g. medical) institutions aim to commercialise.
- Royal Society peers involved in the 2016-2019 campaign involved genetics/gene-editing/biotech experts directly affiliated with institutions with investments in gene editing-related research, or a long history of advocating for biotechnology and gene regulation.

l. Failing to release 2023 results and or a report from a potentially suppressed Ministry for the Environment inquiry into biomedical and laboratory research. This was the only public facing consultation on gene technology regulatory reform.

m. Pretending that a short timeframe and no public input to policy development is appropriate and important.

n. Gaining advantage from disproportionate and propagandistic coverage by New Zealand media by biotechnology-deregulation proponents including the Attorney-General. Such claims included that there has been a 'ban' and that the regulations are out-dated. Media have failed to balance those claims with critical questions, including where interviewees had conflicts of interest.

The above processes have then enabled MBIE to claim a 'level of stakeholder support' based on selective representation:

> *'Through MBIEs targeted engagement, stakeholder feedback from both researchers and industry generally does not support maintaining the current regulatory regime, as it is considered to be overly burdensome for users of the technology and not risk proportionate.'*

Members of Parliament who trust official assurances, including from the Attorney General, and who would reasonably trust that good process has been followed, would then be likely to vote on the legislation.

Risk: Rushed, not-fit-for-purpose laws will keep New Zealand courts busy.

The impact of poor policy development is likely to be felt for years to come. Members of Parliament (MPs), legal counsel and the judiciary cannot be expected to evaluate the policy process. The following is a difficult nuance to pick apart: *scientific and technical experts involved were not experts in risk assessment, regulatory policy and law, but were actually 'experts' whose institutional interests would be impacted should the status quo (the HSNO Act) be retained*. The subtle discrepancy, a quirk of 'whose expertise is the most relevant' to ensure high quality legislation that is fit for purpose, is likely to be missed by MPs, legal counsel and the judiciary, who would conventionally trust official assurances that good process was followed.

New Zealand is always vulnerable to the risks of rushed legislation, poor regulation and the potential for abuse of power. Unlike New Zealand, most governments have two Houses of Parliament – so that scrutiny of legislation takes a little more time. Sir Geoffrey Palmer has persistently drawn attention to the powers of the large agencies, and the vulnerability of Parliament. Part of this is because of a Select Committee process that is largely dependent on the agencies who have overseen the development of the legislation that is under review.

The public, including both experts and lay people, send in their critiques and perspectives on a Bill or amendment that is published on the Parliamentary website. Members of the relevant Select Committee listen to the public and look through the report that is presented to them. In New Zealand, the responsibility for producing that report lies with … the very agency that designed the policy, that worked with the relevant Minister and Crown Law in the drafting of the Bill (and of course, all the instructions for drafting are subject to Cabinet confidentiality arrangements.

The problem with MBIE's 'problem definition'[9] is that it deals exclusively with gene technologies having 'productivity benefits', while stating that the current legislation results in 'missed opportunities'. It fails to declare that GMOs including gene-editing techniques and organisms come with long- and short-term risks. This is the entire point of a regulatory agency – to ensure a technology does not produce harm. MBIE then directly engaged with actors who supported MBIE's problem definition of missed opportunities.

Experts and groups who did not support MBIE's problem definition have been left out of consultation.

At the time of writing, some 15,000 people were reported to have submitted to the Select Committee, with 900 people asking to be heard. A release noted that people who made substantive submissions would be permitted to be heard, and that this would involve over 400 submitters for a total of 45 hours.[10] Officials have been (in the month of April) contacting some submitters and informing them that their submissions are being returned under Standing Order 220.

Legal counsel and the judiciary are unlikely to be aware that the public, including Māori, were deliberately excluded from any policy-consultation, with full awareness by officials that *significant public opposition could develop,* that no scientific evaluation had been produced by the Attorney-General, the Minister in charge, or by MBIE.

Without intervention, and with an agency intent on changing the legislation no matter the costs, PSGR anticipates that legal counsel and the judiciary that the legislation will be subject to ongoing contestation and judicial review into the future.

MBIE appears to have willingly set aside ethical issues aside. PSGR had previously scrutinised the policy process in our February 17, 2025, Submission to the Health Select Committee. We drew attention to what appears to have been a last minute inclusion of Subpart 5, which unconstitutionally requires New Zealand to rubber stamp offshore medical approvals. As PSGR informed the Health Select Committee: [11]

> *'The 'mandatory medical authorisation' [Subpart 5] was inserted into the Bill with no apparent prior discussion nor consultation. It was not discussed in the Regulatory Impact Statement. There is no public-facing policy justifying the MMA. Convention around medical therapy risk assessment for the safety and efficacy of drugs have been set aside without explanation. No policy explanation has been provided and as discussed below, the Regulator will lack the resources and expertise sufficient to satisfy obligations to protect health and safety.'*

Later in PSGRs submission (notes 193-209), we discussed in greater depth the potential for Subpart 5 to create 'extraordinary potential for abuse and harm'. PSGR suspect that the clause not only contradicts principles of the Health Act 1956, but will over-ride existing trusted public law processes, and erode trust.

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[9] Ministry for Regulation. Issue date: December 20, 2024. Regulatory Impact Statement: Reform of Gene Technology Regulation. Document (signed) date: Wednesday 31 July 2024. Page 2/131

[10] New Zealand Parliament. (February 25, 2025). Gene Technology Bill—Submissions received and schedule of hearings https://www.parliament.nz/en/pb/sc/committees-press-releases/gene-technology-bill-submissions-received-and-schedule-of-hearings/

[11] PSGR (February 17, 2024). Gene Technology Bill 2024, Submission to the Health Select Committee. Note 37 and 193-200. https://psgr.org.nz/component/jdownloads/send/1-root/167-gtbill-select-committee

[11] Gene Technology Regulation Technical Advisory Group.

[2] GENE TECHNOLOGY BILL POLICY DEVELOPMENT

The Treasury (April 2017). Government expectations for good regulatory practice.:

'Regulation significantly shapes the everyday lives of New Zealanders. It recognises and protects their wide-ranging rights and interests, and can assist them to interact with others and with the state on clear, fair and efficient terms. But regulation can also impose costs, limit freedoms, stifle innovation, and give rise to other unintended consequences. The well-being of all New Zealanders therefore vitally depends on the quality of our regulatory design and practice. Good regulatory design and practice requires considerable attention, skill, and collaboration. It must accommodate Diversity in people and organisations. It may also need to operate in complex environments in which values, social conditions, markets or technologies may be evolving rapidly, and the behavioural responses are difficult to predict in advance.'

MBIE does not allow an option to retain the status quo.

The justification for the Gene Technology Bill is published in a Regulatory Impact Statement. The Bill was introduced on December 10, 2024, just before the summer recess.

Cabinet documents[12] demonstrate that the purpose and scope of the proposed gene technology regulatory regime has revolved around a high-level plan to deregulate oversight of gene technologies and organisms from conception.

By 2018 officials were advising the Ministry for the Environment (MftE) that new gene editing techniques and organisms would produce outcomes 'indistinguishable' from naturally/conventionally bred organisms.[13] The MftE 2018 briefing paper that made these claims did not cite scientific literature, but appeared to directly draw from Royal Society literature.[14]

In 2018 the Ministry for the Environment advised that they had convened a cross-agency group which included the Ministries of Business, Innovation and Employment, Foreign Affairs and Trade and Health, the Ministry of Primary Industries, the Department of Conservation, the Environmental Protection Authority and the Treasury.[15]

Judith Collins advised officials that biotechnology regulatory reform was her top priority for the Science, Innovation and Technology portfolio, in her first meeting with MBIE officials. The proposed scope of the biotechnology reform work programme was confirmed by December 7, 2023. Initial advice on the regulation appeared to be overseen by Iain Cossar, General Manager, Science, Innovation and International, Labour, Science and Enterprise. [16]

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[12] MBIE (December 10, 2024). Coversheet. Regulation of gene technology- policy decisions. Portfolio Science, Innovation and Technology. In Confidence paper. 6e1wa178jr 2024-08-29 14:03:09. Page 8/60 https://www.mbie.govt.nz/dmsdocument/29938-regulation-of-gene-technologies-policy-decisions-proactiverelease-pdf

[13] Ministry for the Environment. Advice to David Parker. #2018-B-04195 https://environment.govt.nz/assets/Publications/18-B-04195-Genetic-Technology-Overview-and-Next-Steps.pdf

[14] Royal Society (2019). Gene Editing. https://www.royalsociety.org.nz/assets/Uploads/Gene-Editing-FINAL-COMPILATION-compressed.pdf

[15] Ministry for the Environment. Advice to David Parker. #2018-B-04195 [59] page

[16] MBIE. Iain Cossar and Judith Collins. (December 7, 2023). Briefing 2324-1263 Page 8-15/150. https://www.mbie.govt.nz/dmsdocument/29940-regulation-of-gene-technologies-policy-decisions-proactive-release-of-advice-proactiverelease-pdf

In July 2023, the Labour Government consulted on a set of 10 proposed changes to the regulations for genetically modified organisms. No summary report was released following this consultation.

A December 2023 Briefing demonstrates that Collins understood the potential for outdoor applications of gene editing techniques in the form of biocontrol agents, and that Collins considered this would be an 'open decision'. The December Briefing also shows how MBIE officials defer to the Royal Society Gene Editing campaign literature, and that officials recognised that there has been no comprehensive consultation on GMO regulation since the 2001 Royal Commission on Genetic Modification. Officials were also keenly aware of potential Māori interest, and the rights of iwi and hapu over flora and fauna and that they were 'not confident that expectations of the innovation community can be met under the existing legislation'.[17]

The scope of the work programme was to put in place new legislation and a new regulator, to ensure the reform process would encompass a wide range of genetic techniques. This would include the regulation of gene therapies used in health, and an 'open decision' to incorporate the potential for new organisms that are not the result of biotechnology would be included within the legislation.[18]

From December 2023 to February 2024 Ministry advisors worked on regulatory reform objectives and core legislative components, governance, and the approach to consultation.

The February 8, 2024, Briefing by Simon Rae, Director Emerging Technologies demonstrates that MBIE decided to approach consultation strategically through consultation with key stakeholders (Appendix I) and through a Technical Advisory Group (Appendix II).

Simon Rae noted that 'regulatory reform objectives' (which include legislative settings) would underpin the policy work and 'form a critical component of the regulatory impact analysis' and be canvassed through consultation. Rae proposed that these ensure legislation would :

- be proportionate to the risks
- deliver outcomes of benefit to New Zealand while appropriately managing risks to the environment and people
- be future proof as technology advances over time.[19]

Rae stated in the February 2024 Brief that MBIE had decided that the consultation would **not** give respondents a choice to select the status quo, of retaining the Hazardous Substances and New Organisms Act 1996 (HSNO Act), which regulates gene editing techniques, as they are a technical process:

> *'we have discounted improvements to the current process-based status quo as an option for consultation. We will develop and assess product-based and/or hybrid approaches as options for the consultation paper. Our regulatory impact analysis will need to assess these options against the process-based status quo.'*

[17] MBIE. Iain Cossar and Judith Collins. (December 7, 2023). Briefing 2324-1263 Page 8-15/150. https://www.mbie.govt.nz/dmsdocument/29940-regulation-of-gene-technologies-policy-decisions-proactive-release-of-advice-proactiverelease-pdf
[18] MBIE. Iain Cossar and Judith Collins. (December 7, 2023). Briefing 2324-1263 Page 8-15/150. https://www.mbie.govt.nz/dmsdocument/29940-regulation-of-gene-technologies-policy-decisions-proactive-release-of-advice-proactiverelease-pdf
[19] Rae S. (February 8, 2024) MBIE 2324-1836 Regulation of Biotechnology: Process. Page 19/150.

Rae's February 2024 Brief followed the direction of the Minister of Science, Innovation and Technology, Judith Collins. The RIS states[20]:

> *'At Ministerial direction we did not consider options for reforming the HSNO Act.'*

The process-based approach in the HSNO Act could be amended to allow for risk-tiering of gene editing techniques and gene-edited organisms, reducing the uncertainty of an entirely new swag of untested legislation. Judith Collins did not permit this approach to be considered. Groups have recommended this approach to the Select Committee. It is uncertain whether MBIE, who will produce the report of submissions to the Select Committee report, will disclose to the Select Committee the numbers of submitters that explicitly request that the HSNO Act is retained.

The Brief reveals how Australian legislation would become the guiding force of the construction of new legislation, calling it a 'highly regarded framework'. However, it did not provide any evidence of where the Australian legislation stood in relation to key export markets including those in Europe. There was no evaluation undertaken on the New Zealand-based risk-tiering proposal, the purpose of the precautionary approach, or any evaluation on a need for long-term monitoring beyond a short-term containment issue.

Because of the 'tight timeframes' Rae proposed that MBIE adapt and improve an existing model such as Australia's, to reduce the risk, time and resources required.

Public deliberately excluded from early policy development.

MBIE officials were aware that the public could be critical of MBIEs policy position and legislation. Rae warned of a scenario where: *'Significant public opposition develops that risks the reform's timely completion and longevity'.*

To mitigate this, Rae suggested key early targeted consultation, publication of 'a practical and accessible consultation paper that speaks to likely concerns' (this is the 'Media Pack' released in August 2024[21]), a full-length consultation (8 weeks, presumably with targeted groups) and a select committee process 'to ensure concerned parties feel their input is appropriately considered.'[22]

The selection of candidates in February 2024, confirms that MBIE were not going to bring in people who might criticise the problem definition or policy objectives. This includes people who would object to the idea of risk-tiering gene editing techniques and organisms outside regulatory powers or controls.[23]

Public consultation by this stage, was framed by setting 'regulatory reform objectives and the core legislative components for public consultation'. This inferred that consultation would occur once the Bill was published and open for submissions to the Select Committee.[24] In August 2024 the MBIE website advised the public that they could not comment until Select Committee submissions were opened.

This ensured that the general public were unable to comment on the scientific bases that formed the justification for the hybrid policy, exemptions and external risk-tiering and omission of precaution.

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[20] Ministry for Regulation. Issue date: December 20, 2024. Regulatory Impact Statement: Reform of Gene Technology Regulation. Page 3/131. Document (signed) date: Wednesday 31 July 2024

[21] MBIE August 2024 Media Pack. https://www.mbie.govt.nz/dmsdocument/28985-gene-technology-media-pack-pdf
[22] Rae S. (February 8, 2024) MBIE 2324-1836 Regulation of Biotechnology: Process. Page 23/150.
[23] Rae S. (February 8, 2024) MBIE 2324-1836 Regulation of Biotechnology: Process. Page 25/150.
[24] Rae S. (February 8, 2024) MBIE 2324-1836 Regulation of Biotechnology: Process. Page 16-26/150. https://www.mbie.govt.nz/dmsdocument/29940-regulation-of-gene-technologies-policy-decisions-proactive-release-of-advice-proactiverelease-pdf

‘Current regulatory settings are overly restrictive and disproportionate to the risks.’

Simon Rae’s Briefing in March 13 2024 confirms that newly formed National Government Gene Technology Ministerial Group took place on March 19, 2023 and that the Gene Technology Bill would be introduced to the House by December 2024. [25] The Briefing stated that the:

> *‘reform programme aims to address the problem of current regulatory settings for gene technology being overly restrictive and disproportionate to the risks, out of date, and inflexible to emerging science and technology.’*

In the March 2024 Briefing (which would be forwarded to all Ministers), New Zealand cabinet Ministers were told that

> *‘many biotechnologies pose low risks to human health and the environment and do not require regulation’.* [26]

Where is the evidence for such a statement the evidence would need to be backed up by a comprehensive body of research. The RIS problem definition hadn’t raised the question of risks, and cabinet Ministers were being privately assured in briefings that *many biotechnologies only posed low risks and therefore did not require regulation*.

Rae noted that MBIEs guidance would include whether to ‘be at the frontier’ or take a more precautionary approach to managing risks.

> *There are several options on the regulatory approach that would influence how permissive the new regime would be for the use of gene technologies. Following Australia’s example would mean adopting a ‘hybrid’ approach, which exempts certain lower-risk technologies from regulation. Other jurisdictions have gone further to exempt techniques that deliver similar results to conventional selective breeding in crops. Our options analysis would benefit from guidance on whether we should aim to be at the frontier of new technologies or should take a more precautionary approach to managing risks.*

However, as this report discusses below [6], MBIE controlled the conversation around precaution, effectively ruling it out in their communications with the Technical Advisory Group.

Rae’s Briefing, which was designed to be forwarded to the Gene Technology Ministerial Group, shows that Ministers, advisory groups and elected Members would not be granted the opportunity to advocate for a process-based approach, reiterating that the process-based system would be replaced. The choice for New Zealand only appeared to come from other English-speaking nations: with the choice of a hybrid approach (e.g. Australia or England) or an outcomes approach (e.g. USA and Canada). [27]

The Briefing shows how there is no regard for evidence of safety on those gene editing techniques which would be exempt, but rather, just a focus on what will be exempted:

> *The Australian legislation exempts relatively few techniques from regulatory oversight, known as SDN-1 techniques. Other jurisdictions, such as the United States, Canada, and England, exempt a greater number of techniques. Similarly, following approval by the European Parliament’s*

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[25] Rae S. (March 13, 2024). MBIE 2324-2241 Regulation of Biotechnology – Joint Ministers Meeting. P.27-40/150 https://www.mbie.govt.nz/dmsdocument/29940-regulation-of-gene-technologies-policy-decisions-proactive-release-of-advice-proactiverelease-pdf

[26] Rae S. (March 13, 2024). MBIE 2324-2241 Regulation of Biotechnology – Joint Ministers Meeting. P.31/150

[27] Rae S. (March 13, 2024). MBIE 2324-2241 Regulation of Biotechnology – Joint Ministers Meeting. P.33/150 https://www.mbie.govt.nz/dmsdocument/29940-regulation-of-gene-technologies-policy-decisions-proactive-release-of-advice-proactiverelease-pdf

Environmental Committee in January, the European Parliament is beginning negotiations with member states on a proposal to exempt a wider range of gene-editing techniques in plants that produce results equivalent to those that could be achieved through conventional breeding techniques. Changes to EU rules in particular have the potential to set wider norms for international trade, particularly as new techniques for gene editing are difficult to detect.

New gene editing techniques using site-directed nucleases, increases the targeting specificity, but does not make them safer. Site-directed nuclease 1 (SDN-1) reactions differ from SDN-2 and SDN-3 reactions as SDN-1 reactions do not use a nucleic acid template. However, insertions and deletions of applications (SDN-1) can result in the alteration of several different DNA sequences – and thus several properties – simultaneously (multiplexing).

> *'By producing multiple gRNAs and a Cas protein in vivo, researchers can build layered genetic circuits that control cellular behavior or modulate metabolic pathways with the simultaneous editing, activation, and down regulation of multiple target genes.'*[28]

SDN reactions, without a template (SDN-1), or with (SDN-2 and SDN-3) are powerful potential mutagens. The technologies are far more efficient at creating mutations at both intended *and* unintended sites. The frequency of mutations from SDN reactions, in comparison to spontaneous (natural) mutations can be orders of magnitude higher.[29] [30] For example, CRISPR/Cas9 is an SDN tool. Scientists continue to identify problems of off-target activity, such as induced mutations at sites other than the intended site when using CRISPR/Cas9 gene editing technology.[31] [32] [33]

New combinations of geno- and phenotypes can emerge that were neither intended nor previously considered or tested for their safety. Non-notifiable and exempt plants will evade any assessment of this likelihood.[34]

No scientific risk evaluation of the risk that these technologies present, should the Bill be passed, has occurred in New Zealand. There has been no risk assessment, only references to the Royal Society paper claiming that newer gene editing techniques and organisms could be indistinguishable from conventional species. The RIS relies on scientifically indefensible claims.

To promote transparency and accountability, governments and regulatory agencies involved in policy development which involve science claims relating to risk to human and/or environmental health follow conventions and processes to limit disagreements and disputes between the regulated industries who

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[28] McCarty, N.S., Graham, A.E., Studená, L. et al. Multiplexed CRISPR technologies for gene editing and transcriptional regulation. Nat Commun 11, 1281 (2020). https://doi.org/10.1038/s41467-020-15053-x

[29] Heinemann J, Kurenbach B, Hiscox TC, McCabe A, and Walker S. (2025) Centre for Integrated Research in Biosafety (INBI). Submission to the Parliament Health Committee on the Gene Technology Bill 2024. January 2025. University of Canterbury.Page 16.
https://www.researchgate.net/publication/388526356_INBI_submission_to_health_select_committee_gene_tech_bill

[30] Robinson C and Antoniou M (2025). Submission to Gene Technology Bill by Claire Robinson PhD (GMWatch), and Michael Antoniou, Professor of Molecular Genetics and Toxicology (King's College London, UK). Page 2 footnote (5). https://gmwatch.org/files/NZ-government-submission_final.pdf

[31] Zhang, XH, Tee, LY, Wang, XG, Huang QS, Yang SH (2015) Off-target Effects in CRISPR/Cas9-mediated Genome Engineering. *Molecular Therapy Nucleic Acids.* E264. Doi: 10.1038/mtna.2015.37

[32] Asmamaw Mengstie M, Teshome Azezew M, Asmamaw Dejenie T, Teshome AA, Tadele Admasu F, Behaile Teklemariam A, Tilahun Mulu A, Mekonnen Agidew M, Adugna DG, Geremew H, Abebe EC. Recent Advancements in Reducing the Off-Target Effect of CRISPR-Cas9 Genome Editing. *Biologics.* 2024 Jan 18;18:21-28. doi: 10.2147/BTT.S429411. PMID: 38260716; PMCID: PMC10802171.

[33] Bravo, J.P.K., Liu, MS., Hibshman, G.N. *et al.* Structural basis for mismatch surveillance by CRISPR–Cas9. *Nature* **603**, 343–347 (2022). https://doi.org/10.1038/s41586-022-04470-1

[34] PSGR (February 17, 2024). Gene Technology Bill 2024, Submission to the Health Select Committee. https://psgr.org.nz/component/jdownloads/send/1-root/167-gtbill-select-committee

wish to sell or release their technologies, and the public, who trust the governments and agencies to ensure that human and environmental health is not damaged. Levels of exposures and emissions will impact people and ecosystems differently, and regulatory decisions can be controversial.

This is why conventionally accepted protocols, such as methods-based systematic reviews of the relevant scientific evidence are in place. For pesticides a benchmark level of harm is required. GMO risks are difficult to predict, from an inflammatory reaction in food, to gene flow into surrounding species. [35] [36] Systematic reviews and risk assessments are vital to ensuring trust there was no bias nor predetermination in the approach of authorities.

These assessments need to provide clear scientific evidence, including how information and data was identified, including declaring the time-frame over which the review took place. References to all pieces of scientific evidence should be cited. These processes act as a safeguard against agencies cherry-picking data to suit a political agenda.

The only way regulations can be risk-proportionate, is if the risks are talked about in the first place. But this wasn't part of the problem definition.

