Physicians and Scientists for Global Responsibility New Zealand.

Gene Technology Bill 2024.

Submission to the Health Select Committee, New Zealand Parliament.

Address

PO Box 16164
Bethlehem
Tauranga 3147
New Zealand

Email

info@psgr.org.nz

Website

www.psgr.org.nz

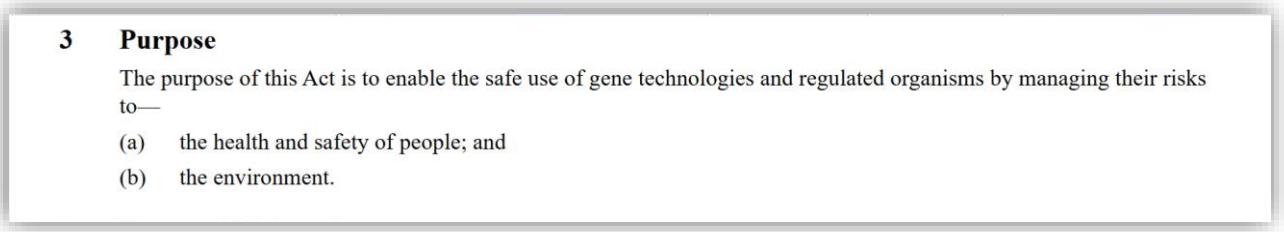
PSGR

New Zealand Charitable Trust

PSGR would welcome an opportunity to speak to this submission.

Physicians and Scientists for Global Responsibility Charitable Trust (PSGR) works to educate the public on issues of science, medicine, technology (SMT). PSGR work to encourage scientists and physicians to engage in debate on issues of SMT, particularly involving genetics and public and environmental health.

PSGR thanks the Health Committee for this opportunity to contribute to scrutiny and examination of this Gene Technology Bill. The Gene Technology Bill cannot result in legislation that will achieve the purposes [see clause 3] drafted into the Bill by the Ministry of Business Innovation and Employment (MBIE), the Honourable Judith Collins and Crown Law. The legislation is marked by what has been *excluded*.



3 Purpose

The purpose of this Act is to enable the safe use of gene technologies and regulated organisms by managing their risks to—

(a) the health and safety of people; and

(b) the environment.

Submission Overview

PSGR's submission is in two parts:

- Part I - details ways in which the Bill's drafters have drafted text to narrowly restrict Regulatory powers and prevent wider regulatory scrutiny. This not only leaves New Zealand vulnerable to slow moving problems, it would result in the Regulator having insufficient scope and inadequate information in emergency situations that would enable the Regulator to assure the health and safety of people.

- Part II – Makes in-depth recommendations and outlines problems and gaps in the Bill text.

In order to claim that the Hazardous Substances and New Organisms Act 1996 (HSNO Act) is out-of-date, MBIE resort to inappropriate citations where those citations fail to lay out an argument that demonstrates any extent of scientific reasoning and impartiality. The 'out-of-date' claim has resulted in the jettisoning of key principles and overriding obligations necessary to guide the production of secondary (delegated) legislation. Such legislation would assist officials to monitor, review and analyse risks from novel, patentable gene editing technologies within highly politicised environments.

The manifold deficiencies reveal an unfortunate knowledge gap, an absence of expertise across MBIE, Minister Judith Collins and Crown Law in drafting this proposed regulatory legislation that is demonstrably unfit for purpose, and unable to achieve the purpose of protecting human and environmental health.

MBIE have failed to justify their scientific claims relating to what organism might be classed as is distinguishable and notifiable, or indistinguishable and exempt. MBIE's unscientific *presumption* is that these organisms present the same risks as do conventionally bred organisms. There is a large body of scientific literature contradicting this belief, that MBIE has failed to disclose. There is no awareness that highly complex methods used by developers and industry, such as multiplexing, can equally lead to complex and unpredictable outcomes.

MBIE's and Minister Collins' actions fails an impartiality test. Policy and Bill text demonstrates a prevailing pre-determination and bias concerning the imagined safety of novel gene edited (GE) organisms.

MBIE fail to communicate that the Productivity Commissioner recommended a public review that would include Māori and the general public. MBIE have short-circuited this recommendation by heading to directly conduct a tightly controlled policy consultation process and then immediately release a Bill.

The analysis by PSGR (see below) suggests that poor policy processes have resulted in deficient and biased policy unfit for purpose. This has resulted in hastily drafted legislation carrying none of the hallmarks of

robust, anticipatory legislation that can guide the conduct of regulatory officials when information is uncertain and complex.

PSGR's response highlights two false assumptions. Firstly, that the risks of current gene technologies can be managed by regulatory organisation and regulatory controls. However, the present state of knowledge about the risks of this technology and its still-emergent science are simply not known with any due rigour; and may not be known for several generations to come because life-forms are so complex in their dynamic organisation and symbioses.

Secondly, proponents of the Bill have been evidently persuaded that current gene technologies that altered life-forms present proportionately greater benefits from their associated patents on new food types rather than presenting massive risks of harm to our nation's people; our nation's established GE-free food exports; and our nation's unique GE-free environment. In eliminating risk-benefit and economic assessment, they have resorted to rhetoric rather than fact, rendering their claims unfit for policy and law-making.

This Bill or any other similar Bill cannot propose effective controls on risks of from genetic modification (including processes of gene editing) because governments around the world have virtually eliminated funding of basic science research in the life-sciences for decades – New Zealand included.

Therefore, there is no adequate pool of relevant science know-how about complex risks arising from applied science genetic manipulation that might credibly be able to administer, effectively, legislation that purports to control risks arising to the public and the environment from that genetic manipulation.

The Regulator and all scientists operating under this legislation would be effectively straight-jacketed into only considering risks of notifiable GMOs, but would have no authority to evaluate risks arising from MBIE's 'exempted and very low-risk' organisms.

Regulators constantly juggle uncertainty, and primary legislation should be designed to empower regulatory officials to proactively identify and review scientific information for public benefit.

MBIE, Minister Collins and Crown Law have drafted a Bill for a watered down, inflexible, arbitrary, and pro-industry regime that is unfit for purpose. The Bill unduly limits regulatory powers in unconstitutional and unethical ways. This Bill cannot and will not protect the safety of human, animal and environmental health.

In addition to our recommendations in Part II, PSGR recommend that your Select Committee should report back to the House that this Bill presents such great risks to our nation's GE-free international trade in food products, and our indigenous flora and fauna, such that the merely *assumed benefits* claimed by proponents of this Bill could never match or exceed those risks in any reasoned argument.

PSGR recommends that the HSNO Act remain the foundation legislation for gene technology using process-based risk assessment to determine regulatory scope, i.e., 'any organism that has been altered using processes of genetic modification, including all gene editing tools and techniques'.

PSGR recommendations describe information gathering and analysis that must be undertaken before the HSNO Act is altered. These actions are required, so that the public and law makers can determine whether or not modifying the HSNO Act 1996, is necessary to do at all. This is PSGRs' preferred approach.

In addition to PSGR's recommendations, PSGR recommend that there is a public enquiry into the conduct of both the Attorney-General and Ministry of Business, Innovation and Employments' conduct concerning the oversight and management of the underpinning policy of the Gene Technology Bill, and the Gene Technology Bill. PSGR consider that there is evidence, that good process may have been by-passed and dismissed in many ways, and that the Attorney General's role in this may have been questionable and inappropriate.

'The present debate on how new and emerging gene-editing techniques will be regulated lacks a fundamental discussion on whether current risk assessment methodologies are adequate to analyze organisms arising from these techniques.'[1]

CONTENTS

[1] Agapito-Tenfen SZ, Okoli AS, Bernstein MJ, Wikmark O-G and Myhr AI (2018) Revisiting Risk Governance of GM Plants: The Need to Consider New and Emerging Gene-Editing Techniques. Front. Plant Sci. 9:1874. doi: 10.3389/fpls.2018.01874

PART I: DEFICIENT POLICY FORMULATION

[A] IS THE ATTORNEY-GENERAL SETTING ASIDE PARLIAMENTARY & SCIENTIFIC CONVENTION FOR POLITICAL PURPOSES?

1. The policy formulation processes, underlying policies and the Bill text will likely contribute to a decline in trust of the Crown and impair public trust in the capacity of elected and administrative officials to carry out their duties with respect to their constitutional and administrative law obligations.
2. **The Bill undermines public law norms of fairness, transparency and accountability. The policy formulation process has been particularly poor, narrowly contrived and short term.**
3. This Bill concerns the stewardship of an emerging technology which is plagued by uncertainty relating to risk and impact. The policy documentation does not and cannot demonstrate evidence of 'systematic and evidence-informed policy development'.[2] [3]
4. PSGR consider that the processes underpinning this Bill are so poor that they may contradict and undermine public law obligations, and obligations drafted into the 2023 Cabinet Manual, 2021 Legislation Design and Advisory Committee Guidelines.
5. Regulators can only safely steward technology if they can understand and assess risk using a variety of interdisciplinary lenses[4]. The policy contains no evidence of:
    a. A methodologically robust risk assessment.
    b. An environmental impact assessment.
    c. An economic risk-benefit assessment.
    d. A biosecurity assessment. The potential for nefarious actors to deploy gene edited technologies for nefarious benefit[5] has not been assessed. (An online search failed to identify biosecurity concerns.)
        i. An evaluation of similar legislation in crucial key export markets to identify if this Bill would harmonise with their legislation and/or would be considered best practice.
6. **The RIS and the Bill are silent on best practice.** The RIS did not evaluate best practice risk assessment or monitoring activities, including different approaches for monitoring the natural environment, versus agricultural produce.
7. **The 'out-of-date' claims are parochial and based on New Zealand government documents, not a review of best practice globally.** MBIE claim in the Regulatory Impact Statement (RIS) that assessment of economic benefits is 'out-dated'.[6] New laws and new regulations must be justifiable on the basis that society will benefit. To put it simply, benefit of a law should outweigh the cost. This encompasses claimed economic benefits. MBIE may recognise that economic justification is impossible. There is

[2] MBIE August 2024 Media Pack. https://www.mbie.govt.nz/dmsdocument/28985-gene-technology-media-pack-pdf
[3] MBIE Regulatory Impact Statement Reform of Gene Technology Regulation. Ministry of Business, Innovation and Employment. https://www.mbie.govt.nz/dmsdocument/29936-regulatory-impact-statement-reform-of-gene-technology-regulation-pdf
[4] Juhas M, Bauer-Panskus A, Then C. (March 2023). Genetic engineering in agriculture: between high flying expectations and complex risks. The use of genetic engineering in agriculture requires a comprehensive technology assessment. https://www.testbiotech.org/wp-content/uploads/2023/03/Technology-Assessment-for-NGTs.pdf
[5] West, R.M. and Gronvall, G.K. (2020) Crispr Cautions: Biosecurity Implications of Gene Editing. Perspect. Biol. Med. 63, 73-92.
[6] MBIE Regulatory Impact Statement Reform of Gene Technology Regulation. Page 3.

evidence that biotechnology investment return is lower than investment in food.[7] In addition, globally dominant biotechnology 'whales' tend to dominate, with few products bringing desired returns.[8]

8. The government has neither assessed the economic return on investment from science investment in biotechnology,[9] [10] nor assessed whether any of the field trials that have been approved in New Zealand and conducted primarily by Crown Research Institutions, have resulted in a commercially profitable product.[11]

9. *Cui bono* (who benefits?). Trade risks continue to be downplayed by prominent advocates with investments in biotechnology who claim benefits for farmers, while failing to disclose their own investment portfolios.

10. **Absence of cost-benefit analysis in underpinning MBIE and Collin's claims – suggests a speculative approach to claimed benefits.** This is inappropriate for regulatory agency development. Cost-benefit analyses are not included in the Bill text as part of the regulatory toolkit. While it is understood that cost-benefit calculations cannot adequately reflect the uncertainty component of risk, such calculations can be a tool to aid decision-making.

11. No policy documentation has been produced by MBIE or the office of the Hon Judith Collins to substantiate the science claims, and claims around improving health and the economy. Neither scientific reasoning nor scientific context has been provided that addresses the current state of scientific knowledge concerning the legitimacy of the Crown's claim that asserts an organism to be 'very low-risk' or 'high-risk'.

12. **Policy documents did not provide a risk assessment nor analysis which would evaluate, determine and transparently disclose the benchmark for 'distinguishable' and 'indistinguishable' and 'very low-risk'.**

    In all likelihood, MBIE, the Hono Judith Collins and Crown Law did not clarify these legally ambiguous, unscientific terms, perhaps because they recognised that any attempt to further define them would be picked apart by a scientifically-literate public.

    The Bill would result, very simply, in bad law that encourages contestation and legal dispute; while simultaneously eroding public trust and driving doubt in the Regulator's capacity to prevent harm to human or the environment. It is impossible to 'hang' robust and trustworthy regulatory legislation off the nebulous 'distinguishability' concepts. A risk-tier trigger that is based on what is 'distinguishable' (or not distinguishable) will inevitably, as INBI's submission[12] notes, set the stage for:-

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[7] 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/

[8] PSGR February 2025 interview with Dr David Bell, public health physician and biotech consultant in global health. https://www.youtube.com/watch?v=3HQIfBcF5t8

[9] AgResearch, Nick Barraclough September 12, 2022. Official Information Act Request Renumeration from biotech investment. https://fyi.org.nz/request/19298-official-information-request-ip-protocols-and-renumeration-and-financial-return-from-biotech-investment#incoming-77203

[10] The New Zealand Institute for Plant and Food Research Limited. June 3, 2022. Official Information Act request financial return from biotech investment. https://fyi.org.nz/request/19297-ip-protocols-and-renumeration-and-financial-return-from-biotech-investment#incoming-73871

[11] MBIE February 13, 2025 Information Act Request to Claire Bleakley. DOIA-REQ-0008002

[12] 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.

'future semantic disputes of what conventional breeding means, and technical challenges to distinguishability. These debates and contests aren't focussed on safety and are not efficient ways to regulate.'

13. PSGR express concern that the Select Committee are likely to claim that 'the science is settled' and that any information that addresses the underlying policy may be irrelevant, and that the Select Committee's purpose is to address the content of the Bill.

14. PSGR consider that this would be a grievous error. Members of Parliament must be informed that MBIE and then-Minister for Science, Innovation and Technology Judith Collins, deliberately and intentionally excluded any opportunity to comment on the scientific reasoning that formed the basis of the policy that has then resulted in this Bill. The scientific reasoning was simplistic, portrayed mainly as a chart, with absolutely no scientific analysis nor risk assessment to underpin that information.

15. The proposed legislation automatically *exempts* some activities and regulates some other activities as *non-notifiable*. This is the most onerous and hazardous component of the legislation.

    - *exempt activities: minimal-risk products of gene editing, for example, products of editing techniques that result in organisms that cannot be distinguished from those produced by conventional processes:*
    - *non-notifiable activities: very, very low-risk activities that do not require active monitoring by the Regulator, for example, gene therapies that are also regulated by Medsafe:*

16. **MBIE have conflated in-process and unconfirmed overseas legislation as finalised, inferring that New Zealand is lagging behind, when this is not the case.**

17. MBIE and members of Parliament may be uninformed that New Zealand's regulatory environment closely resembles European Commission (EC) legislation. At this stage, proposals to deregulate gene edited techniques (referred to as new breeding techniques, NBTs) and organisms have stalled in the EC after drafting changes amended the proposal to include greater protections for the public and growers.[13] In December 2024 a U.S. court reversed deregulatory rules put in place by the United States Department of Agriculture that exempted biotechnology crops from regulatory oversight.[14]

18. MBIE, Judith Collins and Crown Law write out any capacity for the Regulator and the enforcement and monitoring authority to navigate regulatory grey areas. They've achieved this firstly, by pretending normative approaches to risk assessment are 'out-of-date'. However, these requirements are expressly in the legislation to support regulators make decisions when the facts are uncertain and contested. Then they've secondly, prevented the regulator from taking an active role to broadly assess risk, by expressly confining regulatory activities in the Bill's text and failing to define terms used for risk-tiering.

19. MBIE and Judith Collins claim that provisions including the Precautionary approach, an obligation to take into account economic factors, and process-based regulations are out-of-date. Their citations do not justify this claim. MBIEs claim that the HSNO Act 1996 contains 'out-of-date-provisions', citing

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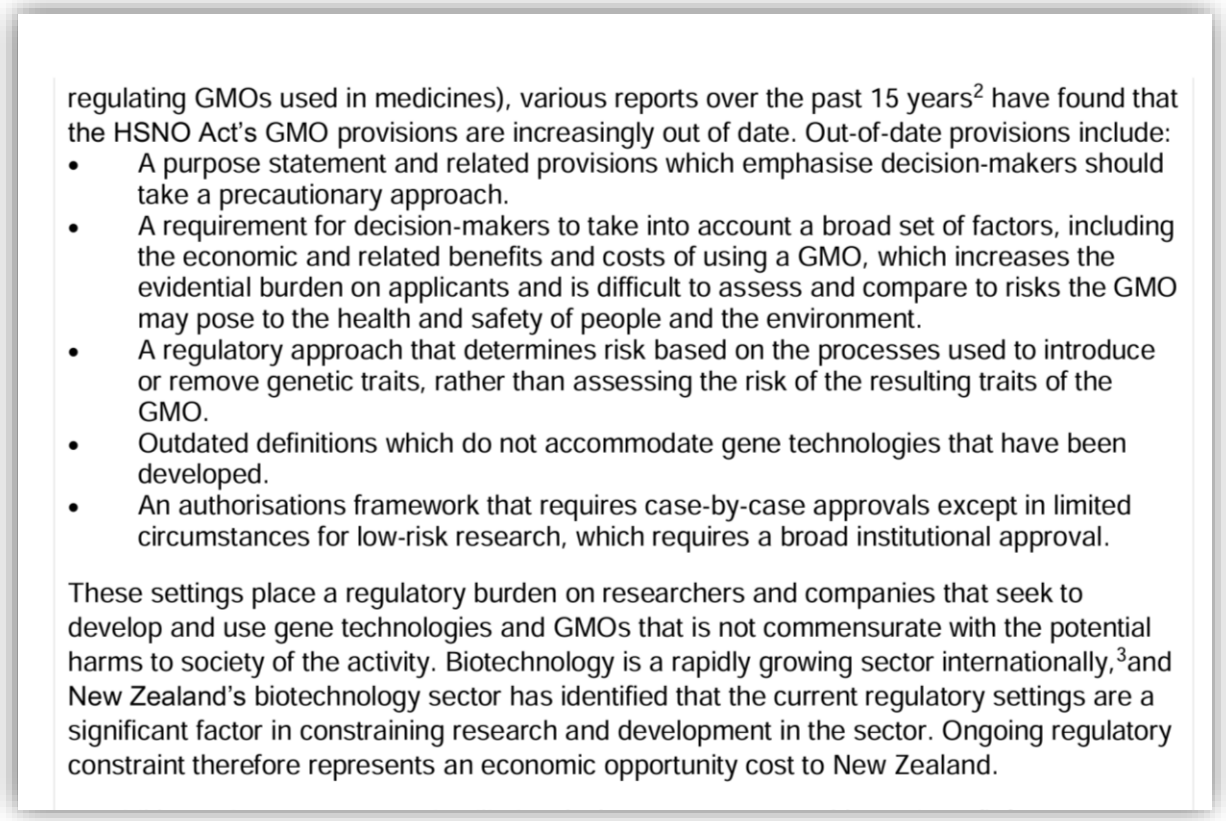
https://www.researchgate.net/publication/388526356_INBI_submission_to_health_select_committee_gene_tech_bill_2024

[13] European Parliament. 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

[14] O'Driscoll, S. December 6, 2024) USDA's Genetically Engineered Plants Ruling Overturned. *Newsweek*. https://www.newsweek.com/department-agriculture-genetically-modified-crops-tom-vilsack-federal-court-monsanto-1996749

'*Including by the Royal Society, the Productivity Commission, and the Prime Minister's Chief Science Advisor*'.[15]



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.

