GE Free New Zealand

PO Box 13402, Wellington, Aotearoa | NZ

12 February 2025

Re: Proposed Gene Technology Bill

Tēnā koutou katoa,

Please accept our submission and attachments.

GE Free New Zealand in Food and Environment Inc: is a non-profit organisation. The Board members come from around the country, and we have representatives in the regions around New Zealand.

We have a loyal following of people around the country, 1,800 followers and a reach of 4,000 on social media platforms.

Our activities include:

- **Regular updates** on the current information about developments concerning Genetic Engineering, New Breeding Techniques (NBTS), gene editing (GE) - local - national - international.
- **Member information** through newsletters, Press Releases and media.
- **Providing valuable information** and resources to member & the public (e.g. website, info for public libraries, public meetings, public awareness activities) regarding current GE activities
- **Engaging with the** Government, Select Committees, Environmental Protection Authority (EPA) or Food Standards Australian New Zealand (FSANZ).
- **Updating our members** when submissions from Council or Government bodies are due.
- **Assistance and advice** to the public of the details raised in notification and application on GE matters.
- **Presenting submissions** & calling expert witnesses – when attending hearings.

Nāku iti nei, nā,

Jon Muller
Secretary/ Treasurer GE Free NZ

Cc:

Claire Bleakley – President
Jon Carapiet – Spokesperson
Kara Vandeleur – Administrator .

GE Free New Zealand
PO Box 13402, Wellington, Aotearoa | NZ

Table of Contents

Re: Proposed Gene Technology Bill 3
The Purposes Of The Gene Technology Bill 4
MBIE Regulatory Impact Statement (RIS) 5
Medical Biotech
Health, Environmental & Economic Outcomes 7
Australian Gene Technology Act 8
Threat To The Economy, Regions And Non-GE Sectors 9
Climate Change Solutions 10
Increase In Pesticides With GE Plants 13
Evidence of Bt insect resistance 15
Super weeds - Evidence of emergence 15
Forestry 16
Subpart 7 - Recognised Overseas Authorities -cl: 57 17
GE Results From New Zealand 18
NZ Scientific Research 19
Import Breaches 19
Laboratory Breaches . 19
Field Trial Outcomes 19
AgResearch GM Animal Trial 20
AgResearch GM HME Rye grass 20
MBIE Regulatory Report 21
Subpart 4 - Non-Notifiable And Notifiable Activities 22
Exempt Activities 22
Non-notifiable and notifiable low risk activities 23
Licensed Pre-assessed Activity 24
Licensed - Expedited assessment 24
Licensed - Full assessment 24
The Cartagena Protocol On Biosafety (CPBS) 25
Amendments To Other Legislation 26
Amendments To Hazardous Substances And New Organisms Act 1996 26
Amendments To Resource Management Act 1991 27
Interface Of HSNO, Gene Technology Bill And RMA And Economics 28
Economic Impact Of GE On Primary Producers 30
Contamination Is Real 31
Health Threats To Insect And Aquatic Life And Small Animals 33
Technical Advisory Committee (TAC) 34
Ending The "Ban" Of Genetic Modified Organisms 36
Reinterpretation Of All Genetically Modified/ Engineered/
Gene Edited Organisms 38
Summary 39

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Re: proposed Gene Technology Bill

Tēnā koutou katoa,

We would like to be heard.

We oppose the Gene Technology Bill, and it must be withdrawn in its present form.
We also request extra time to allow for expert witnesses.
We also ask, given the GE Technology area is ever evolving, that we can add this evidence to our submission.

We would like to refer the Select committee for further comments that we have not discussed, in the submissions from the Centre for Integrated Research in Biosafety (INBI[1]), Dr Guy Hatchard, PSGR, Te Waka Kai Ora, and Organic Aotearoa New Zealand (OANZ).

The Gene Technology Bill is usurping the democratic process by making public policy with a selected private faction of interested parties who will both monetarily and privately benefit.

The Gene Technology Bill is not fit for purpose and will not achieve the objectives of safe use of gene technology to protect people and the environment.