Europe still hasn't finalised their policies and regulations. On March 7, 2025, member states' representatives endorsed the Council's negotiating mandate on the regulation on plants obtained by new genomic techniques (NGTs) and their food and feed. The draft regulation text amending Regulation 2017/625 includes plants, i.e. organisms in the taxonomic groups Archaeplastida or Phaeophyceae, but does not include microorganisms, fungi and animals. [37] [38] [39]

The gene editing of animals has not been permitted in the European Union. However, a draft Scientific Opinion was released (March 14 2025) to consider the use of SDN technologies in animals.[40] The Opinion will be scientifically controversial because it sustains the claim that off-target mutations from genome editing using SDN processes are similar in nature to mutations that arise from conventional breeding, and claims that no new potential hazards are expected. This claim continues despite a lack of methods-

[35] Eckerstorfer, M.F., Grabowski, M., Lener, M., Engelhard, M., Simon, S., Dolezel, M., Heissenberger, A., Lüthi, C. (2021) Biosafety of genome editing applications in plant breeding: Consideration for a focused case-specific risk assessment in the EU. biotech 10, https://doi.org/10.3390/biotech10030010

[36] Koller, F. et al. (2023): The need for assessment of risks arising from interactions between NGT organisms from an EU perspective. Environmental Sciences Europe 35, 27. https://doi.org/10.1186/s12302-023-00734-3

[37] European Parliament (April 24, 2024) P9_TA(2024)0325 Plants obtained by certain new genomic techniques and their food and feed https://www.europarl.europa.eu/doceo/document/TA-9-2024-0325_EN.pdf

[38] Council of the European Union. (March 14 2025). New genomic techniques: Council agrees negotiating mandate. https://www.consilium.europa.eu/en/press/press-releases/2025/03/14/new-genomic-techniques-council-agrees-negotiating-mandate/?utm_source=brevo&utm_campaign=AUTOMATED%20-%20Alert%20-%20Newsletter&utm_medium=email&utm_id=3318

[39] Council of the European Union (March 7, 2025). Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625. Annex: Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their products food and feed, and amending Regulation (EU) 2017/625. https://data.consilium.europa.eu/doc/document/ST-6426-2025-INIT/en/pdf

[40] New developments in biotechnology applied to animals: an assessment of the adequacy and sufficiency of current EFSA guidance for animal risk assessment. EFSA Panel on Genetically Modified Organisms. https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000003Wxsr/pc1293

based risk assessment that demonstrate that the literature on risk has been systematically evaluated.[41] [42] [43]

There is a strong possibility that in Europe, nothing will be completely 'exempt' but that all GMOs will be regulated to some extent. Regulators would require the industry to supply data to prove that a particular gene edited crop would be sufficiently safe to require light touch regulation.[44]

In a letter to MPs in December, PSGR urged that MPs halt the progress of the Bill until Europe has finalised new GMO laws.[45]

The closed nature of government processes (Rae's Briefings would only become available in December 2024) revealed that the key gene technology reform was administered by policy-makers who recognised that they were fundamentally shifting GMO oversight to an industry-friendly paradigm, and who recognised the potential for public disquiet. With this acknowledged, MBIE was working quickly to selectively consult, while controlling how much information was released to the public.

Deliberate exclusion of the public (including Māori) from consultation

Until the publication of the Gene Technology Bill and Regulatory Impact Statement (RIS) in December 2024, the August 2024 Media Pack was the only literature released by MBIE to inform the public of the scientific basis for the entire regulatory reform of gene technologies. Yet, neither the RIS, nor the Media Pack would provide evidence of any systematic evaluation of the scientific literature to justify the claims that some GMOs could be indistinguishable from conventionally bred organisms. These assumption were used to claim that such GMOs posed no risk to human or environmental health, and could therefore be risk tiered outside the legislation.

Once the RIS was released, the public could see that neither a cost-benefit analysis, nor an economic analysis had been done. The public could not comment on the inaccurate assertions made in the Media Pack.

Public concerns with the absence of scientifically robust evaluations would likely be ruled by the Select Committee as outside the scope of discussion, as the Technical Advisory Group had been consulted throughout the process, ensuring that the science was settled. Science, by definition, is never settled and should always be open to scrutiny. In the past, Select Committees have moved quickly to dismiss comments by experts and the public when they have questioned the validity and the robustness of scientific information used to justify new legislation.[46]

Rae recognised that the proposed deregulation of gene editing technologies would be of particular concern to Māori, due to the potential for contamination of taonga species. Despite earlier papers

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[41] Dolezel M, Lang A, Greiter A, Miklau M, Eckerstorfer M, Heissenberger A, Willée E, Züghart W. Challenges for the Post-Market Environmental Monitoring in the European Union Imposed by Novel Applications of Genetically Modified and Genome-Edited Organisms. BioTech (Basel). 2024 May 15;13(2):14. doi: 10.3390/biotech13020014. PMID: 38804296; PMCID: PMC11130885

[42] See. E.g. GeneWatch UK response to EFSA's consultation on GM animals March 2025. https://genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/gw-response-to-efsa-genetically-modified-animals-fin.pdf

[43] Test Biotech (March 2025). Use of new genetic engineering in farmed vertebrates: a critical assessment. https://www.testbiotech.org/wp-content/uploads/2025/03/NGT-Livestock.pdf

[44] Hodgson, R. (February 24, 2025). European governments heading towards GMO deregulation. *Euronews* https://www.euronews.com/my-europe/2025/02/24/european-governments-heading-towards-gmo-deregulation

[45] PSGR (December 19, 2024). PSGR request that MPs put the Gene Technology Bill on hold pending a European Commission outcome. https://psgrnz.substack.com/p/psgr-request-that-mps-put-the-gene

[46] Bruning J. (November 28, 2023). Locking in Mandated Medicine by Short-Circuiting Democracy. *Brownstone Institute.* https://brownstone.org/articles/locking-in-mandated-medicine-by-short-circuiting-democracy/

recommending that wide consultation occur, Rae's Brief showed that specific Māori and iwi groups would be targeted, with the general population excluded from consultation.

While MBIE documents repeatedly claim that their proposed regime would result in risk-proportionate and safe use of gene technologies, their actions demonstrate that they have not consulted with experts in regulatory policy and legislation. This is despite claiming that some technologies and organisms are so safe, that they never need to be regulated, monitored, traced or labelled.

A large body of submissions to the Gene Technology Bill 2024 has detailed how this Bill cannot assure the safe use of gene technologies and regulated organisms. Submitters in this category include scientists with international expertise in biotechnology and risk assessment of GMOs.[47]

To any concerned organisation or individual, the actions of MBIE along with Hon. Judith Collins KC, and the evidence available in Cabinet documents, strongly suggests that a small quorum of officials have effectively reverse-engineered policy to fit their aimed desires for the final legislation.

Collins: Repeated political framing around economic benefit. Risk not addressed.

The Attorney-General Judith Collins repeatedly frames New Zealand's out-dated laws around removing regulatory barriers to support the biotechnology industry. [Appendix III].

On completing the bulk of consultation and having drafted the Regulatory Impact Statement, in August 2024 the Attorney-General Honourable Judith Collins announced the gene regulation reform.[48] Her public statements arguably misled officials, elected members and the general public as the key objective of risk management and protection of human and environmental health, was downplayed in her release, in favour of proposed economic benefits. Collins stated that a 'ban' would be ended (there never was a ban) and that New Zealand GMO laws lag behind other countries (when they don't), going on to declare that the existing legislation would 'be based on Australia's Gene Technology Act 2000 and modified to work here in New Zealand'.

It's noteworthy that Collins is also responsible for digitising government policy-oversight. Collins released guidelines in February for clear expectations relating to the adoption of Artificial Intelligence (AI) in the public sector.[49]

No gene technology regulatory reform document has addressed the potential for AI-driven tools to enhance and accelerate gene editing research and output, including by automating the synthesis of novel genetic sequences at an unprecedented scale. MBIE acknowledge that:

> *'Under the new regime, there is likely to be greater prevalence of regulated organisms and related activities in New Zealand.'* [50]

Despite this admission, the potential for technologies to scale up the adoption and release of GMOs into people and the environment has not been evaluated or discussed in New Zealand gene technology reform policy. As PSGR noted in our Submission to the Select Committee:

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[47] See for example: Submission to Gene Technology Bill by Claire Robinson PhD (GMWatch), and Michael Antoniou, Professor of Molecular Genetics and Toxicology (King's College London, UK) https://gmwatch.org/files/NZ-government-submission_final.pdf

[48] Collins J. (August 13, 2024). New Zealand to benefit from end to gene tech ban. *Beehive Press Release*. https://www.beehive.govt.nz/release/new-zealand-benefit-end-gene-tech-ban

[49] Collins J. (February 3, 2025). Guidance for safe use of AI in the public sector. *Beehive Press Release*. https://www.beehive.govt.nz/release/guidance-safe-use-ai-public-sector

[50] MBIE (June 18, 2024) Event briefing on a Meeting with the New Zealand Environmental Protection Authority. Page 19.

> *'The Regulatory Impact Statement (RIS) has not been transparent on how the pace of change comes with its own risks. It has failed to communicate that the rapid development and application of CRISPR/Cas gene technologies, has caused a revolution in the field of genetic and genomic studies and shortened the bench-to- market timeline. New developments no longer require a lab to gene edit which is now possible in-field. Artificial Intelligence (AI) will further speed these processes up.'*[51]

The December 2024 Hansard Transcript[52] of the First Reading of the Gene Technology Bill demonstrates how Judith Collins rhetorically emphasises the alleged safety of the proposed regime, but correspondingly reveals Collins political position and lack of interest in transparently justifying to members of Parliament just how the legislation will proportionately steward risk:

> *Today, New Zealand moves into the present with a safe enabling regulatory regime. The legislation will enable the sorts of innovation that will benefit New Zealand while effectively managing risks to the health and safety of people and the environment.*
>
> ...
>
> *'Our current regulations for genetically modified organisms are some of the most backward looking in the world. New Zealand has lagged behind other countries, such as Australia, Canada, and England, which have safely embraced these technologies for the benefit of their people and their economies.*
>
> ...
>
> *We want to see that this legislation actually works for longer, because this is a technology that is advancing really, really fast. That's why it's important that the legislation is not based on technique, but on risk. Regulation should be proportional to risk.'*

Collins persistently advocates for the technologies that will be deregulated, telling members of Parliament (MPs) that the Bill will enable a pathway to regulatory assessment which 'is designed to ensure the public and environmental safety of New Zealand'. Collins does not discuss the gene editing technologies and organisms that are exempted that broadly contradict the 'risk-proportionate' claim – as they are entirely drafted out of any future regulation.

The language shows how future deregulation can occur through secondary legislation. However, the Bill content clearly demonstrates that there is no capacity for the regulator to reassess risk from any exempted categories that are risk-tiered outside the scope of the Gene Technology Bill. [53]

Collins enthuses to MPs on the potential applications, many if not most are speculative and have not yet shown commercial viability. The basis for Collins' excitement comes from claims by the Royal Society from 2016-2019. Yet Royal Society claims from five years ago have never re-evaluated their benefits to see if the claimed benefits eventuated. There are many other ways science research budgets can be directed to solve human and environmental problems.

Collins does not discuss global consumers resistance to purchasing and consuming GMO foods. Nor does Collins disclose the fact that most biotechnology start-ups fail as they are unable to produce the

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[51] PSGR (February 17, 2024). Gene Technology Bill 2024, Submission to the Health Select Committee. Page 11. https://psgr.org.nz/component/jdownloads/send/1-root/167-gtbill-select-committee
[51] Gene Technology Regulation Technical Advisory Group.
[52] Collins J. (December 17, 2024). Gene Technology Bill — First Reading https://www.parliament.nz/en/pb/hansard-debates/rhr/combined/HansDeb_20241217_20241217_32
[53] PSGR (February 17, 2024). Gene Technology Bill 2024, Submission to the Health Select Committee.
[53] Gene Technology Regulation Technical Advisory Group.

much-vaunted promises. It is likely that without government funding, most would not survive in the first place.[54] [55] If biotech startups require government investment to succeed and if they require the government to reduce regulations to enable biotech startups to avoid regulatory processes, is this the 'free market' or market distortion?

New Zealand's focus on premium food production is undoubtedly a 'better bet' with evidence that returns from investment in food are known to be higher than those from investment in biotechnology.[56] In addition, once start-ups are spun off, globally dominant biotechnology 'whales' tend to dominate, with few products succeeding.[57] Would research monies be better directed to business development that is less ethically questionable, that doesn't result in patented ownership of natural organisms and resources?

Biotechnology is speculative and ethically problematic. The large investments for development are not countered by investment into risk, e.g.,, gene flow from GE grasses, or impact on digestion and metabolism from GE grasses or methane biologic drugs. Such research could inform regulatory guidelines, for example to highlight biological biomarkers that could be used to identify metabolic changes.

The media has failed to take an active interest in the veracity of claims, and the quality of the policy process.

Scientists challenge MBIE information-gaps and risk-proportionate assertions

The development of technologies that can enhance, speed up and increase the potential for risk to human and environmental health from gene edited techniques and organisms has not been evaluated in MBIE policy documents. As Dr Nicole Wheeler and Associate Professor Paul Gardner noted in their submission to the Bill:

> *Advances in synthetic genomics (Hoffmann et al., 2023) and AI-assisted bioengineering (Wheeler et al., 2024) demonstrate that gene technologies can be used both for beneficial and potentially harmful purposes. Screening and monitoring frameworks need to be strengthened to prevent the misuse of synthetic DNA technologies, particularly in cases where gene-editing tools could be exploited for malicious purposes or where AI-based predictive models might facilitate unregulated or unintended genetic modifications.*
>
> ...
>
> *AI-driven tools can design, optimize, and automate the synthesis of novel genetic sequences at an unprecedented scale. While these technologies accelerate innovation, they also introduce risks related to the unintended emergence of highly virulent or resistant genetic variants (Yu et al., 2025). Without explicit AI-specific safeguards, there is a risk that regulatory oversight will lag behind technological developments.'*

[54] PSGR (February 17, 2024). Gene Technology Bill 2024, Submission to the Health Select Committee. Page 14.
[54] Gene Technology Regulation Technical Advisory Group.
[55] Shin, K., Park, G., Choi, J. Y., & Choy, M. (2017). Factors Affecting the Survival of SMEs: A Study of Biotechnology Firms in South Korea. *Sustainability*, *9*(1), 108. https://doi.org/10.3390/su9010108
[56] Visual Capitalist. February 10, 2025. Ranked: U.S. Industries Where Companies Are Least Profitable. Data sourced from Damodaran Online, NYU Stern School of Business. https://www.visualcapitalist.com/ranked-u-s-industries where-companies-are-least-profitable/
[57] PSGR February 2025 interview with Dr David Bell, public health physician and biotech consultant in global health. https://www.youtube.com/watch?v=3HQIfBcF5t8

In an article in non-legacy media that Google search engines don't pick up, Professor David Williams of the University of California, Los Angeles School of Medicine who is working with gene therapies to treat inherited human diseases wrote:

> *'Recent progress in methods for gene manipulation have made it easier (and faster) to make GMOs. New methods, such as gene editing, have been described as more precise, because they may involve smaller changes in the genome. However, precision doesn't equate with less risk. The newer methods still involve the introduction of foreign genetic material, and they still carry the risk of unintended changes; e.g. making alterations to other genes in addition to the gene being targeted. Small changes in genes can be just as devastating as large changes. Hence, current GMO methods mean it's also easier (and faster) to cause harm, making regulation of GMOs even more essential – not less.'*[58]

Professor of Molecular Genetics and Toxicology, King's College London Michael Antoniou and Claire Robinson of GMWatch emphasised that regulators cannot generalise that gene-edited organisms will result in far fewer mutations than conventionally bred organisms.[59] Their submission to the Health Select committee advised that out necessity, industry applicants must provide the evidence to prove legally and scientifically that an organism would be indistinguishable from conventional organisms and hence pose no risks beyond conventionally bred organisms. The data that would enable this would include:[60]

> *In order to change these assumptions about the relevant GMOs into legally sound and scientifically based facts, the applicant must be required to prove that their GMO cannot be distinguished from conventionally bred organisms and therefore poses minimal risk. The applicant must therefore be required to provide*
>
> - *Long-read and deep whole genome sequencing, which is generally seen in the scientific community as the best way of capturing unintended large-scale deletions and rearrangements, as well as unintended insertions of foreign DNA that can be missed by the more frequently performed short-read sequencing.*
> - *"Omics" molecular compositional analyses (proteomics protein profiling, metabolomics biochemical profiling) should be required to be performed, to ensure that the GMO is truly compositionally, including nutritionally, equivalent to the non-GM parental organism with the exception of the intended genetic modification, that no unexpected toxins or allergens have been created in claimed-exempted plants, and that no unexpected allergens have been created in claimed-exempted animals. There is broad scientific support for this approach.*

The RIS and Gene Technology Bill fails to require the applicant to scientifically and legally prove that the distinguishability (or lack thereof) of their so-called exempt organism. A ticking the box scenario is not rigorous and could lead to abuses of process. This submission highlights that the current process-based HSNO Act remains relevant, and could be adjusted, with secondary legislation to require a certain Long-read and deep whole genome sequencing and omics molecular analyses to be provided as evidence that any changes will be indistinguishable.

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[58] Williams D.S. The Risks of GMO Deregulation to NZ Farmers. *Concerned Farmers NZ*. https://www.concernedfarmersnz.org/news/nzier-report-on-potential-cost-of-regulatory-change-54pya-ngzgb

[59] See e.g. Tang, X., Liu, G., Zhou, J. *et al.* A large-scale whole-genome sequencing analysis reveals highly specific genome editing by both Cas9 and Cpf1 (Cas12a) nucleases in rice. *Genome Biol* **19**, 84 (2018). https://doi.org/10.1186/s13059-018-1458-5

[60] Robinson C and Antoniou M (2025). Submission to Gene Technology Bill.

Molecular geneticist Professor Jack Heinemann, Director of the Centre for Integrated Research on Biosafety and colleagues, expressed in their submission to the Gene Technology Bill that New Zealand regulations would end up being far weaker than most Western countries:[61]

> *Of the 20 countries that have changed their regulations, 15 have taken the decision to reduce regulation on all species – microorganisms, plants, fungi, and animals. Many retain a case-by-case evaluation even if operationally they expedite some pre-defined outcomes. Only 2 of them, Japan and Australia, are in New Zealand's top 5 export markets at 5% and 16% by revenue, respectively. The remainder have amended regulations for use on only plants (3 countries), or only on plants and animals (2 countries). All 29 of the countries still consulting on their laws, including the EU countries, are only considering regulation changes for use on plants.*
>
> *The proposed changes in our gene technology laws does not align us with trading partners. We would open our borders to, or produce within our borders, unregulated outcomes that our trading partners regulate.'*

MPs are likely poorly informed, whether they turn to the responsible Minister or to the media. The media do not have to intimately understand the complexities of the scientific concepts and language, but the media can call attention to unverified claims by officials, poor policy development and biased consultations and highlight when people have conflicts of interest.

Dr Valentina Dinica, an Associate Professor in Victoria University's School of Government, has evaluated, and demonstrates, a persistent and sustained bias in New Zealand media that advocates for deregulatory viewpoints. This includes a frequent failure to declare the conflicts of interests held by scientists, or their employing institutions, in articles which discuss gene technology regulatory reform.:

> *Communications in the mass media, elite media and official policy advisory reports have been dominated by vested-interested scientists, from a narrow range of disciplines. As detailed below, my research shows that since January 2017, actors advocating for the deregulation of a wide range of genome-engineering biotechnologies (GEB - which includes all gene editing techniques) have had their views significantly overrepresented in the policy-relevant public arena, relative to scientists from other disciplines and actors holding other values, worldviews and interests.*

Dinica's research has also identified that channels of media and policy advisory reports used by scientists with vested-interests and by biotech industries have been often misused, resulting in three types of misinformation: omissions, misrepresentations and falsehoods.

> *Communications affected by significant quality issues have been contributed by some of the politicians supporting this Bill, several journalists, pro-GEB [genome-engineering biotechnologies] businesses and some vested-interest scientists…'*
>
> …
>
> *These actors, who dominated public discourse for many years, have provided no insights into GEB application performance other than claims of benefits; provided no communications on the ethical, cultural, biosecurity, the broader socio-economic and ecological aspects of GEB applications – other than sweeping claims of safety.*

The purpose and scope of any regulatory regime must a priori focus on risk and safety *a priori,* without a presumption that the technologies are safe. This involves being transparent about scientific information

[61] Heinemann J, Kurenbach B, Hiscox TC, McCabe A, and Walker S. (2025) Centre for Integrated Research in Biosafety (INBI). Submission to the Parliament Health Committee on the Gene Technology Bill 2024. January 2025.

and about the decision-making processes regulators must go through to ensure that risks are not downplayed, so as to prevent negative outcomes.

[3] POLITICAL NEUTRALITY & GOOD REGULATORY PRACTICE

The *Government expectations for good regulatory practice*[62] document states that:

> *'The government expects any regulatory system to be an asset for New Zealanders, not a liability.*
>
> *By that we mean a regulatory system should deliver, over time, a stream of benefits or positive outcomes in excess of its costs or negative outcomes. We should not introduce a new regulatory system or system component unless we are satisfied it will deliver net benefits for New Zealanders. Similarly, we should seek to remove or redesign an existing regulatory system or system component if it is no longer delivering obvious net benefits.'* [63]

The *Government expectations for good regulatory practice* document requires agencies conduct robust analysis before any changes to regulatory systems, including by:

- *clearly identifying 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*
- *undertaking 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.*
- *making genuine effort to identify, understand, and estimate the various categories of cost and benefit associated with the options for change.*[64]

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.

A pervasive issue faced by regulatory agencies is the challenge of identifying when irreversible harm to a biological system – whether it be a human body, to an insect, livestock, soils and vegetation or a water course – may commence. This is why precaution is often integrated into legislation, such as in Europe.[65] [66] [67]

The regulatory reform process has clearly been designed by MBIE to support the biotechnology industry and deregulate technologies and organisms. One could reasonably expect that there would have been engagement and evaluation of the nature and types of risk that could arise from the deregulated organisms being risk-tiered outside the regulatory scope. This has not occurred.

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[62] The Treasury (April 2017). Government expectations for good regulatory practice. Page 4. https://www.treasury.govt.nz/sites/default/files/2015-09/good-reg-practice.pdf
[63] The Treasury (April 2017). Government expectations for good regulatory practice. Page 4.
[64] The Treasury (April 2017). Government expectations for good regulatory practice. Page 6.
[65] European Food Law general principles (including precautionary principle). https://food.ec.europa.eu/horizontal topics/general-food-law/food-law-general-principles_en
[66] See PSGR discussion on the Precautionary Principle. https://psgr.org.nz/precautionary-principle
[67] Scott, Dale. (2016) Masters thesis (School of law): Application of the precautionary principle during consenting processes in New Zealand: Addressing past errors, obtaining a normative fix and developing a structured and operationalised approach. Victoria University of Wellington. 2016-01-01 https://openaccess.wgtn.ac.nz/articles/thesis/Application_of_the_precautionary_principle_during_consenting_processes_in_New_Zealand_Addressing_past_errors_obtaining_a_normative_fix_and_developing_a_structured_and_operationalised_approach/17018624

MBIE have not conducted a *systematic impact and risk analysis*, nor has it made a *genuine effort to identify, understand, and estimate the various categories of cost and benefit associated with the options for change.*[68].

The *Government expectations for good regulatory practice* document states that new regulation must conform to established legal and constitutional principles and support compliance with Treaty of Waitangi obligations. It notes that harmonisation with international standards and practices must not come at a cost of important domestic objectives and values.

New regulation must have '*scope to evolve in response to changing circumstances or new information on the regulatory system's performance.'* The writing out of some gene editing techniques and organisms as exempt, as MBIE have predetermined these organisms to be of negligible or low risk, expressly contradicts this last point.

The sole focus of the problem definition has revolved from commencement, around a claim that a new regulatory regime for gene technologies was required, based on research, development and commercialisation benefits.

> *'The government expects regulatory agencies to:*
>
> *maintain a transparent compliance and enforcement strategy that is evidence-informed, risk-based, responsive, and proportionate to the risks or harms being managed'*[69]

As the underlying scientific claims which have resulted in the MBIE pre-designating exempt categories of gene editing technologies and organisms, this expectation that regulation will be 'evidence-informed, risk-based, responsive, and proportionate to the risks or harms being managed' cannot be upheld.