Extract above from MBIE Regulatory Impact Statement, Reform of Gene Technology Regulation, Page 3.

20. The out-of-date claim has not been backed up by any review of the global literature on risk assessment, and the role of purposes, guidelines and the precautionary principle.

21. Policy decisions take place under conditions of incomplete information about alternatives, costs and benefits, of limited calculative capacity, and of disagreements about values.[16] To claim that this is out-dated begs the question, what are Judith Collins, MBIE and Crown Law attempting to achieve here?

22. **Royal Society Te Apārangi.** PSGR recommend that policy-makers and researchers review the Royal Society Te Apārangi 2017 GMO campaign for evidence of bias concerning the safety of novel, patentable gene edited organisms that are commonly designed for commercial release.

    Advisers and experts drawn in to work with the Royal Society were frequently affiliated with organisations that have funding to develop biotechnologies, and who hold patents. The ones who weren't, lacked expertise new gene editing techniques and their risk-potential. Others involved, such as Sir Peter Gluckman have advocated for the deregulation of biotechnologies for many years. As trustee Jodie Bruning opined in an article[17] published in Stuff 'The reports released by the Royal Society are troubling as they resemble a lobbyist approach'.

[15] MBIE Regulatory Impact Statement Reform of Gene Technology Regulation. Page 3.
[16] Braybrooke D, Lindblom CE (1963) A Strategy of Decision. Policy Evaluation as a Social Process. Free Press, New York
[17]Bruning, J. (September 12, 2019) Gene editing risks are still too big a warrant a change in the law. Stuff. https://www.stuff.co.nz/science/115517513/geneediting-risks-are-still-too-great-to-warrant-a-change-in-the-law?

23. **Prime Minister's Chief Science Advisor.** MBIE reference the Prime Minister's Chief Science Advisor, who holds a political office to claim that existing legislation is outdated. As the advisor is in the Office of the Department of Prime Minister and Cabinet she is not independent, and unlikely to contradict a predetermined policy. The Office of the Prime Minister's Chief Science Advisor (OPMCSA) Briefings consistently downplay risk, and fail to identify known problems with gene editing. Most recently the page[18] was updated by Revel Drummond who works at Plant and Food, genome editing plants for potential commercialisation.

    a. The Prime Minister's Chief Science Advisor Juliet Gerrard has a direct conflict of interest, as Gerrard founded the company Hi Aspect in collaboration with the University of Auckland.[19]

    b. Articles and course outlines on the University of Auckland indicate that the institution struggles to balance the risk of gene editing technologies with potential commercial gains. The organisation may be politically compromised. Recent reports reveal that the University of Auckland received $500 million from the Agency for International Development, a funding institution that is designed to capacity build assets for United States agencies.

24. **Productivity Commissioner.** PSGR consider that these comments are incorrect and misleading. The Productivity Commissioner never stated that HSNO Act contained out-of-date provisions.

25. Most submissions to the 2021 Productivity Commission 'Frontier Firms' review did not concern GMO legislation. Instead, the Productivity Commissioner cited Ministry for the Environment's belief that the 'regulatory settings were quickly becoming outdated'. *[20]*

    a. The basis of the Productivity Commissioners knowledge was from the discussions with the Ministry for the Environment, and from Crown Research Staff, science sectors funded to undertake biotechnology research. Sectors that would financially benefit from a deregulated environment.

    b. That 2021-2022 review did not investigate the cost of environmental risk, nor the economic impact to the non-biotech food sector.[21] [22] [23]

26. The Productivity Commissioner recommended a review of the GM regulatory framework and stated that the review which would include Māori and the general public. *[24]*

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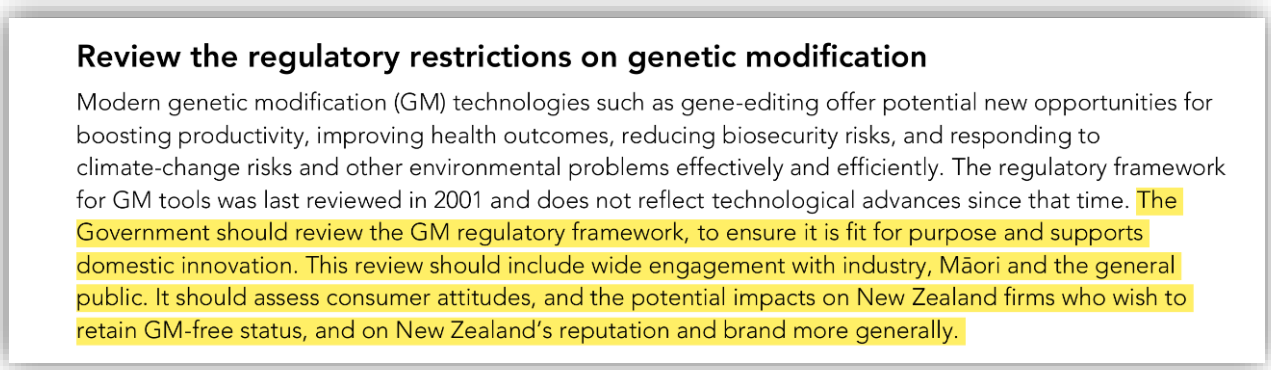
[18] https://www.pmcsa.ac.nz/topics/gene-editing/
[19] https://www.hi-aspect.com/
[20] New Zealand Productivity Commissioner. April 2021. New Zealand firms: Reaching for the frontier. Final Report. ISBN: 978-1-98-851961-6 (online). Page 179.
[21] New Zealand Productivity Commission, Shelley Catlin. June 7, 2022. Response to Official Information Act Request. Returns on investment from biotech. Environmental risk from biotech release. https://fyi.org.nz/request/19319-reaching-for-the-frontier-biotech-gene-editing-questions-to-case-study-participants#incoming-73945
[22] New Zealand Productivity Commission, Shelley Catlin. June 3, 2022. Response to Official Information Act Request. https://fyi.org.nz/request/19293-analysis-of-investment-return-from-biotech-gene-editing-tech-between-2000-2020#incoming-73883
[23] New Zealand Productivity Commission, Shelley Catlin. June 3, 2022. Response to Official Information Act Request. Impact to Organics sector. https://fyi.org.nz/request/19295-organic-sector-productivity-integrated-soil-health-climate-benefits#incoming-73879
[24] New Zealand Productivity Commissioner. April 2021. New Zealand firms: Reaching for the frontier. Final Report. ISBN: 978-1-98-851961-6 (online). Page 9.



New Zealand Productivity Commissioner. April 2021. New Zealand firms: Reaching for the frontier. Final Report.

27. One month later, the New Zealand Government then drew from the Productivity Commissioner's findings to make an 'immediate recommendation' to claim that a full review of genetic modification regulation was necessary.[25]

28. MBIE and Judith Collins directly failed to follow the Productivity Commissioner's recommendations.

    c. MBIE's Regulatory Impact Statement acknowledges the Productivity Commissioner's advice that a full review of the regulation of genetic modification should be undertaken.[26]

    d. MBIE jumped directly to undertake a contrived consultation which was then used as the underpinning policy that would form the underlying policy rationale for the release of the Gene Technology Bill.

    e. This consultation directly contradicted the Privacy Commissioner by controlling who would be assigned as experts, including the Technical Advisory Group. MBIE failed to signal the groups and people who have conflicts of interest, as their institution is working on biotechnology research that they intend to financially profit from.

    f. Groups whose perspective politically differ from the aims of MBIE in deregulating gene edited techniques and organisms, including groups such as PSGR (who have engaged in discussion and debate on the safety of genetically modified organisms for 25 years) were not invited to participate.

29. MBIE fail to disclose the absence of funding channels for researchers to evaluate GMO risk. MBIE's RIS states:

    'The New Zealand research community, comprised by universities and research institutes, Crown Research Institutes, biotech companies, and primary industry research bodies, is particularly concerned with the current regulatory settings for laboratory research with gene technologies, and these concerns have been expressed through several avenues.'

    MBIE fails to acknowledge, that as the Ministry responsible for controlling science policy and science funding, current funding policy for 'New Zealand's research community' writes out non-innovation-related funding, and directs scientists to research intended to produce a commercial, economic return.

[25] New Zealand Government, March 2022. Government response to the Productivity Commission's Frontier Firms inquiry. Online: ISBN 978-1-99-102231-8

[26] MBIE Regulatory Impact Statement Reform of Gene Technology Regulation. page 17.

Therefore, there is no research community funded to research GMO risk.[27] New Zealand scientists and researchers are hamstrung by science policy that demands that scientists build innovation into all funding applications. Scientists advocating for deregulation, is a reflection of policy incentivisation.

30. **Gene Technology Bill policy formulation.** MBIE and Judith Collins selected the 'experts' for technical advice but failed to engage with experts that might openly criticise the policy. When MBIE released the 'Media Pack' a note at the bottom of the website page advised the public that they could get to submit when the Bill would be released for public consultation. Many groups who submitted evidence to the 2001 Royal Commission on Genetic Modification, including PSGR would have welcomed being invited into early-stage policy processes.

31. 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.[28]

    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.'

32. The Attorney-General appears to have plucked responsibility out of the hands of the Ministry for the Environment, the administering agency for the HSNO Act, and supplanted it with no-Ministry having direct responsibility for the Act.

33. In 2023 the Ministry for the Environment demonstrated they were keen to have an active role in updating GMO legislation, releasing the consultation document: *Improving our GMO regulations for laboratory and biomedical research*.[29] However, despite a consultation being carried out, any findings have not been published, or have it would appear, been suppressed.

34. The responsible Select Committee is the Health Committee. Yet the Bill predominantly concerns a paradigm shift of deregulation so that undeclared and notifiable organisms can be released into the environment.

35. **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 the that the rapid development and application

[27] Bruning, J. 2022. University of Auckland Master of Arts (sociology). Thesis. Innovation and Ignorance: How Innovation Funding Cultures Disincentivise Endocrine Disruption Research. https://researchspace.auckland.ac.nz/handle/2292/57929
[28] Gene Technology Regulation Technical Advisory Group. https://fyi.org.nz/request/29246/response/114976/attach/4/DOIA%20REQ%200006620%20Gene%20Technology%20Regulation%20Technical%20Advisory%20Group%20Terms%20of%20Reference%20FINAL.pdf
[29]Ministry for the Environment July 3, 2023. Improving our GMO regulations for laboratory and biomedical research. ME1762. https://environment.govt.nz/publications/improving-our-gmo-regulations-for-laboratory-and-biomedical-research-consultation-document/

of CRISPR/Cas gene technologies, has caused a revolution in the field of genetic and genomic studies[30] and shortened the bench-to- market timeline[31]. 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.[32]

36. MBIE, Judith Collins and Crown Law appear broadly unaware of the extent to which policy-makers and scientists recognise that biotechnology presents an existential risk. In extremely deregulated environments (which is where New Zealand would be), annual production and releases [of novel entities, which includes GMOs] are increasing at a pace that outstrips the global capacity for assessment and monitoring.[33]

    d. Increasing biosecurity concerns given the global boom in construction of BSL4 and BSL3+ labs.[34]

    e. The problem of laboratory leaks.[35]

    f. The risk from gain-of-function (also known as dual use) research in a deregulated environment. New Zealand lacks published policy which expressly prohibits domestic enhanced potential pandemic pathogen (ePPP) gain-of-function research.[36] [37] [38]

    g. Patents as an inhibitor of research.[39]

37. **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.

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[30] Schaart JG, van de Wiel CCM, Smulders MJM. Genome editing of polyploid crops: prospects, achievements and bottlenecks. *Transgenic Res*. 2021 Aug;30(4):337-351. doi: 10.1007/s11248-021-00251-0. Epub 2021 Apr 12. PMID: 33846956; PMCID: PMC8316217.

[31] Whelan Agustina I. , Gutti Patricia , Lema Martin A. Gene Editing Regulation and Innovation Economics. *Frontiers in Bioengineering and Biotechnology,* 2020, volume 8, doi:10.3389/fbioe.2020.00303

[32] Bose, S., Banerjee, S., Kumar, S. *et al.* Review of applications of artificial intelligence (AI) methods in crop research. *J Appl Genetics* **65**, 225–240 (2024). https://doi.org/10.1007/s13353-023-00826-z

[33] Persson L et al. (2022) Outside the Safe Operating Space of the Planetary Boundary for Novel Entities. Environmental Science & Technology 56 (3), 1510-1521 DOI: 10.1021/acs.est.1c04158

[34] Kings College London. 2023. Global Biolabs Report. https://static1.squarespace.com/static/62fa334a3a6fe8320f5dcf7e/t/6412d3120ee69a4f4efbec1f/1678955285754/KCL0680_BioLabs+Report_Digital.pdf

[35] Nasrallah IM, El Kak AK, Ismaiil LA, Nasr RR, Bawab WT. Prevalence of Accident Occurrence Among Scientific Laboratory Workers of the Public University in Lebanon and the Impact of Safety Measures. Saf Health Work. 2022 Jun;13(2):155-162. doi: 10.1016/j.shaw.2022.02.001. Epub 2022 Feb 19. PMID: 35664908; PMCID: PMC9142354.

[36] U.S. Homeland Security. June 18, 2024. Origins of COVID-19: An examination of Available Evidence. https://www.hsgac.senate.gov/hearings/origins-of-covid-19-an-examination-of-available-evidence/?

[37] Committee on Oversight and Accountability. (December 2024). FINAL REPORT: COVID Select Concludes 2-Year Investigation, Issues 500+ Page Final Report on Lessons Learned and the Path Forward

[38] Ebright RH et al (2025) Comment letter: Implementing governmental oversight of enhanced potential pandemic pathogen research. *Journal of Virology* Vol 98, Issue 4, 10.1128/jvi.00237-24 1

[39] Metzger, A. Legal options for changing the patent protection of plants in Germany, Europe and in international law. https://www.martin-haeusling.eu/images/Legal_study_possibillities_for_a_bio_patent_reform_parliamentary_Group_B%C3%BCndnis90DieGr%C3%BCnen.pdf

a. It appears that the Minister responsible for emergency authorisation of the 'Mandatory medical authorisation' (MMA) is to be the Minister responsible for the Bill when enacted.

b. Contrary to conventional processes where Pharmac assess drugs for safety and efficacy, the Minister responsible would be legally bound to approve and accept the authorised genetic drug.

c. Once released into the environment, there is no obligation for the responsible Minister to take responsibility for monitoring the biologic medicines, including mRNA gene therapies.

38. **Regulation can never be risk-proportionate when the Regulator has no power to re-evaluate risk from techniques and organisms.** Contrary to the past 3 decades of GMO regulation this legislation pre-determines that an entire category of gene editing techniques and organisms are safe forever more. Effectively, an entire risk tier is placed outside either the Regulators or enforcement agencies powers. No obligations or powers to assess risk and monitor 'exempt' or 'very-low risk' organisms are granted – at all.

39. No methods-based analysis was published on the veracity of the externalised 'exempt' risk tier. The safety of the decision to 'exempt' organisms rests upon a purely pseudo-scientific claim, yet this is the lynchpin on which the entire 'risk-proportionate' rhetoric is based.

40. PSGR and others[40] consider that nothing in the policy or the Gene Technology Bill can assure the public that it is scientifically accurate – or even plausible.

41. MBIE are also aware that proposed P1055 changes at FSANZ would amplify the deregulation process. Members of Parliament (MPs) remain uninformed of the relationship between current Food Standards Australia New Zealand (FSANZ) P1055 consultation/policy process, which is highly deregulatory and yet unfinished, and the current MBIE process, which further deregulates genetically modified organisms (GMOs) including gene edited (GE) organisms. The RIS did not discuss this.

42. Members of Parliament (MPs) would vote on a Bill without any knowledge of how many gene edited organisms would fly under the regulatory radar and not be disclosed to themselves or the public.

    a. Firstly, if the FSANZ P1055 deregulation occurred, as much as 94% of gene edited foods could be excluded from any requirement for transparency, traceability and labelling measures. Any conversation about how many foods could be excluded has not occurred, for MPs to understand the potential extent of deregulation.[41]

    b. Secondly, the external risk tiering by the Gene Technology Bill leaves exempt organisms without oversight. How many novel gene edited organisms would come under this category? No-one knows.

43. **The Select Committee and voting members of Parliament can never know what proportion of gene edited organisms in production will be categorised as 'exempt' from regulatory assessment,** and therefore from any requirement for monitoring, tracking and tracing. The RIS did not disclose the extent of exempt novel gene edited organisms that could bypass regulatory assessment, registration and tracking. It is unlikely that any policy-maker or scientist in New Zealand can answer such a question.[42]

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[40] 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.
[41] Bohle F, Schneider R, Mundorf J, Zühl L, Simon S., Engelhard M. (2024). Front. Genome Ed.Vol 6, doi: 10.3389/fgeed.2024.1377117
[42] PSGR Interview with Centre for Integrated Research in Biosafety (INBI) coauthors of the Submission to the Parliament Health Committee on the Gene Technology Bill 2024. https://youtu.be/3KGqPcpldKc

44. The Judith Collins, MBIE and Crown Law officials have drawn from Australian consultations, policies and regulatory guidelines that depend entirely upon scientific claims where the policy documents lack any scientific rigor.

45. FSANZ have never applied any standard risk assessment framework, which would involve a systematic (methods-based) review of the available literature on outcomes following gene editing of organisms that are unexpected and off-target. FSANZ have not assessed potential predictive risks for an off-target adverse event in the organisms that they intend to deregulate.[43]

46. MBIE then piggyback on the Australian Office of the Gene Technology Regulator (OGTR) 'legislative framework'. With the exception of the Australian Gene Technology Act 2000, other relevant regulations are not explicitly listed in the RIS and readers are left in the dark.

47. MBIE's preferred Option 3 involves adopting changes that were simply proposed in a recent review, but not voted in in the Australian Parliament.[44]

48. The public expect officials to impartially and methodologically assess risk relating to the Bill's powers for New Zealand, but this is not evident in any policy documents. As with policy formulation, impartiality is demonstrated by following publicly disclosed processes that promote both accountability and public trust. This has not happened.

49. **MBIE have not transparently communicated in the 'Media Pack' nor in the RIS, the differences in global regulatory approaches.** MBIE fail to transparently evaluate the difference between more liberal regimes (north and south America for example) versus more tightly regulated environments (Europe, for example), nor conducted any evaluation of cost-benefit analysis (including for 'weedy' volunteer, escape modified species, and the off-target impacts in other jurisdictions, for example increased herbicide resistance in non-GMO species) of different regulatory approaches.

