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New Zealand 'does not pay sufficient attention to the future or guard against risks that can be readily foreseen.' (Palmer and Butler 2018)

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New GMO's from gene editing. Currently here are 2 parallel deregulatory processes in play:

- FSANZ - Proposal to deregulate. Most GMO foods would be out of scope for pre-market assessment.
- MBIE NZ - Deregulating to permit environmental releases (a media pack has been released claiming laws will be risk-proportionate).

PSGRNZ:

- Deregulation is based on scientific claims of 'comparatively the same' and/or that legislation will be 'risk proportionate'.
- Governments historically make science claims after following established scientifically robust processes to review and assess scientific information.
- No formal risk evaluation process has been undertaken to assess risk from new techniques of genetic modification by FSANZ or MBIE or the NZEPA.
- There is no understanding of risk that arises from development & environmental releases scaling up exponentially, especially with deregulation.
- Enormous funding is (and will be) directed to biotech research in New Zealand.
- Scientific funding is not available for monitoring & assessment of tech risk.
- There is considerable uncertainty about risk, but officials would like to remove the requirement to take a precautionary approach, from GM legislation.
- European Commission April 2024 proposed legislation: 'With full regard to the precautionary principle.'

There has not been risk assessment. Policy papers making scientific claims - without impartial review and assessment of those scientific claims - are unfit for purpose in New Zealand. Without this, legislation cannot be 'risk-proportionate'.
This is in two parts:

- Part 1 - fact checking 101 - numbered 1-24
- Part 2 - Covers issues in more detail: [a] Europe, [b] Precaution, [c] New NZ-based gene technology laws, [d] PSGR response to FSANZ, [e] scalability impact, [f] NZ underfunding risk research.

FACT CHECKING 101

1. Techniques of genetic modification (GM) include latest generation gene editing (GE) tools. Companies patent the genetically modified organisms (GMO) that they create. The patented GMOs might contain or produce novel DNA or a novel protein, or they might have had DNA sequences added into them and then removed, resulting in genome alterations, and a desired trait or traits. Such GMOs are normally then marketed, returning royalties to the patent owner. Edits to the genome can include point mutations, small insertions/deletions (indels) and larger deletions of the DNA. Whilst the gene editors may know what they are doing to the DNA, they do not necessarily know what the DNA and hence the cell, will do in response to these DNA interferences.

2. Trust erodes when institutions fail to act in a fair and accountable manner. Recently a public consultation on a new definition of GMO was proposed by Food Standards Australia New Zealand (FSANZ), and the definition would, as FSANZ noted, produce a paradigm shift from process based (was it made using GM/GE technology?) to outcomes based (because the GM/GE process resulted in novel DNA or a novel protein). The public were given questions to answer that were over simplified and did not permit the public to discuss the most important concerns about food safety.

3. Mainstream media in New Zealand and Australia failed to publicly report that this consultation was even occurring. Even though it was a 'paradigm shift' in regulation there was no coverage. Democracy is contingent upon the fourth estate reliably reporting on the goings on in public institutions. However, as FSANZ releases notification circulars, not press releases, who knows if media reviews them.

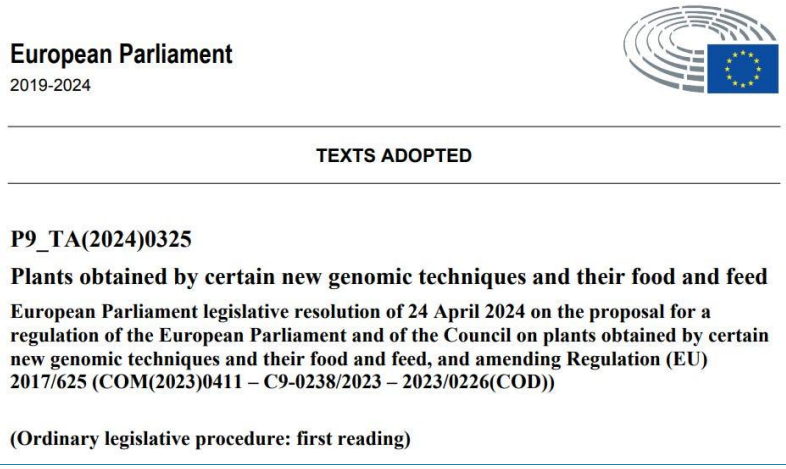
4. Regulatory agencies can adjust language to downplay GE edited food. The Australian and New Zealand food safety regulator calls them 'new breeding techniques' (NBTs) while Europe calls them 'new genomic techniques' (NGTs). FSANZ aimed to lock down this new definition without any public debate on broader issues.

5. FSANZ has been selective in its disclosure of European decisions. FSANZ reported on a February 2024 European Parliament decision in the July 30 2024 Updated compilation of regulatory approaches and definitions. FSANZ then failed to disclose an April 24 decision which included substantial and precautionary caveats that European lawmakers placed on NBTs/NGTs. Such decisions – relevant to European decisions - were raised by public groups including PSGR. However, they would have likely out of scope in FSANZ's September deadline document, as public was trapped by the narrowly framed questions.