Impact Analysis documentation missing. Claim it 'partially meets the criteria'.

> *'Regulatory agencies are expected to adopt a whole of-system view, and take a proactive, collaborative approach to the care of the regulatory system(s) within which they work. The Impact Analysis Requirements focus in particular on the expectation that agencies provide robust analysis and advice to Ministers before decisions are taken on regulatory change.'*

An Impact Analysis should be completed and summarised in a Regulatory Impact Statement before the Cabinet paper is drafted. Regulatory Impact Statements summarise an agency's best advice on the Impact Analysis. [70]

Impact Analysis appears to have been perfunctory and brief. No Impact Analysis was published in the Regulatory Impact Statement. There was no disclosure of any assessment of the costs, benefits and risks across the New Zealand economy and the environment.

[68] The Treasury (April 2017). Government expectations for good regulatory practice. Page 6.
[69] The Treasury (April 2017). Government expectations for good regulatory practice. Page 7.
[70] The Treasury (June 2020). Guide to Cabinet's Impact Analysis Requirements.
https://www.treasury.govt.nz/sites/default/files/2020-06/guide-cabinet-ia-requirements-june2020.pdf

MBIEs Regulatory Impact Analysis Review Panel from the very Ministries that will directly benefit from the new Bill convened to look through the RIS. This was viewed to act as a sufficiently robust Impact Analysis[71] [72]:

> '[89] A joint MBIE, MfE and MPI Regulatory Impact Analysis Review Panel has reviewed the attached Impact Statement prepared by MBIE. The Panel considers that the information and analysis summarised in the Impact Statement partially meets the criteria necessary for Ministers to make informed decisions on the proposals in this paper.'

Impact Analysis is 'essentially just robust policy development within a transparent framework'. Why is an Impact Analysis, summarised in a Regulatory Impact Assessment, beneficial?

- *Enhancing the evidence-base to inform decisions about regulatory proposals—to ensure that all practical options for addressing the problem have been considered and that the benefits of the preferred option not only exceed the costs but will deliver the highest level of net benefit, and*
- *Transparency—the presentation of agencies' free and frank advice to decision-makers at the relevant decision points provides reassurance that the interests of all sectors of the New Zealand public have been considered. Impact Analysis also aims to encourage the public to provide information to enhance the quality of regulatory decisions, to further inform the evidence-base.*[73]

The Treasury Guidance Note for Best Practice Impact Analysis emphasises that a good problem definition will explain the gap between the current situation and the outcome. The problem definition will make the central case for regulatory intervention. What has been avoided by officials, is an honest appraisal of the size of the problem – including any future risks that must evaluated and weighed up.

The problem definition needs to do more than identify the gap between status quo and objectives: it should discuss its size and importance. This involves identifying the costs and benefits of the current arrangements, including:

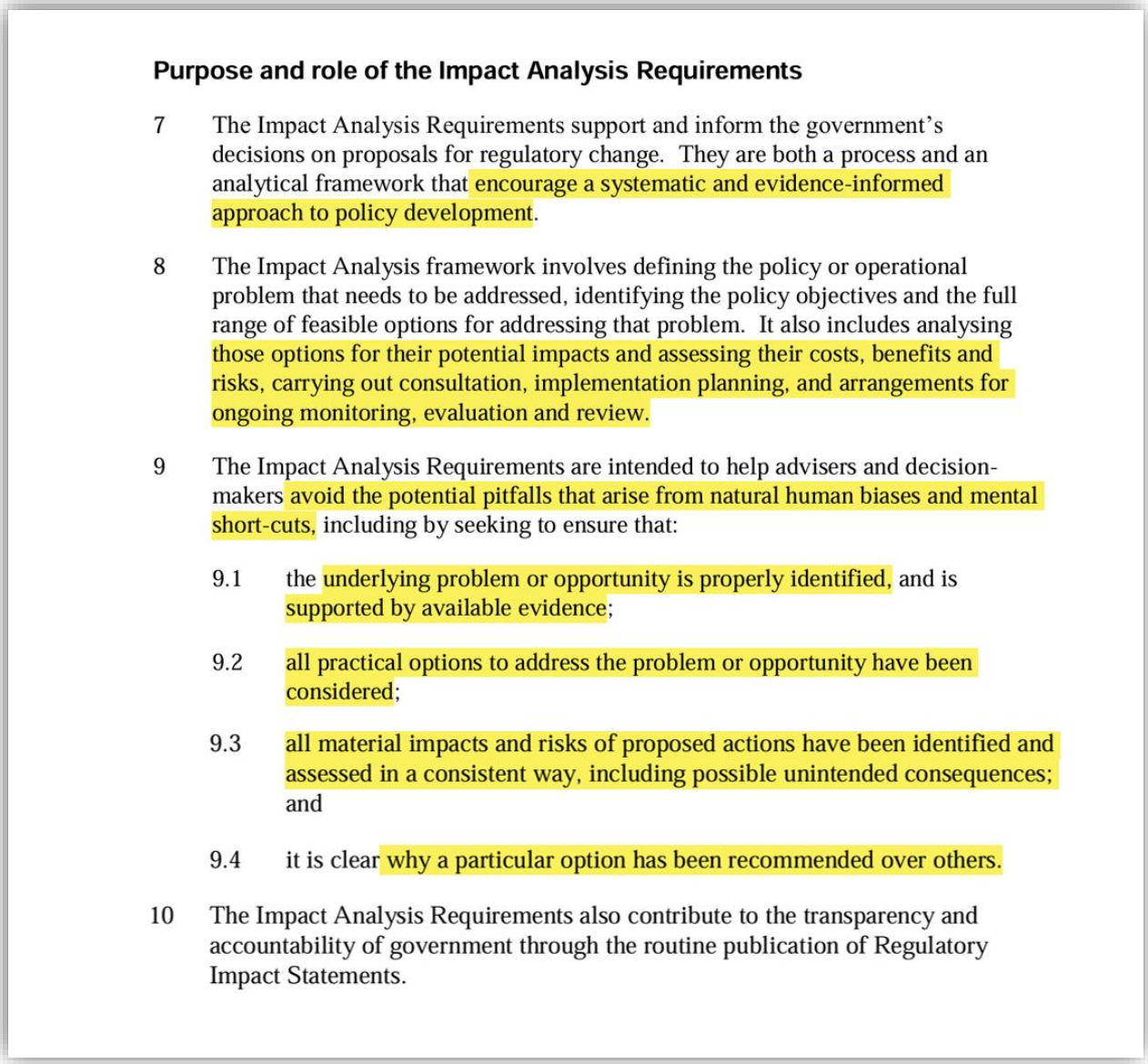
- *the nature and probability of the adverse outcome/s that will arise in the absence of further government intervention (in addition to the interventions already in place), and*

[71] MBIE (December 10, 2024). Coversheet. Regulation of gene technology- policy decisions. Portfolio Science, Innovation and Technology. In Confidence paper. 6e1wa178jr 2024-08-29 14:03:09 Page 118/150https://www.mbie.govt.nz/dmsdocument/29938-regulation-of-gene-technologies-policy-decisions-proactiverelease-pdf

[72] Ministry for Regulation. Issue date: December 20, 2024. Regulatory Impact Statement: Reform of Gene Technology Regulation. Page 11/131. Document (signed) date: Wednesday 31 July 2024 https://www.regulation.govt.nz/our-work/regulatory-impact-statements/regulatory-impact-statement-reform-of-gene-technology-regulation/

[73] The Treasury. Guidance Note Best Practice Impact Analysis June 2017. https://www.treasury.govt.nz/sites/default/files/2018-03/ia-bestprac-guidance-note.pdf

- *who is likely to be affected by the adverse outcome, including how widespread it is likely to be (ie, how many individuals, groups, firms etc. are affected), what harm or injury is likely to occur, and the magnitude of these impacts.*[74]



Purpose and role of the Impact Analysis Requirements

7 The Impact Analysis Requirements support and inform the government's decisions on proposals for regulatory change. They are both a process and an analytical framework that encourage a systematic and evidence-informed approach to policy development.

8 The Impact Analysis framework involves defining the policy or operational problem that needs to be addressed, identifying the policy objectives and the full range of feasible options for addressing that problem. It also includes analysing those options for their potential impacts and assessing their costs, benefits and risks, carrying out consultation, implementation planning, and arrangements for ongoing monitoring, evaluation and review.

9 The Impact Analysis Requirements are intended to help advisers and decision-makers avoid the potential pitfalls that arise from natural human biases and mental short-cuts, including by seeking to ensure that:

9.1 the underlying problem or opportunity is properly identified, and is supported by available evidence;

9.2 all practical options to address the problem or opportunity have been considered;

9.3 all material impacts and risks of proposed actions have been identified and assessed in a consistent way, including possible unintended consequences; and

9.4 it is clear why a particular option has been recommended over others.

10 The Impact Analysis Requirements also contribute to the transparency and accountability of government through the routine publication of Regulatory Impact Statements.

Fig.1: Cabinet Office Circular (June 20, 2020). CO(20)s.

In addition, no evaluation was undertaken to identify whether provisions regarding 'affected persons' which is in the Resource Management Act 1991 should be adopted in the Gene Technology Bill.

The sole discussion of expected costs and benefits on different groups appears to be contained in page 113-116 of the Regulatory Impact Statement.[75] [76]

[74] The Treasury. Guidance Note Best Practice Impact Analysis June 2017. Page 10.
[75] Collins, J (Undated) Response to OIA request. Ref:JCOIA-230 https://fyi.org.nz/request/29214/response/114609/attach/2/230%20response.pdf
[76] MBIE (December 14, 2024). Response to OIA request. DOIA-REQ-0006467-J Bruning https://fyi.org.nz/request/29216/response/114691/attach/3/DOIA%20REQ%200006467%20J%20Bruning%20Response%20letter.pdf

'Inadequate impact analysis often arises from incomplete problem definition, unclear objectives and a failure to consider all feasible options.' [77]

[4] WHEN THE ECONOMIC GROWTH AGENCY CONTROLS SCIENCE FUNDING

To prevent abuses of power and to ensure maximum transparency, government agencies tasked with economic growth do not by convention, take on the task of creating the legislation that is tasked with regulating the very technologies that they view as contributing to economic growth.

MBIES massive funding budget persistently tracks to tie science and research funding to commercialisation outcomes. It is important to note that the extraordinary funding budget that MBIE controls. Research scientists in New Zealand are unlikely to contradict the agency that provides the funding for staff, equipment and laboratory reagents.

New Zealand's Economic Development and Infrastructure Sector controls science funding and MBIE control the science funding policy and budget.[78] The Minister of Science, Innovation and Technology is responsible for appropriations of just over $1,212 million in the 2024/25 financial year.[79]

- $359 million for the Strategic Investment Fund to support long-term programmes of mission-led science with
- $247 million for the Endeavour Fund to invest in the highest quality, mission-led research proposals for areas of future growth and critical need
- $125 million for the Health Research Fund to achieve an improvement in health and well-being through health research.
- $92 million for Research & Development Growth Grants, Targeted Business Research and Development Funding, and Repayable Grants for Start-Ups, to co-fund private businesses for investment, research, development projects, and funding for students to work in research and development active businesses.
- $86 million to allow Callaghan Innovation to support businesses to successfully develop new and improved products, processes and services through research and development, and technology-driven innovation.
- $79 million for the Marsden Fund for fundamental research.
- $53 million to the Catalyst Fund to achieve improved international flows of people, ideas, investment and trade through support of international research relationships.

Responsibility for gene technology reform was transferred from the Ministry of the Environment to MBIE, without any senior academics or bureaucrats pointing to the inappropriate nature of an economic growth agency, with a culture that prioritises industry development, then steering regulatory laws and standards.

[77] Cabinet Office Circular (June 20, 2020). CO(20)s https://www.dpmc.govt.nz/sites/default/files/2020-06/coc20-2-impact-analysis-requirements.pdf
[78] MBIE (October, 2015) National Statement of Science Investment 2015-2025. https://www.mbie.govt.nz/assets/2eaba48268/national-statement-science-investment-2015-2025.pdf
[79] Vote Business, Science and Innovation. The Estimates of Appropriations 2024/2025 – Economic Development and Infrastructure Sector. https://budget.govt.nz/budget/pdfs/estimates/v1/est24-v1-buscin.pdf

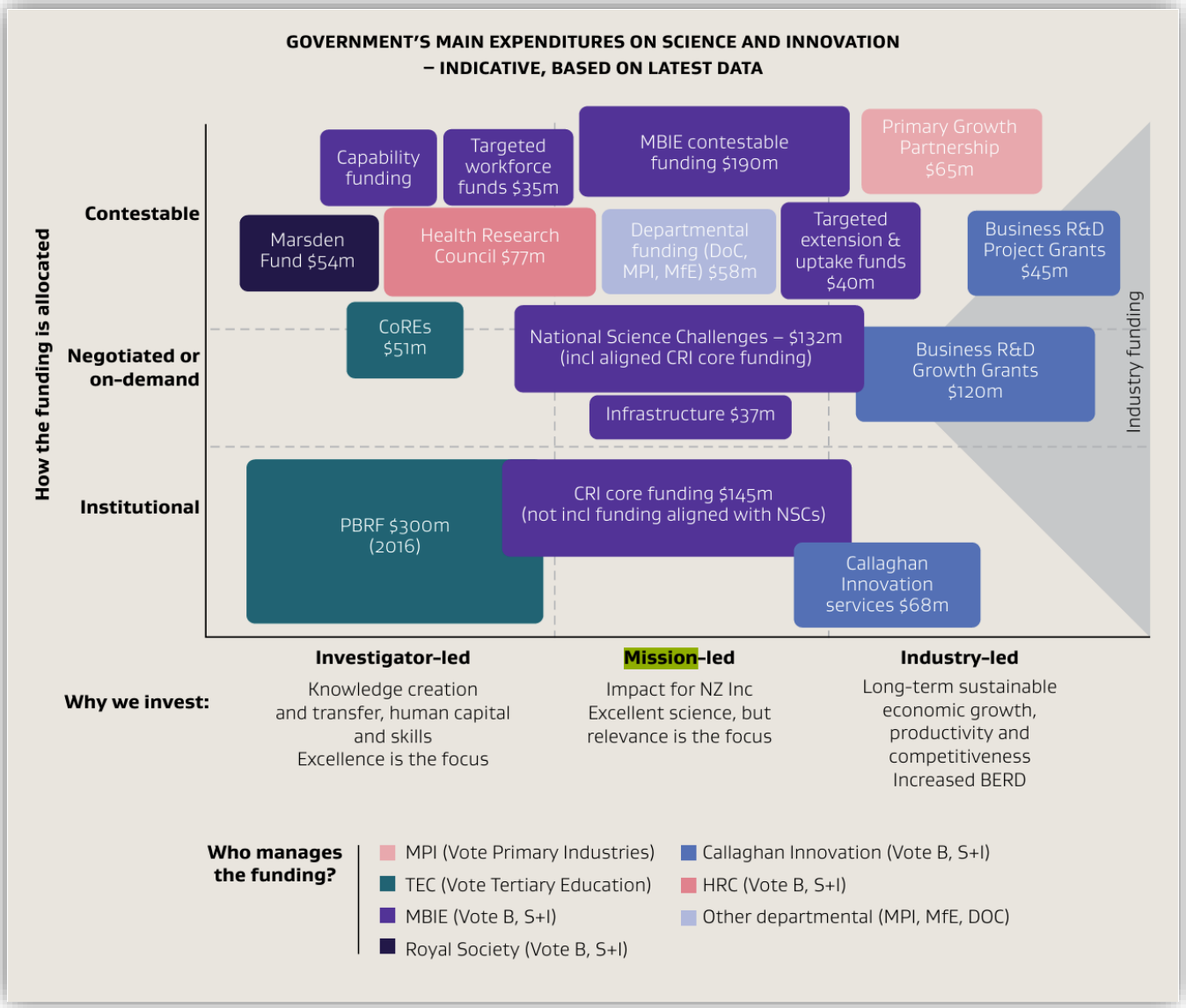


Fig.2: National Statement of Science Investment 2015-2025.[80]

No funding pathways for scientists to research human and environmental health risks

Elected members, the judiciary, the media and the law may question where the scientists are, that are directly funded to evaluate and research risk from hazardous chemicals and GMOs including gene edited technologies. They will come up empty.

There is no funding authority which directly funds long-term research into human health and the environmental risk. There are no scientists who receive New Zealand research grants to research risks from GMOs. Scientist researchers are not directly funded to chemical pollutants, chemical mixtures and risk from GMOs. New Zealand does not track harm to biological systems from man-made technologies

[80] MBIE (October, 2015) National Statement of Science Investment 2015-2025. https://www.mbie.govt.nz/assets/2eaba48268/national-statement-science-investment-2015-2025.pdf

other than one long-term study of contaminant levels in groundwater. There is no funding to evaluate the harm from chemical groups or mixture risk in that groundwater.[81]

This can explain why, from meetings at the local government level, to meetings with government agencies, and when plaintiffs are calling for witnesses in court trials, it can be extraordinarily difficult to locate scientific experts. There are no domestically-funded scientists with long-term research funding to investigate human and environmental harms from the technologies that the government has approved for market release, as years progress. There is no feedback loop into regulatory agencies to compel them, or shame them, to look at literature on risk.

With no funding pathways and funding controlled by an innovation and economic growth agency, scientists struggle for funding for non-innovation related public good research which can investigate long-term risk.

Royal Society: Building social acceptance of emerging technologies.

The Royal Society is a service provider to the government. The Marsden Fund is managed by the Royal Society on behalf of the New Zealand Government with funding from MBIE. MBIE currently directs $79 million to the Royal Society to administer the contestable Marsden fund, providing grants for investigator-initiated research projects. Many research grants are for research and development of gene editing techniques and organisms.

Funding for the Royal Society's gene technology research in 2016-2019 appears to have been primarily derived through monies provided by the Marsden Fund.

In 2016 information was placed on the Royal Society website, which described gene editing technologies and listed use of gene editing techniques and experiments, with gene editing techniques that were used globally.[82] The success or failure of the gene-related research documented in 2016 has not been assessed.

By September 2017 the Royal Society was working with RNZ, scientists and opinion leaders to promote conversations about the benefits of new gene editing technologies.[83]

By 2017 the Royal Society had established an Expert Panel on Gene Editing. The panel was convened to[84]:

- raise awareness of the scientific possibilities and associated societal issues of new gene editing technologies to inform debate
- provide information and guidance for policy makers to address new issues needing to be clarified or resolved
- show where gene editing applications are covered by established policies and regulations and where changes are now needed
- provide an Aotearoa New Zealand perspective to the global discussion on this technology, particularly where global consensus is important.

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[81] Aotearoa New Zealand Policy Proposals on healthy waterways: Are they fit for Purpose? (2019) Published by: The Soil and Health Association of New Zealand and Physicians and Scientists for Global Responsibility Charitable Trust New Zealand Wellington, New Zealand ISBN (digital) 978-0-473-50130-3. https://psgr.org.nz/component/jdownloads/send/1-root/64-2019-freshwater

[82] Royal Society (2016). Current gene-editing uses. https://www.royalsociety.org.nz/what-we-do/our-expert-advice/all-expert-advice-papers/gene-editing-technologies/current-gene-editing-uses/

[83] Royal Society (September 28, 2017) Editing our Genes: Promises and Pitfalls on RNZ. https://www.royalsociety.org.nz/news/editing-our-genes-promises-and-pitfalls-on-rnz

[84] Royal Society (2019). Gene Editing. Page 24, 62, 108/152. https://www.royalsociety.org.nz/assets/Uploads/Gene-Editing-FINAL-COMPILATION-compressed.pdf

Many of the panel members did not have practical expertise in biotechnology and gene-editing, but were well placed to envisage the possible potential from gene editing techniques or gene edited organisms in their specific disciplines. A relatively small number of panel members had the expertise to fully understand how gene editing techniques and organisms might not result in intended outcomes, might become cross-contaminated with other biological organisms in the gene-editing process, and might result in unintended or off-target outcomes.[85]

Co-Chair and entomologist David Penman presented to the global biotechnology lobby group[86] International Life Sciences Institute (ILSI), in Japan in 2017, the subject of his talk: 'Gene Editing in New Zealand: Building Social Acceptance of Emerging Technologies.[87] Penman's talk revealed that the Royal Society was focused on considering the implications of gene-editing with an aim to raising public awareness of the technologies, promoting acceptance of opportunities for Māori, and crafting a narrative around how new technologies could be used (as case studies).

Unintended effects (e.g. the production of food allergens[88] [89] and off-target risks (such as to organisms with similar biological pathways[90]) is rarely discussed in the Royal Society literature and confined to a few case studies, with any impact minimalised. The Royal Society does not discuss problems, such as contamination in laboratories from, for example, reagents.

The Royal Society placed great emphasis on the benefits to Māori, but the consultations with Māori were targeted and confined to relatively narrow interest groups.

Māori consultation – by Plant and Food who want gene edited organisms deregulated.

Because of policy constraints to science and research funding, Māori researchers also face barriers to accessing funding for investigating risk from gene editing techniques and organisms. Funding schemes are rarely broad enough that funding committees would be able to prioritise proposals to evaluate e.g. global surveillance and monitoring of GMOs or the ethical and cultural, ethical and economic objections by indigenous groups to the ownership of patents of biological organisms long-used by indigenous groups. Funding schemes would likely not stretch to enable long-term evaluations and research in laboratories on risk pathways via *in silico* or *in vitro* laboratory-based methods, including the risks of accidental laboratory releases, and risks from intentional environmental releases.

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[85] Royal Society (2019). Gene Editing. Compilation document. APPENDIX 1 Contributors to the technical paper Page 20. Page 132/152. https://www.royalsociety.org.nz/assets/Uploads/Gene-Editing-FINAL-COMPILATION-compressed.pdf

[86] Steele S, Ruskin G, Stuckler D. Pushing partnerships: corporate influence on research and policy via the International Life Sciences Institute. Public Health Nutrition. 2020;23(11):2032-2040. doi:10.1017/S1368980019005184

[87] Penman D. (10 July, 2017) Co-Chair of the Royal Society of New Zealand's Expert Panel on Gene Editing. Part II. Challenges and efforts towards social implementation (including regulatory considerations). Director, David Penman and Associates Ltd. New Zealand. ILSI Workshop on Genome Edting Technology in Agriculture. https://ilsijapan-org.prm-ssl.jp/ILSIJapan/LEC/biotech/GenEd2017/08Penman.pdf

[88] Benevenuto, R.F., Zanatta, C.B., Waßmann, F. et al.(2023). Integration of omics analyses into GMO risk assessment in Europe: A case study from soybean field trials *Environ Sci Eur* 35, 14 (2023). Doi: 10.1186/s12302-023-00715-6

[89] Ozgur M and Ucar Asli (2024). Food Allergen Risks in Genetically Modified Foods Current Approaches. Food Safety. CRC Press ebook ISBN 9781003333913

[90] Hoepers AM, Heinemann JA, Zanatta CB, Chu P, Hiscox TC, Agapito-Tenfen SZ (2024) Predicted multispecies unintended effects from outdoor genome editing. *Ecotoxicology and Environmental Safety* 282, 1 September 2024, 116707. https://www.sciencedirect.com/science/article/pii/S0147651324007838#bib25

A February 2024 MBIE Brief[91] showed that MBIE were keenly aware that Māori would understand the potential for patents on gene technology to over-ride and obfuscate Māori rights to taonga Māori. Natural cross-fertilisation or the erosion of the mauri, the health of species would be difficult to detect and harm could occur from wilding species, before the escaped genes could be identified.