50. While in Europe plants would only be considered under the new genomic techniques (NGT) legislation, New Zealand's less transparently named new breeding techniques (NBT) legislation encompasses (potentially heritable) genetically modified (GM) microorganisms (including viruses[45]), plants, fungi, and animals.

51. There are no obligations to assess if regulated or unregulated organisms change through outcrossing to become a threat/environmental contaminant.

MBIEs pro-deregulation policy bias keeps MPs in the dark

[43] Physicians and Scientists for Global Responsibility New Zealand. September 8, 2024. Submission Consultation: Food Standards Australia New Zealand (FSANZ). Proposal P1055 - Definitions for gene technology and new breeding techniques. https://psgr.org.nz/component/jdownloads/send/1-root/146-p1055-2ndcall-2024

[44] Option C, discussed in Modernising and future-proofing the National Gene Technology Scheme: Proposed regulatory framework to support implementation of the Third Review of the Scheme. Source: https://www.genetechnology.gov.au/sites/default/files/2022-02/2017-review-consultation-regulation-impact statement-explanatory-paper.pdf

[45] Eckerstorfer MF, Dolezel M, Miklau M, Greiter A, Heissenberger A, Engelhard M. Scanning the Horizon for Environmental Applications of Genetically Modified Viruses Reveals Challenges for Their Environmental Risk Assessment. Int J Mol Sci. 2024 Jan 25;25(3):1507. doi: 10.3390/ijms25031507. PMID: 38338787; PMCID: PMC10855828.

52. Policy bias is a real problem when governments have a predetermined position. This can provoke distrust and cynicism, and undermine confidence in government officials. An Australian study revealed how participants considered that policy material was biased in favour of gene technology.[46]

53. Currently, the New Zealand government strictly regulates biosecurity to protect indigenous species and the agricultural sector.

54. Officials have acted evasively to avoid any obligation to expand early policy development to include groups and individuals that might view their policy critically.

[B] TRUST IN FOOD QUALITY – PREMIUM MARKETS DEMAND GMO FREE STATUS

55. **MBIE ignore the consumer's right to be informed on what is in a food product.** MBIE has not evaluated global public preference and have not considered the public's right to choose whether to consume GMO food (which includes products which contain gene edited organisms) or not, (an informed choice) to be a relevant consideration.

56. MBIE are seemingly ignorant of the long history of government regulations that are in place to enforce transparency of food ingredients, so as to promote consumer autonomy, sustain public trust and protect public health.[47] [48]

57. Reputation as a quality food producer may be eroded, repositioning New Zealand as a competitor with other poorly regulated jurisdictions. MBIE have not addressed the importance of consumer confidence in the quality and safety of food produced, processed, sold or exported from New Zealand, and any consequences to New Zealand's reputation as a high quality food producer. Globally, people pay a premium for GMO free food.[49] [50] [51] [52] [53] [54] Social media research indicates people are more likely to view GMOs negatively.[55]

58. While MBIE hint at an Australian report, however MBIE does not disclose another Australian report which surveyed Australian consumers, that revealed that nearly half of the respondents were

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[46] Ankeny RA and Harms R (2021) Focus groups on consumers' responses to the use of New Breeding Techniques (NBTs) in food production. https://digital.library.adelaide.edu.au/dspace/handle/2440/137654

[47] E.g. See Food Standards Australia New Zealand Act 1991, s.3, Object of Act. https://www.legislation.gov.au/C2004A04193/latest/text

[48] E.g. European Food Law general principles (including precautionary principle). https://food.ec.europa.eu/horizontal-topics/general-food-law/food-law-general-principles_en

[49] France and USA. Stéphan Marette, Anne-Célia Disdier, John C. Beghin, A comparison of EU and US consumers' willingness to pay for gene-edited food: Evidence from apples, Appetite, doi:10.1016/j.appet.2020.105064.

[50] Japan. Akihiro Mine, Sawako Okamoto, Tomoya Myojin, Miki Hamada, Tomoaki Imamura. (2023) Willingness of Japanese people in their 20s, 30s and 40s to pay for genetically modified foods (Preprint). doi: 10.1101/2023.10.29.564581

[51] Consumers Union of Japan (February 15, 2025). Surprise, Shock and More Worries: Japanese Consumers React to New Zealand Regarding Genetically Modified Foods. https://www.nishoren.org/en/

[52] Russia. Anthony R. Delmond, Jill J. McCluskey, Mirzobobo Yormirzoev, Maria A. Rogova, (2018) Russian consumer willingness to pay for genetically modified food, Food Policy, doi: 10.1016/j.foodpol.2018.02.004.

[53] China. David L. Ortega, Wen Lin, Patrick S. Ward, (2022) Consumer acceptance of gene-edited food products in China, Food Quality and Preference. doi: 10.1016/j.foodqual.2021.104374.

[54] Vietnam. Tong, Yen Dan Khuu, Dong Toan, Truong Duc Nguyen, Phuong Duy Pham, Nhai (2021) Consumer Responses Towards Non-GM Food: Evidence From Experimental Auctions In Vietnam. International Journal of Food and Agricultural Economics. doi: 10.22004/ag.econ.316274

[55] Sohi M, Pitesky M, Gendreau J. (2023) Analyzing public sentiment toward GMOs via social media between 2019-2021. *GM Crops Food* 31;14(1):1-9. doi: 10.1080/21645698.2023.2190294.

concerned about GM food. [56] The report reverted to claiming people had 'low-self reported knowledge'. This is a strawman argument as people's perceptions drive their concerns.

59. In PSGR's submission to the FSANZ P1055 consultation, PSGR criticised the food safety regulator for also, as with MBIE's submission, failing to undertake a cost-benefit analysis of returns to the agricultural sector for export product recognised globally as being GMO free. [57]

60. New Zealand officials responsible for the Gene Technology Bill policy development, advised the organic industry association that they are well aware of the overlaps with the FSANZ proposed deregulatory classification.

61. In the RIS, MBIE misleadingly claims that *'consumer preferences and public perceptions in New Zealand and globally have somewhat changed over time to be more accepting of gene technologies'*. This is misleading as it fails to communicate the extent to which the public actively view non-GMO foods as worthy of premium prices.

62. Why might consumers require a process-based approach and restrictions on environmental releases of GMO/GE food crops? Increasing levels of digestive issues and food intolerance in consumers, and increased food allergy rates have resulted in increasing awareness about GMO contamination in food.[58]

63. PSGR trustee Jodie Bruning, in response to claims that GMO food can receive a price premium wrote recently:

    Biotechnology industry organisation head Dr William Rolleston dismissed the report also, citing the price premium for GMO eggplants, which have a ethically-questionable research and development history, and which the public would prefer not to eat, with respondents in a recent trial preferring a native, or local eggplant. Rolleston also claimed GMO canola received a price premium (without a link to 2024 data) – I'm not sure if Rolleston is correct in 2024.[59]

64. MBIE's policy failed to comprehensively assess any benefits of tracking and traceability for all GMOs including gene edited organisms.

[C] POLICY PAPERS PAY INSUFFICIENT ATTENTION TO MONITORING

65. **The Regulator must be able to monitor the global literature, to assess how risk will change over time.** Standard risk assessment framework for regulatory purposes involves a systematic (methods-based) review of the available literature on outcomes following gene editing of organisms that are unexpected and off-target, the potential predictive risk for an off-target adverse event. Watered down versions, which are increasingly substituted for rigorous process, do not serve the public interest.

66. **The RIS and Bill are silent regarding expectations relating to processes of information-gathering to monitor all GMO organisms released into the environment.** Information gathering includes

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[56] Australia. (2022) P1055 – Consumer Survey Report Consumers' perceptions of and attitudes towards genetically modified foods. FSANZ https://www.foodstandards.gov.au/sites/default/files/2024-01/P1055%20Consumer%20Survey%20Report.pdf

[57] PSGRNZ. September 8, 2024. FSANZ Proposal P1055 - Definitions for gene technology and new breeding techniques. https://psgr.org.nz/component/jdownloads/send/1-root/146-p1055-2ndcall-2024

[58] Santos-Vigil et al (2018) Study of the allergenic potential of Bacillus thuringiensis Cry1Ac toxin following intra-gastric administration in a murine model of food-allergy. Int. Immunopharmacol. 61:185-196

[59] Bruning J. (December 11, 2024). Judith Collins' new Gene Technology Bill – A sticky, unconstitutional mess? https://dailytelegraph.co.nz/opinion/judith-collins-new-gene-technology-bill-a-sticky-unconstitutional-mess/

monitoring over time. The Ministry of Primary Industries is vested with the compliance monitoring and enforcement function for the HSNO Act. The Director-General of the Ministry for Primary Industries (MPI) will be responsible for compliance, monitoring, and enforcement of the regulatory regime, consistent with comparable enforcement responsibilities for other regimes, including for hazardous substances and new organisms.

67. The Regulatory Impact Statement[60] briefly discusses monitoring in a taken-for-granted, rudimentary style, and presumes that MPI will have all the answers. The RIS:

    a. Predetermines that responsibility will be held by MPI, even though that agency is predominantly agriculture-focussed. Has redacted documents which hide the cost of MPI undertaking monitoring.

    b. Does not consider the potential for EPA to expand powers and take responsibility for monitoring of non-agricultural GMOs.

    c. Does not discuss the challenges of environmental monitoring, and the need for species specific monitoring e.g. fish, microalgae, viruses or plants to assess and understand if they are outcrossing/cross-breeding with native organisms. Does not discuss a requirement to monitor potentially affected organisms (including predators or predated species, pollinators etc.). [61]

    d. And the Bill exclusively requires that 'regulated' activities will be monitored. Unregulated activities may expand at scale, but the RIS does not consider any need to monitor, track and trace unregulated activities.

    e. Is prima facie ignorant of the technologies and methods to appropriately monitor either agricultural or the natural environment.

    f. Has not conducted an evaluation of best global practice for monitoring of currently approved GMOs and MBIE have failed to evaluate and consider the specific problems that arise should exempt or regulated gene edited organisms be released into either agricultural and food producing environments or the natural environment.

68. There are many ways scientists can analyse off-target activity, for example in CRISPR modification. This includes: (i) in silico prediction (using computational methods), (ii) in vitro genome-wide assays (in laboratories), (iii) cell-based assays (in laboratories) and (iv) in vivo screening (the process of testing compounds, drugs, or genetic material directly in a living organism in a contained or non-regulated environment to assess their effects).[62]

69. Such language is not in the Australian Gene Technology Act 2000. Nor does the Australian Act establish high level public interest principles.

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[60] MBIE Regulatory Impact Statement Reform of Gene Technology Regulation. Ministry of Business, Innovation and Employment. https://www.mbie.govt.nz/dmsdocument/29936-regulatory-impact-statement-reform-of-gene-technology-regulation-pdf

[61] 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.

[62] Agapito-Tenfen SZ, Okoli AS, Bernstein MJ, Wikmark O-G and Myhr AI (2018) Revisiting Risk Governance of GM Plants: The Need to Consider New and Emerging Gene-Editing Techniques. Front. Plant Sci. 9:1874. doi: 10.3389/fpls.2018.01874

70. Historically, New Zealand authorities have struggled to be transparent when trials have had adverse outcomes[63], or when trial conditions were breached.[64] These events were not investigated by media.

71. In contrast, European legislators intending to release GMOs into the environment, must also take into account Annex II to Directive 2001/18/EC which stipulates a wide range of considerations.

[D] POLICY PROCESS CONTRADICTS/UNDERMINES OPEN GOVERNANCE NORMS

72. Strikingly, for at least the first month of release of the Bill for public consultation (from December 19 onwards), no reports or public policy documentation, including Hansard reports, have been inserted (by convention in a docket) on the Parliamentary page for public access.

73. PSGR recently found that during 2022, the Government mysteriously decided that it was not necessary to lodge Bills Digests on the Parliamentary website, to inform the public about what work had been undertaken, and what policy documents had been produced to support a given Bill. This action both obfuscates public access, and narrows who can easily access relevant information to a small group of experts who are familiar with the policy process.

74. The public cannot know what information has been provided to their MPs prior to the first reading, and what information MPs currently hold.

75. MPs remain uninformed as to what proportion of gene edited techniques and organisms would be excluded from premarket assessment, versus notifiable and declared. MPs may not be aware that New Zealand would become one of the most deregulated environments globally due to the extent of techniques and gene edited organisms that would be out-of-scope for regulatory risk assessment.

76. There has been no public consultation prior to the construction of the Bill which would permit public debate and dialogue on a risk acceptance, or tolerability criteria, i.e., how much contamination would the public be willing to accept? How many losses would export industry be willing to sustain. Do Māori mind if gene flow contamination into Rongoa species occurs inadvertently?

77. How can risk be reduced if no discussion of risks has been permitted?

78. Over the same period Parliament has been in summer recess, there has been no capacity for MPs to ask public questions.

[E] OMISSION IN POLICY PROCESS: EXCLUDING NEW ZEALAND ROYAL COMMISSION FINDINGS

79. The Regulator should be tasked with a broader range of powers, as the Government has failed to put in place, or sustain the findings of the Royal Commission on genetic modification.

80. The Royal Commission on Genetic Modification was an extensive two-year process.

    'In the formal part of its consultation it heard from approximately 400 witnesses and other interested people in more than three months of formal hearings resulting in close to 5,000 pages of transcripts. The

[63] Bleakley, CE. GE Animals in New Zealand: the first fifteen years. GE Free NZ in Food and Environment. https://www.gefree.org.nz/assets/pdf/GE-Animals-in-New-Zealand.pdf
[64]GEFree (2009) GE Brassica - GMF 06001 at Plant and Food, Lincoln, Boundary Road, Canterbury. https://www.gefree.org.nz/assets/pdf/brassica-reassessment.pdf

people who gave evidence during those hearings included representatives from research institutions and the biotechnology industry, New Zealand's primary production sector, the organics industry, church and religious groups, Maori organisations, the health and food sectors and environmental groups.

As well, more than 10,000 members of the public provided written submissions and, in the course of its 14-month inquiry, the Royal Commission consulted widely with the New Zealand public, holding 50 public meetings, hui and workshops in regional centres from Invercargill in the south to Kaikohe in the north.'[65]

81. Then Prime Minister Helen Clark stated:

    "It is the most wide-ranging inquiry into genetic modification ever undertaken in any country, and the government thanks the commission for the balanced and thorough report it has produced."[66]

82. *'The scoping process revealed high levels of public interest in issues of human health, environment and ethics. Within the crops and food topic, human health and environment were significant issues. For the topic of uses of genetic modification in medicine, human health and ethical issues were at the fore.'*[67]

83. Over 200 recommendations were made by the Commissioners. [68]

84. The Royal Commission recommended a three-pronged approach including the establishment of a Parliamentary Commissioner on Biotechnology, a Bioethics Council and a biotechnology strategy.

85. Many of the recommendations following the Royal Commission have been discarded. These have occurred quietly, without public input.

PART II: RECOMMENDATIONS INCLUDING CRITICAL ANALYSIS OF BILL TEXT

[A] BASIC RECOMMENDATIONS

86. **PSGR recommend that this Gene Technology Bill 2024 is withdrawn.**

The Gene Technology Bill does not create risk-proportionate regulation. The regulator will be straightjacketed by the wide variety of exempted gene editing techniques and gene edited organisms and by being legally bound to decisions made in foreign jurisdictions. The Regulator has no powers to (a) review the exempt techniques and organisms (including undeclared accidents and failures) for risk; (b) monitor and trace all gene edited organisms; and (c) surveil public and published literature to identify new knowledge on all risks associated with gene editing technologies. The Technical & Māori Advisory Committee powers are extremely restricted. These sections undermine national sovereignty: Subpart 5, mandatory medical authorisations and [163(4)(c)] the exclusion of organisms based on Australian decisions.

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[65] Hobbs M. February 13, 2003. About the Royal Commission on Genetic Modification. https://www.beehive.govt.nz/release/about-royal-commission-genetic-modification
[66] Beehive.July 30, 2001. Report of the Royal Commission on Genetic Modification https://www.beehive.govt.nz/release/report-royal-commission-genetic-modification
[67] 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/

87. **PSGR recommend that the Hazardous Substances and New Organisms Act 1996 (HSNO) can remain the administering legislation for all GMOs, including gene editing techniques and outcomes.**

    a. Risk-tiering of processes and outcomes of genetically modified organisms (GMOs) including gene edited organisms can be placed inside HSNO.

    b. HSNO Act clauses [4-8] require the Regulator to consider ethics-based principles.

    c. The **Gene Technology Bill** skirts obligations by merely suggesting Regulators must have 'regard' for certain conventions.

    d. The **Gene Technology Bill** uses statute to set aside broad Treaty obligations, which appear to be proxied into the Māori Advisory Committee that is expected to sufficiently and comprehensively address cultural/legal/ethical issues.

    e. Both hazard and exposure assessments are required to characterise overall risk. These are ignored in the **Gene Technology Bill**.

    f. HSNO has a well thought out Controls section, the **Gene Technology Bill** ignores this.

88. **That work to amend the HSNO Act with risk-tiering inside the Act and no exempt activities, *only* commence after:**

    a. Related legislative changes to GMO legislation by our major export markets,[69] including the European Union and the United States, have been finalised to ensure New Zealand harmonises with key premium markets, adopts best practice guidelines for gene edited organisms in food, and is not 'caught short' with banned or unknown GMO including gene edited organisms in export products. This includes any potential international, reputational impact (as blowback) should product be turned back or destroyed.

    b. The Parliamentary Commissioner for the Environment undertakes a fully funded review to assess: Environmental Protection Authority (EPA) costs of regulatory risk assessment; the history of open-air trials in New Zealand; and the financial resourcing necessary for the EPA to risk assess, monitor and trace GMOs outdoors and in food.

    c. Independent assessment of all GMO including gene edited agriculture and food products, assessing consumer demand, long-term yields, and on and off-target risks, including risk of transfer of risk assessment obligations from biotech developers to food businesses.

    d. Transdisciplinary assessment (ethics, law, culture, biology) of the utility of a Bioethics Council (see Royal Commission on Genetic Modification 2001, recommendation Ch.14) that would act as an advisory body, provide guidelines on biotech issues which interface with social, ethical and cultural factors, and promote transparency.

89. **PSGR recommend: To be 'risk-proportionate' the Regulator must have the powers to assess the risk, which is a function of both hazard and exposure.**

[69] For example, as discussed here: New Zealand's Top 10 Exports https://www.worldstopexports.com/new-zealands-top-10-exports/

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.

a. None of these approaches of risk assessment are discussed in the **Gene Technology Bill**. Risks cannot be mitigated if an assessment has not taken into account exposure and context, in order to assess the probability of harm. Comparative hazard analyses which ignore use-patterns, are unfit for purpose.

b. 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.

90. **PSGR assert: The *process* is the technology. Gene edited organisms can be heritable, as, like all GMOs, they can reproduce. However, the *process* can also be used to kill or sterilise.**

The technology is the *hazard*. What also must be considered is who, how and what will be exposed to decrease or increase risk. The *technology* immediately places all GMO organisms (including exempt classes) in a class of 'persistent' and potentially 'bioaccumulative' technologies and contaminants. Gene editing techniques enable rapid scaling up of the production of new organisms. The same cannot be said for conventionally-bred organisms.