The truth? We contacted the researchers at GMWatch to clarify where the European Commission stood right now concerning broad deregulation of GMOs:
'The proposal for deregulation is still stuck in the Council. The Parliament wants labelling and traceability for all new GMOs but whether that demand will survive the other EU institutions is not known.'

(The FSANZ consultation might have promoted public trust by being frank about the complex issues concerning NBTs/NGTs which were included in an April 2024 European Parliament decision. This EU decision may still be amended). In Europe, an 'NGT plant' means 'a genetically modified plant obtained by targeted mutagenesis or cisgenesis'.

Cisgenesis is a type of genetic modification wherein both the donor and the recipient are from the same species. European legislators are considering many issues including: the role of the precautionary principle, prohibition in organics, labelling, patent rights, transparency and traceability measures (including information on techniques used to obtain traits), public listing of NGTs on databases, monitoring plans, exclusions for herbicide tolerant plants, 5 year evaluations, breeder access to the genetic material of NGT plants, exclusion from patentability of NGT plants (reside under the Community Plant Variety Rights (CPVR) system), limits on the effects of patents, that the regulation must not undermine organic farming goals, traceability for food and feed produced from NGTs to ensure accurate information is available for freedom of choice, emphasising protection of health and restriction on genetic material used for conventional breeding purposes.)



European Parliament
2019-2024

TEXTS ADOPTED

P9_TA(2024)0325

Plants obtained by certain new genomic techniques and their food and feed

European Parliament legislative resolution of 24 April 2024 on the proposal for a regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 (COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))

(Ordinary legislative procedure: first reading)

P9_TA(2024)0325 Plants obtained by certain new genomic techniques and their food and feed European Parliament legislative resolution of 24 April 2024 (EU) 2017/625 (COM(2023)0411 – C9-0238/2023 – 2023/0226(COD)) https://www.europarl.europa.eu/doceo/document/TA-9-2024-0325_EN.pdf

6. FSANZ claims that GE innovations can help with climate and sustainability goals but historically GE varieties have not fulfilled this promise. Herbicide-tolerant GM plants were redesigned to be triple stacked with multiple herbicides as weeds grew resistant to glyphosate, the original herbicide that plants were engineered to tolerate. With GM plants now being tolerant to multiple herbicides, surrounding communities and environments have been exposed to more toxic herbicide cocktails. Bt cotton has failed, as insects feeding on the cotton have become resistant to the Bt insecticidal toxins. GM drought resistant wheat (HB4) that has been planted across Argentina, has produced yields that were found to be 17% lower than yields from traditional wheat strains.

7. People do not want to consume GM/GE food. The idea that GM/GE plants might not be transparently identified, i.e., not tracked and traced, is not only unethical because people prefer not to consume GMO food [1] [2] [3] [4] [5], but

obfuscates knowledge about whether a technology is worthy, whether that technology creates broader risks, or whether that technology should be abandoned.
For twenty years lobbyists have worked with regulators to reposition foods produced using GM/GE as substantially equivalent (the comparative approach) to conventional foods by claiming that conventionally-bred food and GE can have similar genomic alterations.

8. Adopting FSANZ criteria could result in most GM/GE plants not being classified as a GMO and therefore not requiring risk assessment before market approval. A European study has shown that 94% of the current GM/GE plant applications affected by the European NGT proposal would not be classified as GMOs. The remaining 6% would fit new criteria with an adapted risk assessment.[6]

9. Process-based pre-market risk assessment is *not* out of date. Many people who write or speak about the 'outdated rules' in New Zealand are employed by institutions such as Crown Research Institutes (CRIs), which are involved in patenting products of biotechnology and receive research funding for biotechnology research. Funding advisory panels often include a considerable number of members who have conflicts of interest.[7] [8]

10. The evidence used by the food safety authority to claim equivalence with conventionally-bred plants is not scientifically robust. A 2019 review[9] and 2021 safety assessment [10] by FSANZ lacked a methods section. In addition, the language used, led the reader to believe that alterations and mutations in conventional breeding were comparable to GM techniques.
Science is trustworthy when the processes of gathering and assessing information are transparent, which is why scientific papers have a section describing methods. To date, FSANZ has substituted robust risk assessments with weaker reviews and 'safety assessments'. No robust processes for information review and data collection are declared in these important papers underpinning the current P1055 call to shift risk assessment away from process-based (was it made using GM/GE technology?) to outcomes-based (the GM/GE process resulted in novel DNA or a novel protein).

11. FSANZ avoids discussion on important issues central to trust as a guardian of food safety. Using outcomes-based assessments, most GM/GE foods may not have to be declared and/or labelled in future. A large spectrum of gene edited organisms could avoid pre-market risk assessments. This would undermine both the organic and non-GMO status, despite both of these being high value and high growth market sectors. The regulatory 'paradigm shift' may serve as a precedent for other outdoor applications (including onto food), such as where biopesticides remain largely unregulated.[11] In silico metabolic enrichment analysis suggests [12] that outdoor genome editing may result in unintended adverse effects in non-target organisms. Such concerns are material but have been set aside by FSANZ.