We ask that the Select committee –

- Restore the interpretation of genetically modified/engineered organisms (GE) from regulated organisms in HSNO and reproduce the original HSNO interpretation in the Gene Technology Bill.
- Restore the precautionary principle, removed from current legislation by the Bill.
- Require labelling of products from Gene Edited organisms to protect the rights of consumers and farmers to know what they are consuming and growing.
- Restore Te Tiriti O Waitangi principles.
- Restore the right for Local and Territorial Bodies to adopt precautionary and protective rules around GE.
- Restore New Zealand sovereignty by removing all automatic approvals based on decisions of foreign Regulators for release of products from new breeding techniques (NBTs) or other products produced by genetic engineering (GE).
- Require comprehensive insurance on developers and users of gene technology to include GE pollen drift, GE seed and plant contamination, to pay costs for clean-up and to compensate for economic loss caused by the polluting party/parties.
- Require dedicated segregation facilities for GE organisms to ensure security and purity of the production chain.

1 *https://ir.canterbury.ac.nz/server/api/core/bitstreams/0e1aa118-5e68-4b43-b395-2a4487d90aa4/content*

- Require protection for market access and the economic advantage for New Zealand in being able to meet the demand for GE-free products.
- Require environmental and food safety testing for all GE products, with no exemptions.
- Address the absence of diagnostic tools for health professionals to be able to detect any adverse effects from gene edited food entering the supply chain.

The Gene technology Bill is clear on the intent to enable industry but fails to balance the risks to other stakeholders and the environment, and transfers costs of the biotechnology industry onto others.

The proposal to amend and change legislation to allow exempted, unlabelled and unregulated genetically engineered/ gene edited organisms into the country has no merit. This lack of regulation is a threat to economic wellbeing, health and the environment. The scale of the economic threat has yet to be confirmed but could be a loss in value of exports between $10-$20 Billion per annum.

The proposed Gene Technology Bill removes all precautionary principles that protect the environment and people's livelihoods.

The transfers of costs, risks and remediation onto affected parties, like the food industry, taxpayers and ratepayers, consumers will effect society and future generations. A recent Food Standards Australia New Zealand (FSANZ) Organic Consumer Survey (see attachment 1) and a twenty country peer review conducting in the EU has warned in the Pew Research Centre poll[2] and the IPSOS poll[3] showing significant consumer resistance of GMOs.

The HSNO Act has the precautionary principle to balance the socialised risk and the absence of strict liability on companies using Gene Technology.

The Gene Technology Bill removes all environmental and socio-economic precaution from legislation but does not address the need for liability or insurance by Gene Technology companies and users. It instead socialises costs to the public and non-GE businesses.

There is no “ban” on GE/GM organisms only the need, under the HSNO Act to show that a product or organism is safe to release into the environment. This is central to social license and there is no proof that regulation is the key factor driving industry failure. (Failures exist in less regulated markets such as the US, where gene edited hornless cows were released onto the market then found to have unwanted DNZ including antibiotic resistance genes.)

Under the HSNO Act The Crown Research Institutes (CRI) have not been denied the ability to develop in containment GMOs. The Biological Clearing house has imported and exported hundreds for Living Modified Organisms (LMO),[4] seeds, animals to countries across the globe. The Environmental Protection Authority[5] has approved hundreds of laboratory contained approvals.

It appears the CRIs are not willing to apply for the field testing that includes environmental and safety effects and clean up after the trial. These should be accepted as a cost of business. For essentially commercial reasons these safety measures are being blamed as too stringent (cost and paperwork) under the HSNO legislation.

2 *https://www.pewresearch.org/short-reads/2020/11/11/many-publics-around-world-doubt-safety-of-genetically-modified-foods/*
3 *https://www.greens-efa.eu/files/assets/docs/gmo_survey_data_30032021.pdf*
4 *https://www.gefree.org.nz/assets/Uploads/Appendix-One-10.pdf*
5 *https://www.gefree.org.nz/assets/Uploads/All-s42B+s45-GMC-approvals.pdf*

The comprehensive reporting end points required by current law for GM field trials is proof of the scientific method around the risks and benefits of a given process and product.

THE PURPOSES OF THE GENE TECHNOLOGY BILL ARE LACKING.

The Bill does not specify how or what type of avoidance, mitigation, liability or accountability the applicant is required to abide by.

Many exempt organisms will bypass the Regulator and there will be no application, validation of the gene editing, registration of the organism, traceability in the food chain, public notification or right of appeal.