91. **PSGR emphasise: All gene editing techniques are powerful mutagens,** including techniques that would be exempt in the **Gene Technology Bill**.

92. **PSGR have been unable to identify the precedent of a hazardous substances and new organisms Regulator that has automatically presumed that a previously-regulated substance/organism would be 'safe' for all time and exclude it from regulatory oversight.**

Humanity has a long history finding out that previously stated 'safe' technologies are instead, harmful and/or deadly. This evidently global initiative to deregulate gene editing techniques and organisms can be rejected.

93. **The process must be regulated – the Regulator must not underestimate the potential for harm**

The potency of the mutagenic process; the potential for reproduction or to kill and sterilise; and the potential of commercial scaling cannot be underestimated. This is the basis of the case for regulation. If gene editing tools are used, this is regarded as a genetic modification process. All organisms should then be assessed on a case-by-case basis.

94. **PSGR recommend: All gene technology activities, including the proposed 'exempt activities', must be registered for traceability, regardless of whether the resultant GMOs advance to regulatory assessment and release.**

a. A possible scenario is the release of undeclared 'failed' gene edited organisms which then contaminate export product and are identified by foreign jurisdictions as an unauthorised gene edited organism. This could result in rejection and/or condemnation of that shipment.

b. Precise edits can result in unpredictable outcomes. They may occur at other locations in the DNA that are similar to the target locations. Even if not, a 'precise' edit does not mean that the end product will be safe. Precision and safety are two very different things to consider. The cell could respond to gene edits in unpredicted ways, as a single change is likely to cause a domino-

effect resulting in biochemical alterations. Reagents and equipment used during the gene editing process can carry DNA contamination from other biological organisms.

c. Exempt activities cannot be assumed to be exempt if they have not been screened for unintended changes (which developers may be unable to control). It is unscientific to believe that exempted gene edited organisms are free of transgenes. Gene editing processes (including from reagents used in the process) can introduce and contaminate genetic material from multiple species.

d. Regulators must require that all GMO (including gene edited organisms) are verified free of unintended DNA changes including insertions or off-target, or unintended on-target effects.

95. **PSGR warn: Cost burden on food producers and exporters:** A European legal opinion identified that deregulation (i.e. via exemptions) would lead to 'a transfer of the implementation of risk assessments from genetic engineering law to novel food law and thus to the food businesses'. Associated costs would then be passed on to the food business/industry.

96. **The Regulator must *not* be scientifically and ethically straitjacketed.**

a. The **Gene Technology Bill** proposes that for scientific information on risk, the Regulator is limited to sourcing information from: (i) Other regulators who may be similarly restricted; and (ii) The Technical Advisory Committee, which has a limited scope of reference [113-119].

b. Risk cannot be mitigated if it is not yet known how an organism may be hazardous, and what evidence exists in the published and peer reviewed literature, and if legal evidence following legal and local and/or global court proceedings, is excluded from review.

97. **The Regulator must have powers to demand disclosure of intended *and* unintended genetic changes in all GMO organisms.**

This should be part of a mandatory thorough molecular characterisation and risk assessment of any modified organism (including all gene edited organisms) intended for environmental releases, or for market authorisation. This should also include the unintentional integration of novel DNA and rearrangements of the organism's own DNA, for every genetic event that has been detected in the genome of a genetically manipulated species.

98. **HSNO Act 1996 - precautionary principle clauses must remain in place.**

The Ministry for Business, Innovation and Employment (MBIE) has failed to state that with emerging technologies, there is relatively little known about the extent to which random changes following gene editing can rearrange genomes, and what changes would occur as a result of this. Such changes could not only affect the health of the edited organism/s, but also the health of any other organisms in the immediate and surrounding environments. It could also affect the biochemistry and hence the safety of plants and animals used for food. The need for precaution is also greater as technologies including AI, Nanotechnology and Synthetic biology converge with gene editing tools, enhancing the scale and speed of releases.

a. Contamination by replicating organisms would likely be irreversible and beyond financial instruments' scope to remedy the losses.

99. **MBIE have no role in the development of future GMO/gene editing technologies policy and regulation.**

MBIE is a ministry concerned with business innovations and is not qualified to be drafting scientifically-determined guidelines and environmental regulations.

100. **Gene editing techniques and gene edited organisms are called 'gene editing techniques' and 'gene edited organisms'.**

'New breeding techniques' (NBTs) is confusing and misleading. The use of ambiguous euphemistic terms should not be used in policy or legislation.

101. **PSGR emphasise that legislation (e.g. Subpart 5—Mandatory medical authorisations) and s163(4)(c) which effectively delegate powers to foreign jurisdictions, and which legally bind New Zealand regulatory agencies must be removed from, and not inserted in, any future legislation, including but not limited to, the HSNO Act 1996.**

a. to in Subpart 5: automatically authorise and mandate any foreign substance/s, including medical therapeutics.

b. 163(4) delegates exemptions of GMOs from regulation in New Zealand, to decisions made under the Australian Gene Technology Regulations 2001 (expressed in Schedules 1A and 1).

102. **PSGR RECOMMEND THAT IN *ANY* FUTURE LEGISLATION:**

a. **All use of gene technology must be confined to a containment facility.** All modified/edited organisms must then undertake process-based risk assessment on a case-by-case basis before release.

b. All repeat/serial or multiplex reaction processes must be notifiable activities.

c. Applicants must verify that the organism conforms to their description of it, and screen for intended *and* unintended genetic changes.

    i. The Regulator must participate in an international collaboration to produce a global data-base which would act as a resource for intended and unintended genetic changes.

d. The administering agency would remain the Ministry for the Environment, with agriculture and food administered by MPI.

e. Powers for monitoring and enforcement for non-agriculture or food-system GMOs would be held with the Environmental Protection Authority. Monitoring by MPI and the NZ EPA would be undertaken, in accordance with best global practice, and not seek equivalence with low-bar regulatory agencies.

    i. Monitoring takes into account different approaches for agriculture and the natural environment.

    ii. Monitoring would be conducted of all modified/edited organisms released into the environment. Annual reports would be presented to the administering agency.

    iii. The Regulator would have funding for monitoring and powers to assess new instrumentation, commonly used by biotechnology institutions that would be useful for such assessments.

f. The Parliamentary Commissioner for the Environment would have the powers to review New Zealand risk assessment practices and compare these with best global practice.

g. All GMO production, using all current and future gene editing processes, is undertaken in a certified, contained facility.

h. HSNO clauses [4-8] can form the basis for principles. Insert an obligation to consider ethics-based issues, including societal values and animal welfare, and to provide call-in powers for the regulator for bioethics issues.

i. The Regulator would have the discretion to identify low- and high-risk organisms via risk categories. In order to characterise overall risks, these categories would include assessments for both hazard and exposures (such as probable use-patterns). It would also include the extent to which the applicant intends to scale up production and release following market authorisation.

j. The Regulator is given the powers to identify and review the relevant scientific literature, and provided call-in powers for these reviews. Information surveillance to include published white papers, court findings and papers used in the discovery process to analyse global risks associated with the use of all gene technology processes.

k. Gain-of-function/dual-use research of concern is prohibited. Weaker regulatory jurisdictions will enable gain-of-function/dual use research to be exploited, due to weaker/non-existent governance frameworks.

[B] SCIENTIFICALLY INDEFENSIBLE: 'DISTINGUISHABLE' AND 'INDISTINGUISHABLE'

103. **The Gene Technology Bill does not define 'distinguishable' or 'not distinguishable'.** Yet this language is the basis for risk tiering gene editing techniques and organisms outside the legislation.

104. In inappropriately risk tiering gene editing techniques and organisms outside the legislation, the legislation obstructs officials from applying risk assessment pathways to identify new risks and challenges presented across gene editing activities, and from harnessing appropriately targeted technologies to monitor, screen and assess risk across all GMOs in New Zealand.

105. The effect is absurd, tying the hands of administering agencies. Effectively, risk-proportionate regulation cannot be achieved. The Regulator can never assess the 'exempt' category outside the legislation, without amending the primary act. The enforcement agency has no powers to evaluate whether techniques and organisms that fall within the exempt category are contaminating indigenous flora and fauna or agricultural product.

106. MBIE have not quantified how many new organisms would evade risk assessment, and the public and MPs remain ignorant on what proportion of gene edited organisms will be ruled out-of-scope.

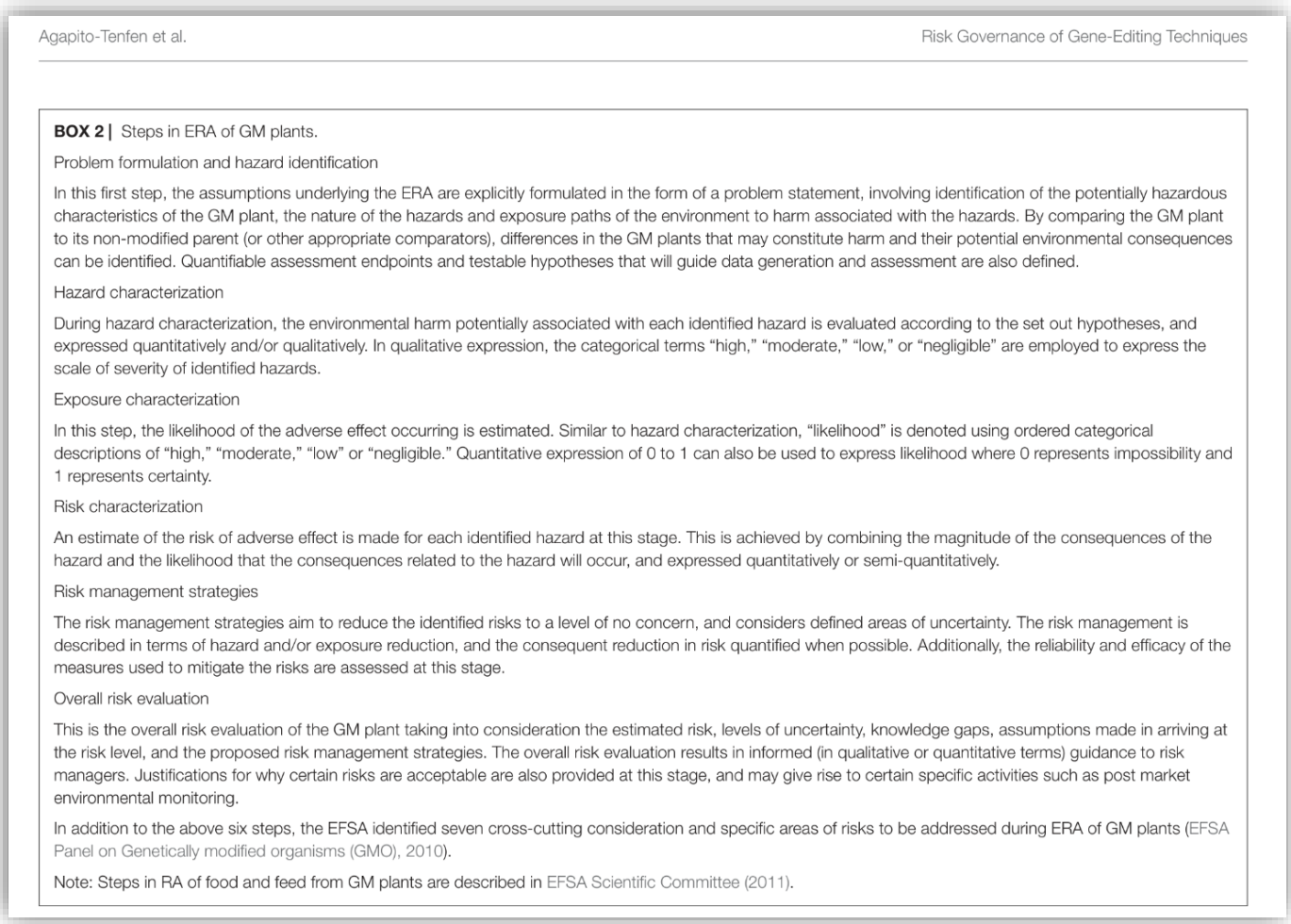
107. Risk assessment is a science, not a regulatory burden. 'Risk science is defined as the practice that provides us with the most epistemically warranted or justified statements or beliefs that can be produced at the time being on the subject matter covered by the risk field.'[70]

108. To be a science, underpinned by impartial and process-based reasoning, a document must be supplied showing the methods and outlining the processes by which an impartial and independent assessment of how the classifications of 'indistinguishable' which would exempt GMOs from premarket assessment, and very, very low-risk were understood. This has not happened.

[70] Aven T (2021) The reliability science: Its foundation and link to risk science and other sciences. Reliability Engineering & System Safety Volume 215, November 2021, 107863. https://doi.org/10.1016/j.ress.2021.107863

109. The legislation provides no structure, which is what a primary Act should do, that demonstrates any knowledge of GMO risk governance, and the processes that are required to assess risk, for example, for environmental risk assessment (ERA). Europe's current framework can give officials some idea of the extent of gaps, and the confusing nature of the proposed Gene Technology legislation.

110. Legislation to regulate a technology and potential environmental emissions should provide a clear, accountable pathway for officials to follow, that downstream (secondary legislation) regulations can hang off. The current Bill provides no such practical pathway. As an example, the Select Committee and MPs could contrast the summary box produced by Agapito-Tenfen et al (2018)[71] against the outline of how risk will be managed in MBIE's proposed Gene Technology Bill:



BOX 2 | Steps in ERA of GM plants.

Problem formulation and hazard identification

In this first step, the assumptions underlying the ERA are explicitly formulated in the form of a problem statement, involving identification of the potentially hazardous characteristics of the GM plant, the nature of the hazards and exposure paths of the environment to harm associated with the hazards. By comparing the GM plant to its non-modified parent (or other appropriate comparators), differences in the GM plants that may constitute harm and their potential environmental consequences can be identified. Quantifiable assessment endpoints and testable hypotheses that will guide data generation and assessment are also defined.

Hazard characterization

During hazard characterization, the environmental harm potentially associated with each identified hazard is evaluated according to the set out hypotheses, and expressed quantitatively and/or qualitatively. In qualitative expression, the categorical terms "high," "moderate," "low," or "negligible" are employed to express the scale of severity of identified hazards.

Exposure characterization

In this step, the likelihood of the adverse effect occurring is estimated. Similar to hazard characterization, "likelihood" is denoted using ordered categorical descriptions of "high," "moderate," "low" or "negligible." Quantitative expression of 0 to 1 can also be used to express likelihood where 0 represents impossibility and 1 represents certainty.

Risk characterization

An estimate of the risk of adverse effect is made for each identified hazard at this stage. This is achieved by combining the magnitude of the consequences of the hazard and the likelihood that the consequences related to the hazard will occur, and expressed quantitatively or semi-quantitatively.

Risk management strategies

The risk management strategies aim to reduce the identified risks to a level of no concern, and considers defined areas of uncertainty. The risk management is described in terms of hazard and/or exposure reduction, and the consequent reduction in risk quantified when possible. Additionally, the reliability and efficacy of the measures used to mitigate the risks are assessed at this stage.

Overall risk evaluation

This is the overall risk evaluation of the GM plant taking into consideration the estimated risk, levels of uncertainty, knowledge gaps, assumptions made in arriving at the risk level, and the proposed risk management strategies. The overall risk evaluation results in informed (in qualitative or quantitative terms) guidance to risk managers. Justifications for why certain risks are acceptable are also provided at this stage, and may give rise to certain specific activities such as post market environmental monitoring.

In addition to the above six steps, the EFSA identified seven cross-cutting consideration and specific areas of risks to be addressed during ERA of GM plants (EFSA Panel on Genetically modified organisms (GMO), 2010).

Note: Steps in RA of food and feed from GM plants are described in EFSA Scientific Committee (2011).

Agapito-Tenfen SZ, Okoli AS, Bernstein MJ, Wikmark O-G and Myhr AI (2018) Revisiting Risk Governance of GM Plants: The Need to Consider New and Emerging Gene-Editing Techniques. Front. Plant Sci. 9:1874. doi: 10.3389/fpls.2018.01874

111. As Agapito-Tenfen acknowledge, the current ERA framework in Europe does not take account of new challenges presented by gene editing technologies. Their flowchart shows the potential source of genome-editing mediated genome changes.

[71] Agapito-Tenfen SZ, Okoli AS, Bernstein MJ, Wikmark O-G and Myhr AI (2018) Revisiting Risk Governance of GM Plants: The Need to Consider New and Emerging Gene-Editing Techniques. Front. Plant Sci. 9:1874. doi: 10.3389/fpls.2018.01874

112. No evaluation of these potential changes – changes that could happen in both exempt, very, very low risk and notifiable categories has been conducted by MBIE in the policy documentation.

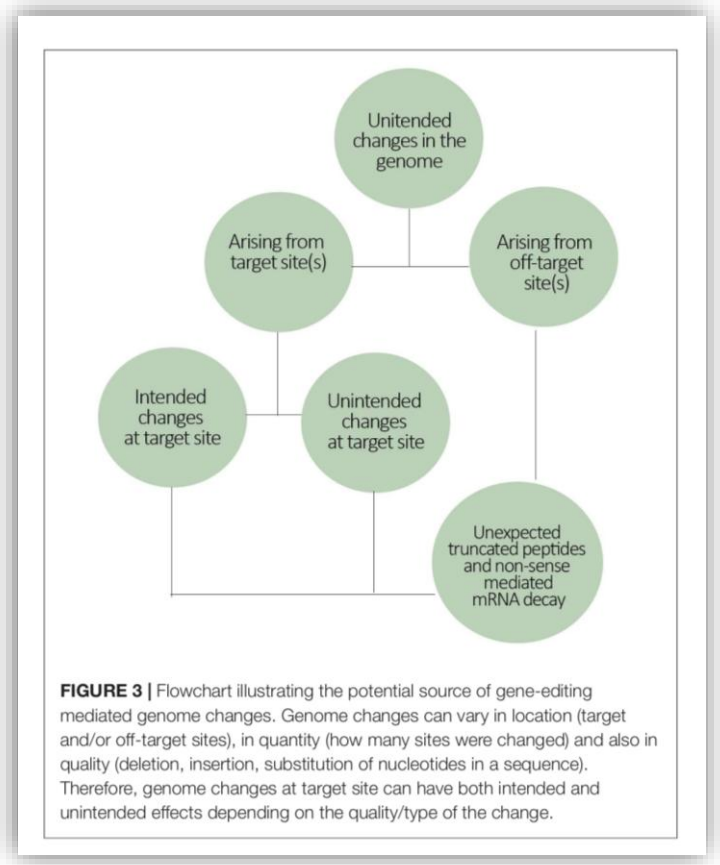


FIGURE 3 | Flowchart illustrating the potential source of gene-editing mediated genome changes. Genome changes can vary in location (target and/or off-target sites), in quantity (how many sites were changed) and also in quality (deletion, insertion, substitution of nucleotides in a sequence). Therefore, genome changes at target site can have both intended and unintended effects depending on the quality/type of the change.

