PSGR

New Zealand Charitable Trust

March 14th, 2025. Gene Technology Bill 2024.

TRANSCRIPT. Oral presentation to the Health Subcommittee

Subcommittee members present: Dr Hamish Campbell, Dr Deborah Russell.

JR Bruning on behalf of the Physicians and Scientists for Global Responsibility (PSGR) (2:30:00-2:40:00).

Good morning Chair, thank you for this opportunity to present to the Health Select Committee. My name is Jodie Bruning, I'm a trustee for the PSGR. PSGR were established in 1999, and became a charity nearly 20 years ago. We research and educate the public on risk-related issues relating to science, medicine and technology, including genetic engineering and biotechnology.

The Health Committee have been listening to CRI scientists, Sir Peter Gluckman, biotech lobbyists, and public and private sector groups with investments in gene editing research.[1] A common call is to follow the science; to support a 'tiered science-based framework' which is 'risk proportionate'. They want the regulator to be evidence based, and use the best available science. They assure MPs that this is a 'Serious question of science – getting this Bill right depends on the underlying facts.'

PSGR's substantive 50-page submission[2] clearly outlines the conundrum – or *fact*s that MPs face - because no evaluation of scientific risk has occurred – there is no robust scientific evidence base to draw from. These scientists have not informed you that the Royal Society's 2016-2019 work revolved around the benefits of newer gene editing techniques and organisms.

The Royal Society was not tasked to assess risks of newer gene editing techniques and organisms.[3] No evaluation of the appropriateness of Australia's exemptions - and whether this has stood the test of time has been conducted.

MBIE have not evaluated risk from the gene editing techniques and organisms that they risk tier *outside* the legislation. That's not **risk** tiering. That's socialising any risks outside of regulatory control.

MPs, there is no scientifically robust 'evidence base' for this regulatory legislation.

Policy development and the Regulatory Impact statement (RIS)[4] reveal gaping deficiencies in the policy and Bill text.

No economic analysis has occurred, despite economic growth being a key predicator for completely new legislation. Stunningly, and failing regulatory protocol, no cost-benefit analysis has occurred.

Despite 3 decades of investment in gene editing research and commercialisation, no return on investment analysis has ever taken place.

Professor emeritus Jane Kelsey tried to inform MPs, and highlighted the predefined scope – the RIS problem definition placed deregulation, not risk and stewardship as the key 'problem' to solve.[5] This definition excluded the key issue of risk management to protect the health and safety of people and environment.[6]

By February 2024 MBIE had – fully aware of the potential public interest – deliberately written out public engagement. MBIE then handpicked the technical advisory group and the stakeholders for advice and consultation. The Productivity Commissioner had earlier suggested wide-ranging public consultation to inform legislative processes. This was ignored. MBIEs consultation favoured MBIE funded scientists and organisations, or organisations involved in public private partnerships with MBIE funded scientists.

By February 2024 MBIE had decided that any choice to select the status quo, of retaining the HSNO Act would be removed from consultation. Reasoning for this came from the 'Harnessing Biotech' manifesto which quoted the Royal Society.[7] The MBIE funded Royal Society's legal and regulatory recommendations read more like an industry wish-list.[8] We repeat, the RS over 2016-2019 was never funded to assess risk, but simply to look at opportunities.

Do MPs know that the majority of TAG 'experts' have insufficient expertise or independence to navigate regulatory processes and the public interest? Their role and their 3 hour per month workload was largely decorative. An OIA request on the precautionary principle showed that MBIE controlled the information and that the TAG did not challenge MBIE's assertions.[9]

The RIS claims ethics and precautionary concerns are outdated – have you seen their evaluation of European legislation? No. RIS claims mislead you – no evaluation was ever undertaken in a global context.

So-called 'out-of-date' provisions play an important role in dealing with complexity, uncertainty, ambiguity and ripple effects – the grey areas that MBIE is pretending don't exist, but that are confronted by every regulatory agency in the world.

The Bill before you fails in many ways: It places certain classes of techniques and organisms outside regulation. The legislative framework neglects to specify a requirement for hazard and exposure assessments to characterise overall risk. The primary legislation would straitjacket the regulator from active enquiry into risk and harm, including to reassess the exempted categories and it would also legally bind the regulator to defer to offshore jurisdictions.

Dr Hamish Campbell has repeatedly implied that gene editing has the same 'safe' risk as conventionally bred organisms. But he does not refer to any scientific risk assessment, because it hasn't occurred.

Conflating slow tech with fast-paced tech misleads MPs. For example - MBIE funded scientists know that multiplex genome editing using the CRISPR/Cas system enables developers to mutate multiple genetic loci within one or more genes simultaneously. This tech can build layered genetic circuits that control cellular behaviour or modulate metabolic pathways with simultaneous editing, activation, and downregulation of multiple target genes. They know that in the scaling up of advanced tech, they also scale up the risk of unknown and off-target effects. Then there is the ever-present problem of contamination from the biological reagents, for example, DNA cutting enzymes which also increases risk.