12. FSANZ has actively 'gamed' consultation in the past. FSANZ has carried out two consultations where questions were put to the public. Many people and organisations (including PSGR) responded:

- August 2018. 664 Submissions. Preliminary report: Review of food derived using new breeding techniques – consultation outcomes.
- November 2022. 1736 Submissions. The Stakeholder Feedback Summary Report. Proposal P1055 – Definitions for gene technology and new breeding techniques.

As the papers show, FSANZ broadly dismissed public comments (including subject matter experts) on the 2019 and 2021 papers. They did not disclose the balance of comment responding to the individual questions, but simply generalised all comments to broader opinion.
Following these consultations FSANZ then proposed a new definition for GM/GE which reflected the deregulatory positions of the biotechnology industry and GM/GE developers, but carried none of the nuance seen in recent European decisions. Despite the science on safety still being contested, European regulators are in the process of deregulating a considerable percentage of these GMOs.

13. The claim of 'substantial equivalence' with conventional food has not been backed by impartial risk assessment. FSANZ white papers and the September 2024 webinar demonstrates that FSANZ maintains an internal (institutional) consensus position on gene edited foods. This position has, however, been arrived at by failing to conduct transparent scientific risk assessments and by ignoring public input.

14. FSANZ does not consider unknown, unanticipated or off-target risk beyond a small subset of genomic alterations in the genome being edited. [13] [14] FSANZ states that edits to the genome including point mutations, small insertions/deletions (indels) and larger deletions occur 'spontaneously in nature' or through mutagenesis, which is not regulated. However, the examples they used have been cherry-picked to support their argument, because no methods were declared in the literature review phase, to demonstrate impartiality.

15. Damage occurs not only in plant biochemistry, but also to off-target organisms, including protected species, which may be harmed.[15] [16] [17] GE techniques used to modify the plants' microRNA and to silence production of essential proteins via gene silencing, would not be assessed for risks in the new 'paradigm shift'. [18] The narrow safety assessment does not take a big picture perspective.

16. FSANZ does not consider the scale of the risks. [19] [20] FSANZ has failed to act on information from experts on the scale of risks associated with this technology, and has instead dismissed this information. [21] Risks range from intended alterations, which can lead to unrecognised, undesirable alterations in the DNA, to harm arising from lowering the barriers to the use of this technology. Because more laboratories are doing this work, there are increased risks at the experimental level. There are also risks to staple food groups (e.g. rice, wheat or corn) and risks from the scale and pace of release into the food chain and into the environment.

17. IP rights incentivise GMO/GE development and release. While FSANZ considers risks from GMOs as being equivalent (using a contested 'comparative approach' which is also referred to as 'substantial equivalence' which often fails in the courts) to their conventionally-bred counterparts , they ignore the potential scale and pace of release into the environment of such patented biotechnologies.

18. Null segregant GMOs are used as non-GMO comparators for food safety assessment.[22] This is the equivalent of vaccine manufacturers using a placebo that contains generic vaccine ingredients in it.

19. A cost-benefit assessment of investment by the New Zealand government into biotechnology research has *never* been undertaken. The past 20 years of government funding to universities and Crown Research Institutes for biotech research and development have never been subjected to a cost-benefit analysis.

20. New Zealand media misleadingly repeat claims that biotechnology is 'banned' for outdoor releases, when instead products of gene editing technologies are regulated on a case-by-case basis. As we have discussed:
REGULATING *PROCESS*, New Zealand legislation is good, as it recognises the simple fact that scientists, lawmakers and the public simply do not know what new *techniques* lie around the corner.
New Zealand's existing legislation on GMOs (including gene edited organisms), added to by territorial and local government input, is robust and fit for purpose.

This is where New Zealand stands:

1. Gene editing processes trigger regulation. Regulation of technology involved in the manufacture and operations of aeroplanes, cars and chemicals, for example, is necessary at every stage.[29]
2. Our current regulations align with a recent European Union court decision. The decision stated that newer gene editing technologies require regulation, just like the older techniques of genetic modification which incidentally, are still in widespread use.
3. Our legislation is precautionary, hence not allowing uncontrolled releases into the environment. As many unanticipated problems continue to arise with both the older techniques and with new techniques, the precautionary principle continues to be the best mechanism to protect human and animal health, and the health of the environment.
4. Our oversight can improve. We need to recognise the risks associated with the potential for technologies (increase in development and release speed, increase in speed to market) to quickly scale up.

By regulating the *process* (as opposed to a product, outcome or novelty), New Zealand should have complete transparency around the regulation of all genetic engineering processes. This is the case for the majority of countries in the world, which are united under the Cartagena Protocol for Biosafety.

21. The biosecurity risk is paradoxically ignored. Biosecurity protection is a serious concern for the Australian and New Zealand governments. However, they do not view risk from biotechnology as a biosecurity risk. The recommendations from the 2001 Royal Commission (RC) have been discarded. The RC recommended a three-pronged approach including the establishment of a Parliamentary Commissioner on Biotechnology, a Bioethics Council and a biotechnology strategy. None of these initiatives are in operation in 2024.