Agapito-Tenfen SZ, Okoli AS, Bernstein MJ, Wikmark O-G and Myhr AI (2018) Revisiting Risk Governance of GM Plants: The Need to Consider New and Emerging Gene-Editing Techniques. Front. Plant Sci. 9:1874. doi: 10.3389/fpls.2018.01874

113. The Gene Technology Bill did not evaluate how monitoring might occur, to ensure the primary Act was future proof and to ensure officials had access to instrumentation that was as sophisticated as industry technology. For example, molecular characterisation could be integrated into early-stage risk assessment.

'the assessment of the unintentional integration of exogenous DNA is already part of the molecular characterisation in the risk assessment of GM plants, under EU Regulations. Therefore, this is not to be considered a new requirement for risk-assessing genome-edited plants.'[72]

114. Just as techniques to speed up gene editing are improving, so are the techniques to identify when, e.g. food products have been contaminated via gene editing. *Omics* technologies, including

[72] Koller, F. and Cieslak, M. (2023) → A perspective from the EU: unintended genetic changes in plants caused by NGT—their relevance for a comprehensive molecular characterisation and risk assessment.
Front. Bioeng. Biotechnol. 11:1276226. doi: 10.3389/fbioe.2023.1276226

transcriptomics, proteomics and metabolomics are high throughput technologies that enable scientists to measure different biomolecules, their structure, functions and interactions.[73] [74] [75]

115. **The scientific claims that the Crown rests on to form the basis for this Bill (authorisation framework) have not been outlined in the RIS and cannot be substantiated by the Crown.** The scientific claims are based on an arbitrary and undefined claim that certain forms of gene edited techniques, and the genetically modified organisms that they produce can be considered 'very low-risk'.

116. The RIS does not link to scientific papers and risk assessments which demonstrate the veracity of MBIEs claims relating to 'indistinguishable' or 'distinguishable'. The 'indistinguishable' category has not been backed up by any scientifically rigorous evaluation that accords with due process (i.e. which reflects both scientific and public law conventions).

117. The Regulatory Impact Statement (RIS) claims that the 'very low-risk ' moniker hinges on the belief that a genetic 'makeup' or 'trait' will be 'indistinguishable' as a result of modification using particular processes or following modification which results in genome rearrangements which do not include the production of a novel protein or novel DNA.[76]

a. This 'indistinguishable' concept appears to be based on the 'comparative approach' concept which is also similar to the 'substantial equivalence' concept, a term originally applied to technical medical devices.

b. MPs may wonder, what then will be regulated? Gene editing organisms which produce novel protein/s or DNA. However, what is not prima facie apparent, is that 'novel' exclusively refers to protein or DNA arising from insertion by a *foreign* organism which is expressly inserted into the genome of the organism undergoing gene editing.

c. New proteins or DNA arising from rearrangements *within* the organism undergoing genome editing will be specifically excluded. MBIE has made no effort to assess whether any new intra-genome DNA or protein/s produce any risk to the integrity of the genome.

d. Likewise, if an organism is inadvertently gene edited into the organism undergoing gene editing (such as microbial organisms residing in the extra-cellular matrix) and the DNA is contaminated (polluted), there is no obligation for the corporate applicant to screen and declare inadvertent pollution, which may lead to unintended effects and compromise the integrity of the patented organism.

118. The degree to which (i.e. the percentage of) new organisms that would be exempt due to being claimed to be 'indistinguishable' has not been communicated to MPs or to the public. What may be possible, but is not discussed nor evaluated, is that if most organisms are exempt due to MBIE's claim

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[73] Dai X, Shen L. Advances and Trends in Omics Technology Development. Front Med (Lausanne). 2022 Jul 1;9:911861. doi: 10.3389/fmed.2022.911861. PMID: 35860739; PMCID: PMC9289742.
[74] Sanches, P. H. G., de Melo, N. C., Porcari, A. M., & de Carvalho, L. M. (2024). Integrating Molecular Perspectives: Strategies for Comprehensive Multi-Omics Integrative Data Analysis and Machine Learning Applications in Transcriptomics, Proteomics, and Metabolomics. *Biology*, *13*(11), 848. https://doi.org/10.3390/biology13110848
[75] Mesnage R et al (2016). An integrated multi-omics analysis of the NK603 Roundup-tolerant GM maize reveals metabolism disturbances caused by the transformation process. Scientific Reports 6:37855. http://www.nature.com/articles/srep37855
[76] MBIE Regulatory Impact Statement Reform of Gene Technology Regulation. Ministry of Business, Innovation and Employment. https://www.mbie.govt.nz/dmsdocument/29936-regulatory-impact-statement-reform-of-gene-technology-regulation-pdf

that they are indistinguishable, the public will be ignorant of the extent to which GMOs (including failures) are in food and the environment. This does not mean that GMOs in the environment would be a rare occurrence, simply that the GMOs in the environment would fall outside of the provisions for premarket assessment and hence regulatory scrutiny.

119. The Bill cannot stand the test of time due to the arbitrary nature of how high and very, very low-risk is determined.

(i) Inside the cell: Undeclared problems (risks) from (e.g.) multiplexing.

120. **Process-base premarket assessment is crucial, as there is a real risk of non-disclosure or failure to screen for inconvenient alterations and RNA or DNA contamination by industry applicants.** No gene technology Regulator, nor monitoring and enforcement agency should be naïve to corporate industry failing to disclose inconvenient data, if disclosure would result in a shift from an exempt to a notifiable category.

121. It's entirely possible and practical for gene edited organisms that are currently designated as 'indistinguishable' and exempt and very low-risk and non-notifiable to be screened to assess the entire genome, so as to understand the potential risk that could arise from potential genome rearrangements.

122. Policy documents did not review the costs of characterising gene edited organisms on a case-by-case basis. MBIE should not 'pretend' that molecular characterisation and risk assessment of GMOs intended for environmental releases or market authorisation is not practicable

123. The Gene Technology Bill exemptions and very, very low-risk categories may result in most gene edited techniques, organisms and contaminating DNA, evading regulatory risk assessment, simply because these problems have not been voluntarily screened for by the industry applicant.[77] [78] [79] [80]

124. Biotechnology companies in the normal course of their work, use technologies to rearrange genomes. Multiplex genome editing using the CRISPR/Cas system enables developers to mutate multiple genetic loci within one or more genes simultaneously. It can build layered genetic circuits that control cellular behaviour or modulate metabolic pathways with the simultaneous editing, activation, and downregulation of multiple target genes.[81]

125. Multiplex editing is an example of the way gene editing can increase both the efficiency and speed of trait creation. We quote Professor Jack Heinemann and colleagues:

'Their targeting specificity does not make them safer. It makes them more efficient at creating mutations at both intended and unintended sites (Table 1, primary submission), at multiple sites in the same

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[77] Demasi, M. (February 10, 2025). Internal emails reveal Merck's negligence in Gardasil safety testing. https://substack.com/@maryannedemasi/p-156651477

[78] Solomon, S.M. (2020) Genome Editing in Animals: Why FDA Regulation Matters. Nat Biotech 38, 142-143.

[79] Braatz, J. et al. (2017) Crispr-Cas9 Targeted Mutagenesis Leads to Simultaneous Modification of Different Homoeologous Gene Copies in Polyploid Oilseed Rape (Brassica Napus). *Plant Physiol* 174 (2), 935-942.

[80] Norris, A.L. et al. (2020) Template Plasmid Integration in Germline Genome-Edited Cattle. *Nat Biotechnol* 38 (2), 163-164.

[81] 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

genome simultaneously (sequential and multiplex), and in multiple species simultaneously, whether or not this were the intention of the user."[82]

126. It is non-controversial that gene editing processes such as multiplex editing, biochemically, sets the stage for subsequent unintended (domino-like) changes in the cell:

'In comparison to methods of conventional breeding (including non-targeted mutagenesis), NGTs can overcome the boundaries of natural genome organization: Relevant factors include repair mechanisms, gene duplications, genetic linkages and other epigenetic mechanisms... By overcoming these boundaries, NGTs can make the genome much more extensively available for genetic changes.' [83]

127. Koller and Cieslak (2023) (in a study which could have been evaluated by MBIE) proposed that unintended changes of gene edited organisms could be classified under five categories.[84]:

a. Unintended genetic changes resulting from the insertion of transgenes via established genomic techniques (off-target).

b. Unintended insertion of transgenes with new genomic technique processes.

c. Unintended genetic changes without the insertion of transgenes (on-target and off target).

d. Chromothripsis-like effects.

e. Unintended genetic changes that may cause the formation of new gene products (without insertion of transgenes).

128. **The Enforcement agency's powers are not able to protect individuals and organisations whose inadvertently contaminated product ends up containing GM content that is licensed by someone else**. This problem of contamination by 'an organism, a regulated organism, gene technology' where a person or organisation is in possession of an organism, that prior to the establishment of this legislation, would not have been contaminated through gene edited processes, but now is contaminated and therefore 'regulated'. This legislation could through omission, enable patent owners to claim ownership over gene edited organisms, for example in food produce that has been contaminated with gene edited DNA through natural processes such as cross-fertilisation.

(ii) Outside the cell: From outdoor to supermarket applications.

129. **Outdoor applications, e.g. biopesticides remain unregulated.** New technologies allow DNA, RNA and proteins to be delivered to cells, tissues and organisms in the open environment. These penetration technologies allow gene silencing and genome editing to be

[82] 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_committee_gene_tech_bill_2024pdf

[83] Koller, F. and Cieslak, M. (2023) → A perspective from the EU: unintended genetic changes in plants caused by NGT—their relevance for a comprehensive molecular characterisation and risk assessment. *Front. Bioeng. Biotechnol.* 11:1276226. doi: 10.3389/fbioe.2023.1276226

[84] Koller, F. and Cieslak, M. (2023). A perspective from the EU: unintended genetic changes in plants caused by NGT—their relevance for a comprehensive molecular characterisation and risk assessment.

used at ecosystem levels as biocides. Intended, unintended, or malicious releases of biologically active nucleic acids and proteins could occur.[85]

130. Genomic alterations may occur in unintended organisms, underscoring the significance of understanding potential hazards and implementing safety measures to protect human health and the environment.[86]

131. MBIE did not address the risk from outdoors application. For example, delivery routes for pest and disease control in agriculture could potentially include (but are not limited to) applications via water, fumigation and fertiliser, and non-target organisms could be directly or indirectly exposed.

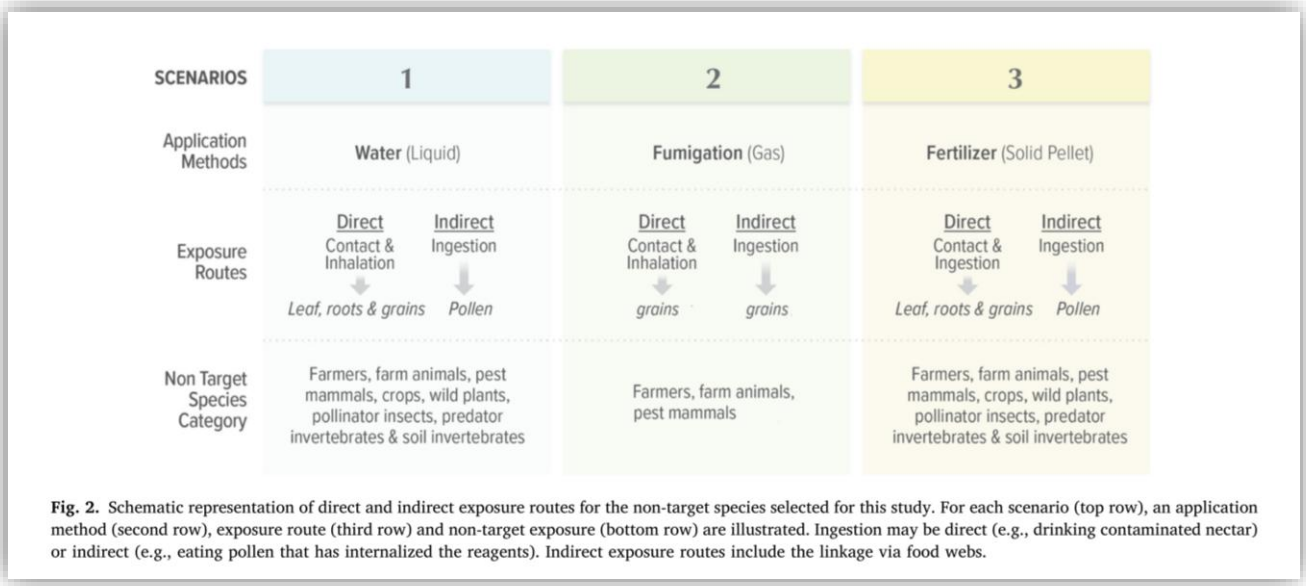

Fig. 2. Schematic representation of direct and indirect exposure routes for the non-target species selected for this study. For each scenario (top row), an application method (second row), exposure route (third row) and non-target exposure (bottom row) are illustrated. Ingestion may be direct (e.g., drinking contaminated nectar) or indirect (e.g., eating pollen that has internalized the reagents). Indirect exposure routes include the linkage via food webs.

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.

132. Outdoors applications using gene editing reagents that could be outside of regulatory standards, present future risk. However, this 'brand new' legislation carries no capacity to capture those risks, and it cannot be expected that secondary legislation will regulate them.

133. Harm to developing respiratory and nervous systems of non-target insects has been predicted by Hoepers et al (2024). In a study using metabolic enrichment analysis software to *in silico* (computationally) identify off-target genes, Hoepers et al (2024) identified exposed species from the outdoor in situ gene editing activities.

134. In a Supplementary submission to the Gene Technology Bill, Heinemann et al (2025) highlighted a patent which described the role of nanoparticles in delivering genome editing reagents. The reagents are the active molecules that cause gene editing. This would enable the

[85] 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

[86] 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

technology to be deployed into outdoor (including publicly accessible) environments. As the Supplementary paper notes, the patent focussed on use in mammals, including people.[87]

135. In the same submission, the authors noted the potential for surfactants and formulation additives (for example, as pesticides) which could be dispersed through aerosol or mechanical equipment to contain minicells (a different kind of nanoparticle vector) inside. This would not be regulated under the Bill. In the example provided, lipid-based liquid crystalline nanoparticles would be used as a surfactant to improve delivery of a biologically active compound through the cuticle layer of the cell. The minicells would effectively be translocated inside the plant. [88]

136. Gene editing activities could be undertaken for example, in supermarkets. Reagent sprays could be emitted through the hydration nozzles (mist sprays) in supermarkets to reduce fruit ripening. [89] [90] [91]

(iii) Outside the cell: Post-market environmental monitoring.

137. *Compliance, monitoring, and enforcement*. The Director-General of the Ministry for Primary Industries (MPI) will be responsible for compliance, monitoring, and enforcement of the regulatory regime, consistent with comparable enforcement responsibilities for other regimes, including for hazardous substances and new organisms.

138. **The Gene Technology Bill excludes 'exempt' and non-notifiable activities from monitoring.** Monitoring powers are limited to the monitor a place where a regulated organism is, or may be present. [68(e)]. There are no powers for broader general surveillance either to identify if a regulated organism is shifting beyond suspected locations, or to identify off-target, environmental effects. This can only be undertaken if funding has been explicitly set aside in the primary act to ensure that the authority will be able to carry out activities sufficiently independently of any industry applicant.

139. The Gene Technology Bill does not require the monitoring authority to prepare monitoring plans and undertake nationally-relevant monitoring to ensure that organisms are not contaminating the environment.

140. **Monitoring provisions should encompass both case-specific and general surveillance.** General surveillance is in place to detect long-term effects and effects not foreseen or detected in earlier risk assessments. Currently for example, in Europe, monitoring plans have only been developed and submitted for the GM crop plants, maize, oilseed rape and soybean.

141. The Gene Technology Bill obfuscates the capacity for the Regulator and monitoring authority to understand and evaluate any potential contamination, because of the exempted categories. As

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[87] 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_committee_gene_tech_bill_2024pdf

[88] Heinemann et al. 2025. Supplementary submission to the Parliament Health Committee. Page 7.

[89] Heinemann, J.A. and Walker, S. (2019) Environmentally Applied Nucleic Acids and Proteins for Purposes of Engineering Changes to Genes and Other Genetic Material. Biosafety Health 1, 113-123.

[90] Deikman, J. et al. Methods and Compositions for Delaying Senescence and Improving Disease Tolerance and Yield in Plants. US9840715Bl https://patents.google.com/patent/US9840715B1/en

[91] Heinemann et al. 2025. Supplementary submission to the Parliament Health Committee. Page 5.

Professor Jack Heinemann noted in an interview with PSGR, environmental contamination would not only include 'wanted' gene edited organisms but any/all failures. As Heinemann noted:

'You have to know what you are making in order to have the tools to monitor it. If you're exposing millions of species simultaneously, you won't know- which ones (of the many) that you have to look for. It makes no sense to have a monitoring provision for something that has no regulatory oversight. If through the simple solution of requiring all research and pre-commercial development to be in a registered containment facility, you will know what that organism is, and if you wanted to monitor it, you would have the tools to do so.'[92]

142. Explicit requirement must be included in future legislation, that resources are set aside for environmental monitoring in the parent Act and that the enforcement agency is given wider powers to consider affected species and surrounding environments. A release might concern a fruit crop, a virus, or microalgae, and factors will be different for the different risks presented by each class.[93]

143. **Enforcement agency. The legislation has allowed for enforcement officers but not monitoring officers.** Monitoring officers are required and this must be stated in the primary legislation.

a. For example, no obligation is drafted into the legislation to require that MPI undertake general surveillance of New Zealand food crops, non-native and indigenous species to ensure that the genome has been contaminated. No reporting mechanism for monitoring processes has been established in this primary legislation.

144. **The Gene Technology Bill does not include a provision and specification of pathways for education and training for officials and scientists responsible for monitoring and assessment of risk to ensure guidelines, skills, instrumentation and capacity keep pace with new knowledge developments.**

145. Dolezal et al (2024)[94] considered the challenges of post-market environmental monitoring, stating that '*Monitoring requirements for novel GMO applications differ from those for GMO crop plants'*. Their 2024 paper reviewed the challenges that would arise following gene editing of fruit trees, fish and microalgae. In this study, adverse environmental effects could include:

'the spread of the GMO in the environment, the transfer of the inserted genetic material to other organisms, phenotypic and genetic instability, interactions with other organisms and changes in management, including agricultural practices.'

146. **There are many ways that the GMOs currently designated as 'exempt' or 'non-notifiable' could present a risk or hazard to human or environmental health:**

a. Off-target effects.

i. Brassicas designated exempt were found to have altered fatty acid composition. For example, no studies are required to evaluate the impact from this altered composition to pollinator health. Bees are not only dependent on commercial crops, but on wild

[92] PSGR. February 2025. NZ Gene Tech Bill Q8: Should monitoring requirements be in laws that regulate gene edited organisms? YouTube. https://www.youtube.com/watch?v=MHOG5IF1RPs

[93] 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.

[94] Dolezel M, et al (2024) Challenges for the Post-Market Environmental Monitoring in the European Union Imposed by Novel Applications of Genetically Modified and Genome-Edited Organisms.

species which could easily naturally hybridise via pollination across modified and unmodified species.

ii. A broad range of brassica species can cross fertilise and pollination can occur over long distances. Brassica seed species can remain viable in the soil for long periods of time, establishing risk of persistence and volunteer (wilding) species that could present a biosecurity and food risk.[95]

b. *Reduced plant fitness*. Desirable traits can be inadvertently altered as many genes can be involved in multiple biologic processes which the developers and Regulators can be unaware of. For example, insertions and deletions of site-directed nuclease 1 applications (SDN 1) can result in the alteration of several different DNA sequences – and thus several properties – simultaneously (multiplexing). 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.