> *Treaty considerations for gene technology*
>
> *11. We will need to give careful consideration to how legislation would address the interests and expectations that iwi and Māori have in this area. We will need to take any concerns into account during the policy development process and clearly communicate this in the consultation paper.*
>
> *12. Of particular relevance to this topic is the Wai 262 Treaty of Waitangi claim. While this claim encompasses a range of considerations including data sovereignty and intellectual property, a key relevant aspect is the protection of taonga Māori by tāngata Māori. A particular area of concern for iwi and Māori will be whether new legislation will provide sufficient protection of taonga species and whether it will allow iwi and Māori to sufficiently exercise kaitiakitanga (guardianship) over those taonga species.*

These considerations aside, there has been no funding allocated for [are no funding streams for] Māori to assess the scientific credibility of MBIE's claims that the legislation would be 'risk-proportionate,' and that it would not result in gene flow to taonga species. There is no funding set aside for monitoring once the Act is signed into force.

Engagement with Māori has been undertaken by groups with direct MBIE funding. Firstly, this occurred through the Royal Society via a Māori Reference Group, who ran a huihuinga with whānau Māori in Wellington in October 2018 to seek Māori views on gene editing in the primary industries. Dr Barry Smith (Te Rarawa, Ngāti Kahu), chaired the Society's Gene Editing Panel Māori Reference Group from 2017–19.[92]

Secondly, this has occurred via an MBIE Endeavour Fund grant: 'New breeding technologies for New Zealand's high value plant industries'. The New Zealand MBIE funded research programme was led by Plant & Food Research Ltd, and retitled 'Turbo-breeding for New Zealand's plant industries'.

Plant and Food's research focussed on Māori cultural perspectives and opinions. The papers, and presumably the consultations, all broadly draw from Royal Society literature to communicate that current regulatory standards are out-of-date and to presuppose a level of risk that can be managed. This inferred that a risk evaluation has occurred, which it has not.

These research priorities into Māori perspectives reflect MBIE priorities. MBIE's funding mechanisms are expressly designed to foster innovation-based research. Therefore, conversations which enable researchers to develop and shape policy language that embeds Māori cultural perspectives into policy - which necessarily promotes and permits the release of gene editing techniques and organisms into the environment, can be funded. These innovation-based conversations also have the effect of shaping participant knowledges through an educational, participative nudging process.[93] [94] Participants are presented with a set of facts and ideas that are discussed throughout the research process. It is not

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[91] Rae S. (February 8, 2024) MBIE 2324-1836 Regulation of Biotechnology: Process. Page 20/150. https://www.mbie.govt.nz/dmsdocument/29940-regulation-of-gene-technologies-policy-decisions-proactive-release-of-advice-proactiverelease-pdf

[92] Royal Society (2019). Gene Editing. Compilation document. Pages 110, 132 / 152 Compilation document.

[93] Weijers, R.J., de Koning, B.B. & Paas, F. Nudging in education: from theory towards guidelines for successful implementation. *Eur J Psychol Educ* 36, 883–902 (2021). Doi: 10.1007/s10212-020-00495-0

[94] Kuyer, P., & Gordijn, B. (2023). Nudge in perspective: A systematic literature review on the ethical issues with nudging. *Rationality and Society*, *35*(2), 191-230. Doi: 10.1177/10434631231155005

evident that Māori were ever advised about New Zealand's absence of research on the risk of GMOs. This was not the purpose of the research funding frameworks.

Funding for all these papers are from science funding channels which promote innovation and economic growth. Andrew Allan and David Chagné are Plant and Food Research employees.

- (C11X1602) Hudson M, Mead ATP, Chagné D, Roskruge N, Morrison S, Wilcox PL and Allan AC (2019) Indigenous Perspectives and Gene Editing in Aotearoa New Zealand. Front. Bioeng. Biotechnol. 7:70. doi: 10.3389/fbioe.2019.00070
- (C11X1602) Kathlene L, Munshi D, Kurian P, Morrison SL (2022). Cultures in the laboratory: mapping similarities and differences between Māori and non-Māori in engaging with gene-editing technologies in Aotearoa, New Zealand. *Humanities and Social Sciences.* 9:100 doi: 10.1057/s41599-022-01104-9
- (C11X1602[95]) Spok A, Sprink T, Allan AC, Yamaguchi T, Daye C. (2022) Towards social acceptability of genome-edited plants in industrialised countries? Emerging evidence from Europe, United States, Canada, Australia, New Zealand, and Japan. *Front. Genome Ed.* 4:2022. Doi 10.3389/fgeed.2022.899331
- (C11X1602) Clark A, Wilcox P, Morrison S, Munshi D, Kurian P, Mika J, Chagne D, Allan A, Hudson M. (2024). Identifying Māori perspectives on gene editing in Aotearoa New Zealand. *Communications Biology.* 7:221. Doi: 10.1038/s42003-024-05896-1

For example, the 2024 paper led by Amanda Clark notes that The Royal Society report that observed that 'process based regulatory systems … will become increasingly obsolete and unsustainable' proposing instead a 'risk-tiered approach', as per that being developed in Australia (Legislative and Governance Forum in Gene Technology).

Endeavour Fund monies have also been directed to Māori-based Te Kotahi Research Institute, a Waikato University-based institute which is established to enhance engagement in research and development by improving access to research and providing pathways for innovation.

This pattern appears to be global, i.e., innovation-based research and development trajectories are funded, but risk-evaluation scientific research is not funded, or is dramatically under-funded. Scientists are funded by universities directly engaged in gene-editing research and discovery commercialisation, who conduct side-research on social, cultural and economic perspectives of consumers, to establish the extent of public resistance to the technologies and outcomes that they have a financial interest in researching.

Globally, since the 2000-era pivot to innovation in the west, economic outcomes have become a top priority of funding schemes. Scientists must adhere to the terms of reference and demands of the funding schemes, Inevitably, funding applications demand an innovation pathway. Funding applications are then reverse engineered to fit social, cultural and other-health-based perspectives inside the application. However, without an innovation pathway, the funding application is likely to be quickly rejected.

[95] Funding: The work of AA, AS, CS, and TS on which this paper is based received funding from the European Commission Horizon 2020 Research & Innovation Programme under Grant Agreement No. 760891. AA also acknowledges funding from the New Zealand Ministry of Business, Innovation and Employment (Grants C11X1602 and C11X2101).

[5] STRATEGICALLY MANAGED CONSULTATION PROCESS

> *'Legislation is information-intensive and ensuring it is effective and reducing the risk of unintended consequences requires consultation at all stages.'*[96]

Part [2] reviewed the MBIEs plans in February/March 2024 to narrowly structure consultation, and exclude the public from that consultation. In August 2024, a media-pack was released declaring that certain gene editing techniques and organisms would be completely exempted from any regulatory oversight.[97] The public were then advised at that date, that their chance to provide input would be when the Gene Technology Bill was released.

There was no targeted consultation with sector experts in regulatory risk assessment and regulatory law. This is despite the fact that MBIE was given the responsibility for designing policy and legislation to steward technologies and their emissions.

Groups such as the GE Free New Zealand, the Sustainability Council, the Centre for Integrative Research on Biosafety (INBI), and the Physicians and Scientists for Global Responsibility, have been actively involved in discussion on GMO-related policy and law for years, and who had most recently expressed an interest in gene technology reform policy development in submissions in 2023 (below) were not invited into any 'targeted engagement'.

MBIE would already recognise that these groups were in favour of the status quo. As a 2023 Interim Regulatory Impact Statement noted:

> *'In contrast to New Zealand's biotechnology industry, researchers and research organisations, a number of organisations, local government bodies and individuals are supportive of New Zealand's strict GMO legislation.'*[98]

MBIE acknowledge in the RIS that 'Public consultation would have enabled increased or more comprehensive understanding and analysis of the diverse Māori interests, opportunities, and concerns on gene technology', but seem to believe that a tight timeframe was more important.

2023: Laboratory and Biomedical research consultation.

MBIE refer to a public consultation undertaken in August 2023 which received 80 responses. In March 2023 the Ministry for the Environment released an Interim Regulatory Impact Statement: Improving our GMO regulations for laboratory and biomedical research.[99] Respondents, including PSGR, submitted to the Regulatory Impact Statement between July-August 2023.[100] This consultation exclusively concerned contained research environments. It proposed a general risk-tiering framework modelled on the Australian risk-tiering framework where 'certain low-risk research from a) containment facility requirements and b) EPA assessment and approval requirements' would be exempted.'

While some responses have been published, to date a report resulting from the March 2023 Ministry for the Environment (MfE) consultation has not been released. Apparently, the work on this was placed on hold once the new government announced its plans.

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[96] Legislation Design and Advisory Committee. Legislation Guidelines: 2021 edition. https://www.ldac.org.nz/guidelines/legislation-guidelines-2021-edition
[97] MBIE August 2024 Media Pack. https://www.mbie.govt.nz/dmsdocument/28985-gene-technology-media-pack-pdf
[98] Ministry for the Environment (March 10, 2023). Interim Regulatory Impact Statement: Improving our GMO regulations for laboratory and biomedical research. consult.environment.govt.nz/comms/gmo-regulations/
[99] Ministry for the Environment (March 10, 2023). Interim Regulatory Impact Statement: Improving our GMO regulations for laboratory and biomedical research. consult.environment.govt.nz/comms/gmo-regulations/
[100] Ministry for the Environment. (July 2023). Improving our GMO regulations for laboratory and biomedical research https://consult.environment.govt.nz/comms/gmo-regulations/

An Official Information Act request[101] suggests that Judith Collins has not corresponded with MfE to discuss the reform of the gene technology regulations, even though the MfE is the Ministry charged with oversight of GMO regulation.

The public can speculate that it is likely after the National party came to power in October 2023, information advising the shift from the Ministry for the Environment to MBIE may have occurred during confidential cross-agency gene technology reform Ministerial group meetings.

MBIE claim 'the views expressed in the public consultation are applicable to this broader, current regulatory proposal.' Yet the findings in the form of a report, were never published.

2024: Sector experts and key stakeholders – complex issues and COIs set aside.

MBIE proceeded with a targeted consultation with institutions which included companies, Crown Research Institutes, universities, government agencies, agricultural sector organisations and biotechnology and gene editing sector-experts.

The views that gene technology reform are critical to address the impact of climate change and solve disease resistance, is misleading when non-innovation pathways for basic, boots on the ground agricultural research for drought, disease and insect resistance is scarce, compared to the funding dedicated to biotech across all research disciplines.

There is a well-known saying 'privatise the benefits and socialise the costs'. When the biotechnology industry demand regulatory reform that involves the non-declaration, and the absence of risk assessment for gene-editing techniques and organisms, they then socialise future costs. If those techniques and organisms are later found to be harmful, it is too late. The heritable nature, the persistence of gene flow, or even the fall-out from gene-edits that might sterilise or kill, cannot be recalled or reversed. Like a genie that cannot be put back in the bottle, the harm cannot be reversed.

There is an argument to be made, if the profits are not so substantial that the industry cannot bear the compliance costs, which promote transparency and accountability, which ensure that regulators can understand and assess risk pathways, then that technology should not be developed.

Included in the 'key views' was the requirement that the frameworks should align with global markets, and that the new regulatory framework is future proofed. However, as discussed, New Zealand is proceeding apace, and not sitting back to evaluate decisions in key trade markets.

Because there have been no independent experts in regulatory reform of biotechnology, and because MBIE risk-tiered some gene-organisms to be outside of regulation, the framework cannot be future-proofed nor globally competent.

MBIE stated in the RIS that they have held 'targeted engagements with sector experts and key stakeholders'. Many if not most of these institutions have direct financial interests, or the institutions that employ them, have direct financial interests where they would likely benefit from deregulation.

Individuals and institutions for targeted engagement sessions ('key stakeholders' listed in Annex I) were identified because (page 125) they:

- are directly involved in gene technology / GMO research, development and commercialisation
- would be impacted by a new regulatory regime that would oversee technologies or products used in their value chain, or

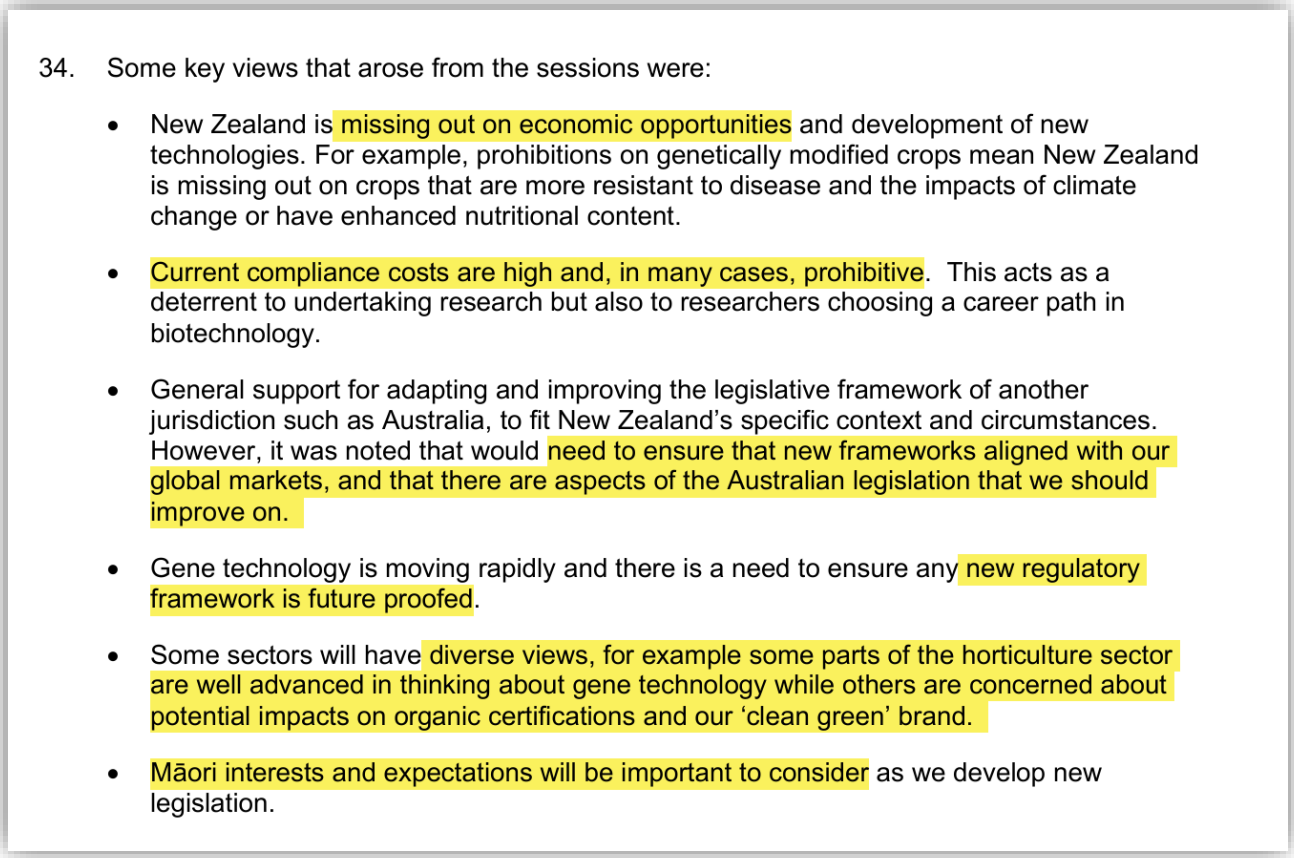
[101] Collins, J (undated) Official Information Act request. Ref: JCOIA-203
https://psgr.org.nz/component/jdownloads/send/1-root/157-oia-request-2024-oct-collins-genetechregulator

- offered a level of expertise relevant to understanding issues in the sector

Lacking in this line-up, were scientists with expertise in technology regulation and risk assessment.

A scientific cohort in New Zealand who have been, for some decades now, working with gene editing technologies and producing scientific papers that address risks and concerns with GMO regulation[102] [103] [104] [105], were excluded from targeted engagement.

By March 13 2024 Simon Rae was advising the Gene Technology Ministerial Group that following targeted engagements, science system stakeholders were positive about the reforms. [106]



34. Some key views that arose from the sessions were:

- New Zealand is missing out on economic opportunities and development of new technologies. For example, prohibitions on genetically modified crops mean New Zealand is missing out on crops that are more resistant to disease and the impacts of climate change or have enhanced nutritional content.
- Current compliance costs are high and, in many cases, prohibitive. This acts as a deterrent to undertaking research but also to researchers choosing a career path in biotechnology.
- General support for adapting and improving the legislative framework of another jurisdiction such as Australia, to fit New Zealand's specific context and circumstances. However, it was noted that would need to ensure that new frameworks aligned with our global markets, and that there are aspects of the Australian legislation that we should improve on.
- Gene technology is moving rapidly and there is a need to ensure any new regulatory framework is future proofed.
- Some sectors will have diverse views, for example some parts of the horticulture sector are well advanced in thinking about gene technology while others are concerned about potential impacts on organic certifications and our 'clean green' brand.
- Māori interests and expectations will be important to consider as we develop new legislation.

Fig.3: Rae S. (March 13, 2024). MBIE 2324-2241 Regulation of Biotechnology – Joint Ministers Meeting. P.35/150

[102] Heinemann, J.A.; Walker, S. Environmentally applied nucleic acids and proteins for purposes of engineering changes to genes and other genetic material. *Biosafety Health* 2019;1:113-123
[103] Hoepers AM, Heinemann JA, Zanatta CB, Chu P, Hiscox TC, Agapito-Tenfen SZ (2024) Predicted multispecies unintended effects from outdoor genome editing. *Ecotoxicology and Environmental Safety* 282, 1 September 2024, 116707. https://www.sciencedirect.com/science/article/pii/S0147651324007838#bib25
[104] Heinemann J (2019). Should dsRNA treatments applied in outdoor environments be regulated? *Environment International*. 132:104856 doi: 10.1016/j.envint.2019.05.050
[105] Heinemann J, Agapito-Tenfen S, Carman J (2013) A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments. *Environment International*. 55:43-55. Doi: 10.1016/j.envint.2013.02.010
[106] Rae S. (March 13, 2024). MBIE 2324-2241 Regulation of Biotechnology – Joint Ministers Meeting. P.34/150 https://www.mbie.govt.nz/dmsdocument/29940-regulation-of-gene-technologies-policy-decisions-proactive-release-of-advice-proactiverelease-pdf

The language in the 'key views' communicated to Ministers, that emphasises economic opportunities and which claims that gene-editing deregulation is essential to solve agricultural, including weather change challenges, are misleading when factors other than genetics are not taken into account.

While government rhetoric focusses on opportunities for New Zealand, the acquisition of medium-size enterprises by larger firms is an ongoing problem.[107] It is highly likely that patents on New Zealand plant and livestock varieties would end up being acquired by off-shore owned companies.

Three companies, Dow DuPont, Syngenta ChemChina and Bayer (Monsanto) control the patents, and demand the royalties on the majority of seed and traits market for GMO herbicide tolerant varieties. While advocates claim that costs have not been passed onto markets, this evidence is limited and distortions have occurred through U.S. farm subsidy programmes. [108] [109]

New Zealands' science system is poorly structured to fund independent scientific research into weather change patterns and the impact on farmers and growers. Different agricultural sectors have complex needs. For example, hundreds of genes can interact to promote drought tolerance in a single plant variety. Resilience in agriculture, including disease resistance in plant crops and livestock is frequently tied to soil health, including carbon levels, soil mineral levels and the degree to which farming patterns prevent soil degradation and contamination (from synthetic inputs, including heavy metals).[110]

Consideration must be given to a history of corporate consolidation in the biotech industry and the impact on competition and pricing. Farmers and growers face increasing supply chain costs, from the cost of seeds to the cost of equipment. Scientific research that is geared to products that ultimately patent inputs, and increase input costs, may not result in the best outcomes for farmers and growers. GMOs used in agriculture, once patented can become locked in by powerful monopoly actors,[111] [112] potentially driving undesirable path dependencies,[113] increasing costs and reducing farmer/grower choice[114]. Controversy remains around yield increases over the longer-term, particularly if one GMO trait becomes the dominant trait for years. Claims that pesticide use is down, fail to clarify that insecticide use may decline while herbicide contamination has increased.

Some key stakeholders who may not be publicly identified as biased towards technology deregulation, have a direct financial interest in biotechnology research and development. This includes the Ministry of Primary Industries (MPI), which is named as the enforcement agency in the Gene Technology Bill.

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[107] Fuglie K, King K, Heisey H & Schimmelpfennig D (2012), Rising Concentration in Agricultural Input Industries Influences New Farm Technologies, ambeR WaveS (Dec. 3, 2012), https://www.ers.usda.gov/amber-waves/2012/december/rising-concentration-in-agricultural-input-industries-influences-new-technologies/

[108] Deconinck K. (2020) Concentration in Seed and Biotech Markets: Extent, Causes, and Impacts. Annual Review of Resource Economics. 12:129-147

[109] Jennifer Clapp; Mega-Mergers on the Menu: Corporate Concentration and the Politics of Sustainability in the Global Food System. *Global Environmental Politics* 2018; 18 (2): 12–33. doi: https://doi.org/10.1162/glep_a_00454

[110] Jacobsen, SE., Sørensen, M., Pedersen, S.M. *et al.* Feeding the world: genetically modified crops versus agricultural biodiversity. *Agron. Sustain. Dev.* **33**, 651–662 (2013). https://doi.org/10.1007/s13593-013-0138-9

[111] Bonny, S. (2017). Corporate Concentration and Technological Change in the Global Seed Industry. Sustainability, 9(9), 1632. https://doi.org/10.3390/su9091632

[112] Antitrust Institute (2020) . Consolidation and concentration in agricultural biotechnology: Next generation competition issues. https://www.antitrustinstitute.org/wp-content/uploads/2022/05/CPI-Moss.pdf

[113] Desquilbet, M., Bullock, D. S., & D'Arcangelo, F. M. (2019). A discussion of the market and policy failures associated with the adoption of herbicide-tolerant crops. *International Journal of Agricultural Sustainability*, *17*(5), 326–337. https://doi.org/10.1080/14735903.2019.1655191

[114] U.S. Dep't. of Agric., Nat'l Agric. Stat. Serv., Acreage (June 30, 2001 and June 30, 2019) https://downloads.usda.library.cornell.edu/usda-esmis/files/j098zb09z/0k225n39n/ jw827p632/acrg0619.pdf. In 2001, only 26 percent of corn acres, 69 percent of cotton acres, and 68 percent of soybean acres were planted with GM varieties.

However it is one of the 'reviewing agencies' that signed off on MPI's quality assurance for the RIS (page 11).

The RIS repeatedly seertsthat GMOs could theoretically solve the 'climate change' challenge, and notes that genetically modified products could inhibit greenhouse gases.

Yet MPI – the gene technology enforcement agency, could directly financially benefit from a deregulated environment. A 'world first' multimillion dollar joint venture, titled AgriZeroNZ, was signed between the Ministry of Primary Industries and Fonterra, ANZCO Foods, Rabobank, Ravensdown, Silver Fern Farms, Synlait, would likely involve biotechnology. The public private partnership is envisaged to reduce biogenic methane. 'The partners will contribute around a combined $35 million a year until 2025 with the Government matching this contribution, resulting in at least $170 million invested over this time.'[115] [116] These large monopoly providers now have 'skin in the game' and can actively profit from farmers.

DairyNZ have invested over NZD3 million in HME ryegrass while MBIE have invested NZD8.5 million. It's not clear to what extent DairyNZ value consumer preference for GMO-free dairy products, but the investment in GMO research suggests that DairyNZ does not place a value on GMO free export status.[117]

The only public-facing consultation (which most of the above-listed groups submitted to), has not resulted in a published report.