If there is no ability for the public to be able to interact and place their concerns in front of the Regulator the Gene Technology Committee advisors will have an extraordinary power and influence on the term “safety”.

Genetic technologies from genetically modified organisms, gene editing and any developing new genomic technologies and new breeding technologies still pose a threat. These must be regulated to show that risk and benefit tests have been conducted by applicant companies.

The previous conduct of contained GM field trials has shown they have many problems and these risks can now be assessed in light of the effects they have on release to the environment. The Bill unreasonably excludes consideration of issues that the HSNO Act currently requires.

The Gene Technology Bill has the largest category in any jurisdiction, of exempted species scope (microorganisms, plants, animals) and process (e.g. SDN2), without the safety net of a case-by-case confirmation step, prior to considering release.

By relaxing permission and regulatory oversight this opens New Zealand up to risks that in a worse-case scenario could collapse the agricultural sector regional economy. The largest negative impacts will be on the organic and non-GE sector.

The Gene Technology Bill should be more precautionary and ethical in it's approach. The lack of transparent Regulatory oversight of exempt GE organisms, may cause the social license for the biotechnology industry to evaporate, as MBIE mentions in their Regulatory Impact Statement (RIS). When the public interest is not being served there is a clear possibility that more public protest will rise, as seen in previous glasshouse trials.[6]

RECOMMENDATIONS:

1. The HSNO Act is fit for purpose and should be retained. Unlike the Bill, it ensures continued regular, safe and progressive transfer of living modified organism (LMOs) microbes, seeds, plants and animals across to collaborating partners and countries through the Cartagena Protocol Biological Clearing House.[7]

6 *https://www.nzherald.co.nz/nz/protests-seen-as-threat-to-ge-research/ZPNWUJIP3SA6OOWPETQ7WK2MNY/#google_vignette*

7 *https://www.gefree.org.nz/assets/Uploads/Appendix-One-10.pdf*

MBIE Regulatory Impact Statement (RIS) –

MBIE Regulatory background statement shows that the Gene Technology Bill intends to:

> "support our scientists in using gene technologies to make advancements in healthcare and climate change, protect our unique environment, lift our agricultural productivity, and boost exports".

Claimed benefits of the Bill can already be achieved through conventional agriculture and current legislation.

Medical Biotech –

The overview says –

> *"Recent advances that could support better health, environmental and economic outcomes for all New Zealanders include:*
> *• new therapies for hard-to-treat genetic diseases and cancers"* (MBIE,2024)

It is the responsibility the Health Select Committee to consider the effects of harm to the health of the people.

It is imperative that pharmaceutical preparations undergo the three accountable stages of clinical trials to highlight any harm that may occur.

Rushed and incomplete pre-marketing trials create a new level of risk and should not be allowed under mandatory or emergency approvals.

Experience has documented that gene therapy recombinant drugs have dangerous adverse effects.

- The early clinical stage 1 trial for the human recombinant CD28 superagonist antibody TGN1412 with 6 healthy individuals ended in serious medical anaphylaxis, organ failure and near death.
- Recombinant Fialuridine failed the phase 2 clinical trial leading to death of five human subjects.
- The Showa Denko genetically engineered , bacterial fermented L-Tryptophan supplement disaster led to the death of 36 healthy people and over 1500 developing Eosinophilia Myalgia Syndrome.
- The SARS -COV 19 gene therapy release on all vaccines found significant adverse effects on myocarditis, pericarditis, Guillain Barre syndromes, deep vein thrombosis (DVT) that due to emergency approval conditions did not conduct long term clinical trials on all ages of the population. This affected the young demographic especially.

As seen with Thalidomide, COX2 inhibitors, Opioid addiction (Oxycontin), the redirection and suppression of certain adverse trial information led to deaths and serious addictions.

New Zealand has participated in a series of gene therapy trials and they have unfortunately ended early due to not meeting their end points. The Health sector is struggling just to keep up with the basic health care needs.

There is nothing to stop these trials from continuing under current HSNO Act. Medsafe and the Environmental Protection Authority (EPA) both have a close authority over these trials.

The reliance on conflicted pharmaceutical businesses to declare or conduct trials that are beneficial to the public health are not always reflective of safety and once released unknown and unexpected outcomes occur.