22. New Zealand's science policy writes out basic curiosity driven, public good research. The science policy does not enable scientists and researchers to engage in research that assesses and reviews the potential for risks arising from biotechnologies that are released into the environment or into humans or animals. This research is not sufficiently in scope.

23. The New Zealand Environmental Protection Authority (NZEPA) does not research risks from GMOs.

24. Most of our experts have conflicts of interest. The barriers that arise from governance structures, political cultures, science policy and limited funding options, inhibit independent research. This means that there are few experts who do not have conflicts of interest. These independent scientists are among the very small number of people who have sufficient expertise to independently comment on GM/GE policy in an objective way. While researchers in New Zealand do not currently benefit financially from the patents and the royalties their organisations may secure from their work, they do want to secure funding for future projects, so are unlikely to speak out on any risks and problems associated with GMOs.

A. EUROPE – BENDING TO DEREGULATION – BUT WITH CAVEATS

Traditionally Europe has regulated GM/GE foods strictly, and their approach and New Zealand's, has been process-based and a case-by-case basis. A 2018 court decision confirmed the European position. Since that time, the biotech industry and biotech developers have conducted a systemic lobbying campaign that revolves around climate friendly 'flagship products' to shift opinion.[23]

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES), was asked to review risk[24] on GE (NGTs). ANSES determined that knowing the size and number of genetic modifications is insufficient to assess the functional consequences of a GE/NBT/NGT plant.

'certain potential risks appear repeatedly in these case studies' and that '[t]hese include risks linked to unexpected changes in the composition of the plant, which could give rise to nutritional, allergenicity or toxicity problems, or to medium and long-term environmental risks, e.g. the risk of gene flow from edited plants to compatible wild or cultivated populations.'

In January the Committee on Environment, Public Health and Food Safety voted on the European Commission proposal on NGTs:

'MEPs agree with the proposal to have two different categories and two sets of rules for NGT plants. NGT plants considered equivalent to conventional ones (NGT 1 plants) would be exempted from the requirements of the GMO legislation, whereas for NGT 2 plants this legislation adapts the GMO framework to those NGT plants.
MEPs also agree that all NGT plants should remain prohibited in organic production as their compatibility requires further consideration.'

Then in a plenary session on April 24, European Parliament agreed to NGT regulation, with substantial caveats (as mentioned briefly earlier).

The European Food Safety Authority (EFSA) consequently adopted a scientific opinion in June 2024[25] which failed to address many of the concerns presented by ANSES.

The legislation is now stuck - Parliament wants labelling and traceability for all new GMOs.
Biotech impact assessment group Testbiotech accused EFSA of 'acting like a 'service institution' defending the Commission proposal without sufficiently assessing relevant scientific counter arguments'. Testbiotech went on to state that EFSA's position, where the criteria proposed by the Commission is not meant to define levels of risks – is contradicted by a so-called safe 'threshold' of twenty genetic changes, stating that:

'One crucial criterion proposed by the Commission is a 'threshold' that allows 20 genetic changes per NGT-plant if they are to be seen as equivalent to conventionally-bred plants. ANSES, however, has introduced examples to show that the number of mutations is not a suitable criterion for deciding whether NTG plants can be considered to be as safe as plants obtained from conventional breeding.'

European watchdog GMWatch drew attention to EFSA's reliance on citing scientific papers where random mutagenesis breeding creates defective and abnormal plants, stating that while random mutagenesis had its heyday thirty years ago, the technique has largely fallen out of use –

'Random mutagenesis breeding is known to be highly risky to the plant, creating large numbers of deformed, non-viable and infertile plants. Thousands or millions of undesirable plants are discarded in order to identify plants suitable for further breeding. Is random mutagenesis breeding risky for the human or animal consumer? No one knows, as the necessary safety research hasn't been done.'

FSANZ also drew on mutagenesis as an example of non-target random changes in their 2019 and 2021 papers, without also clarifying that the method had largely fallen out of favour. [26] [27]

Policy in Europe remains under negotiation[28] and Germany hosted a non-GMO summit in October 2024. Different European countries may elect to have different levels of regulation. Switzerland has recently elected to extend their moratorium on the cultivation of GMOs, including GE, until 2027.

B. PRECAUTIONARY PRINCIPLE

New Zealand ratified the Cartagena Protocol for Biosafety in 2005. The Protocol is a supplementary agreement to the Convention on Biological Diversity. The Cartagena Protocols reaffirms the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development (1992). New Zealand was one of the 175 countries who signed the 1992 Rio declaration.

Principle 15 *In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*

A problem with ensuring the safe regulation of biotechnology is the problem of complexity when man-made technologies interact with open-ended biological systems. The identification of how a technology might be hazardous and cause harm, and the likelihood of a harm occurring (the risk) is challenging, particularly if harms occur at the biochemical level, which can result in slow-moving but significant harms over time (such as inter-generationally, for the species which might be impacted). Governance risks are frequently complex, uncertain and ambiguous.