[C] FAILURE TO ADDRESS KEY REGULATORY CHALLENGE: UNCERTAINTY & COMPLEXITY

147. The Gene Technology Bill must ensure that the Regulator can make decisions to safeguard the public interest when information and evidence is uncertain, complex and ambiguous.

148. **There is no language as to how the Regulator could characterise and navigate uncertainty, ambiguity and ripple (such as systemic) effects, to ensure regulations and decisions are risk proportionate. Uncertainty is a prevailing factor when governing technology, risk and biological systems. The Bill remains ignorant as to how regulatory officials will navigate decision-making when risk is uncertain and new knowledges are presented to officials.**

149. The Gene Technology Bill is unrealistic (it is silent) about the difficulty that the Regulator will face in identifying, often systemic risks that arise as a consequence of the relationship between the production and release of a biological gene edited organism, and the impact of a release of a gene editing technology or gene edited organism into the environment.

150. As PSGR discussed earlier, MBIE claimed in the RIS that many of the provisions are 'out-of-date'. **However, these 'out-of-date'provisions play an important role in dealing with complexity, uncertainty, ambiguity and ripple effects – the grey areas which are difficult to navigate, if health and environment are to be protected.**

151. MBIEs premature and poorly cited 'out-of-date' claim, which is silent on the position of the international legal and policy literature, suggests that MBIE is either ignorant of – or wishes to avoid – the central challenge of risk governance in social, biological and economic systems – that risk can be systemic.[96]

[95] Koller, F., Cieslak, M. & Bauer-Panskus, A. (2024) → Environmental risk scenarios of specific NGT applications in Brassicaceae oilseed plants. *Environ. Sci. Eur.* 36, 189. doi: 10.1186/s12302-024-01009-1

[96] Ortwin Renn (2021) New challenges for risk analysis: systemic risks, Journal of Risk Research, 24:1, 127-133, DOI: 10.1080/13669877.2020.1779787 doi: 10.1080/13669877.2020.1779787

152. Uncertainty affects how individuals make sense of regulatory problems and devise regulatory responses.[97] If there is no guidance, officials will resort to decisions that support industry applicants.

153. Officials have closer relationships with industry applicants than the general public. These industries will engage in legal contestation if they believe that their product is being obstructed by an ignorant regulatory authority. The average public is unlikely to engage in legal proceedings.

154. When dealing with systemic risks, four major components have been identified[98]:

a. *Complexity:* the difficulty of identifying and quantifying causal links between a multitude of potential elements and specific adverse effects.

b. *Uncertainty:* Uncertainty comprises different and distinct components such as statistical variation, measurement errors, ignorance and indeterminacy

c. *Ambiguity:* Ambiguity denotes the variability of (legitimate) interpretations based on identical observations or data assessments. Most of the scientific disputes in risk analysis do not refer to differences in methodology, data sets, algorithms, models or statistical procedures but to the question of what all this means for human health and environmental protection

d. *Ripple-Effects beyond the source of risk:* Another key characteristic that sets systemic risks apart from conventional risks is that their negative physical impacts (sometimes immediate and obvious, but often subtle and latent) have the potential to trigger severe ripple effects outside of the domain where the risk is located.

Table 1 Issues that source of uncertainty pose in the component parts of the pre-decisional stage of the regulatory development process for emerging technologies

Component parts of the pre-decisional stage	Types of uncertainties		
	State uncertainty	Effect uncertainty	Response uncertainty
Definition of policy problems	What opportunities and threats are posed by the emerging technology?	How does the emerging technology affect the role and performance of the regulators?	How does a regulatory response affect the impact of the emerging technology?
Scan of the alternatives	What can be done about the emerging technology?	What can the regulators do to cope with the impact of the emerging technology on their role and performance?	What can the regulators do to affect the impact of the emerging technology?
Appraisal of the options available	What is the most advantageous way to cope with the emerging technology?	Which is the most advantageous action for the regulators to cope with the emerging technology?	What is the most advantageous action for the regulators to affect the impact of emerging technology?

Asquer A and Krachkovskaya I. (2021) Uncertainty, institutions and regulatory responses to emerging technologies: CRISPR Gene editing in the US and the EU (2012–2019). Regulation & Governance (2021) 15, 1111–1127 doi:10.1111/rego.12335

[97] Asquer A and Krachkovskaya I. (2021) Uncertainty, institutions and regulatory responses to emerging technologies: CRISPR Gene editing in the US and the EU (2012–2019). *Regulation & Governance* (2021) 15, 1111–1127 doi:10.1111/rego.12335

[98] Ortwin Renn (2021) New challenges for risk analysis: systemic risks, Journal of Risk Research, 24:1, 127-133, DOI: 10.1080/13669877.2020.1779787 Page 128. doi: 10.1080/13669877.2020.1779787

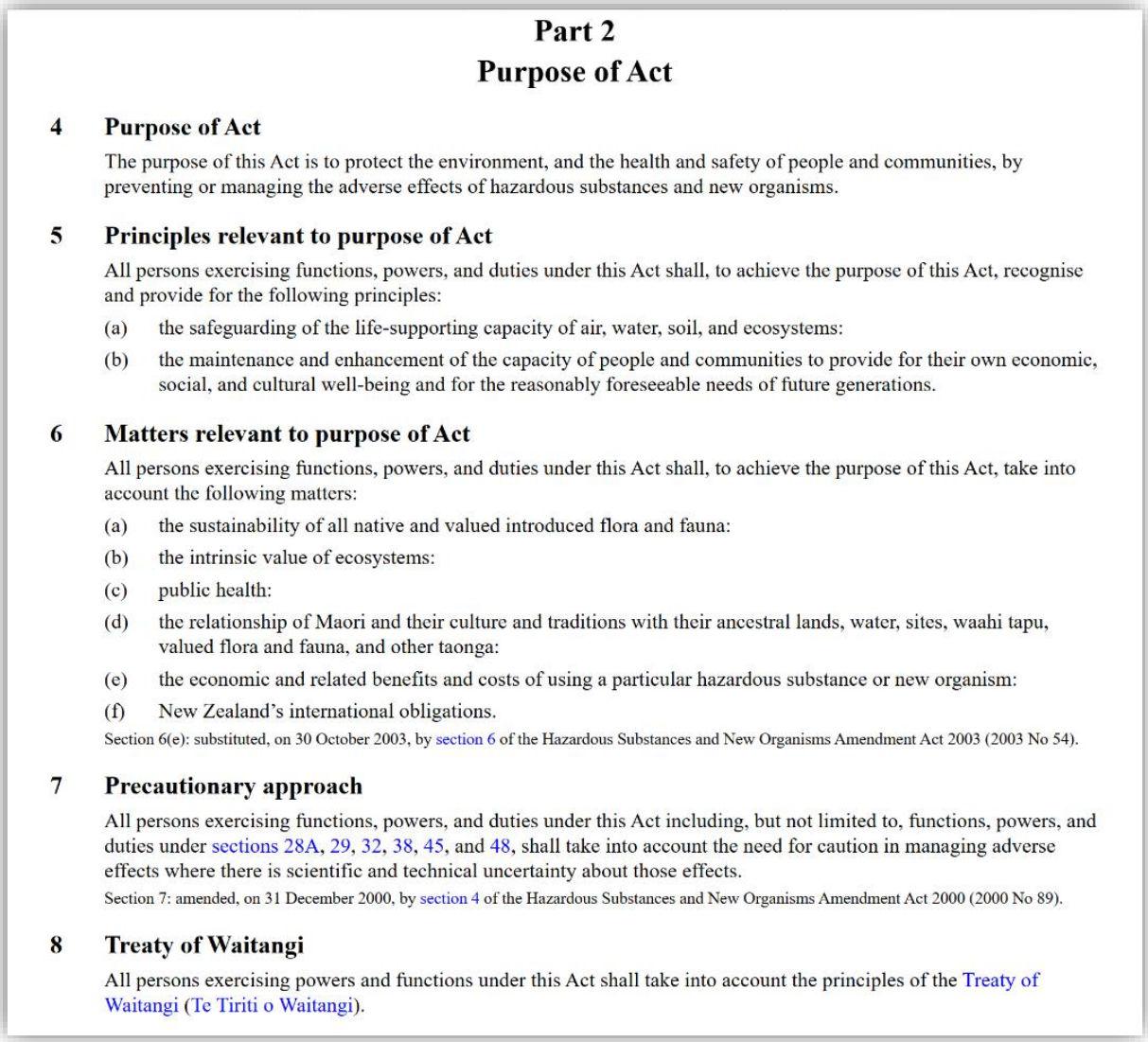
155. Uncertainties relating to changes in the technology itself (state uncertainty) the effect of the technology (challenges in predicting effects) and regulatory guidance for stewardship, mitigation and clean-up of contamination (response uncertainty) remain unstated.

156. The primary legislation lacks language as principles and expectations to assist officials to navigate event uncertainty, 'deep' uncertainty, and uncertainty relating to which parameters (and cut-offs) to include, including in modelling scenarios. It includes which uncertainties must be resolved and which are less key to ensuring that health and environment are protected.

157. Uncertainty must consider both short-term acute risks and long-term chronic and crescive (long term but often slow-moving) risks. There is no language to support regulatory scoping for either form of risk.

[D] PRECAUTIONARY APPROACH IS NOT OUTDATED (MBIE DOCUMENTS MISLEAD THE PUBLIC)

158. **The precautionary approach, embedded in the HSNO Act [s7] is an approach to assist with decision-making when scientific evidence of potential risk is plausible but uncertain.**



Part 2
Purpose of Act

4 Purpose of Act

The purpose of this Act is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms.

5 Principles relevant to purpose of Act

All persons exercising functions, powers, and duties under this Act shall, to achieve the purpose of this Act, recognise and provide for the following principles:

(a) the safeguarding of the life-supporting capacity of air, water, soil, and ecosystems:

(b) the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural well-being and for the reasonably foreseeable needs of future generations.

6 Matters relevant to purpose of Act

All persons exercising functions, powers, and duties under this Act shall, to achieve the purpose of this Act, take into account the following matters:

(a) the sustainability of all native and valued introduced flora and fauna:

(b) the intrinsic value of ecosystems:

(c) public health:

(d) the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga:

(e) the economic and related benefits and costs of using a particular hazardous substance or new organism:

(f) New Zealand's international obligations.

Section 6(e): substituted, on 30 October 2003, by section 6 of the Hazardous Substances and New Organisms Amendment Act 2003 (2003 No 54).

7 Precautionary approach

All persons exercising functions, powers, and duties under this Act including, but not limited to, functions, powers, and duties under sections 28A, 29, 32, 38, 45, and 48, shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

Section 7: amended, on 31 December 2000, by section 4 of the Hazardous Substances and New Organisms Amendment Act 2000 (2000 No 89).

8 Treaty of Waitangi

All persons exercising powers and functions under this Act shall take into account the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

159. MBIE appear to want to whitewash a known challenge that Regulators of human technologies face – complex, uncertain risks, including overlapping systemic risks that arise from interactions between technology and biology, and the role a precautionary approach can take – in the *public interest*. In the previous section, PSGR discussed the common problem of uncertainty, and the anxiety officials may have making decisions that are politically unpalatable to large corporations that will diligently protect their current and future financial bottom-line.

160. The precautionary principle, is embedded in the Cartagena Protocol, the Rio Declaration and European law. The decision to exclude the precautionary principle/a precautionary approach, appears to be a bureaucratic decision. This is evidence by MBIE official Simon Rae claiming that this is 'based on good regulatory practice'[99] – but where no explanation of how and why MBIE, who is not a regulatory agency, has come to this decision; and MBIEs decision (see points 7 and 21-27 above) to cite government white papers to claim a precautionary approach is out-dated, rather than evaluate regulatory principles and guidelines in best practice jurisdictions.

161. MBIE's RIS claims that 'a more precise and efficient application of the precautionary approach is warranted' claiming that this would be based on 'updated regulatory practices as knowledge and understanding of the risks and benefits of gene technology have accumulated.' However, this was not based on a justified review of international legislation or legal literature.

162. As we discuss above in Part II [A]: The out-of-date claim has not been backed up by any review of the global literature on risk assessment, and the role of purposes, guidelines and the precautionary principle. Instead MBIE chose to quote political policy papers from the OPMCSA in the Department of Prime Minister and the Royal Society, both organisations which have persistently adopted a pro-deregulatory stance; and then quote a New Zealand Government paper that repeated the Productivity Commissioner's comments.

163. The RIS states that 'the precautionary approach is appropriate where there are uncertainties about risks and the risks are likely irreversible' (36). This is the case for gene edited techniques and organisms. There are large uncertainties, government agencies are not attempting to fund or quantify risk so as to have a better understanding of risk.

164. The Precautionary Principle as stated by UNESCO (2005)[100]:

When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm. Morally unacceptable harm refers to harm to humans or the environment that is:

- *Threatening to human life or health; or*
- *Serious and effectively irreversible; or*
- *Inequitable to present or future generations; or*
- *Imposed without adequate consideration of the human rights of those affected.*

[99] MBIE June 18, 2024.Event Briefing. Meeting with the Environmental Protection Authority. https://psgr.org.nz/component/jdownloads/send/1-root/156-oia-request-2024-genetechregulator-mbie-nzepa

[100] UNESCO (2005). The Precautionary Principle. World Commission on the Ethics of Scientific Knowledge and Technology (COMEST). Document code: SHS.2005/WS/21 https://unesdoc.unesco.org/ark:/48223/pf0000139578

The judgement of plausibility should be grounded in scientific analysis. Analysis should be ongoing so that chosen actions are subject to review. Uncertainty may apply to, but need not be limited to, causality or the bounds of the possible harm.

Actions are interventions that are undertaken before harm occurs that seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences, and with an assessment of the moral implications of both action and inaction. The choice of action should be the result of a participatory process.

167. As the World Health Organization has noted:
'There is no contradiction between pursuing scientific progress and taking precautionary action. Indeed, applying precaution demands more rigorous science in order to characterize complex risks, clarify gaps in knowledge and identify early warnings and unintended consequences of actions. It also means using science not only for the diagnosis of environmental hazards but to identify, develop and assess safer alternatives to potentially harmful activities.'[101]

168. MBIE has substituted principles and ethics by inserting clause [5]. Clause 5, however only requires that officials operating under the Act must have *'regard for the provisions of'* the Convention on Biological Diversity and the Cartagena Protocol.

169. Legally, having 'regard for' does not place an obligation on officials to take a matter into account. Any thoughts about the Convention on Biological Diversity and the Cartagena Protocol may merely be considered and discarded.

170. In effect, officials would not be required (obligated) take precaution into account.

171. A requirement that officials take a precautionary approach is drafted into the Hazardous Substances and New Organisms Act 1996. Clauses 4-8 contains the purpose, principles, matters relevant and the Treaty of Waitangi, higher level considerations which are designed to guide Regulatory officials.

172. Genomic contamination in the environment would likely be irreversible. Gene flow into non-GMO species and ongoing heritability. This has been observed with herbicide tolerant (HT) varieties in the US, as HT contaminated non-GMO varieties, setting up a chain of tension between growers who did not want GMO contaminated food crops and who wanted to breed non-GMO varieties, and the GMO patent owners, who wished to assert rights relating to royalties.

[E] GENE TECHNOLOGY BILL TIES REGULATORS' HANDS AGAIN & AGAIN.

173. **Functions relating to Regulator practices and processes are vague, leaving the Regulator adrift.** The Regulator is exclusively required to keep abreast of international obligations, and to 'monitor international practice regarding the regulation of gene technologies'.

[101] World Health Organization. 2004 white paper: The precautionary principle: protecting public health, the environment and the future of our children. https://iris.who.int/bitstream/handle/10665/346211/9789289010986-eng.pdf?sequence=1

110 Functions of Regulator

The Regulator has the following functions:

(a) to perform the functions and duties and exercise the powers conferred or imposed on the Regulator under this Act or any other legislation:

(b) to advise the Minister on any matter relating to the Regulator's functions under this Act:

(c) if requested by the Minister, to provide technical advice to the Government on any matter related to the Regulator's functions under this Act:

(d) to contribute to and co-operate with international forums related to the Regulator's functions under this Act:

(e) to facilitate New Zealand's compliance with its international obligations under the Convention on Biological Diversity and the Cartagena Protocol:

(f) to monitor international practice regarding the regulation of gene technologies:

(g) to provide information and advice to the public about the regulation of gene technologies and regulated organisms.

174. State-of-the-art, best practice is not demanded.

a. There is no obligation to ensure that New Zealand's laws, rules and guidelines of GMOs, including gene edited organisms is *best practice* and that the Regulator and the enforcement and monitoring agency keep abreast of best practice – whether this is inside regulatory environments or published in the scientific and policy literature. There is no doubt that industry corporations keep abreast of best practice, however, this is not emphasised in regulatory documents. These gaps likely contribute to the failure of agencies to properly regulate GMOs.[102]

The Bill does not stipulate that the Regulator or that the enforcement agency should review scientific information to identify how 'best practice' might be evaluated, understood and achieved in a dynamic, highly technical environment that demands high levels of expertise.

b. The Bill requires New Zealand's Regulator to piggyback other Regulators and solely look at international practice already involved in regulation. However, as a food-export based economy our Regulator should have a mandate to actively enquire, and lead and investigate risks that could disproportionately impact New Zealand, for example, concerning contamination, of imported and developed inputs involved in dairy-processing.

c. *GE microbes in manufacturing facilities present a trade-based risk.*[103] For example, currently no authorisations are granted for genetically modified microorganisms (GMM) to enter the

[102] Persson L et al. (2022) Outside the Safe Operating Space of the Planetary Boundary for Novel Entities. Environmental Science & Technology 56 (3), 1510-1521 DOI: 10.1021/acs.est.1c04158

[103] D'aes J, Fraiture M, Bogaerts B, Van Laere Y et al (2025) Metagenomics-based tracing of genetically modified microorganism contaminations in commercial fermentation products. *Food Chemistry: Molecular Sciences*. 10:100236. Doi: 10.1016/j.fochms.2024.100236

European food chain. While a GMM may be used to generate a fermentation product, it must be absent from the final consumer product. New Zealand's Regulator would have no capacity to advise, for example, the dairy industry on GMM contamination risks that originate in the production environment.

d. A big problem concerns anticipatory risk. Not knowing what to look for. An ignorant Regulator would not demand specific assays (screens) from input suppliers to ensure their sources were not pre-contaminated. If the industry wasn't aware of this risk, they also wouldn't screen for problems which could include gene edited antimicrobial genes and pathogenic species. The problem could extend to gene escape from gene edited antimicrobial genes in future production lots from insufficiently sanitised environments.