MBIE's RIS also refer to two other consultations: targeted engagement with 32 researchers likely to be conducting research using GMOs in 2022.

MBIE can then claim support for their policy and proposed laws will come from their 'targeted consultation'.

All other consultation has been with people that MBIE has strategically targeted, most of whom have financial conflicts of interest, due to the principles, priorities and funding trajectories of the institutions that employ them, and the departments that they work in. This means that any comments which affirm MBIEs deregulatory perspective, may not be honest or realistic, when it comes to claiming that that policy will be risk-proportionate, or that the legislation would ensure that all use of the technologies and organisms under that legislation would be 'safe'. This group includes researchers who are involved in actively developing GMOs, those isolating DNA or RNA that would be useful for gene editing technologies, people who have actively invested or founded biotechnology start-ups, and people who work for academic institutions in departments where biotechnology-related activities are occurring.

[6] NO EVIDENCE TO BACK UP CLAIM OF OUT-OF-DATE PROVISIONS

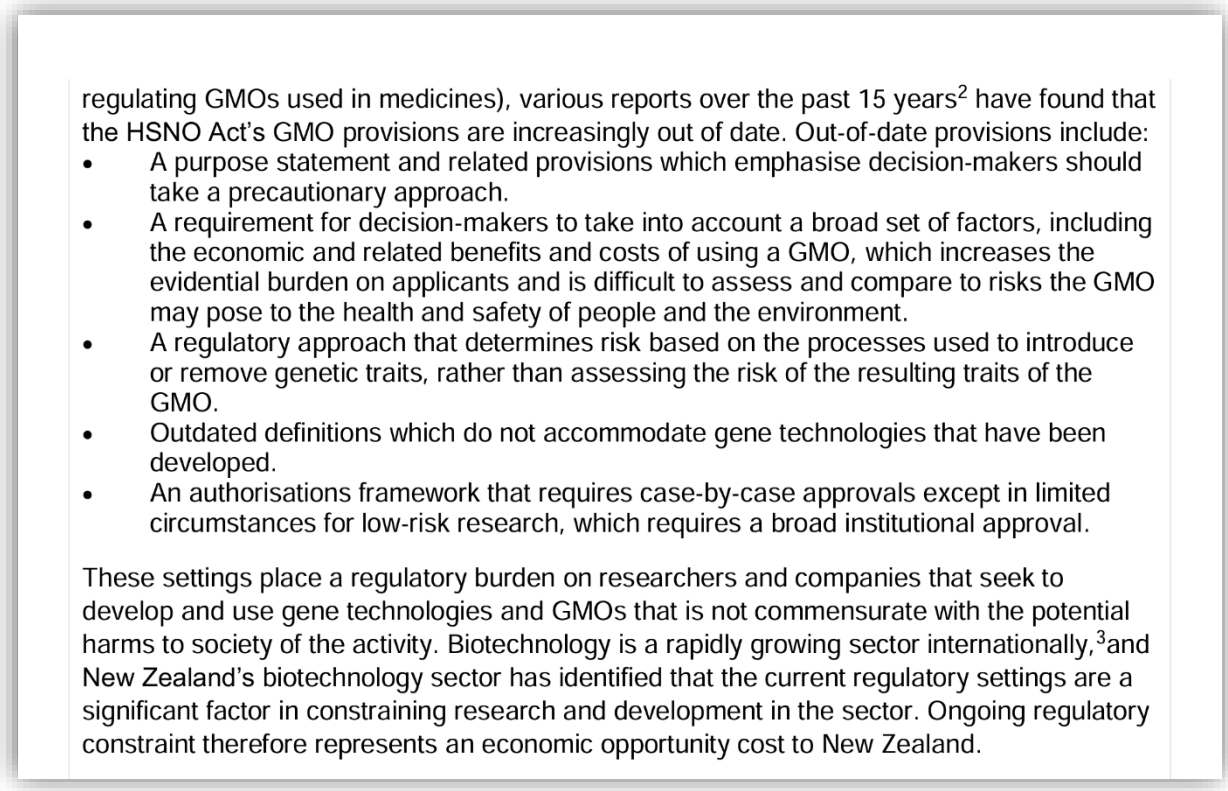
In MBIE's 2024 Regulatory Impact Assessment[118] on the reform of gene technology and GMOs made a sweeping statement. MBIE claimed that the Hazardous Substances and New Organisms Act 1996 contained many out-of-date provisions. Page three of the RIS stated:

> *'various reports over the past 15 years have found that the HSNO Act's GMO provisions are increasingly out of date'*

[115] RNZ (October 3, 2022). Government signs deal with primary sector's major players over cutting emissions. https://www.rnz.co.nz/news/country/475953/government-signs-deal-with-primary-sector-s-major-players-over-cutting-emissions
[116] Powering Zero Emissions Agriculture. https://www.agrizero.nz/
[117] AgResearch Official Information Act Response . Project no.50215. Page 1. https://fyi.org.nz/request/23194/response/90770/attach/9/Part%20A%20OIA%20data%20All%20Projects%20Biotechnology.pdf
[118] Ministry for Regulation. Issue date: December 20, 2024. Regulatory Impact Statement: Reform of Gene Technology Regulation. Page 3/131. Document (signed) date: Wednesday 31 July 2024.

The RIS cites the Productivity Commissioner, the New Zealand Government and the Royal Society. The RIS then explicitly states which provisions are out of date.

MBIE claims that the out-of-date provisions included the purpose statement; a requirement to take a precautionary approach; an obligation that decision-makers to take into account the economic benefits and costs of using GMOs; the approach where the process of genetic modification is the trigger for regulatory assessment; outdated definitions which do not accommodate newer gene-editing techniques; and regulatory authorisation processes that consider GMO risk on a case-by-case basis.



regulating GMOs used in medicines), various reports over the past 15 years[2] have found that the HSNO Act's GMO provisions are increasingly out of date. Out-of-date provisions include:

- A purpose statement and related provisions which emphasise decision-makers should take a precautionary approach.
- A requirement for decision-makers to take into account a broad set of factors, including the economic and related benefits and costs of using a GMO, which increases the evidential burden on applicants and is difficult to assess and compare to risks the GMO may pose to the health and safety of people and the environment.
- A regulatory approach that determines risk based on the processes used to introduce or remove genetic traits, rather than assessing the risk of the resulting traits of the GMO.
- Outdated definitions which do not accommodate gene technologies that have been developed.
- An authorisations framework that requires case-by-case approvals except in limited circumstances for low-risk research, which requires a broad institutional approval.

These settings place a regulatory burden on researchers and companies that seek to develop and use gene technologies and GMOs that is not commensurate with the potential harms to society of the activity. Biotechnology is a rapidly growing sector internationally,[3] and New Zealand's biotechnology sector has identified that the current regulatory settings are a significant factor in constraining research and development in the sector. Ongoing regulatory constraint therefore represents an economic opportunity cost to New Zealand.

Fig.4: Regulatory Impact Statement. 'Out-of-date provisions'. **Reform of Gene Technology Regulation. Ministry of Business, Innovation Employment. Page 3.**

As we show below, no evidence has been provided to support the out-of-date claims and global literature and government protocols and conventions contradict the RIS claims. It is misinformation[119]. The claims have been made with the intent of a strategic outcome that will exclusively benefit biotechnology industries, by removing provisions that essentially increase transparency, and help regulators judge risks and benefits. The Regulatory Impact Statement is false and misleading, but it will also mislead the MPs, the public and other government officials into believing these provisions should be removed. It is disinformation.

MBIE did not undertake a global assessment of best practice regulatory risk assessment, nor did it publish an in-depth paper to justify these claims. It appears that MBIE merely advised Ministers who had no option but to believe MBIE's stated 'facts'. The Post stated that:

> *'Official documents from the Ministry for the Environment (MfE) from a meeting in June, chaired by Science and Technology Minister Judith Collins, say it was agreed the legislation should not*

[119] Princeton Library. Misinformation, Disinformation & Malinformation: A Guide. Accessed March 2, 2025. https://princetonlibrary.org/guides/misinformation-disinformation-malinformation-a-guide/

include a reference to the precautionary approach and ethics should be excluded from consideration.'[120]

In an *In Confidence* Paper dated August 29, 2024, Minister Collins stated that she believed that ethics considerations were appropriately addressed in other legislation.[121] Her focus did not concern broader societal values and the ethics of releasing a genetically modified potentially heritable gene, or gene designed to kill or maim, into the environment. Collins retained her consideration to narrowly focus on animal and human trials.

There is no critique outlining how officials came to the conclusion that precautionary approach/principle would be outdated and no longer 'good practice'. No discussion documents appear to have been supplied to MBIE to consider these issues in depth. The RIS makes no mention of best practice.

There is a dearth of evidence to suggest that MBIE have assessed legislation in key trade markets to evaluate the extent to which principles and ethics - including precaution - are integrated in the equivalent legislation in these jurisdictions.

Ethics-based conversations have been repeatedly set aside by the government. The Royal Commission recommended a three-pronged approach including the establishment of a Parliamentary Commissioner on Biotechnology, a Bioethics Council and a biotechnology strategy. None of these recommendations are in place in 2025.[122]

A legislative bid for the Gene Technology Bill was drafted by February 2024. Policy creation appeared to be drawn from the National Party *Harnessing Biotech* document.[123]

'A clear set of regulatory reform objectives will form a critical component of the regulatory impact analysis that will underpin policy work. In drafting these objectives to test with you, we will build on the key priorities set out in the Harnessing Biotech manifesto document and your regulatory reform intent and preferences you have expressed in initial meetings.'

Language in the *Harnessing Biotech* document inferred that new gene edited organisms could be approximated as indistinguishable from naturally bred organisms, and inferred as no-risk and harmless, a theme drawn from the Royal Society literature. From February 8, 2024, at the latest, Simon Rae and Judith Collins were ruling out process-based regulation, based on National Party literature. From an early stage it appears that Rae and Collins were planning on exempting some gene editing techniques and organisms.:

'9. Given the stated objectives in the Harnessing Biotech manifesto document are a shift away from the current legislative focus on the process used, we have discounted improvements to the current process-based status quo as an option for consultation. We will develop and assess product-based and/or hybrid approaches as options for the consultation paper. Our regulatory impact analysis will need to assess these options against the process-based status quo.

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[120] Whyte A (September 15, 2024) New GE laws won't have ethical considerations, precautionary approach. https://www.thepost.co.nz/politics/350416033/new-ge-laws-wont-have-ethical-considerations-precautionary-approach

[121] MBIE (December 10, 2024). Coversheet. Regulation of gene technology- policy decisions. Portfolio Science, Innovation and Technology. In Confidence paper. 6e1wa178jr 2024-08-29 14:03:09. Page 8/60 https://www.mbie.govt.nz/dmsdocument/29938-regulation-of-gene-technologies-policy-decisions-proactiverelease-pdf

[122] New Zealand Government. Report Appendix 3 Outcomes of Consultation: Submissions from the Public. https://environment.govt.nz/assets/Publications/Files/Appendix-3-Full.pdf 68 New Zealand Government. March 30, 2001 Report of the Royal Commission on Genetic Modification. https://environment.govt.nz/publications/report-of-the-royal-commission-on-genetic-modification/

[123] National Party. Harnessing Biotech. https://assets.national.org.nz/Plan_Biotech.pdf

10. Should the preferred option proposed be a hybrid approach, the consultation paper will need to detail which technologies or techniques, such as certain gene editing techniques, are to be exempt from regulation and why.'[124]

The reasoning for this was based upon the National Party 'Harnessing Biotech' manifesto document which predominantly drew from Royal Society literature. The Harnessing Biotech document stated that the:

'new legislation will: • Manage risks to people and the environment rather than the details of methods for gene editing or modification. This means regulation can keep pace with future advances while ensuring technology is used responsibly.'

However, the Harnessing Biotech document does not disclose that risk evaluation has not been conducted, as a consequence, the risks have not been evaluated. With current policy, and the Regulator having no idea of risk based on past advances, keeping pace with future advances would be impossible!

Advice to David Parker as Minister for the Environment dated June 2018, by Olivia Chamberlain, and signed by Glenn Wigley demonstrates that officials have for some time, been advising Ministers that newer organisms are much safer and which infer that the process trigger is out of date. The 2018 paper drew directly from Royal Society literature, providing the same envisaged benefits, such as climate mitigating, non-browning apples and using genetic tools to increase the resistance to disease in native populations.[125]

Technical Advisory Group – in place to deliver legitimacy for MBIEs claims?

A November 2024 Official Information Act (OIA) request to understand the extent to which the Technical Advisory Group (TAG) considered uncertainty and future risks, including the use of the precaution and the precautionary principle, and the extent to which the group considered the proposed powers for the regulator[126] (see Appendix II, below) provides no certainty that the TAG has been consulted in an appropriately in-depth manner.

The TAG's consideration of precaution and the precautionary principle appears to be rudimentary and exclusively based on information supplied directly by Simon Rae of MBIE to both the TAG group and the New Zealand Environmental Protection Authority.

Information to the TAG group which was approved by Simon Rae,[127] emphasised that New Zealand wording was significantly more conservative than the internationally agreed definition of the precautionary approach. The TAG group were told that the HSNO Act definition was more conservative than the Rio Declaration text used in the Australian Gene Technology Act[128].

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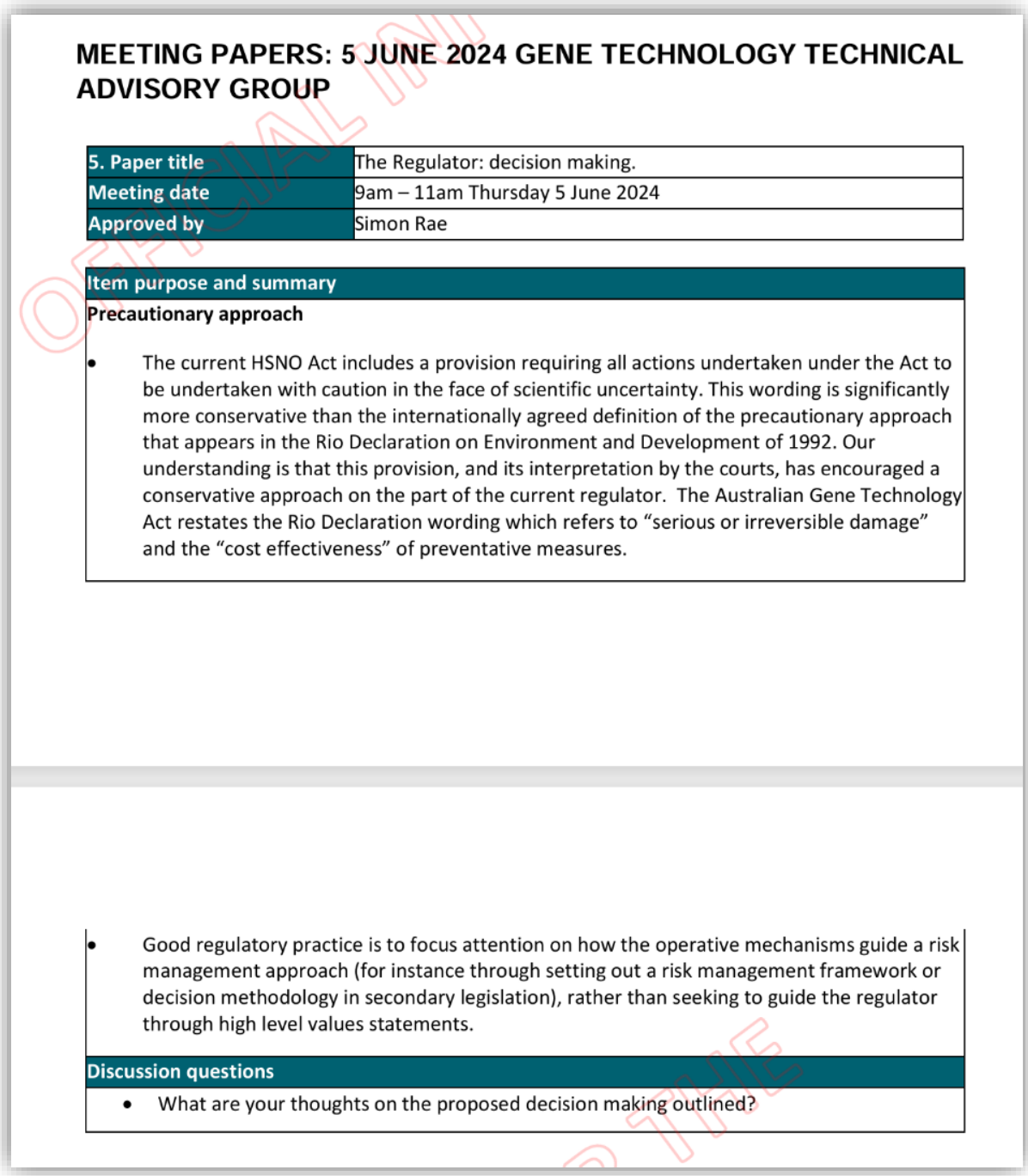
[124] MBIE. Simon Rae and Judith Collins. (February 2, 2024). Briefing March 13, 2023. Regulation of Biotechnology: Joint ministers meeting. Tracking number 2324-2241 Page 28/150. https://www.mbie.govt.nz/dmsdocument/29940-regulation-of-gene-technologies-policy-decisions-proactive-release-of-advice-proactiverelease-pdf

[125] Ministry for the Environment. Advice to David Parker. #2018-B-04195 https://environment.govt.nz/assets/Publications/18-B-04195-Genetic-Technology-Overview-and-Next-Steps.pdf

[126] Official Information Act Request to MBIE, November 19, 2024. Scientific advice - technical focus group - Gene Technology regulations and powers of regulator. DOIA REQ 0006620. https://fyi.org.nz/request/29246-scientific-advice-technical-focus-group-gene-technology-regulations-and-powers-of-regulator#incoming-118012

[127] MBIE (June 5, 2024) Agenda: Gene Technology Advisory Group. https://fyi.org.nz/request/29246/response/118012/attach/3/Extracts%20from%205%20June%202024%20TAG%20meeting%20Redacted.pdf

[128] Australian Government. Gene Technology Act. https://www.legislation.gov.au/C2004A00762/latest/text



MEETING PAPERS: 5 JUNE 2024 GENE TECHNOLOGY TECHNICAL ADVISORY GROUP

5. Paper title	The Regulator: decision making.
Meeting date	9am – 11am Thursday 5 June 2024
Approved by	Simon Rae

Item purpose and summary

Precautionary approach

- The current HSNO Act includes a provision requiring all actions undertaken under the Act to be undertaken with caution in the face of scientific uncertainty. This wording is significantly more conservative than the internationally agreed definition of the precautionary approach that appears in the Rio Declaration on Environment and Development of 1992. Our understanding is that this provision, and its interpretation by the courts, has encouraged a conservative approach on the part of the current regulator. The Australian Gene Technology Act restates the Rio Declaration wording which refers to "serious or irreversible damage" and the "cost effectiveness" of preventative measures.

- Good regulatory practice is to focus attention on how the operative mechanisms guide a risk management approach (for instance through setting out a risk management framework or decision methodology in secondary legislation), rather than seeking to guide the regulator through high level values statements.

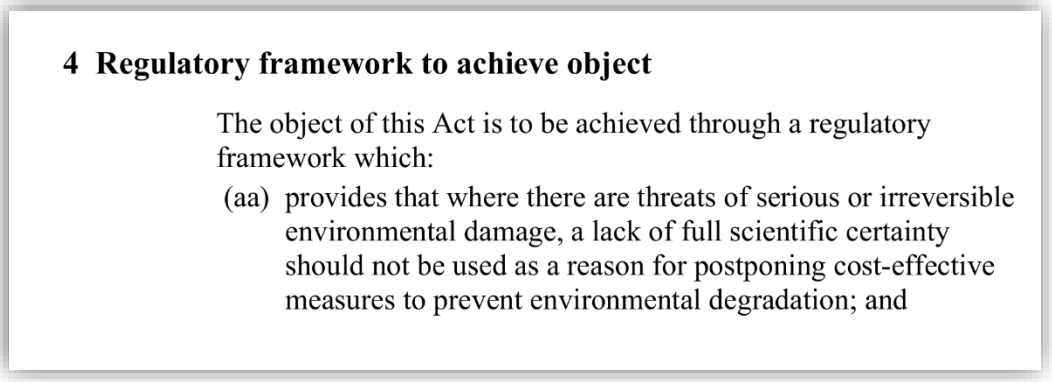
Discussion questions

- What are your thoughts on the proposed decision making outlined?

Fig.5. Response to OIA request – consideration of the precautionary principle. DOIA REQ 0006467

Rae's explanation of the precautionary approach was exclusively couched in relation to Australian legislation. However, while the Australian legislation provides that officials may act where there *are threats of serious or irreversible environmental damage and that full scientific certainty should not be used as a reason for postponing cost-effective measures*, no such content has been drafted into the New Zealand Bill.

The New Zealand Bill does refer to decision-makers having regard for the Convention on Biological Diversity ; and the Cartagena Protocol (s5 (a) and (b)). Having 'regard for' does not impose an obligation to take a matter into account. This includes a requirement to consider precaution and any requirement to act to prevent environmental degradation should there be a lack of full scientific certainty.



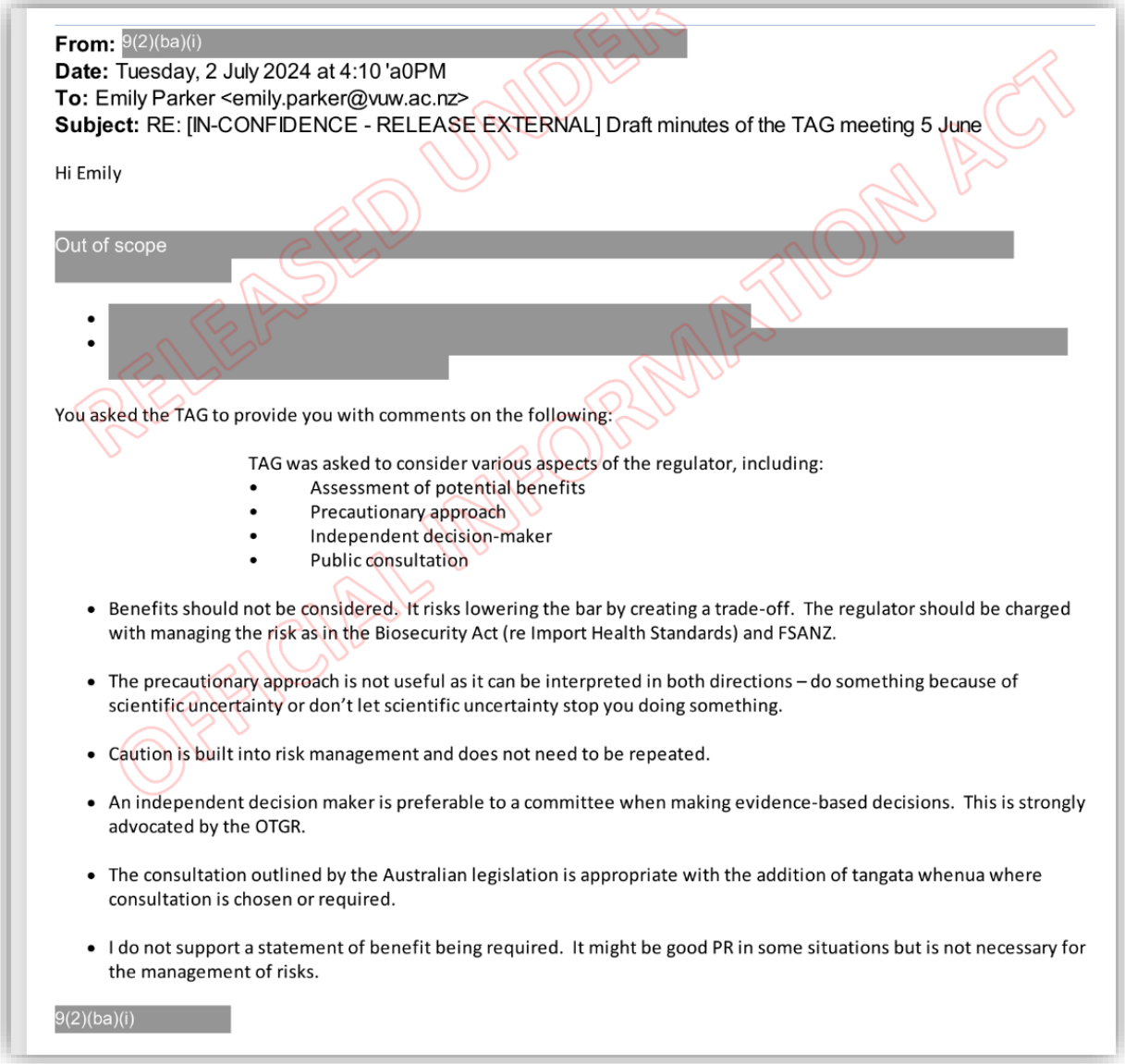
4 Regulatory framework to achieve object

The object of this Act is to be achieved through a regulatory framework which:

(aa) provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation; and

Fig.6: Australian Government. Gene Technology Act.