In such an environment, information and guidance on the application of the precautionary principle can support policy and decision-making by officials. But there is no evidence that such information is generally available and easily accessible to officials (including legal counsel) across central government agencies, or who work for territorial and local authorities.

The NZEPAs Risk Assessment Methodology (Updated 2022) does not provide a decision-making pathway. In New Zealand, implementation of the precautionary principle is inconsistent and poor. There is no evidence of policy work/briefings undertaken to develop frameworks and understandings that might support officials in using the precautionary principle, or a precautionary approach in decision-making.

In a recent South African Supreme Court of Appeal judgement, *African Centre for Biodiversity NPC v Minister of Agriculture, Forestry and Fisheries and Others* five judges unanimously ruled that evidence provided by the applicant (in this case Monsanto) in support of a gene edited maize (MON87460) was inadequate to prove safety of the product. The African Centre for Biodiversity's appeal was upheld:

The thrust of the appellant's case is that the State respondents accepted, at face value, the claims made by Monsanto and failed to independently and critically evaluate Monsanto's application to satisfy themselves that the health and safety risks associated with the general release of MON87460 had been properly addressed. The appellant contends that the expert evidence that served before the State respondents, ought to have triggered the application of the precautionary principle enshrined in s 2 of NEMA. This, for two main reasons: first, there was a lack of scientific data from which conclusions about the safety of MON87460 could be drawn; and second, the 7 data that had been made available supported concerns about health risks arising from the use of MON87460.'

The precautionary principle was triggered and ought to have been applied.

In 2018, a European Court of Justice Ruling on genome editing concluded that under the EU regulation on genetically modified organisms, modern techniques and methods of directed alteration of genetic material (genome editing) constitute a genetic modification and do not fall under the mutagenesis exemption. As a consequence of the judgment, trial releases of plants and animals obtained by genome editing will be subject to the requirements of risk assessment and authorisation.

'The Court's major arguments were the legislative history of the Directive (Recital 17 refers to positive experience with conventional mutagenesis); the rule of narrow interpretation of exceptions; the protective objective of GMO regulation; and in particular, the precautionary principle as set forth in Article 4(1) and Recital 8 of the Directive. The Court underlined that direct mutagenesis might have the same adverse, possibly irreversible effects on the environment as the insertion of foreign genetic material and therefore needed to be subject to an advanced risk assessment. The Court was also concerned about the rate and quantity of new GMOs would be out of proportion to those of plants obtained from conventional breeding. This reasoning was also held to be applicable to the regulation of GM seeds.'

Note: The precautionary principle in New Zealand:

- The Food Standards Australia New Zealand Act 1991 does not contain the word precaution/precautionary.
- Hazardous Substances and New Organisms Act 1996 specifies (s.7) '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.' However, since 1996 the New Zealand Environmental Protection Authority does not appear to have released guidance for officials in taking a precautionary approach. It appears that officials would be unlikely to consider precaution without guidance.

C. NEW GENE TECHNOLOGY LAWS (NEW ZEALAND)

New Zealand Attorney-General Judith Collins with her science, technology and innovation hat on, released information on New Zealand deregulation of current GE laws. A Gene technology media pack [DOCX 362KB] was released with a Q&A and 'Myth Busters' section.

No policy papers have been released. They will likely be released when the Bill - new legislation will released for public consultation. The policy will contain the scientific justification. The new law will be based on the science claims.
The public will only be permitted to talk to the subject matter of the Bill, discussion relating to the science claims relating to level of risk will be out of scope, and discarded by the Select Committee.

What are the key features of the new law?

The legislation is intended to enable New Zealand to safely benefit from gene technologies by managing risks to the health and safety of people and the environment.

The new law:

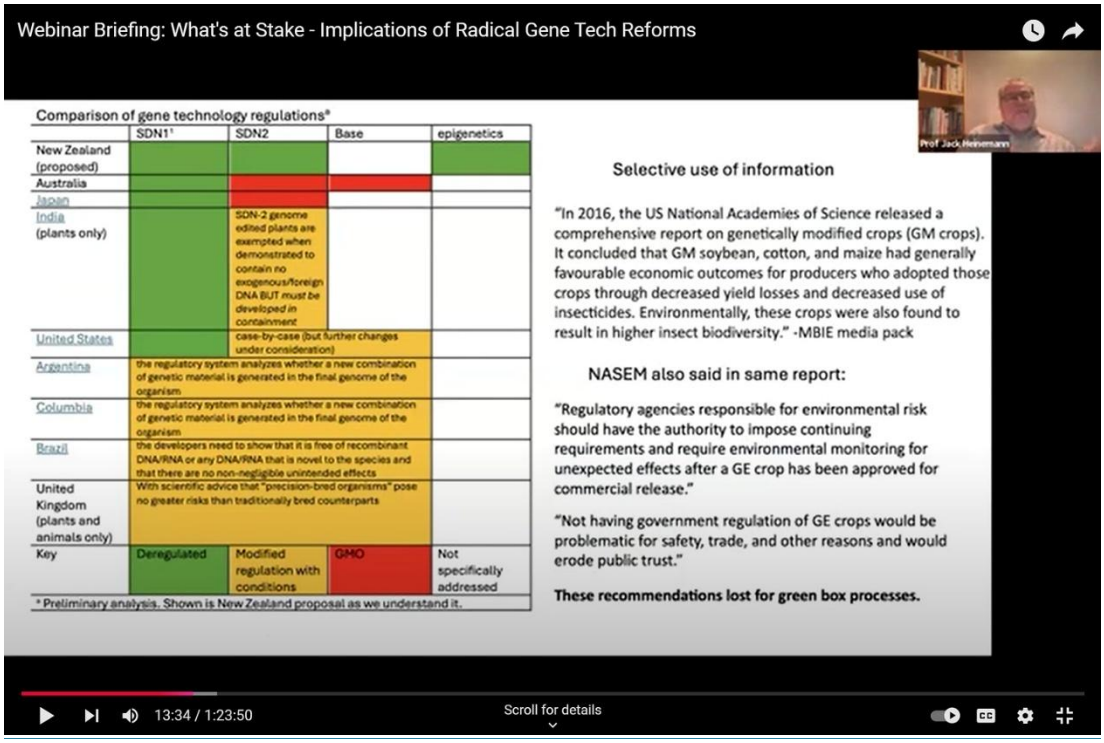
- Allows for greater use of gene editing
- Is risk-proportionate and evidence-based
- Internationally aligned
- Retains public participation
- Focuses on the management of risks
- Leverages overseas expertise
- Has streamlined, efficient and transparent processes

'The new law is risk proportionate and evidence based.' Gene technology media pack [DOCX 362KB]

GMO contamination is a direct threat to the organic sector, as GMO contamination is not permitted. Facing a lack of information, after consultation with ministers and authorities, New Zealand's organic sector concluded that the process was rushed and flawed and that ministers had a poor understanding of the implications of the proposed changes, which would make New Zealand one of the most weakly regulated jurisdictions globally.

In a later presentation to the organic sector Professor Heinemann stated:

'It could open the door to New Zealand being the experimental playground for anyone else. For the large companies, or for rogue scientists to want to relocate here. To do their experiments in the most liberalised regulatory framework without risk of damaging their home agroecosystems. '



OANZ **Webinar Briefing: What's at Stake - Implications of Radical Gene Tech Reforms. Nov 8, 2024.**

Dr Jessica Hutchings discussed the history of Māori activism and opposition to GMOs because 'this is not a new thing for us'. Starting with the lodging of the Y262 Claim - which talks about the
'protection of Māori cultural and property rights within the sphere of new technologies. GMO's were defined as a present threat for Māori protection of our taonga and of our flora and fauna.'

In 2007 Māori organic authority Te Whaka Kai Ora joined the Y262 Claim and presented over 100 pieces of evidence to the Waitangi Tribunal. The Ko Aotearoa Tēnei report was released. (See recommendations Chapter 9.2).

Hutchings also emphasised the requirement that the Crown consult with Māori regarding free trade agreements.
'The bilateral and multilateral free trade agreements that are circulating are harmonizing, or paving the way for GMOs in nation states like Aotearoa New Zealand. There's no Treaty exception clause... they're not effective and we've been unable to secure those.

A 'race to the bottom' may suit technology developers, but may not be most appropriate for New Zealand and growers seeking to protect their reputations on global export markets, nor for Māori, nor for consumers (see [7] above) who persistently and repeatedly choose to pay a premium for non-GMO/gene edited food.

We note that somewhat surprisingly, Professor Jack Heinemann, with a published record of studying risk from genetically modified organisms and a key witness in the South African court case, is not included in MBIE's Technical Advisory Group.

To our knowledge, no other NZ scientist has published equivalent research on this topic.

'Precaution' may be removed from New Zealand legislation with the New Zealand government proposing to imitate Australia's Gene Technology Act 2000. MBIE claims that the precautionary principle is 'out-of-date', even as the European Commission quotes the precautionary principle in April 2024 legislation (page 12):

> *'With full regard to the precautionary principle.'*

Simon Rae, MBIE, Emerging Technologies: [18] 'We are also proposing to remove the precautionary approach for risk assessments under the new regulatory regime. This is based on good regulatory practice, which prompts the designers of regulatory regimes to focus attention on how the operative mechanisms guide a risk management approach, rather than seeking to guide the regulator through high level value statements.'