175. The Bill text fails to recognise newer forms of risk assessment frameworks that might bring a complex systems approach to assessment, which might also accord with Treaty of Waitangi principles. New concepts relating to resilience engineering, which would bring older more linear risk assessment processes, based on causal chains, event analysis, failure reporting and calculating historical data-based probabilities, have not been integrated into the Bill text.[104]

risk assessment, in relation to an activity, means a document that—

(a) identifies any relevant risks of the activity; and

(b) assesses the likelihood of harm occurring as a result of the risks; and

(c) assesses the likely degree of harm occurring as a result of the risks; and

(d) identifies any material adverse effect on a kaitiaki relationship that may result from an environmental risk posed by the activity; and

(e) contains any information prescribed by regulations

176. **The Bill writes out a long-established role: that Regulators must balance benefits with risks.** No requirement nor guidance for cost-benefit analyses as part of the risk assessment process, is drafted into the text.

177. There is no requirement that risk assessment comply with best global regulatory practices.

a. There is no explicit capacity drafted into the Bill text to resource the regulator to keep abreast of new scientifically and legally-relevant information. This would include a capacity to review global court decisions and the scientific literature to assess the changing understanding of risk from gene editing techniques and gene edited organisms.

b. Laboratory or containment biosecurity risk has not been included within the obligations of the regulator. Early New Zealand outdoor trials were plagued with containment issues.[105] Laboratory spills produce containment risks[106].

[104] Aven T. (2016). Invited Review Risk assessment and risk management: Review of recent advances on their foundation. *European Journal of Operational Research*, 253;1:1-13. doi: 10.1016/j.ejor.2015.12.023

[105] Bleakley, C. GE Animals in New Zealand. The First Fifteen Years. GE Free NZ. https://www.gefree.org.nz/assets/pdf/GE-Animals-in-New-Zealand.pdf

[106] Nasrallah IM, El Kak AK, Ismaiil LA, Nasr RR, Bawab WT. Prevalence of Accident Occurrence Among Scientific Laboratory Workers of the Public University in Lebanon and the Impact of Safety Measures. Saf Health Work. 2022 Feb 19;13(2):155–162. doi: 10.1016/j.shaw.2022.02.001

c. The Regulator may only be required to recognise offshore Gene Technology Regulators if they operate within a comparable legislative framework. If other regulators detect risk that use a different framework approach, including more up-to-date practices, they can be ignored.

178. **The Regulator's information sources are narrowly specified**. The Regulator may only source information from a specified group of individuals and organisations:

'In making its decisions on declarations, licences, and conditions, the Regulator will take expert advice from the Technical Advisory Committee and may seek advice from the Māori Advisory Committee where an activity may have a material adverse effect on Māori kaitiaki relationships with indigenous species. The Regulator may also seek and receive advice from other agencies.'

179. **The Technical Advisory Committee are not in a position to actively review scope for new information.** The Committee are reliant on the Regulator to request advice and are not charged with the independent autonomy to review and scope for risk.

a. The Bill, Subpart 3— Technical Advisory Committee specifies that the EPA will provide administrative support. The Technical Advisory Committee do not have a mandate to consider scientific information and risk more broadly than the Regulator stipulates, when asking for advice.

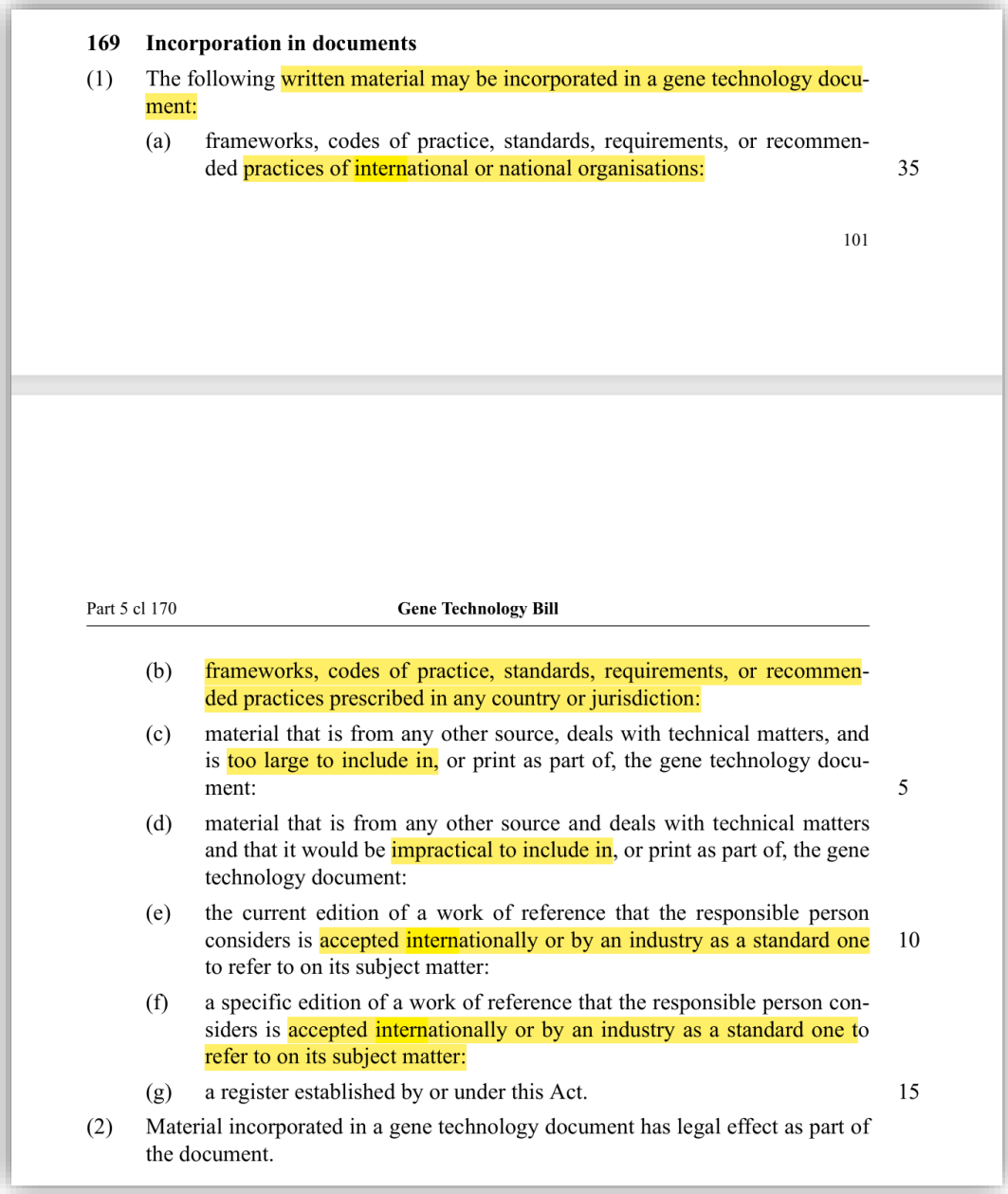
b. The current terms of reference, funding, and estimation of time required to fulfil the current Technical Advisory Group's duties as advisors to MBIE and the Gene Technology Bill policy and text, constrains the group from effectively performing their role. Their scope, resources and time commitment is overly restrictive. As such this group have been prevented from scrutinising risk to an extent demanded by such a deregulatory effort. [107]

180. **Significant new information.** Gene technology is regulated by 'requiring a risk assessment or risk management plan to be prepared for all authorisations except emergency authorisations, and in response to significant new information received' [6(b)(iv)]. However, the regulator is not required to prepare a risk assessment and risk management plan for public consultation unless 'the Regulator has not become aware of any significant new information in relation to the relevant risks of that activity'.[28(2)(a)(ii)] and [30].

181. **The Regulator appears exclusively dependent on other Regulators and the 'licence holder' for 'significant new information.** 'The licence holder must notify the Regulator and the enforcement agency in writing within 10 working days of becoming aware of any significant new information about the relevant risks of an activity' [37(1)(d)].

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

182. **Clause [169] shows how published information must be limited to pre-ordained, uncontroversial, standardised information.** Information that would contradict a status quo is likely to be ruled out of scope. The text in (c) and (d) is confusing, but suggests that material from other sources may be excluded.



169 Incorporation in documents

(1) The following written material may be incorporated in a gene technology document:

(a) frameworks, codes of practice, standards, requirements, or recommended practices of international or national organisations:

101

Part 5 cl 170 **Gene Technology Bill**

(b) frameworks, codes of practice, standards, requirements, or recommended practices prescribed in any country or jurisdiction:

(c) material that is from any other source, deals with technical matters, and is too large to include in, or print as part of, the gene technology document:

(d) material that is from any other source and deals with technical matters and that it would be impractical to include in, or print as part of, the gene technology document:

(e) the current edition of a work of reference that the responsible person considers is accepted internationally or by an industry as a standard one to refer to on its subject matter:

(f) a specific edition of a work of reference that the responsible person considers is accepted internationally or by an industry as a standard one to refer to on its subject matter:

(g) a register established by or under this Act.

(2) Material incorporated in a gene technology document has legal effect as part of the document.

183. Neither the policy documents nor the Bill conceptualises what might constitute risk over the longer term. The *risk concept* is not defined, nor are principles relating to future classification drafted, and so remain unmeasurable. What forms of risk must the regulator consider? How does the regulator quantify or model risk?

184. **Regulators are fire-walled against information if the legislative scope prevents active enquiry, and unless industry applicants/licence holders supply the information.** The deliberate vagueness drafted into the Bill text, the absence of scoping powers and the absence of any requirement for continuous improvement aligned with best practice based on new scientific evidence, creates a merry-go-round where all collegial Regulators, practicing the same techniques are fire-walled against new information. As a result, new risks are not identified unless pre-ordained by industry (as

industry essentially streams what is considered 'new information' to regulatory agencies. This reduces the likelihood regulators will place controls or bans on the product or its emissions.

185. The Regulator cannot keep abreast of new risk-based scenarios which could constitute 'significant new information'. The Regulator cannot address risk at scale, although it is probable that an increasing proportion of organisms will be deployed into the (deregulated) environment

a. *The problem of risk at scale:* Intellectual property rights protections are stronger for gene edited organisms than naturally bred organisms. This increases the likelihood of use and deployment. It also increases the probability that undetected harms could be amplified as release scales up.[108]

b. *How is emerging risk assessed?* There is increasing evidence that outbreaks have occurred during the process of laboratory-based operations involving infectious bacteria and viruses, which generally involve the genetic modification or editing of organisms.

c. No provisions for education and training to update regulatory officials' knowledge as both gene editing technologies, techniques and their products become more complex, on new methods for quantification of risk are established and new pathways of risk are defined.

d. Potential risk scenarios that at this stage, could not be freely considered by the Gene Technology Regulator:

   Risk to the genome, risk to fertility, risk as DNA contamination occurs in off-target organisms who might have similar genetic pathways. Risk to off-target organisms which might predate on an effected organism which has been altered. Risk of uncontrolled escape. Risk of disrupting high quality breeding stock and risk of the emergence of new diseases due to genomic instability. Risk to New Zealand's food quality reputation. Risk to supply offshore chains which not only demand transparency but prohibit certain GMOs in food that New Zealand has not regulated and prohibited. Risk as economic loss from a deregulated environment that ultimately downgrades New Zealand's reputation as a high-quality food producer.

186. There is a history of regulatory agencies closing their minds to new information unless it is exclusively supplied by either a collegial regulatory agency, or an industry applicant. Agency capture is to be expected when regulators are under-resourced and their powers are constrained.

a. The example of pesticides regulation in New Zealand demonstrates that regulatory agencies will refuse to recognise 'significant new information' unless it has been supplied directly by another Regulator, or by an industry applicant.

b. In the case of the herbicide glyphosate, New Zealand's Environmental Protection Authority (EPA) has resisted carrying out a risk assessment, claiming no significant new information, despite a major finding by the International Agency for Research on Cancer that glyphosate is a probable carcinogen, and following court proceedings where court proceedings disclosed that the applicant understood that dermal exposures on applicators were more persistent, and increased exposure levels, and that this information had not been disclosed to the Regulator. United States court proceedings have consistently found in favour of applicants, yet their decisions and the evidence disclosed has been ignored by New Zealand's EPA.

[108] Heinemann J. (2021). Submission on Proposal P1055 Definitions of Gene Technology. https://hdl.handle.net/10092/103141

c. The Gene Technology Bill replicates that terminology: Significant new information.

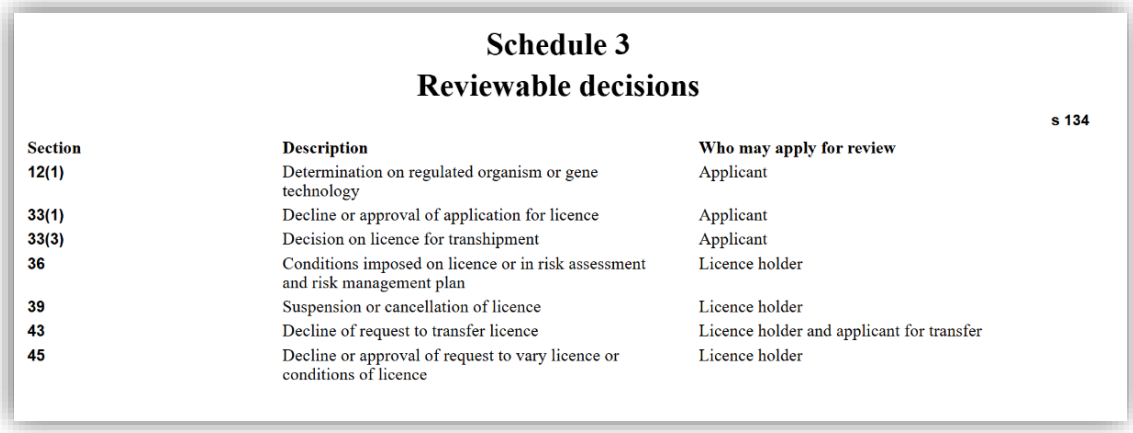
d. The public is increasingly aware that court action is necessary to remedy regulatory reluctance when it comes to skirting risk assessment. A judge in the United States recently determined that the U.S. EPA failed to follow its own risk assessment guidelines in relation to fluoride.[109] In New Zealand, litigators are challenging the New Zealand EPA's claim that grounds for reassessment of glyphosate do not exist.[110]

187. The captured Regulator will be unlikely to identify 'significant new information'. The regulator is not obliged to review global court decisions and the scientific literature and publish findings, the regulator can claim that they are not aware of any significant new information. This is a well-worn pattern of regulators who, not obliged to regularly undertake and publish reviews of information on risk of the technologies that they regulate will then not be aware of significant new information.

a. Significant new information: If offshore regulators have also failed to consider new information the Regulator will not have to consult on draft risk assessment and draft risk management plan for a licensed activity.

188. Only applicants and licence holders will have a right to request that the Regulator review certain licence decisions. The general public will have no such right.

a. Schedule 3 actively prevents the public from applying for reviews of decisions made by the Regulator.



Schedule 3
Reviewable decisions

s 134

Section	Description	Who may apply for review
12(1)	Determination on regulated organism or gene technology	Applicant
33(1)	Decline or approval of application for licence	Applicant
33(3)	Decision on licence for transhipment	Applicant
36	Conditions imposed on licence or in risk assessment and risk management plan	Licence holder
39	Suspension or cancellation of licence	Licence holder
43	Decline of request to transfer licence	Licence holder and applicant for transfer
45	Decline or approval of request to vary licence or conditions of licence	Licence holder

b. A right of appeal to the High Court is only for parties 'directly' affected by a decision. How does this impact the general public who may be affected by a decision, but cannot claim to be 'directly' affected?

189. Judith Collins as then-Minister for science, innovation and technology had ample opportunity to establish funding opportunities for scientists to independently undertake research to identify gaps and risks in policy and regulation claims and feedback into the regulatory environment. This was not done.

190. Protection from civil and criminal liability must be more fully understood.

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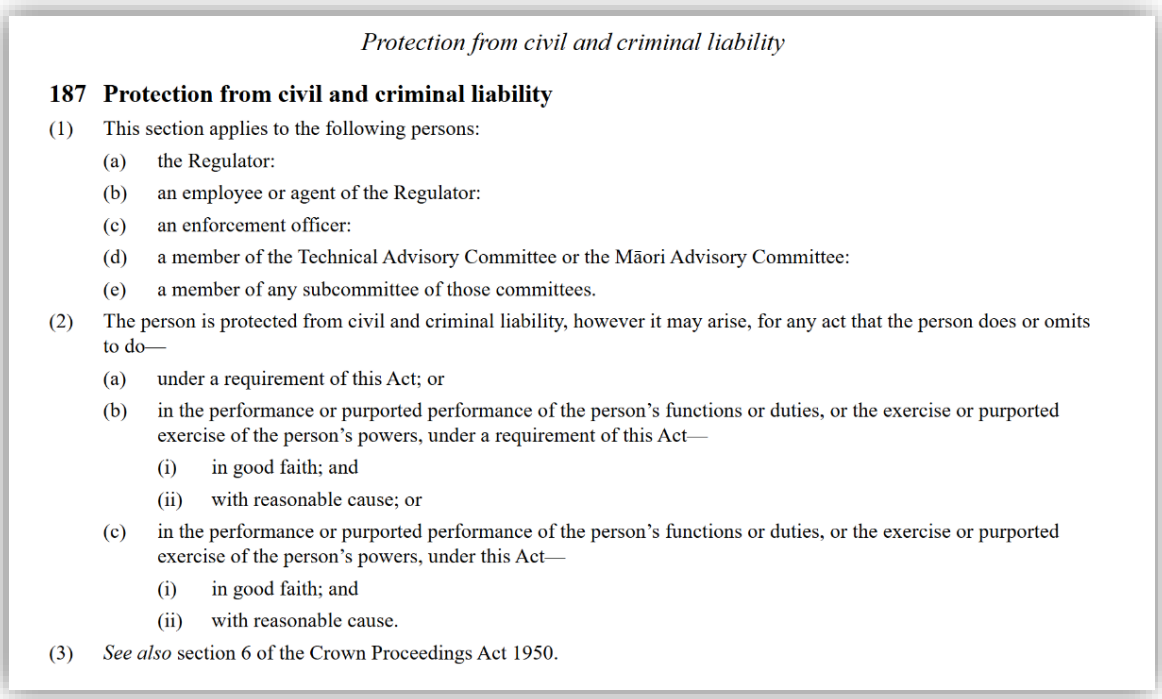
[109] Food & Water Watch, Inc., et al., (plaintiffs) *v.* United States Environmental Protections Agency, et al. (defendants). United States District Court. Northern District of California. Case 3:17-cv-02162-EMC. Judge Edward M. Chen. https://psgr.org.nz/component/jdownloads/send/1-root/150-food-and-water-watch-v-usepa-fluoridated-drinking-water-chen-decision

[110] Environmental Law Initiative (February, 2025). Challenging the EPA's regulatory failure on glyphosate ELI v Environmental Protection Authorityhttps://www.eli.org.nz/cases/glyphosate

a. This must be more clearly understood by the public. PSGR accepts and understands that there is a need for regulatory agencies to be protected from litigious corporations who will seek to defend their products from regulation that has potential to adversely affect their financial bottom-line. However, it appears that the text here is more likely to create barriers to public action if the regulator is deficient in carrying out its duties, particularly in light of the narrow terms specified above, which restrict how the regulator may source information and carry out risk assessment.