From the information that has been publicly released, the TAG were provided with Rae's advice and then asked to provide comments on the following extremely rudimentary statements:



From: 9(2)(ba)(i)
Date: Tuesday, 2 July 2024 at 4:10 'a0PM
To: Emily Parker <emily.parker@vuw.ac.nz>
Subject: RE: [IN-CONFIDENCE - RELEASE EXTERNAL] Draft minutes of the TAG meeting 5 June

Hi Emily

Out of scope

- [redacted]
- [redacted]

You asked the TAG to provide you with comments on the following:

TAG was asked to consider various aspects of the regulator, including:
- Assessment of potential benefits
- Precautionary approach
- Independent decision-maker
- Public consultation

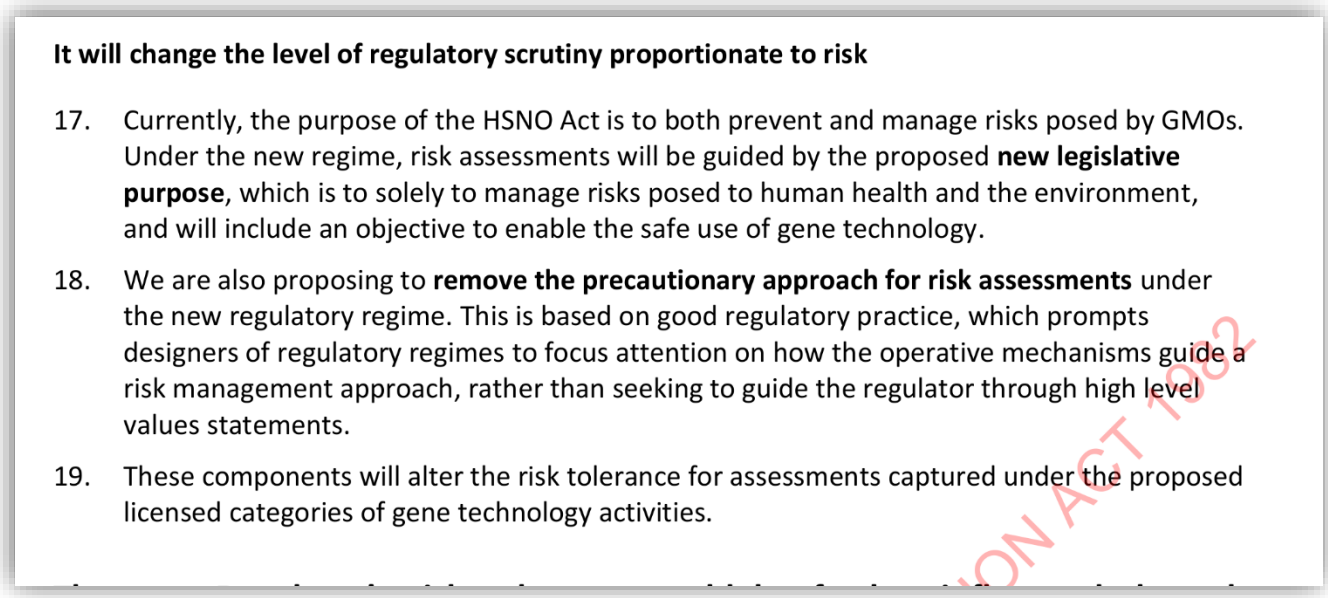
- Benefits should not be considered. It risks lowering the bar by creating a trade-off. The regulator should be charged with managing the risk as in the Biosecurity Act (re Import Health Standards) and FSANZ.
- The precautionary approach is not useful as it can be interpreted in both directions – do something because of scientific uncertainty or don't let scientific uncertainty stop you doing something.
- Caution is built into risk management and does not need to be repeated.
- An independent decision maker is preferable to a committee when making evidence-based decisions. This is strongly advocated by the OTGR.
- The consultation outlined by the Australian legislation is appropriate with the addition of tangata whenua where consultation is chosen or required.
- I do not support a statement of benefit being required. It might be good PR in some situations but is not necessary for the management of risks.

9(2)(ba)(i)

Fig.6: Response to OIA request – consideration of the precautionary principle. DOIA REQ 0006467

Based on the response to DOIA REQ 0006467, no comments were then forthcoming.

Then, in a June 18 event briefing on a Meeting with the New Zealand Environmental Protection Authority[129] MBIE proposed that removing the precautionary approach for risk assessments was based on 'good regulatory practice'.



It will change the level of regulatory scrutiny proportionate to risk

17. Currently, the purpose of the HSNO Act is to both prevent and manage risks posed by GMOs. Under the new regime, risk assessments will be guided by the proposed **new legislative purpose**, which is to solely to manage risks posed to human health and the environment, and will include an objective to enable the safe use of gene technology.
18. We are also proposing to **remove the precautionary approach for risk assessments** under the new regulatory regime. This is based on good regulatory practice, which prompts designers of regulatory regimes to focus attention on how the operative mechanisms guide a risk management approach, rather than seeking to guide the regulator through high level values statements.
19. These components will alter the risk tolerance for assessments captured under the proposed licensed categories of gene technology activities.

Fig.8: MBIE (June 18, 2024) Event briefing on a Meeting with the New Zealand Environmental Protection Authority. Page 5.

It appears that on the basis of MBIEs advice to the June TAG and NZ EPA meetings, that this provided sufficient information to enable the Honourable Judith Collins to make the above claim, published in *The Post,* that it was agreed that a precautionary approach and ethics considerations were not required.

MBIE appears to be communicating authority while contradicting and setting aside long recognised conventions and maxims that are required to underpin regulatory policy development so as to ensure that regulations do not benefit narrow interest groups.

As we discuss above [2], Government expectations for good regulatory practice manual recognises that any statement must be evidence informed. This has not occurred, and rather, as we see here, any narrative around precaution has been tightly controlled by MBIE officials.[130]

MBIE also emphasised to the TAG that good regulatory practice focuses attention on operative mechanisms by way of setting a risk management framework or decision-methodology in secondary legislation.[131] This bureaucratic language for claiming that the secondary legislation will contain the parameters which bureaucrats decide when a GMO is not a GMO.

> *'The proposed legislative trigger for a regulated tier is products and processes that create outcomes distinguishable from conventional breeding. This trigger inevitably leads to future semantic disputes of what conventional breeding means, and technical challenges to*

[129] MBIE (June 18, 2024) Event briefing on a Meeting with the New Zealand Environmental Protection Authority. Page 5. https://psgr.org.nz/component/jdownloads/send/1-root/156-oia-request-2024-genetechregulator-mbie-nzepa
[130] The Treasury (April 2017). Government expectations for good regulatory practice. https://www.treasury.govt.nz/sites/default/files/2015-09/good-reg-practice.pdf
[131] MBIE (June 5, 2024) Agenda: Gene Technology Advisory Group. https://fyi.org.nz/request/29246/response/118012/attach/3/Extracts%20from%205%20June%202024%20TAG%20meeting%20Redacted.pdf

distinguishability. These debates and contests aren't focussed on safety and are not efficient ways to regulate.'[132] [133]

Yet the overarching purposes of an Act for a regulator, is required in place to shape regulatory approaches to risk management, and inform how any decision-methodology will be designed.

MBIE communicates to the TAG that the regulator will not have to make judgments that are inherently and unavoidably value based when regulatory decisions revolve around judgements on values. MBIE language suggests that all decisions will be exclusively technical.

MBIE have shown no interest in evaluating global regulatory practice, but have instead adopted a parochial perspective that seems to at once rely on Australian legislation, but then act to water-down and alter, even Australian laws.

This is evidenced by MBIEs 'strict liability' perspective which would reposition the bar for risk much higher than a precautionary approach based on an observed threat, but lack of full scientific certainty.

Page three of the RIS stated that:

'various reports over the past 15 years have found that the HSNO Act's GMO provisions are increasingly out of date'

MBIE cites three sources: the Royal Society, the Productivity Commission and the Prime Ministers' Chief Science Advisor.[134] PSGR believes that MBIE misrepresents the information coming out of these institutions in producing their page three list of out-of-date provisions in the RIS. None of these institutions have ever studied the global literature on best practice regulatory assessment of GMOs, including gene editing techniques and the gene edited organisms. No institution assessed whether economic and cost-benefit analyses nor whether the precautionary approach was out-of-date.

Royal Society Te Apārangi

The Royal Society Te Apārangi controls the Marsden Fund and the income for the 2016-2019 campaign was sourced from this fund. Between 2016-2019 the Royal Society Te Apārangi convened an expert panel to discuss GMO regulation. The compilation document[135] contains most of the published literature. Many of the people with the specific scientific expertise on biotechnology and gene editing in the vast majority, had considerable conflicts of interest. They, or the institutions they work for, would all benefit from a deregulated environment. The panel was criticised as taking an advocacy view.

The campaign did not review, nor did it assess human health or environmental health risk.

Royal Society of New Zealand in their findings did not directly state that the precautionary approach, or that economic benefit analysis were out-of-date concepts. The Royal Society did not state provisions in the HSNO Act were out-of-date, but did recommend a 'risk-tiered approach where regulatory burden is

[132] Heinemann J, Kurenbach B, Hiscox TC, McCabe A, and Walker S. (2025) Centre for Integrated Research in Biosafety (INBI). Submission to the Parliament Health Committee on the Gene Technology Bill 2024. January 2025.https://ir.canterbury.ac.nz/server/api/core/bitstreams/0e1aa118-5e68-4b43-b395-2a4487d90aa4/content
[133] Heinemann et al. 2025. Supplementary submission to the Parliament Health Committee on the Gene Technology Bill 2024. Centre for Integrated Research in Biosafety at the University of Canterbury Page 6. https://www.researchgate.net/publication/388835965_INBI_supplementary_submission_to_health_select_committe e_gene_tech_bill_2024pdf
[134] Ministry for Regulation. Issue date: December 20, 2024. Regulatory Impact Statement: Reform of Gene Technology Regulation. Page 3/131. Date: Wednesday 31 July 2024 https://www.regulation.govt.nz/our-work/regulatory-impact-statements/regulatory-impact-statement-reform-of-gene-technology-regulation/
[135] Royal Society Te Apārangi (August 2019) Gene Editing Legal and Regulatory Implications. https://www.royalsociety.org.nz/assets/Uploads/Gene-Editing-FINAL-COMPILATION-compressed.pdf

commensurate with risk' similar to Australia which hints at altering a process-based approach. The Society did not assess how Australia stood in relation to best practice regulation.

Office of the Prime Minister's Chief Science Adviser.

The Prime Minister's Chief Science Advisor (2017) highlighted the potential benefits for climate change adaptation, agricultural innovation, health services and pest control from the use of genetic technologies and called for a more open and enabling public and regulatory environment.

In 2019[136] and 2023[137] briefing papers by the Chief Science Adviser, there was no direct mention of the provisions listed by MBIE as being 'out-of-date'.

In the eight years hence, not a single agency has conducted an economic analysis to evaluate the return on investment globally, from research and development into genetically modified technologies and the patented organisms that are released into the environment.

MBIE misstates the Productivity Commissioner & ignores his recommendations

The now disestablished[138] Productivity Commission never made such claims that the. In 2019, following a request that the Commission inquire into technological change and the future of work, the Commission released an issues paper, and consulted with the public. [139] Around 3 responses out of perhaps 80 focussed on biotechnology and genetic modification regulations. This issue was of minor concern to most respondents. In 2020 the Productivity Commissioner engaged with Plant and Food staff, and this engagement formed the basis of the Productivity Commissioners recommendations around the regulation of genetic modification.[140]

Two papers were released. The Technological Change and the Future of Work (2020)[141] paper the Productivity Commission suggested that 'Controls on genetic modification technologies may be out-of-date and overly restrictive' and suggested that the Government should 'review and refresh regulatory settings to make sure they are adequate to deal with emerging technologies (eg, competition policy; data access and consumer data rights) and are not inhibiting technology adoption (eg, restrictions on the use of genetic modification technologies).'

The following Reaching for the Frontier (2021) paper recommended a broad review[142]:

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[136] OPMCSA. Briefing to the Prime Minister on the Report on Gene Editing from Royal Society Te Apārangi, 12/13 August 2019. https://bpb-ap-se2.wpmucdn.com/blogs.auckland.ac.nz/dist/f/688/files/2020/02/Briefing-on-genetic-editing-final.pdf

[137] OPMCSA (June 13 2023) Briefing for PM. Update to 2019 information. https://bpb-ap-se2.wpmucdn.com/blogs.auckland.ac.nz/dist/f/688/files/2023/06/230613-Letter-to-PM-update-to-2019-briefing-for-PM-with-attachments-130623.pdf

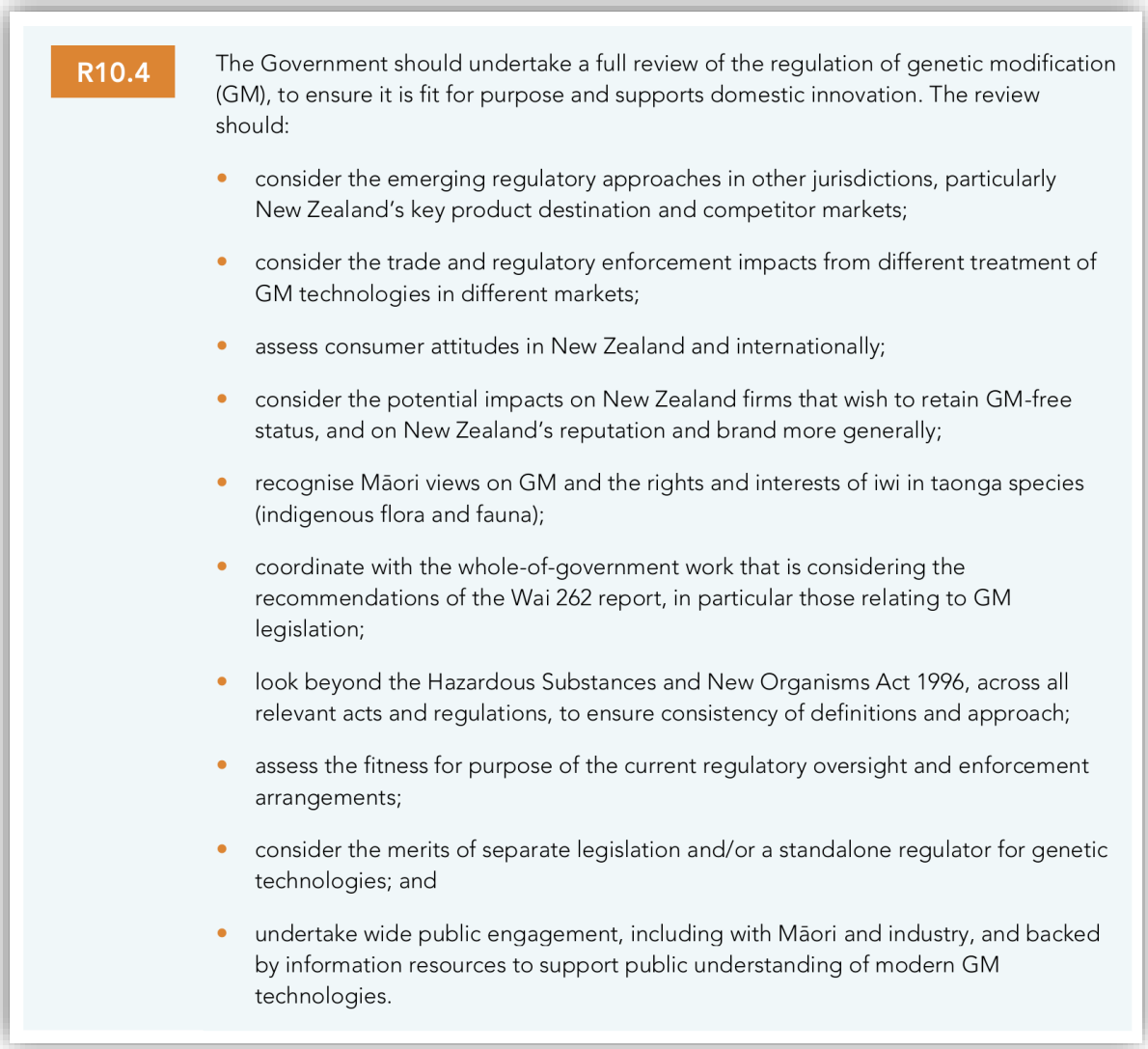
[138] Productivity Commission (2011 - 2024) https://www.treasury.govt.nz/information-and-services/nz-economy/productivity/productivity-commission-2011-2024

[139] Productivity Commission (April 2019) Technological change and the future of work. https://www.treasury.govt.nz/sites/default/files/2024-05/pc-inq-tcfw-technological-change-and-the-future-of-work-issues-paper.pdf

[140] Productivity Commission (June 2022). Official Information Act Request. Reaching for the frontier. Biotech/gene editing - questions to case study participants https://fyi.org.nz/request/19319-reaching-for-the-frontier-biotech-gene-editing-questions-to-case-study-participants#incoming-73945

[141] Productivity Commission (March 2020). Technological Change and the Future of Work https://www.treasury.govt.nz/sites/default/files/2024-05/pc-inq-tcfw-final-report-technological-change-and-the-future-of-work.pdf

[142] New Zealand Productivity Commissioner. April 2021. New Zealand firms: Reaching for the frontier. Final Report. ISBN: 978-1-98-851961-6 (online). Page 179. https://www.treasury.govt.nz/sites/default/files/2024-05/pc-inq-nzfrff-final-report-frontier-firms.pdf



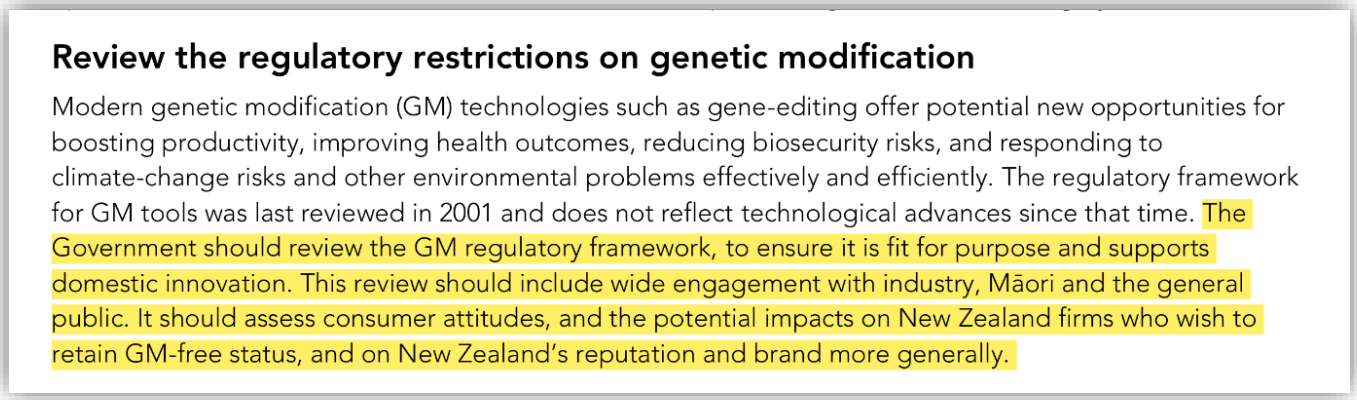
R10.4

The Government should undertake a full review of the regulation of genetic modification (GM), to ensure it is fit for purpose and supports domestic innovation. The review should:

- consider the emerging regulatory approaches in other jurisdictions, particularly New Zealand's key product destination and competitor markets;
- consider the trade and regulatory enforcement impacts from different treatment of GM technologies in different markets;
- assess consumer attitudes in New Zealand and internationally;
- consider the potential impacts on New Zealand firms that wish to retain GM-free status, and on New Zealand's reputation and brand more generally;
- recognise Māori views on GM and the rights and interests of iwi in taonga species (indigenous flora and fauna);
- coordinate with the whole-of-government work that is considering the recommendations of the Wai 262 report, in particular those relating to GM legislation;
- look beyond the Hazardous Substances and New Organisms Act 1996, across all relevant acts and regulations, to ensure consistency of definitions and approach;
- assess the fitness for purpose of the current regulatory oversight and enforcement arrangements;
- consider the merits of separate legislation and/or a standalone regulator for genetic technologies; and
- undertake wide public engagement, including with Māori and industry, and backed by information resources to support public understanding of modern GM technologies.

Fig.9: Reaching for the Frontier (2021) paper 'full review' recommendation. Page 181.

In at least two places, the Productivity Commissioner stressed that the government undertake *wide public engagement*. The Productivity Commissioner did not state that HSNO Act provisions were out-of-date.



Review the regulatory restrictions on genetic modification

Modern genetic modification (GM) technologies such as gene-editing offer potential new opportunities for boosting productivity, improving health outcomes, reducing biosecurity risks, and responding to climate-change risks and other environmental problems effectively and efficiently. The regulatory framework for GM tools was last reviewed in 2001 and does not reflect technological advances since that time. The Government should review the GM regulatory framework, to ensure it is fit for purpose and supports domestic innovation. This review should include wide engagement with industry, Māori and the general public. It should assess consumer attitudes, and the potential impacts on New Zealand firms who wish to retain GM-free status, and on New Zealand's reputation and brand more generally.

Fig.10: Reaching for the Frontier (2021) paper 'full review' recommendation. Page 9 (Overview).

Then in March 2022 a government response to the Productivity Commission's Frontier Firms inquiry white paper[143] the government stated that 'it was timely to start informed conversations around New Zealand's use of GM technologies'. By March 2023, the Ministry for the Environment has started public consultation, as discussed above.

But the review that had been recommended, did not happen. By October 2023, the Ministry for Business, Innovation and Employment, in tandem with the Honourable Judith Collins commenced to create policy for new gene technology regulation outside of the purview of the public. MBIE have no experience in developing legislation that is designed to ensure that a technology and its emission will not present an economic or health-based risk to human or environment or to ecosystems.

In the case of the current Gene Technology Bill, it seems that MBIE, Collins and Crown Law have sought no independent expert advice, rather, they have turned to Royal Society literature which had promoted harmonisation with Australian legislation, evidently turned to scientists that had earlier advised the Royal Society and then turned to Australian law, presuming that would be best for New Zealand.