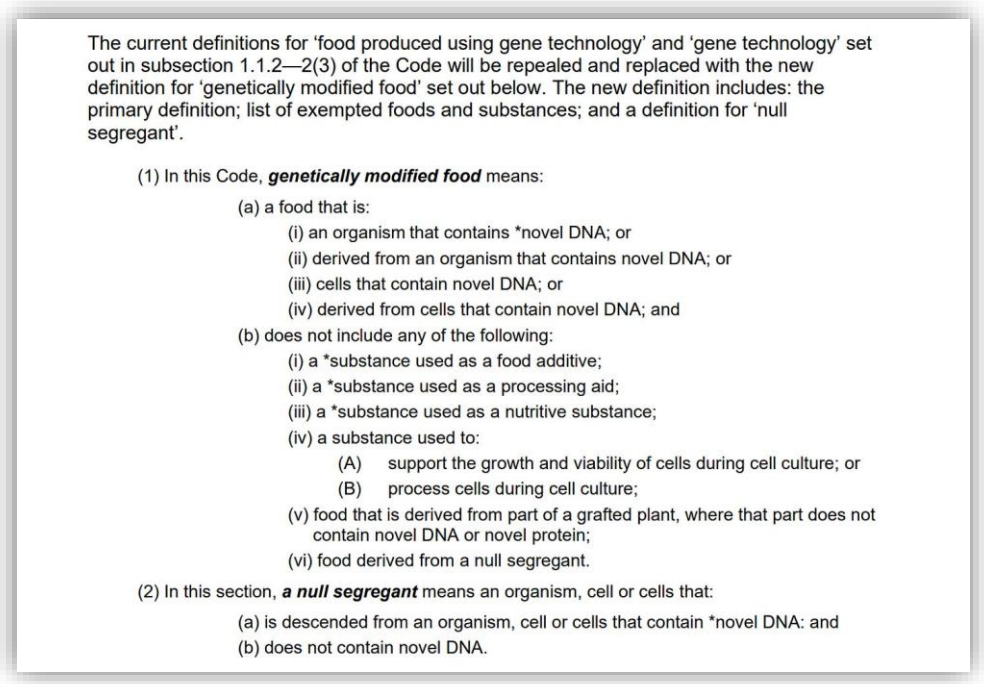
As we discuss in [5] above, a European April 24 decision which included substantial and precautionary caveats that European lawmakers placed on NBTs/NGTs, but this was ignored by FSANZ in their consultation. PSGR and many others will be watching closely to ensure that Attorney General Collins, the Ministry for the Environment and MBIE do not simply 'cherry pick' legislation from weak regulatory jurisdictions, evade discussions about uncertainty and risk particularly concerning releases into the environment, and ignore best practice regulation, such as may be found in Europe.

D. PSGR RESPONSE TO FSANZ SEPTEMBER 2024 CONSULTATION

In July 2024 Food Standards Australia New Zealand (FSANZ) opened a second P1055 consultation, stating:

'P1055 is a proposal to amend the definitions in the Australia New Zealand Food Standards Code (the Code) for 'food produced using gene technology' and 'gene technology' to:

- *make it clear which foods are genetically modified (GM) foods for Code purposes*
- *accommodate new technologies*
- *regulate foods according to the risk they pose.'*



The current definitions for 'food produced using gene technology' and 'gene technology' set out in subsection 1.1.2—2(3) of the Code will be repealed and replaced with the new definition for 'genetically modified food' set out below. The new definition includes: the primary definition; list of exempted foods and substances; and a definition for 'null segregant'.

(1) In this Code, ***genetically modified food*** means:

(a) a food that is:

(i) an organism that contains *novel DNA; or

(ii) derived from an organism that contains novel DNA; or

(iii) cells that contain novel DNA; or

(iv) derived from cells that contain novel DNA; and

(b) does not include any of the following:

(i) a *substance used as a food additive;

(ii) a *substance used as a processing aid;

(iii) a *substance used as a nutritive substance;

(iv) a substance used to:

(A) support the growth and viability of cells during cell culture; or

(B) process cells during cell culture;

(v) food that is derived from part of a grafted plant, where that part does not contain novel DNA or novel protein;

(vi) food derived from a null segregant.

(2) In this section, ***a null segregant*** means an organism, cell or cells that:

(a) is descended from an organism, cell or cells that contain *novel DNA: and

(b) does not contain novel DNA.

30 July 2024 297-24. 2nd Call for submissions – Proposal P1055. Definitions for gene technology and new breeding techniques. Page 23. https://www.foodstandards.gov.au/sites/default/files/2024-07/P1055%202nd%20Call%20for%20submissions%20report.pdf

FSANZ's questions in the consultation involved whether the changes would produce the intended regulatory outcome. They concerned small technical details and the consumer perceptions of such details. FSANZ did not ask if the public considered whether the proposed new definitions would pose risks to health, and reduce consumer confidence.

30 July 2024 297-24. 2nd Call for submissions – Proposal P1055. Definitions for gene technology and new breeding techniques. Page 24. https://www.foodstandards.gov.au/sites/default/files/2024-07/P1055%202nd%20Call%20for%20submissions%20report.pdf

PSGRNZ sent in a submission to FSANZ (published in full for online reading on our Substack) that included a preface speaking to these concerns, in addition to responding to the questions. which were directly concerned with achieving a technical outcome. Our concerns included:

- Likelihood much public input would be dismissed by FSANZ failing to transparently disclose the weight of public opinion (expert and non-expert).
- Claim that GMOs that do not contain novel DNA or a novel protein/s are substantially equivalent to conventionally bred food when all reviews have failed to disclose a transparent methods to ensure that all types of risk have been accounted for and considered.