RECOMMENDATIONS:

1. All gene therapy trials are approved with conditions by a recognised independent Authority.
2. There should be no mandatory medical approvals built into the Bill.

HEALTH, ENVIRONMENTAL & ECONOMIC OUTCOMES FOR ALL NZERS

> *"Recent advances that could support better health, environmental and economic outcomes for all New Zealanders include:*
>
> *• agricultural feed grasses able to reduce animal emissions, and*
> *• better heat and drought resistant crops. (MBIE, 2024)*

The term "could" is a non-scientific approach to the reality over the last 30 years of GMO farming internationally.

What should be relied on is the intrinsic operational yield and performance not the projected hoped for, potential possibility.

Further on the RIS says -

> *Social, environmental, and economic benefits for New Zealand and consumers from the expected increased use of GMOs… products that contribute to mitigating climate change and biodiversity loss. We are unable to comprehensively quantify these expected benefits as technology development is uncertain, there are few "ready for market" gene technologies in New Zealand currently and the make-up of New Zealand's food and fibre industry is distinct.*

The inability to quantify the "benefits" as GE technology is uncertain and as seen above there is a high rate of start-up failures. The economic risks to existing businesses from the GE exempted products was not considered in MBIE's RIS, but there is a clear warning of the imposition of cost on others by developers of gene technology.

Moreover, the challenge of assessing benefits is wrongly used in the RIS to justify removing such considerations entirely in the Gene Technology Bill. Instead, the consideration of benefits, ethics and inequitable transfer or imposition of cost,s need to be part of the regulations.

RECOMMENDATIONS:

1 A Regulatory Economic Impact report must be conducted on the risks /benefits posed to existing businesses from domestic and export market rejection/acceptance. This is needed before the second reading.

AUSTRALIAN GENE TECHNOLOGY ACT.

The purported intent of The Gene Technology Bill is to standardise regulatory requirements with Australian Gene Technology Act.

However, this is deceptive and there are major differences and omissions around exemption categories and precautionary and ethical consultation.

The Australian Gene Technology Act[8] (section 106) has established a 12 member Gene Technology Ethics and Community Consultative Committee (GTECCC).

No Ethics or Community Values to be considered.

There is an absence, however, in the NZ Gene Technology Bill of an ethics and community advisory committee, that is required by the Australian Act.

The Bill removes the Regulator's ability to consider risks and benefits, and ethical and social matters in decisions. These are required in the existing HSNO Act and should be retained as a necessary part of the social license to operate.

The Gene Technology Ethics and Community Consultative Committee [9] is an appointed committee selected from nominated individuals who have skills and experience in –

(a) community consultation;
(b) risk communication;
(c) the impact of gene technology on the community;
(d) issues relevant to businesses developing or using biotechnology;
(e) issues relevant to gene technology research;
(f) issues relevant to local government;
(g) issues of concern to consumers;
(h) law;
(i) religious practices;
(j) human health;
(k animal health and welfare;
(l) primary production;
(m) ethics;
*(n) environmental issues; (*GTA 2000, cl: 108)

This allows the GTECCC when requested, to give advice to the Gene Technology Regulator on:

- *ethical issues relating to gene technology*
- *principles, guidelines and codes of practice for genetically modified organisms (GMOs) and genetically modified (GM) products*
- *community consultation on the process for applications for licences covering dealings that involve the intentional release of a GMO into the environment (DIRs)*
- *risk communication matters for DIRs*

8 *https://www.legislation.gov.au/C2004A00762/latest/text*
9 *https://www.ogtr.gov.au/committee/gteccc*

- *matters of general concern about GMOs*
- *matters identified by the Regulator. (GTECCC)*

RECOMMENDATIONS:

1. Re-establish the independent Bioethics Council as set up following recommendations by the Royal Commission on GM.
   or
2. Establish a Gene Technology Ethics and Community Advisory Committee to be part of the Regulator's required consultation and advice to be considered, in GE decisions.

THREAT TO THE ECONOMY, REGIONS AND NON-GE SECTORS.

The Gene Technology Bill allows exempted and unregulated genetically engineered organisms (GE) into NZ with no case-by-case assessment of risk, registration or traceability.