New Zealand's legislation would likely be weaker than Australia's regulations. 'Australia but potentially not New Zealand defines the use of SDN2 and oligonucleotide mutagenesis (ODM) as distinguishable from conventional breeding.'[144] But Ministers were not appraised of that fact.

[7] TECHNICAL ADVISORY GROUP'S MARGINAL CONTRIBUTION

The public and members of Parliament will be under the impression that the Technical Advisory Group that advised the government on the underlying policy would appropriately ensure that New Zealand's gene technology regulation would be fit for purpose.

By February 2024 Simon Rae was briefing the Minister on Technical Advisory Group candidates.[145]

The Group was comprised predominantly of experts in biotechnology, who work for institutions funded to develop biotechnology.[146] The Technical Advisory Group met 5 times prior to the release of the RIS.

MBIE then, in developing the policy to underpin the legislation have used a Technical Advisory Group to claim that 'officials interpretation of the relevant science is accurate'. Unfortunately, that group's Terms of Reference are so narrowly constructed that the group lacks the power or capacity to challenge any position taken by MBIE.

In addition these '15 representatives from institutes and organisations actively involved in gene technology work' come from institutions that have conflicts of interest due to the companies that they work for, or, indeed, founded.

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[143] New Zealand Government (March 2022) Response to the Productivity Commission's Frontier Firms inquiry. ISBN 978-1-99-102231-8 https://www.treasury.govt.nz/sites/default/files/2024-05/pc-inq-nzfrff-government-response-frontier-firms.pdf

[144] Heinemann J, Kurenbach B, Hiscox TC, McCabe A, and Walker S. (2025) Centre for Integrated Research in Biosafety (INBI). Submission to the Parliament Health Committee on the Gene Technology Bill 2024. January 2025. University of Canterbury. Page 7.

[145] Rae S. (February 8, 2024) MBIE 2324-1836 Regulation of Biotechnology: Process. Page 25/150. https://www.mbie.govt.nz/dmsdocument/29940-regulation-of-gene-technologies-policy-decisions-proactive-release-of-advice-proactiverelease-pdf

[146] Regulatory Impact Statement p.131.

Advisory/focus group participants are detailed below:

Group and description	Number of engagements / sessions (as of RIS drafting)	Participants
Technical Advisory Group *Formal advisory group to provide technical and science advice to MBIE.* *Expected to provide advice until late 2025.*	5	Professor Emily Parker – Chair (Science Advisor, MBIE & Professor Chemical Biology Ferrier Institute) Dr William Rolleston (Co-founder South Pacific Sera Ltd – biotechnology company) Dr Tim Hore (Epigenetics and development, University of Otago) Professor David Ackerley (Professor of Biotechnology, Victoria University of Wellington) Dr Hilary Sheppard (Senior Lecturer Stem Cell and Developmental Biology, University of Auckland) Dr Alec Foster (Bioproducts and Packaging Portfolio Leader, Scion) Professor Jasna Rakonjac (Professor in Microbiology, Massey University) Associate Professor Maui Hudson (Faculty of Māori and Indigenous Studies, University of Waikato) Dr Andy Allan (Biological Sciences, University of Auckland) Dr Nikki Freed (Genomics, University of Auckland & Chief Scientific Officer, Daisy Lab) Dr Rachel Perret (Research Team Leader, Malaghan Institute of Medical Research) Ariana Estoras (Director Māori Strategy, Research and Partnerships, AgResearch) Professor Neil Gemmell (Department of Anatomy, University of Otago)

Fig.11: Regulatory Impact Statement P.123

The Technical Advisory Group's stated role was to[147]:

- Provide technical advice to MBIE on up-to-date gene technology regulation, including regulatory procedures and scientific technical matters related to biotechnology, genetic technologies and gene therapies.
- Ensure that officials' interpretation of relevant science is accurate, that opportunities and risks are clearly understood and that technical considerations are effectively incorporated into policy development.

[147] MBIE. Gene Technology Regulation. Accessed February 21, 2025. https://www.mbie.govt.nz/science-and-technology/science-and-innovation/agencies-policies-and-budget-initiatives/gene-technology-regulation

Yet the TAG membership lacked expertise in the establishment of fit-for-purpose regulation. The TAG appeared to be barely consulted with, and indeed, most, including the chair had financial conflicts of interest that would compromise their capacity to approach the work in an unbiased manner.

In a November 2024 Official Information Act request, PSGR trustee Jodie Bruning asked MBIE a series of questions (see Appendix II, below).

The first involved the content of the Technical Advisory Group's Terms of Reference.[148] Unfortunately, the Terms of Reference severely restricts the Technical Advisory Group from taking a proactive role that might challenge MBIEs belief that directly drawing from Australian legislation is appropriate, or that their stance on the safety of the gene edited organisms that would escape regulation may be fully taken for granted.

As PSGR noted[149] in their submission to the Health Select Committee on the Gene Technology Bill 2024:

> *The Technical Advisory Group used for the purposes of policy formulation, are neither required nor resourced to consider the underpinning scientific information outside of information directly supplied by MBIE.*[150]
>
> a. *Technical Advisory Group 'experts' lack a broad background in regulatory reform or oversight, for the specific purpose of protecting public and environmental health.*
> b. *The Technical Advisory Group are tasked to provide expertise in their 'individual capacity'. They are therefore not tasked to assess the potential of the regulator to fulfill the purposes and aims of the legislation (regulatory reform), even though they are assembled to 'provide advice to MBIE on gene technology regulatory reform'.*
> c. *Regulatory reform is highly complex and nuanced, yet the Technical Advisory Group experts 'expect a workload of three hours per month, that includes a two-hour meeting each month and one hour preparation time.'*

It is unclear to what extent information (if any) on regulation of gene-editing technologies and organisms has been supplied to the TAG who lacked expertise in regulatory risk assessment. A request to see the academic literature and expert reports provided by MBIE to TAG members was declined as the information did not exist. A November 2024 OIA response by manager Tony de Jong[151] asking to view scientific information sent to the Group stated:

> MBIE has not provided the Technical Advisory Group (TAG) with any such information. TAG members were expected to have prior knowledge of the relevant scientific information as they were chosen due to their significant expertise with gene technologies and related issues.

It also added that scientific advice was not sought from the TAG as to how current proposed legislative and regulatory changes by Food Standards Australia New Zealand would also impact New Zealand outcomes.

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[148] MBIE Gene Technology Regulation Technical Advisory Group Terms of Reference. https://fyi.org.nz/request/29246/response/114976/attach/4/DOIA%20REQ%200006620%20Gene%20Technology%20Regulation%20Technical%20Advisory%20Group%20Terms%20of%20Reference%20FINAL.pdf

[149] PSGR (February 17, 2024). Gene Technology Bill 2024, Submission to the Health Select Committee. https://psgr.org.nz/component/jdownloads/send/1-root/167-gtbill-select-committee

[150] Gene Technology Regulation Technical Advisory Group. https://fyi.org.nz/request/29246/response/114976/attach/4/DOIA%20REQ%200006620%20Gene%20Technology%20 Regulation%20Technical%20Advisory%20Group%20Terms%20of%20Reference%20FINAL.pdf

[151] Official Information Act Request to MBIE, November 19, 2024. Scientific advice - technical focus group - Gene Technology regulations and powers of regulator. DOIA REQ 0006620. https://fyi.org.nz/request/29246-scientific-advice-technical-focus-group-gene-technology-regulations-and-powers-of-regulator#incoming-118012

The request then asked for information on discussions between MBIE and TAG members on the powers of the Regulator to surveil and assess risks, including information from third parties and internationally.[152] MBIE responded:

> *'The policy intention was to enable the Regulator to require any surveillance it considers necessary to manage risks appropriately, and therefore MBIE did not need advice from the TAG on these powers.... I am therefore declining your request as the information requested does not exist'*

A question to:

> '*Please supply 'up to date gene regulation' information on how regulations in the top performing OECD nations and the latest decisions by the European Parliament compare against Australia and the proposed hybrid regulations, that have been sent to the technical expert group for assessment*.'

Was declined on the basis that the information was publicly available in the RIS.[153] The decision on European hesitancy and the pause on potential new legislation, had not been communicated to the TAG.

Tony de Jong refused to disclose TAG's advice on risk management approaches to develop the secondary legislation required by the Bill, including how uncertainty would be considered in decision making. This includes how the Regulator would determine the risk level of an activity. The refusal was on the basis of maintaining constitutional conventions to protect the confidentiality of advice.[154]

The TAG was in place to 'Provide technical advice to MBIE on up-to-date gene technology regulation, including regulatory procedures and scientific technical matters'. There seemed to be no cross-talk, nor information on regulatory procedures and technical matters relating to the gene technology reform.

With evidence that the TAG were only vaguely informed on the 'out-of-date provisions', and that no evidence exists that the TAG were fully equipped to understand global practice on risk management, including the current status of legislation in key OECD trading markets, it's remarkably unclear how the TAG was advising MBIE.

It looks remarkably like the Technical Advisory Group appeared to be a 'policy legitimating device', that they were in place to assure the public that appropriate expertise was informing the legislation, rather than a group tasked to critically evaluate policies that made pseudo-scientific claims about being risk proportionate, that were in the process of being enshrined in regulatory legislation, that was expected to providing an overarching structure that would inform secondary legislation, and that was fit-for-purpose for the foreseeable future.

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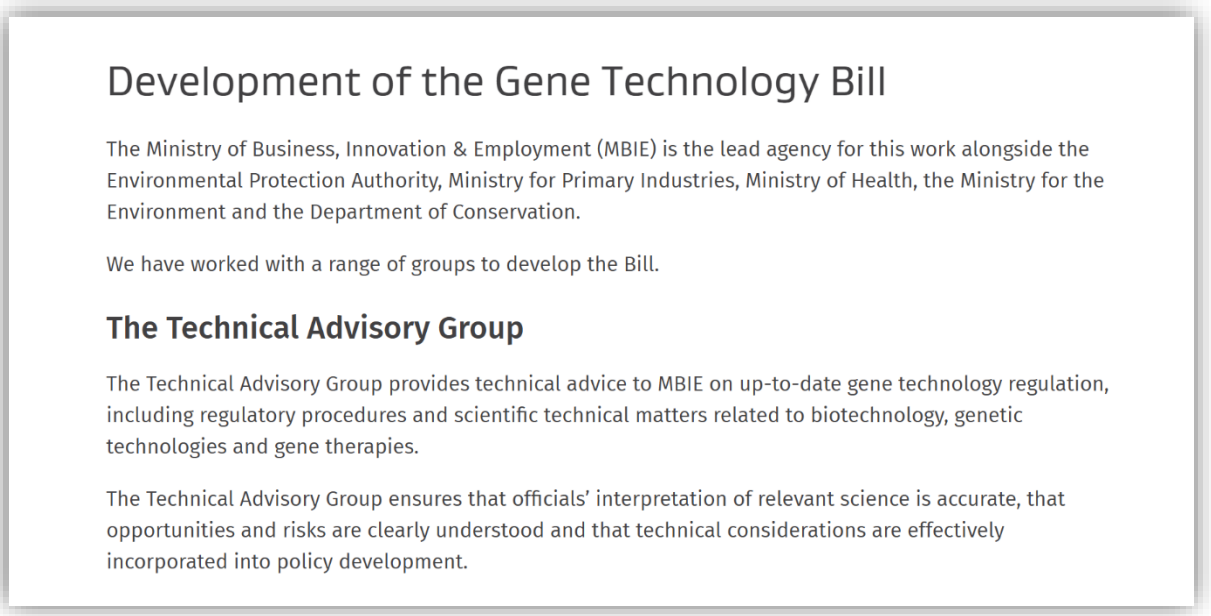
[152] de Jong T. (February 14, 2025). Official Information Act Request to MBIE no. DOIA-REQ-0006620 https://fyi.org.nz/request/29246/response/118012/attach/4/DOIA%20REQ%200006467%20J%20Bruning%20Second%20response%20letter.pdf

[153] De Jong (December 17, 2024). Official Information Act Request to MBIE no. DOIA-REQ-0006620 https://fyi.org.nz/request/29246/response/114976/attach/3/DOIA%20REQ%200006620%20Jodie%20Bruning%20Response%20Letter.pdf

[154] De Jong T (February 13, 2025). Official Information Act Request to MBIE no. DOIA-REQ-0006620. Official Information Act (9(2)(f)(iv)). https://fyi.org.nz/request/29246/response/117959/attach/4/DOIA%20REQ%200006467%20J%20Bruning%20MBIE%20Response%20Letter.pdf



Development of the Gene Technology Bill

The Ministry of Business, Innovation & Employment (MBIE) is the lead agency for this work alongside the Environmental Protection Authority, Ministry for Primary Industries, Ministry of Health, the Ministry for the Environment and the Department of Conservation.

We have worked with a range of groups to develop the Bill.

The Technical Advisory Group

The Technical Advisory Group provides technical advice to MBIE on up-to-date gene technology regulation, including regulatory procedures and scientific technical matters related to biotechnology, genetic technologies and gene therapies.

The Technical Advisory Group ensures that officials' interpretation of relevant science is accurate, that opportunities and risks are clearly understood and that technical considerations are effectively incorporated into policy development.

Fig.12: 'Up-to-date gene technology regulation'. MBIE Website.[155]

What remains to be publicly discussed, is the conflict-of-interest problem. Many, if not most of the technical advisory group members are involved in projects or directly work for institutions who have biotechnology patents and who have a financial interest in sourcing revenue from the development of biotechnology patents. These financial interests have not been declared in public documents.

Technical Advisory Group members:

- Professor Emily Parker (Chair), Professor Chemical Biology, Ferrier Research Institute, Departmental Science Advisor MBIE. Ferrier Research Institute is a biotechnology and drug development organisation owned by Wellington Univentures. Products are intended to be commercialised via licenses or spun out through commercial pathways.
- Associate Professor Tim Hore, University of Otago | Ōtākou Whakaihu Waka. Founder of Totogen service provider of low-cost analysis of sheep DNA. Current work involves identifying target genes in the possum, an invasive species identified by Royal Society as an opportunity for gene editing.
- Dr Richard Scott, AgResearch leader Climate Change and Forage Innovations Team. Projects within the Team include studying forage adaptation to climate change; reducing greenhouse gas production; genetic editing of plants; and continuing the development of HME Ryegrass. Leader AgResearch Genetic Technologies Enabling Platform,
- Professor David Ackerley, Professor of Biotechnology, Biotechnology Programme Director. Victoria University of Wellington.
- Dr Billy Sheppard, University of Auckland | Waipapa Taumata Rau
- Dr Alec Foster, Bioproducts and packaging leader, Scion
- Professor Jasna Rakonjac, Researcher, potential of phage for technology, agricultural and medical applications Massey University.
- Associate Professor Maui Hudson, University of Waikato | Te Whare Wānanga o Waikato
- Dr Andy Allan, University of Auckland | Waipapa Taumata Rau

[155] MBIE Website. Accessed March 21, 2025. https://www.mbie.govt.nz/science-and-technology/science-and-innovation/agencies-policies-and-budget-initiatives/gene-technology-regulation

- Dr Nikki Freed, Genomics, University of Auckland & Chief Scientific Officer, Daisy Lab a precision fermentation food technology laboratory.
- Dr Rachel Perret, Research Team Leader in the Weinkove Laboratory, CAR T-cell research programme, Malaghan Institute of Medical Research.
- Ariana Estoras, Molecular geneticist. Director Māori Strategy, Research and Partnerships, AgResearch.
- Professor Neil Gemmell, AgResearch Chair in Reproduction and Genomics at the University of Otago. Leader Evolutionary Genomics Group, which applies recent advances in genomic technology to the fields of ecology, population, conservation and evolutionary biology.
- William Rolleston: Co-founder of biotechnology company South Pacific Sera Limited. Chair of Genomics Australia. Founding chair of Aotearoa New Zealand's biotechnology industry association (now Biotech NZ) and the Life Sciences Network. Member of the Gene Technology Reform Technical Advisory Group. Advisor to the Royal Society Te Apārangi's 2016-2019 campaign.

[8] TRUSTWORTHY SCIENCE NEEDED TO ESTABLISH HAZARD AND EXPOSURE RISK

To be 'risk-proportionate' the Regulator must have the powers to assess the risk, which is a function of both hazard and exposure. Both hazard and exposure assessments are required to characterise overall risk. However, these classic approaches to risk assessment have been ignored in the Gene Technology Bill.

A hazard is the potential of an organism to cause harm to human and/or animal health and/or to the environment. This is then integrated with an estimated likelihood of exposure and magnitude of adverse effects.

Risks cannot be mitigated if an assessment has not considered exposure and context, in order to assess the probability of harm. Comparative hazard analyses which ignore use-patterns are unfit for purpose.

This legislation can never be 'risk-proportionate' if classes of gene editing techniques and organisms are predetermined as exempt based on a presumption of indistinguishability from organisms produced using conventional breeding and then made exempt or tiered as very-low risk and non-notifiable.[156]

In a recent submission to the Health Select Committee on the Gene Technology Bill 2024, the Centre for Integrated Research on Biosafety (INBI) cited the example of a wasp nest.[157] Each wasp is a hazard. But is the wasp nest away from your home or close to it? Are you at risk from perhaps one sting every couple of years, or a brutal attack on a family member? Are young children at risk?

If we substitute hazard and exposure risk to what a technology can do, how quickly it can do it, and what can be exposed and to what extent an organism or ecosystem can be exposed – that's where the hazard and exposure assessments are critical.

But this information is not included in the primary legislation the Gene Technology Bill, which should be sufficiently rigorous, as a risk framework for regulatory scientists to guide them in their work so that they are not vulnerable to political attack. It should be sufficiently robust that all secondary legislation and

[156] PSGR (February 17, 2024). Gene Technology Bill 2024, Submission to the Health Select Committee. Page 19. https://psgr.org.nz/component/jdownloads/send/1-root/167-gtbill-select-committee

[157] Heinemann J, Kurenbach B, Hiscox TC, McCabe A, and Walker S. (2025) Centre for Integrated Research in Biosafety (INBI). Submission to the Parliament Health Committee on the Gene Technology Bill 2024. January 2025. University of Canterbury.https://www.researchgate.net/publication/388526356_INBI_submission_to_health_select_committee_gene_tech_bill

that the regulations in that legislation will protect the health and safety of people and the environment and prevent the abuse of power. The Gene Technology Bill should promote public trust in regulatory and monitoring agencies, so that the public understand that their safety is assured.

Risk assessment science is political – can the courts navigate this in the public interest?

Risk-assessment science is a socio-political and scientific. Unlike general laboratory development, risk-assessment science is directly political. This is because the legislation will impact firstly, the resourcing that an organisation must put into scientifically proving that the tech and its outputs are safe (such as the costs of producing scientific research); and the likelihood that that technology can be released onto the market – direct profitability.

Legislation and guidelines are not simply scrutinised by industry. Social scientists have extensively documented the ways industries work to influence and shape government decision-making to produce industry-friendly government cultures. Regulatory capture has exponentially expanded from the mostly understood 'revolving door' problem, where industry experts or lobbyists move effortlessly between the regulated industry and the regulatory agency – to control the information environment and ensure that the industry-relevant information is the most authoritative and trustworthy information. [158]

Industries directly lobby public servants including politicians, they establish information forums to promote their perspective, publish peer-reviewed papers, and work hard to ensure that mainstream media, in the majority, reflects their position. Global forums are designed with the intent of advising governments on policy perspectives. Industries liaise at the global level to develop globally relevant policies, which is then transferred into domestic policy when officials and Ministers return from these meetings, or when they appoint management consultancy firms (who attend the same global meetings) to advise governments on policy. [159] [160]

Many instances in the Gene Therapy Bill reveal industry influence. The writing out of risk and hazard, the exclusion of the precautionary principle, the failure to incorporate ethics considerations, avoidance of liability and the tying of regulatory hands to prevent regulators looking at information other than other regulators. The Gene Technology Bill explicitly includes a provision that pre-consent communications between the gene technology regulator and the agency, would be ruled outside the purview of the Official Information Act. Such a clause directly benefits industry, as it enables crosstalk, advice and influence to occur between the regulatory agency and the industry applicant:

> *[59(3)] 'provides that the Official Information Act 1982 does not apply to information provided to the Regulator that is likely to relate to a licence or determination application until the application is actually received.'*

When people take court action seeking judicial review and/or to dispute regulatory claims, it can be difficult for judiciary and legal counsel, who by convention trust the regulatory process, to appreciate the extent of industry influence and control over scientific information, on agency decision-making.

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[158] Saltelli, A, Dankel D, Fiore M, Holland N and Pigeon M, Science, the endless frontier of regulatory capture, *Futures*, vol. 135, no. 102860, 2022.

[159] Russ KN, Baker P, Kang M, McCoy D. (2022) Corporate Lobbying on US positions toward the World Health Organization: Evidence of intensification and cross-industry coordination. Global Health Governance, 2022, Vol 17, Issue 1, p37. https://blogs.shu.edu/ghg/files/2022/05/Spring-2022-Issue.pdf#page=38

[160] See discussion Chapter 8. An influence web: Regulatory Capture. PSGRNZ (2024) Stepping Back from the Brink: The Programmable Ledger. Four democratic risks that arise when Digital IDs are coupled to Central Bank Digital Currencies. Bruning, J.R., Physicians & Scientists for Global Responsibility New Zealand. ISBN 978-0-473-71618-9. https://psgr.org.nz/component/jdownloads/send/1-root/137-2024-cbdc-paperv3

Government and regulatory agencies conventionally defer to industry-supplied data, rather than the scientific peer-reviewed literature. This might not be the best source of information, and it may not reflect the extent of knowledge that is reflected in the peer reviewed scientific literature.

Scientific information is funded by industry to support regulatory approvals, but also to produce doubt and prevent decisions that would reduce market access for their products. Regulators are often funded by the industries whose products that they regulate.[161] [162] Close relationships result in that agency acting more like a service provider. For example, in the lead up to making the application for market approval for the mRNA gene therapy, regulatory agencies coached Pfizer to support an approval.[163]

Judicial habits of deferring to the agency who regulates the technology, and the agency provision of tightly controlled science may alter over the coming years. A U.S. court decision recently overturned the landmark 1984 *Chevron* decision:[164]

> *By a vote of 6-3, the justices overruled their landmark 1984 decision in Chevron v. Natural Resources Defense Council, which gave rise to the doctrine known as the Chevron doctrine. Under that doctrine, if Congress has not directly addressed the question at the center of a dispute, a court was required to uphold the agency's interpretation of the statute as long as it was reasonable. But in a 35-page ruling by Chief Justice John Roberts, the justices rejected that doctrine, calling it "fundamentally misguided."*

The capacity for judges and legal counsel to look outside, and actively explore non-industry information sources, and not weight judgements to favour data supplied by the agencies who work closely with relevant industries, is central to sound decision-making and the reduction of future disputes.

[9] CONCLUSION

The gene technology reform policy process has been led by Ministry of Business, Innovation, and Employment (MBIE) and the Honourable Judith Collins, Kings Counsel and Attorney-General. It has failed to publicly disclose that risk evaluation to identify why gene editing techniques and organisms can present problems, via contamination, heredity and the potential to kill, has never been undertaken.

PSGR recommends that a public inquiry be convened to investigate the conduct of MBIE and Hon. Judith Collins in connection with the implementation of gene technology reforms.

PSGR notes that the entire pro-GMO deregulatory process, including all underpinning scientific justification, has been sponsored by MBIE, and that it cannot be identified as a left or right issue. Deregulation of gene edited technologies and organisms has been steadfastly pursued by MBIE. MBIE has a disproportionate influence over science funding and resourcing, and the existing science policy and the future reforms demonstrate that MBIE will continue to encourage and incentivise biotechnology research over other forms of research that do not result in the production of IP and patents.