- Proof that FSANZ ignored expert evidence by experts that GMOs that would not be categorised as GMO can potentially produce unintended effects and off-target genomic changes.
- Failure of FSANZ to call attention to fundamental differences in the scale and pace of biotechnology development. The incentivisation of market release of patented GMO products comes from stronger IP rights than developers using conventional breeding techniques can access. FSANZ did not address this.
- The 'substantial equivalence' claim is a technique historically applied by the biotechnology industry to infer that GMOs are as safe as conventionally bred foods. This tactic has enabled regulators to avoid comprehensive risk assessment.
- Merging premium food producers with ultraprocessed producers as one category.

E. THE SCALABILITY IMPACT

Biotechnologies continue to require regulation and oversight because of their potential to be emitted or deployed at scale, whether in medicine, personal care, agriculture in pest control or for other applications. However, current regulatory triggers don't allow for risk from release or deployment at scale, and scientists have proposed that a scale trigger can be embedded in regulation. Scale is explained here:

'Scale is a complex concept that differs in meaning across disciplines. It is not exclusively a measure of distance, area, volume, and time but also a mixture of these and their relationship with human activity. Where human activity intersects with the environment, there is risk, putting the intersection at the place where we may best control risks of our own making. The highest priority for technology regulation, after deciding to adopt a technology, are harmful or beneficial effects that scale up quickly and/or widely as a result of human activity.'[30]

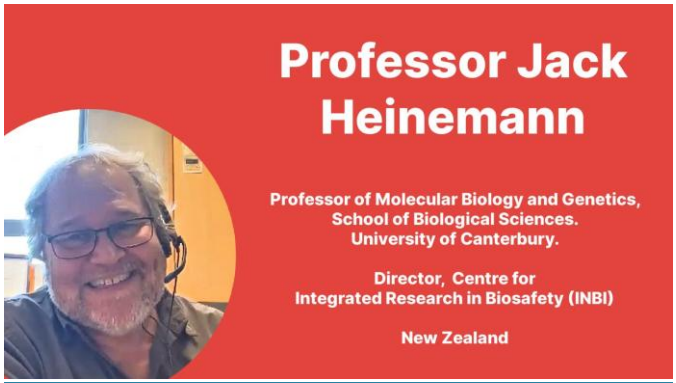
However, as the 'scale of control afforded by science advances, so does the domain of uncertainty and potential risk.'[31] The rationale for continued oversight of biotechnology was outlined by Professor Jack Heinemann, from the Centre for Integrated Research in Biosafety, in a 2021 submission[32] which looked at definitions of gene technology: 'Describing techniques of gene technology by their biochemistry, whether it be the reactions that lead to the insertion of a 'transgene' and the reactions that lead to genome editing, provides little clarity for technology governance.

The characteristic of the technology that justifies social governance through legislation is that it can amplify the rate and magnitude of harm by increasing the ease of use, number of people using it, range of types of organisms and numbers of individuals it is used on, and the number of environments where it can be applied.'

Heinemann's work on scalability and uncertainty complements Dr Jan Wright's criteria[33] for assessing when an environmental threat has potential to cause harm, to the degree to which it might be:

- irreversible
- cumulative – building up over time
- large in scale or pervasive
- increasing or even accelerating in scale and/or distribution
- likely to tip a natural system over a threshold into another state

EXCERPTS FROM PSGR'S 2023 PAPER: Deregulation? Biotechnology & gene editing: New Zealand context. PDF



Spotify Podcast: Heinemann: Biotechnology - risk that scales up as efficiency increases. Heinemann on risk management & policy.

F. GM/GE – AN EXISTENTIAL THREAT MADE WORSE BY UNDERFUNDING RISK RESEARCH?

GMOs and gene edited organisms, can be viewed as a potential existential threat. Together with chemicals and increased use of trace or heavy metals, are known as novel entities:
'new substances, new forms of existing substances and modified life forms that have the potential for unwanted geophysical and/or biological effects... These potentially include chemicals and other new types of engineered materials or organisms not previously known to the Earth system as well as naturally occurring elements (for example, heavy metals) mobilized by anthropogenic activities.'

Stockholm Environment Institute scientists proposed that

'annual production and releases [of novel entities] are increasing at a pace that outstrips the global capacity for assessment and monitoring.'

Current regulatory protocols fail to require independent reviews of the changing scientific literature which might demonstrate that biotechnology is not necessarily safe. The lack of funding means that appropriate feedback loops are not established. These loops could funnel monitoring and research information back into the regulatory environment concerning novel entities (GMOs, trace metals, and pesticides). This would include monitoring data on contaminant levels present in food, the environment and in humans and animals as well as research to assess and understand risk and harm.

Government agencies can neither predict risk or harm, nor can they steward these technologies precautionarily in order for the principles of the Treaty of Waitangi to be upheld. When legislation requires officials in health and environment agencies to protect health, this is impossible if there is no cross-talk to inform officials of how exposures may drive poor health and chronic disease (such as when people are exposed to diets high in plant grains and proteins that may be genetically modified and/or treated with a range of herbicides and insecticides).

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