MPs, there is a bitter truth that is implicitly understood by every scientist – they know they will not survive the next funding round if you openly discuss problems like reagent contamination, off-target effects or gene flow into the environment.

AgResearch's dirty little secret is that they expect gene flow into the environment and contamination in stockfeed.[10] AgResearch's problem – like every scientist presenting to you on this Bill - is that if a funding proposal doesn't tick MBIEs box for innovation they won't get funded. AgResearch are unlikely to model gene flow from grasses, movement and migration of patches of gene edited organisms over time.

Plant and Food interviewed Māori – but the interviews were predicated on the safety of gene editing based on presumptions drawn from the Royal Society document – that did not conduct risk analysis.

Chair and Dr Campbell, we suggest that our recommendations are every bit as relevant as the MBIE funded scientists who are funded to use modern technologies in every way to scale up development, throughput and commercialisation.

MBIE are silent on what best practice might mean in this rapidly advancing field. The Regulator and the enforcement and monitoring agency lack any obligation to keep abreast of industry developments, including the integration of artificial intelligence.

MBIE is entranced by biotechnology and prepared to short-circuit the democratic process to fast-track industry-friendly legislation. Your Select Committee report will be overseen & produced by MBIE.

MPs are expected to vote for a bill that promises a regulatory framework that is built on shifting sand, and that lacks any rigorous scientific analysis.

As one biotech lobbyist stated 'if you accept misinformation, then the rest of the argument seems quite logical.'

MPs how should you proceed? PSGR recommends that the current legislation is set aside. New Zealand must scrutinise global best practice including evaluation of risks well understood by corporate industry.

Page 18-50 of our submission lists our recommendations. Thank you for this opportunity.

[1] New Zealand Parliament (March 5, 2025). Health Select Committee. Vimeo recording 2025 03 05 - HE (Part 2) https://vimeo.com/1062548868
[2] PSGR Gene Technology Bill 2024. Submission to the Health Select Committee, New Zealand Parliament. https://www.parliament.nz/resource/en-NZ/54SCHEA_EVI_22059628-b0cc-4931-5e07-08dd18a12bfb_HEA11046/4521292c060e93576f5895d6abffc102f449bd26
[3] Royal Society Te Apārangi Gene Editing Campaign documents. https://www.royalsociety.org.nz/assets/Uploads/Gene-Editing-FINAL-COMPILATION-compressed.pdf
[4] MBIE Regulatory Impact Statement. https://www.mbie.govt.nz/dmsdocument/29936-regulatory-impact-statement-reform-of-gene-technology-regulation-pdf
[5] New Zealand Parliament (March 5, 2025). Health Select Committee. Professor Emeritus Jane Kelsey oral submission. At 7.25-13.50 minutes. 2025 03 10 - HE Subcommittee B (Part 1) https://vimeo.com/1058045632
[6] Kelsey, J. Submission on the Gene Technology Bill. https://www.parliament.nz/resource/en-NZ/54SCHEA_EVI_22059628-b0cc-4931-5e07-08dd18a12bfb_HEA12017/6d348397200e9dcf52674fa7e54ee321711370e8
[7] National Party. 'Harnessing Biotech'. https://www.national.org.nz/policies/harnessing-biotech
[8] Royal Society Te Apārangi Gene Editing Campaign documents. Legal and Regulatory Implications (pages 140-150) https://www.royalsociety.org.nz/assets/Uploads/Gene-Editing-FINAL-COMPILATION-compressed.pdf
[9] Official Information Act Request. FYI. DOIA REQ 0006467 https://fyi.org.nz/request/29246-scientific-advice-technical-focus-group-gene-technology-regulations-and-powers-of-regulator#incoming-118012
[10] Gene flow in grasses is 'normal'. Note acknowledgement, i.e. expectation of a degree of contamination in Select Committee Presentation. New Zealand Parliament (March 5, 2025). Health Select Committee. Vimeo recording 2025 03 05 - HE (Part 2) https://vimeo.com/1062548868

List of the Select Committee hearings for the Gene Technology Bill:

2025 03 05 - HE (Part 2)

2025 03 10 - HE Subcommittee A (Part 1)

2025 03 10 - HE Subcommittee A (Part 2)

2025 03 10 - HE Subcommittee B (Part 1)

2025 03 10 - HE Subcommittee B (Part 2)

2025 03 10 - HE Subcommittee B (Part 3)

2025 03 14 - HE Subcommittee A

2025 03 14 - HE subcommittee B (Part 1)

2025 03 14 - HE Subcommittee B (Part 2)

2025 03 17 - HE Subcommittee A (Part 1)

2025 03 17 - HE Subcommittee A (Part 2)

2025 03 17 - HE Subcommittee A (Part 3)

2025 03 17 - HE Subcommittee B (Part 1)

2025 03 17 - HE Subcommittee B (Part 2)

2025 03 17 - HE Subcommittee B (Part 3)