Protection from civil and criminal liability

187 Protection from civil and criminal liability

(1) This section applies to the following persons:

- (a) the Regulator:
- (b) an employee or agent of the Regulator:
- (c) an enforcement officer:
- (d) a member of the Technical Advisory Committee or the Māori Advisory Committee:
- (e) a member of any subcommittee of those committees.

(2) The person is protected from civil and criminal liability, however it may arise, for any act that the person does or omits to do—

- (a) under a requirement of this Act; or
- (b) in the performance or purported performance of the person's functions or duties, or the exercise or purported exercise of the person's powers, under a requirement of this Act—
  - (i) in good faith; and
  - (ii) with reasonable cause; or
- (c) in the performance or purported performance of the person's functions or duties, or the exercise or purported exercise of the person's powers, under this Act—
  - (i) in good faith; and
  - (ii) with reasonable cause.

(3) *See also* section 6 of the Crown Proceedings Act 1950.

191. **Remove [59(3)] Official Information Act request exemption.** Delete/reject Clause [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.*'

a. Advice provided by the Regulator to the industry applicant on what information to include in the license must not be determined as outside the Official Information Act. This is because there is a potential for undue influence to be exerted, either to assist applicants in evading certain requirements, or to influence Regulators to act improperly.

192. **Withholding of information [60].** Provision that information can be withheld if it relates to a National Security Risk must contain a caveat that contamination of agricultural exports and New Zealand grown food by a gene technology cannot be considered a National Security Risk as the greater public interest requires that this information must be disclosed at all times.

a. Confidential (protection) of information provisions must not extend where there is an emergency authorisation and the technology is being fast tracked, to secrecy relating to the general mode of action of an innovative medicine and the synthetic ingredients that facilitate entry into human bodies.

[F] A TROJAN HORSE FOR ERODING SOVEREIGNTY? BEING LEGALLY BOUND TO DECISIONS BY OFFSHORE JURISDICTIONS.

193. **The Gene Technology Bill in at least two sections undermines national sovereignty by improperly delegating authority to foreign jurisdictions.** The following sections should be immediately ruled as unconstitutional and *ultra vires* (beyond the powers). They must not be included in any gene technology regulatory legislation:

a. Subpart 5 – Mandatory medical authorisations.

b. 163(4)(c) – Where New Zealand accepts decisions made under the Australian Gene Technology Regulations 2001 (expressed in Schedules 1A and 1).[111]

194. The Regulatory Impact Statement does not refer to either Mandatory medical authorisations or to the plan to insert clauses that create automatic exemptions that are directly linked Australian regulations.

195. The purpose of the Bill 'is to enable the safe use of gene technology by managing their risks to the health and safety of people' [3(a) yet the Regulator is mandated to accept foreign decisions automatically no matter the quality of regulatory assessment and the safety profile.

a. The health and safety of the environment and of humans, as per the purpose of the Act, have been over-ridden as there is no legislative requirement to assess hazards and exposures in relation to New Zealand human and environmental health.

b. Human rights considerations are over-ridden, as is the principle of informed consent.

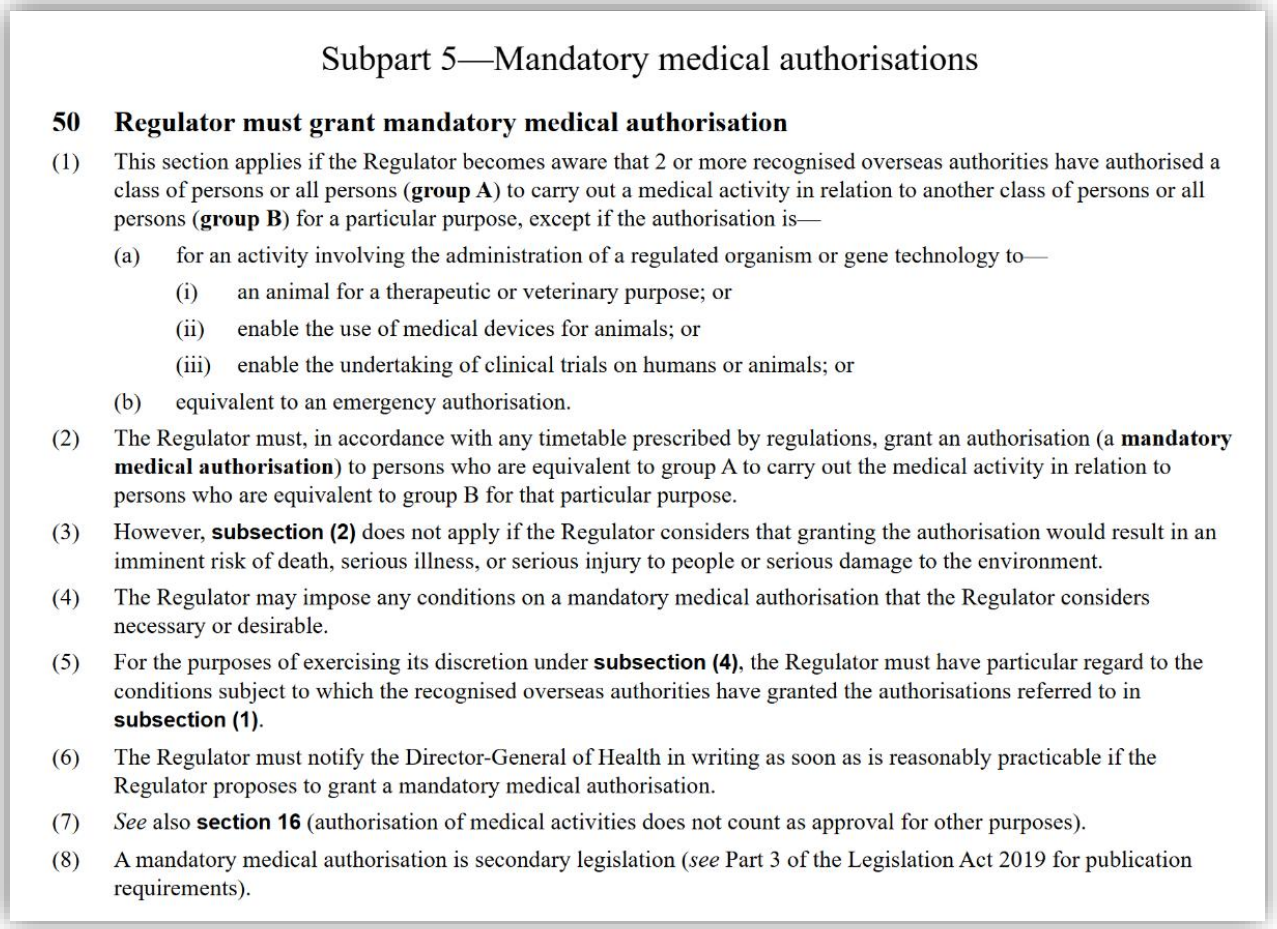
c. The Treaty of Waitangi is ignored.

d. Bioethics is ignored. A mandatory medical authorisation (MMA) implicitly throws vulnerable populations including pregnant women and the frail and elderly and healthy populations under 'the same bus'. Deference to Australia over-rides any impact on New Zealand flora and fauna.

[111] https://www.legislation.gov.au/F2001B00162/latest/text

(i) Undermining national sovereignty: Subpart 5 – Mandatory medical authorisation.

196. It can never be assumed that a foreign, offshore decision is appropriate for *all* New Zealand people, particularly when it concerns a potential breach of human rights, as mandated medical therapeutic.



Subpart 5—Mandatory medical authorisations

50 Regulator must grant mandatory medical authorisation

(1) This section applies if the Regulator becomes aware that 2 or more recognised overseas authorities have authorised a class of persons or all persons (**group A**) to carry out a medical activity in relation to another class of persons or all persons (**group B**) for a particular purpose, except if the authorisation is—

(a) for an activity involving the administration of a regulated organism or gene technology to—

(i) an animal for a therapeutic or veterinary purpose; or

(ii) enable the use of medical devices for animals; or

(iii) enable the undertaking of clinical trials on humans or animals; or

(b) equivalent to an emergency authorisation.

(2) The Regulator must, in accordance with any timetable prescribed by regulations, grant an authorisation (a **mandatory medical authorisation**) to persons who are equivalent to group A to carry out the medical activity in relation to persons who are equivalent to group B for that particular purpose.

(3) However, **subsection (2)** does not apply if the Regulator considers that granting the authorisation would result in an imminent risk of death, serious illness, or serious injury to people or serious damage to the environment.

(4) The Regulator may impose any conditions on a mandatory medical authorisation that the Regulator considers necessary or desirable.

(5) For the purposes of exercising its discretion under **subsection (4)**, the Regulator must have particular regard to the conditions subject to which the recognised overseas authorities have granted the authorisations referred to in **subsection (1)**.

(6) The Regulator must notify the Director-General of Health in writing as soon as is reasonably practicable if the Regulator proposes to grant a mandatory medical authorisation.

(7) *See* also **section 16** (authorisation of medical activities does not count as approval for other purposes).

(8) A mandatory medical authorisation is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

197. **There is no requirement drafted into the legislation that the mandatory medical authorisation (MMA) must prevent severe illness or hospitalisation and death by age and health status.** Virulence or pathogenicity of a virus or bacteria, of itself, should not be conflated to confer powers to mandate a medicine to groups of people.

198. 'Mandatory medical authorisation' (MMA) creates extraordinary potential for abuse and harm as any medical intervention demands assessment of individual risk and benefit. The Regulator is not a public health expert and is not tasked to evaluate risk and benefit. The Regulator has no independent powers nor resourcing to undertake broad-ranging investigations, including to review the scientific literature to understand and evaluate a public health risk that would necessitate any public health intervention.

a. **Clause [50] is antidemocratic and fails the sovereignty test as it is not elective but compulsory, and 'requires' that New Zealand authorities '*grant a mandatory medical authorisation*'.**

b. **Clause [50] is antithetical to the Health Act 1956 as there is no capacity to require that the regulator take steps to protect health, i.e. to understand health risk by age, health status and developmental status.**

c. The Bill of Rights Act is not required to be considered.

d. A *mandatory medical authorisation* (MMA) fails to require regulators and officials to take into account locally relevant public health considerations which may result in there not being a risk in New Zealand. This risk would not be sufficiently onerous to permit the deployment of a genetic technology into mammals including humans. This includes seasonality, health status and other interventions which may pose less risk.

e. Existing interventions (including medical and nutritional) that present less risk by age and health status are not required to be considered.

199. Clause [50] is unethical and immoral as there must be a weight of evidence of harm before the Regulator can act to reject the MMA.

'*death, serious illness, or serious injury to people or serious damage to the environment'* for the regulator to deny the MMA.

a. The Regulator lacks the relevant expertise, powers and resourcing to seriously evaluate the published literature to assess whether the authorisation would unduly harm people or the environment.

b. Chronic health conditions as a result of treatment may not be taken into account. This includes (but is not limited to) inflammatory responses, allergies, and fatigue.

200. The *mandatory medical authorisation* (MMA)appears to apply to entire classes of persons, and the precedent of COVID-19 suggests that the government is prepared to over-ride existing processes and laws to mandate genetic therapeutics at the population level, regardless of individual risk or benefit.

201. This extraordinary Subpart 5 may be the reasoning the Health Select Committee is strangely tasked with reviewing public comments on this Bill.

202. Much of the '*mandatory medical authorisation'* (MMA) process can be carried out as secondary legislation and bypass Parliamentary process, and be difficult for the public to identify and understand.

'A mandatory medical authorisation is secondary legislation (see Part 3 of the Legislation Act 2019 for publication requirements).' [50(8)]

203. Mandates carried out using secondary legislation create demonstrated potential for abuse of power, as Cabinet, in approving secondary legislation for mandates have refused to consider individual risk-benefit of therapeutics. During COVID-19 mandates were rolled out under secondary legislation without any review of individual risk and benefit in relation to the pathogenicity of the virus and the immediate risk of extreme illness or hospitalisation and death.

204. [6(b)(viii)] pretends that 'regulating' includes demanding that the Regulator grant mandatory medical authorisations (MMA), when the automatic approval is instead, a rubber stamping process.

205. Clause [51] requires a high bar of evidence to revoke a '*mandatory medical authorisation'.* This would only apply if 'the relevant criteria no longer apply' or if necessary to avoid an imminent risk of death/illness/injury.

206. The Trojan-horsing of medical mandates (rather than providing the New Zealand regulator with a choice) into this legislation must be closely investigated [Subpart 5].

207. MBIE has conflicts of interest and has publicly downplayed the extent of MBIE's early-stage role in purchase arrangements of Pfizer's BNT162b2 gene therapy – a technology which unlike any prior

vaccine would cross the cell membrane, introducing an entirely new class of risks.[112] MBIE was party to the Pfizer contract, which still has not been disclosed to the New Zealand people. The scientific literature contains thousands of studies on risk, and MBIE have taken no active role to understand, assess and evaluate this, despite overseeing the New Zealand science and research budget.

208. New Zealand authorities did not scrutinise the peer reviewed literature on risk[113] during the pandemic and afterwards. Authorities ignored the ethics of socially and financially pressuring the generally healthy public to accept the technology, while creating manifold barriers to financial compensation for people injured by the BNT162b2 injection.

209. Biologic drugs which are developed using gene editing techniques are plagued by contamination risk.[114] Manufacturers have skirted this problem by utilising a differently manufactured product for premarket assessment, including for drug trials, than used in end-stage processing for consumer use. COVID-19 drugs which instruct human cells to reproduce mRNA evaded carcinogenicity and mutagenicity trials. Claims that the mRNA would remain localised and would not persist have been found to be untrue.

(ii) Undermining national sovereignty: Deferring to Australian regulations [163(4)(c)].

210. No risk framework can be applied when New Zealand automatically – in clause [163] that is hidden low in the Bill, cedes decision-making to the Australian Gene Technology Regulator.

211. RIS mentions aligning regulations with the Australian Gene Technology Act but does not discuss that the Bill would directly link to Australian law by exempting organisms and techniques that are exempted in the Australian Gene Technology Regulations.

212. The RIS never evaluated whether piggybacking Australian gene technology regulations is best practice, or whether Australian legislation harmonises with New Zealand's key export markets.

213. Proxying regulation through Australia. The Gene Technology Regulations 2001

a. Schedule 1A - Techniques that are not gene technology.[115]

[112] Gene therapy needs a long-term approach. Nat Med 27, 563 (2021). https://doi.org/10.1038/s41591-021-01333-6
[113] Igyarto, BZ and Qin Z (2024) The mRNA-LNP vaccines – the good, the bad and the ugly? *Front. Immunol*. 15:1336906. doi: 10.3389/fimmu.2024.1336906
[114] Janghorban, M., Kazemi, S., Tormon, R., Ngaju, P., & Pandey, R. (2023). Methods and Analysis of Biological Contaminants in the Biomanufacturing Industry. *Chemosensors,* 11(5), 298. https://doi.org/10.3390/chemosensors11050298
[115] Gene Technology Regulations 2001 Statutory Rules No. 106, 2001 made under the Gene Technology Act 2000. *Schedule 1A Techniques that are not gene technology.* https://www.legislation.gov.au/F2001B00162/2024-10-14/2024-10-14/text/original/epub/OEBPS/document_1/document_1.html#_Toc180417624

b. Schedule 1 – Organisms that are not genetically modified organisms.[116]

163 Power to make further exemptions from operation of Act and non-regulated activities

(1) Regulations may be made under **section 155(1)(a)** exempting from the operation of this Act—

(a) organisms or categories of organisms specified in the regulations:

(b) gene-editing techniques or gene technology specified in the regulations.

(2) The Minister must not recommend the making of regulations—

(a) referred to **subsection (1)(a)**, in the case of an organism or a category or organisms, unless the organism or category of organisms cannot be distinguished from organisms or categories of organisms created through conventional processes:

(b) referred to **subsection (1)(b)** unless the Minister is satisfied that the gene-editing technique or gene technology in question creates no more than a minimal level of risk to the health and safety of people or the environment.

(3) Regulations made under **section 155(1)(a)** may empower the Regulator to—

(a) impose conditions on any exemption:

(b) amend or revoke an exemption in any specified circumstances.

(4) The following are not regulated by this Act:

(a) things that are determined under section 26 of the Hazardous Substances and New Organisms Act 1996 not to be genetically modified organisms:

(b) gene technology to which the Hazardous Substances and New Organisms Act 1996 does not apply, being gene technology used in respect of organisms listed in the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998:

(c) any of the following:

(i) organisms specified in Schedule 1 of the Gene Technology Regulations 2001 (Aust):

(ii) techniques specified in Schedule 1A of the Gene Technology Regulations 2001 (Aust).

[G] OMISSION: EMERGENCY AUTHORISATION DECISIONS BLACKBOXED

214. **Emergency Authorisations, Subpart 6.** The Bill states that the Minister can grant an emergency authorisation if there is 'an actual or imminent threat to the health and safety of people or the

[116] Gene Technology Regulations 2001 Statutory Rules No. 106, 2001 made under the Gene Technology Act 2000. *Schedule 1 – Organisms that are not genetically modified organisms*. https://www.legislation.gov.au/F2001B00162/2024-10-14/2024-10-14/text/original/epub/OEBPS/document_1/document_1.html#_Toc180417627

environment' [52(1)(a)(i) and if the Regulator confirms 'that the threat is likely to outweigh any relevant risks of the activity, having regard to certain factors.'

215. The Bill is not transparent nor accountable and creates undue potential for abuse of power.

216. The Minister is not required to publicly publish the information that the Minister [52(1)(a)] has used as the basis for decision-making. The Minister is not required to source opinions from other sources that might contradict the advice 'from a relevant Minister'.

217. The Regulator can claim that it 'is satisfied, that the actual or imminent threat is likely to outweigh any relevant risks of the activity' [52(1)(b)]. However, as described earlier, the Regulator lacks powers of independent enquiry. This arises from the TAG's limited scope and the restrictions on the Regulator where it must only seek advice from other regulatory agencies. This leaves the Regulator with insufficient skills and resources, nor sufficient public-interest powers in the primary act to direct its assessment of whether threats will outweigh relevant risks to benefit the people and environment of New Zealand.

218. The Emergency Authorisation process should not be permitted, as it can be opaquely carried out as secondary legislation and bypass Parliamentary process, and subvert democratic norms of transparency and accountability.

END.

INDEX

EC	European Commission.
EU	European Union.
GMO	Genetically Modified Organism.
HSNO	Hazardous Substances and New Organisms Act 1996.
INBI	Centre for Integrated Research in Biosafety, University of Canterbury.
MBIE	Ministry for Business, Innovation and Science.
MMA	Mandatory Medical Authorisation.
NZEPA	New Zealand Environmental Protection Authority.
OPMCSA	Office of the Prime Minister and Cabinets' Chief Science Advisor.
PSGR	Physicians and Scientist for Global Responsibility, New Zealand Charitable Trust.
RIS	Regulatory Impact Statement.
TAC	Technical Advisory Committee (for the new regulatory agency).
TAG	Technical Advisory Group (for the policy to support the Gene Technology Bill).
US EPA	United States Environmental Protection Agency.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PSGR New Zealand have
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service of the public's right to be
independently informed on issues
relating to human &
environmental
health.