The gene technology reforms demonstrate that MBIE now wants to lower the regulatory barriers to improve market access of the very technologies that it funds, including turning gene edited organisms.

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[161] Demasi M, From FDA to MHRA: are drug regulators for hire? *BMJ,* vol. 377, p. o1538, 2022.
[162] New Zealand Environmental Protection Authority. Annual Report 2023/24. Financial Statetment page 85. Fees and Charges for Hazardous Substances and New Organisms. https://www.epa.govt.nz/assets/RecordsAPI/EPA-Annual-Report-2024.pdf
[163] Ministry of Health.(August 13, 2021) Official Information Act Request. 9(2)(a) H202106950. All documents discovered by the Crown in the Nga Kaitiaki Tuku. https://www.health.govt.nz/system/files/2021-10/h202106950_-_response.pdf
[164] Howe A. (June 28, 2023). Opinion Analysis: Supreme Court strikes down Chevron, curtailing power of federal agencies. *Scotus Blog.* https://www.scotusblog.com/2024/06/supreme-court-strikes-down-chevron-curtailing-power-of-federal-agencies/

Despite controlling New Zealand's science funding, MBIE has been unwilling to fund scientific research which would assess the potential risk from deregulation, i.e. the costs and risks which following deregulation, could be transferred to others.

The claims by MBIE that the legislation will be 'risk-proportionate' cannot be substantiated. The data to justify that the legislation could manage the risks from gene editing techniques and organisms does not exist. Without the data, MBIEs claims that the legislation would protect the health and safety of people and the environment is not honest, but misleading and deceptive.

As the policy documents reveal, the Hon Judith Collins has tightly controlled the policy process. Collins' expertise in Parliamentary process and law, suggestions that there has been an undermining or deliberate corrosion of process, and scant disregard for democratic norms of accountability and transparency. Collins' appears more concerned that the legislation should exclusively benefit commercial interests, because it is organisations, or individuals working for organisations with potential commercial interests that have dominated the consultation process.

It must be noted that Collins is New Zealand's Attorney-General, and that Collins is tasked with preeminent responsibility for ensuring that the operations of the government are conducted lawfully and constitutionally.

> *'Responsibilities include being the senior Law Officer of the Crown with principal responsibility for the government's administration of the law, the principal legal adviser to the government, the principal plaintiff or defendant on behalf of the government in the courts, and ensuring the operations of government are conducted lawfully and constitutionally, maintaining the relationship of the government with the judiciary, and overseeing the government's role in the administration of the criminal law.'*[165]

An extraordinary range of actors and institutions with pervasive financial conflicts of interest can be identified to have exerted a disproportionate influence for nearly a decade. The primary actors who are presented as 'experts' have interests in innovation and commercialisation of gene editing technologies. As can be seen, there are many ways the policy and legal process can be shaped to under-regulate a technology, while misrepresenting and downplaying risk from the technology and its emissions.

The control of science funding by MBIE has resulted in a disproportionate bias to investigator-led innovation-based research. The investigator, as PSGR discuss, must prioritise innovation and commercialisation potential, rather than worthiness as a public-good research project, to be funded. This can result in research trajectories by elites that entrench path-dependency in scientific systems that can lead these systems to misallocate scientific research to issues that are less socially, environmental, culturally and economically important.

The Royal Society information from the 2016-2019 campaign has been represented broadly across policy and in the scientific literature to justify the replacement of the Hazardous Substances and New Organisms Act 1996, with new legislation currently in the form of the Gene Technology Bill.

While the Royal Society talked about opportunities for gene editing technologies and commercialisation, any discussion on risk from gene editing organisms was brief and downplayed.

[165] New Zealand Government. Ministerial Portfolio: Attorney-General. https://www.dpmc.govt.nz/cabinet/portfolios/attorney-general

As PSGR discuss in Part II[166], MBIE does not create long-term funding pathways for basic research for institutions to identify the drivers of human and environmental health harms. This research is outside MBIE's scope.

PSGRs 2023 discussion paper: *When does science become propaganda? What does this suggest for democracy?*[167] concluded with this comment:

> *'Innovation may be central to our largest challenges, but it is the stewardship of innovation that is the key issue. Resilient, healthy democracies require governance systems with the capabilities and intelligence to produce, analyse and communicate challenging, contradictory and politically inconvenient information.'*

Recommendation: That the Chief Ombudsman convene an inquiry

That the Gene Technology Bill be placed on hold. PSGR emailed the Chief Ombudsman on April 15, 2025 to request that the Ombudsman convene an inquiry to establish whether the actions and processes undertaken by the Ministry of Business, Innovation, and Employment (MBIE) and the Hon. Judith Collins, Kings Counsel and Attorney-General over the period 2016-2025, directly undermined public law conventions and processes to pursue policies and laws in favour of the deregulation of gene editing technology. That the terms of reference of an inquiry by the Office of the Ombudsman pay particular attention to the benefits of observing the principle of open justice, and require that the inquiry follows independent, impartial and fair processes to evaluate:

i. Whether the MBIE funded Royal Society Te Apārangi adhered to the spirit of the Royal Society's professional code. The Royal Society did not evaluate the risks of gene technologies, but made recommendations for legislative reform, using language which implied that risks were understood. MBIE, the National Party and the Hon Judith Collins then drew on Royal Society information as a formal justification for the deregulation of gene technology legislation.

ii. That the Royal Commission on Genetic Modification 2001 (RCGM) recommendations produced a path for the stewardship of techniques of genetic modification (which includes gene editing technologies) that remains relevant in 2025. The extent to which RCGM recommendations have been implemented, reversed or undermined in the two decades hence. The precedent that is established if government agencies, such as MBIE, undertake a policy process but fail to take into account the findings of a Royal Commission, and take meaningful steps to ensure that the recommendations are adhered to.

iii. Contract scientists with expertise in gene-editing techniques and regulatory risk assessment to undertake a methodological evaluation of the scientific claim that gene-editing techniques and organisms may be exempted based on the outcome being indistinguishable from conventional breeding or nature. Ensure that these scientists are free of conflicts of interests, and that they are not working in departments or agencies who are conducting research which is intended to have a commercial outcome. Assess the practical reasoning behind why the biotechnology industry and MBIE would desire that specific gene editing techniques and organisms would be completely excluded from

[166] PSGR (2025) When powerful agencies hijack democratic systems. Part II: The case of science system reform. See recommendations pages 49-52. Bruning, J.R. April 2025. ISBN 978-1-0670678-1-6.
[167] PSGR (2023) When does science become propaganda? What does this suggest for democracy? Page 19. Bruning, J.R., Physicians & Scientists for Global Responsibility New Zealand. ISBN 978-0-473-68632-1. https://psgr.org.nz/component/jdownloads/send/1-root/106-23-propaganda

regulation and why. Factors could include: difficulties in removing contaminants during the reagent process, errors, non-target and off-target risks from multiplex reactions.

iv. Why MBIE officials did not follow accepted administrative law conventions. Cost benefit and economic analyses were not undertaken. MBIE did not contract independent scientific researchers to undertake a methods-based, scientifically rigorous risk assessment to confirm that the proposed regulatory changes would be appropriate and not present an undue risk to human or environmental health and safety. A biosecurity risk assessment (for native and non-native species) was not undertaken.

v. Evidence of bias. Investigate whether gene technology regulatory reform processes inappropriately commandeered policy by selecting stakeholders for consultation and advisory committees to favour the advice of industries and particular institutions who had financial investments in gene technology.

vi. Whether it was fair and reasonable that MBIE and Judith Collins would exclude the option of retaining and amending the Hazardous Substances and New Organisms Act 1996, i.e., the status quo, from any consultation process.

vii. The extent to which the Attorney-General, Judith Collins steered the policy and consultation process.

viii. Use an independent contractor to run an artificial-intelligence based assessment of the submissions to the Gene Technology Bill, and evaluate the basis for public concerns regarding:

a. Trade and economic risks.

b. Environmental and human health risks.

c. Exclusion of the precautionary principle and other bioethics-based issues.

d. Medical clauses.

e. Deference to offshore jurisdictions.

f. Extent of support for the Bill, versus extent of support for the HSNO Act.

g. Concerns expressed by individuals/organisations with scientific expertise.

h. Food safety risks and food transparency concerns.

i. Outdoors risks and risks from use outside containment facilities.

j. The capacity of the regulator to assess new and future risks.

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CRISPR	Clustered regularly interspaced short palindromic repeats. Repeating sequences in a bacterial genome.
CRISPR/Cas technologies	Use two components, firstly, a guide RNA molecule to match a desired target gene, and secondly, a CRISPR-associated protein (for example Cas9) as an endonuclease to cause a double-stranded DNA break, allowing modifications to the genome.
DNA	Deoxyribonucleic acid
FSANZ	Food Standards Australia New Zealand
Gene/genome editing	The use of gene technology to direct the location of change in a genome. Terms ODM, SDN and SDN1-3 refer to gene editing.
HSNO Act	Hazardous Substances and New Organisms Act
MBIE	Ministry of Business, Innovation and Employment (2012 to current day)
NZEPA	New Zealand Environmental Protection Authority
mRNA	Messenger RNA
OECD	Organisation for Economic Cooperation and Development.
PSGR	Physicians and Scientists for Global Responsibility
Reagents	The necessary, inseparable, or facilitating chemical ingredients in gene technology procedures.
RNA	Ribonucleic acid
RIS	Regulatory Impact Statement Reform of Gene Technology Regulation Ministry of Business, Innovation and Employment. 31/07/2024
SDN	Site-directed nuclease
SDN1	Repair of site-directed nuclease activity without a nucleic acid template.
SDN2/SDN3	Repair of site-directed nuclease activity involving nucleic acid templates to guide repair of SDN action. Different templates are used.
SSAG	Science System Advisory Group
TAG	Technical Advisory Group

APPENDIX

Appendix I: List of Key Stakeholders in MBIE 'targeted' consultation.

Ministry for Regulation. Issue date: December 20, 2024. Regulatory Impact Statement: Reform of Gene Technology Regulation. Document (signed) date: Wednesday 31 July 2024 https://www.regulation.govt.nz/our-work/regulatory-impact-statements/regulatory-impact-statement-reform-of-gene-technology-regulation/

Key Stakeholders	Description / relevance to the programme
HortNZ (Zespri, KBC, Apples and Pears, Potatoes, Tomatoes, Vegetable Growers, Onions)	Horticulture industry advocacy body and members' association
Primary sector (Fed Farmers, NZFOA, MIA, DairyNZ, Fonterra, Beef and Lamb, DCANZ)	Group of industry advocacy bodies / members' associations for food and fibre producers
Community Supported Agriculture partnerships	Partnership model between consumers and farmers
Te Puna Whakaaronui / 'Fit for a Better World'	Food and fibre sector transformation group – government, industry and Māori
New Zealand Agricultural Greenhouse Gas Research Centre	Partnership of agricultural greenhouse gas emissions research providers
New Zealand Food Safety Science & Research Centre	Food safety partnership group between industry, government, Māori and research organisations
Association of Biosafety for Australia and New Zealand	Biosafety advocacy body
Food and Grocery Council	Industry advocacy body / members' association for food, beverage and grocery manufacturers and suppliers
Food and Fibre Leader Forum	Forum for leaders of industry advocacy bodies
Food Safety Australia New Zealand	Independent statutory agency in the Australian Government Health portfolio, develops food standards for Australia and New Zealand
Office of the Gene Technology Regulator Australia	Independent statutory office responsible for administering Australia's Gene Technology Act 2000.
Privacy of natural (Rautaki Solutions) and Privacy of (SGA Solutions)	Experts in biotech, specifically in the agriculture supply chain
New Zealand Veterinary Council	Statutory body responsible for upholding veterinary standards
Forest Owners Association and Scion	Forestry industry advocacy body Crown Research Institute for forestry and wood products

Key Stakeholders	Description / relevance to the programme
Fonterra	Dairy co-operative
Independent Research Association of New Zealand	Members' association for science and research organisations in New Zealand
Gene Technology and Our Environment Research Team	Experts in social research undertaking research into the role that gene technologies may play in the future of environmental conservation in Aotearoa
Beef and Lamb NZ	Meat sector industry advocacy and export facilitation body
Cawthron Institute	Independent science organisation specialising in primary industries
Seafood sector: King Salmon, Sandford	Major New Zealand seafood sector companies
Organic Exporters Association of New Zealand Executive Board	Elected members representing most organic exporting sectors
Hawkes Bay Regional Council, Bay of Plenty Regional Council	Regional council policy advisors

Key Stakeholders	Description / relevance to the programme
Genomics Aotearoa	Alliance of universities and Crown Research Institutes, and a members' association for researchers or end-users of genomics and bioinformatics
Biotech NZ	Members' association consisting of biotechnology-related investors, companies, regulators, researchers.
Science NZ and CRI CEOs	Representative body for New Zealand's Crown Research Institutes
Universities New Zealand	Representative body for New Zealand's eight universities
Parliamentary Commissioner of Environment	Independent Officer of Parliament with powers to investigate environmental concerns
Royal Society Te Apārangi	Independent national academy of sciences

Appendix II: Technical Advisory Group Official Information Act Request.

Official Information Act Request to MBIE, November 19, 2024. Scientific advice - technical focus group - Gene Technology regulations and powers of regulator. DOIA REQ 0006620

Respondent: Tony de Jong, Manager, Biotechnology Policy & Regulation Labour, Science and Enterprise, MBIE

https://fyi.org.nz/request/29246-scientific-advice-technical-focus-group-gene-technology-regulations-and-powers-of-regulator#incoming-118012

[1] Please supply the terms of reference sent to the technical focus group. This is to confirm that there are systems in place to ensure that the information is free of bias and that there are protocols to ensure that the technical focus group have powers and resources to review and consider probabilities, risks, uncertainties and magnitude of likely impact outside the information sent to them by them, so that science advice is independently provided.

Response: GENE TECHNOLOGY REGULATION TECHNICAL ADVISORY GROUP TERMS OF REFERENCE

https://fyi.org.nz/request/29246/response/114976/attach/4/DOIA%20REQ%200006620%20Gene%20Technology%20Regulation%20Technical%20Advisory%20Group%20Terms%20of%20Reference%20FINAL.pdf

[2] Please supply all scientific information, including that which is listed in policy papers, including references and appendices, sent to the technical focus group.

Confirmation: request for all academic literature or expert reports provided to the TAG.

After searching our records, MBIE has not provided the Technical Advisory Group (TAG) with any such information. TAG members were expected to have prior knowledge of the relevant scientific information as they were chosen due to their significant expertise with gene technologies and related issues.

I note that FSANZ considers food standards independently from the gene technology provisions in the existing HSNO Act, and this will not change as a result of the Gene Technology Bill. MBIE therefore did not seek advice from the TAG regarding FSANZ's work on genetically modified foods.

[3] This question concerns the extent to which the technical focus group can consider uncertainty and future risks, and the extent to which MBIE have provided them with existing policy documents.

a. Please supply all meetings/memos/email discussions with the technical focus group with regards to how scientific uncertainty will be managed and how future risk from the scaling up of releases into the is scientifically, culturally and politically justifiable.

Please include all meetings/memos/email discussions with the technical focus group referencing precaution and/or the precautionary principle; and the findings of the Royal Commission and work by the Parliamentary Commissioner for the Environment.

MBIE Confirmation 3a: Managing scientific uncertainty: We assume the scientific uncertainty part of this question covers how the Regulator will consider uncertainty when making decisions. We note the TAG's role was to provide technical advice and it was not asked to justify any policy decisions.

b. The technical focus group will presumably be interested in there being sufficient regulatory powers to surveil and assess the changing risk environment, so as to protect health, the economy and the environment. Please supply all discussions with the technical focus group concerning proposed powers for the regulator.

This may include the potential powers to monitor the published scientific literature and surveil the global environment (for newly identified risks from off-target and unanticipated impacts from GMO development and release, regulatory changes, court decisions), and monitor and assess releases into the environment for the long term.

MBIE Confirmation 3b: We assume this covers information on the regulator's powers to surveil and assess the changing risk environment, and not for other, unrelated powers of the Regulator.

[4] Please supply 'up to date gene regulation' information on how regulations in the top performing OECD nations and the latest decisions by the European Parliament compare against Australia and the proposed hybrid regulations, that have been sent to the technical expert group for assessment.

Appendix III: Judith Collins pro-gene editing deregulation rhetoric

11 March 2024 - Speech to Life Sciences Summit

https://www.beehive.govt.nz/release/speech-life-sciences-summit

Hon Judith Collins KC

Science, Innovation and Technology

- Good morning all, it is a pleasure to be here as Minister of Science, Innovation and Technology.
- It is fantastic to see how connected and collaborative the life science and biotechnology industry is here in New Zealand.
- I would like to thank BioTechNZ and NZTech for the invitation to address this summit and to acknowledge the great effort both groups are making to grow New Zealand's biotechnology sector.

Rebuilding the economy

- This Government has been elected with a clear mandate to rebuild the New Zealand economy.
- New Zealand has many challenges and to address them we need you.
- We need innovative, world leading companies that provide good jobs, and valuable products and services for Kiwis and the world.
- Today I would like to talk about how this Government is reforming gene technology regulation to give you the tools you have been calling for, and how science and innovation will help us address the economic improvements we need to get this country back on track.
- The transformative power of innovation is key to our country's future.
- From advances in health treatments in our hospitals, to improved crops in our supermarkets, technology has the power to make New Zealanders lives better.
- Fantastic work happens here at home, in your labs and in your companies.
- New Zealand is home to amazing science, and I stand before you with a deep appreciation for the incredibly valuable work you all contribute across our science and innovation ecosystem.
- You know better than me about how biotechnology can deliver enormous benefits for New Zealand, from making advances in health science, combatting climate change, to lifting agricultural productivity and boosting exports.
- I'm sure that many of you have felt frustrated at how our outdated gene technology legislation has held you back. Having the right regulatory environment in which to function in is essential to enable advancements in your work.
- While innovations such as CRISPR have made gene technologies more predictable and safer than ever, New Zealand's outdated rules make it all but impossible for you to apply these technologies outside the lab.

- Under the current Hazardous Substances and New Organisms Act, fewer than ten Gene Edited or Genetically Modified products have been approved for release outside labs.
- No commercial GE or GM crops are grown in New Zealand, and no fresh produce developed using gene technologies is sold here.
- Countries like Australia, Japan and the United Kingdom have safely embraced gene technologies, and the European Union is working to liberalise its rules.
- We are being left behind, putting our climate goals at risk and depriving Kiwis of significant advances in healthcare, environmental protection and economic growth.

Our plan

- This Government will reform New Zealand's gene technology rules, removing barriers that prevent you from just getting on with your jobs.
- We will ensure that you are empowered to do you research here, instead of forcing you to go overseas for trials and field testing.
- We will pass legislation by the end of 2025 to enable greater use of gene technologies while ensuring strong protections for human health and the environment.
- The new rules will be future focused and designed to accommodate advances in gene technologies and methods.
- They will be based on managing the risks of these technologies, rather than focusing solely on the methods of genetic modification.
- The regulator will oversee the new system and ensure ethical and cultural concerns are well managed.
- It will involve a streamlined approval process to reduce the burden on both our scientists and businesses, and help you to navigate the approvals process so you do not get lost in confusing bureaucracy.
- MBIE officials are holding round table events here at this Summit, and I encourage you to participate because these changes are being designed to support your research.
- I am also keen to hear from you on what we can do to ensure the system works both now and into the future.

Better business connections

- I intend to encourage private participation and co-investment in the sector, and incentivise areas of focus for science and research with commercial value.
- This will position us to continue developing world leading solutions to address some of our greatest global challenges.
- We have a great community of spin outs and start-ups that have come from New Zealand's science system and industry involvement in research and development is essential for our companies to deliver the economic impact we need.

- There is already an established base for this work to build on, such as our Research and Development Tax Incentive which has now provided over 1,000 businesses with tax credits, supporting over $3.3 billion dollars of business investment in research and development.
- Beyond this, we need businesses to actively engage with our science system to ensure cutting edge knowledge and technology is deployed where it is most needed.
- Getting more of the right people from across businesses, universities and research institutes to connect in a meaningful manner will be essential for New Zealand to benefit from the great work you do.

Technology sector commitments

- I will also pursue the technology sector commitments signalled in our manifesto to make New Zealand more attractive to technology companies, founders and to high skilled workers.
- We need to aim for the highest possible goals when it comes to economic growth, which means focusing on growing high value, exporting technology firms, and focusing on the science that will support them with cutting edge technology.
- As a first step, our 'Boosting the Tech Sector' manifesto commitments outline new potential visas as well as changes to the taxation of employee stock ownership plans.
- The technological advancements we need won't be possible without our public science system.
- We will also support you to rapidly test areas of promising, innovative research, refreshing and diversifying the scientific expertise around the country.
- Diversity in the science system at a fundamental level will contribute to our ability to meet many challenges that lay ahead of us.
- We've seen the real-life impact of this, such as the importance of previous mRNA research leaving us in a position to rapidly react to a pandemic.
- We need to be ambitious, increasing focus on the science and innovation that will create and support firms working at the cutting edge of their field, that will allow us to face the upcoming challenges head on.

Closing statement

- These challenges that we face may be complex, but they are not insurmountable.
- It is through your work across science, innovation and technology that we find solutions to some of the world's most pressing issues.
- Your work not only contributes to the advancement of knowledge, but also brings tangible progress and meaningful impact to our communities.
- The collaborative nature with which you undertake this work is very valuable to me, and these next two days are a fantastic opportunity to update each other.
- Thank you and I wish you all the best for the rest of the Summit.

13 August 2024 - New Zealand to benefit from end to gene tech ban

https://www.beehive.govt.nz/release/new-zealand-benefit-end-gene-tech-ban

Hon Judith Collins KC

Science, Innovation and Technology

The Government is ending New Zealand's nearly 30-year ban on gene technology outside the lab in a move which will bring health, productivity and climate gains for New Zealanders.

Science, Innovation and Technology Minister Judith Collins today announced legislation ending the ban and implementing a dedicated regulator to oversee applications to use gene technology will be introduced to Parliament by the end of the year.

"This is a major milestone in modernising gene technology laws to enable us to improve health outcomes, adapt to climate change, deliver massive economic gains and improve the lives of New Zealanders," Ms Collins says.

"New Zealand has lagged behind countries, including Australia, England, Canada and many European nations in allowing the use of this technology for the benefit of their people, and their economies.

"New Zealand's biotech sector, of which gene technology is a part, generated $2.7 billion in revenue in 2020.

"The changes we're announcing today will allow researchers and companies to further develop and commercialise their innovative products. Importantly it will help New Zealanders to better access treatments such as CAR T-cell therapy, which has been clinically proven to effectively treat some cancers. It can also help our farmers and growers mitigate emissions and increase productivity, all of which benefits our economy," Ms Collins says.

"Restrictive rules and time-consuming processes have made research outside the lab almost impossible, resulting in New Zealand falling behind. These changes will bring New Zealand up to global best practice and ensure we can capitalise on the benefits."

The new legislation will be based on Australia's Gene Technology Act 2000 and modified to work here in New Zealand. Like Australia, a regulator will be established to enable the science while managing potential risks to human health and the environment.

"Updating gene technology laws while ensuring strong protections for human health and the environment is something we campaigned on and committed to in the Government's coalition agreements with the New Zealand First and ACT parties, and the Prime Minister's Q3 Plan.

"I am proud to be driving these changes for our country. We are working to having the legislation passed and the regulator in operation by the end of 2025," Ms Collins says.

The MBIE website (mbie.govt.nz) has been updated with information for the public, including this simple explainer video: https://youtu.be/I_O9DGT_jy4