This indirectly threatens the employment and livelihoods of 360,000 people who rely on the agricultural sector. They will be directly affected if there is a billion dollar downturn in demand, or a major biosecurity incident that loses public trust and consumer confidence in our export markets.

The Bill places costs and liability for GE contamination on others, including the Food industry and particularly all current producers and retailers operating in the GE Free sector; impacting the livelihood of all farmers and rural communities.

Comments on the Gene Technology Bill by Government Minister Judith Collins show that there is little and totally inadequate awareness of the economic benefits to New Zealand from meeting the global demand for GE-free food in 2025 or the historical failed genetic engineering trials in New Zealand. (see Scientific Research outcomes GM field Trials)

Extreme deregulation and enabling of the biotechnology industry in The Bill puts New Zealand exports under threat.

The commercialisation of any NZ genetically engineered/ gene edited biotechnology has benefits for multiple international patent[10]co-inventors, but at the cost of other sectors of the economy.

The Trade Economy figure NZ[11] organisation puts the New Zealand agricultural exports in 2024 at $54 Billion projected to build to $57 billion in mid 2025. This income came from the demand for New Zealand's existing high quality, GE Free products.

The Ministry of Primary Industries (MPI) 2024 Situation and Outlook report[12] sole focus is on the excellent growth in demand for our GE Free agricultural produce.

The MBIE RIS states –

> *"Costs are to the non-GE primary producers cannot be quantified. There is no supply chain segregation protection.*
> *Cost for testing produce to be non-GE will be born by the non-GE supply chains."*

10 Patents owned by foreign countries https://figure.nz/chart/FfAHRZZdBrft7N3o

11 *Trade Economy figure NZ https://figure.nz/search/?query=trade+economy*

12 Situation and Outlook.. https://www.mpi.govt.nz/dmsdocument/66648-Situation-and-Outlook-for-Primary-Industries-SOPI-December-2024

This statement implies that contamination is inevitable. As has been seen in the Canadian experience, contamination causes GE produce to be sold as animal feed, which returns low prices.

The New Zealand Institute of Economic Research (NZIEI) report [13] commissioned by Organic Aotearoa New Zealand (OANZ) projected a $10-20 billion dollar drop in export demand across the whole agricultural export sector. This will not be offset by allowing commercialisation of unregulated and untraceable genetically engineered products that have no environmental or safety trials.

Exempting Gene Edited products from regulation and traceability will contaminate seed supply and New Zealand high quality produce will be substituted with pesticides and GE.

The non-GM and organic farming sector stakeholders were not consulted in the development of the Gene Technology Bill, nor were the Ministry of Foreign affairs and Trade, exporters or the public.

Exempting new gene editing precision breeding techniques removes protection of the economic advantage to New Zealand of its positioning as a GE Free nation, which currently don't require a compliance testing. The additional cost of implementing a verification system to satisfy our export markets, will cripple our fragile farming communities.

Markets will seek out GE Free produce from trusted sources elsewhere, because consumers demand it.

RECOMMENDATIONS:

1. The Regulator must at all times require an independent economic regulatory impact report on the risks and benefits of an application for GE release.
2. The Regulator must be required to protect Non-GMO and GE-Free production in decision making.

CLIMATE CHANGE SOLUTIONS

New Zealand farmers are already implementing innovative climate change solutions that benefit the environment, health and protects soil, bees and indigenous pollinators.

Organic regenerative, Integrated pest management (IPM) agroecology has been working with nature and successfully finding solutions to the pressing climate change, pest management and biodiversity loss issues for many years.

Results show that these systems are more resilient in climate extremes and have protective outcomes for the soil and insect pollinators.

The Wales-based company operating in New Zealand - Germinal pastural organisation [14] has already successfully developed excellent forage and grass varieties that are climate change adapted, reducing methane and increasing weight and milk solids. Germinal are developing a non-GE ryegrass with increased lipid content which will "*significantly boost milk and meat production while also lowering methane emissions*".

13 *Potential cost of Regulatory Changes https://drive.google.com/file/d/1U_E4gdKm8ijNhqMNqSjpCPwK2T6rGRp3/view*

14 *https://germinal.co.nz/non-gmo-ryegrass-developed-nz-farmers/*

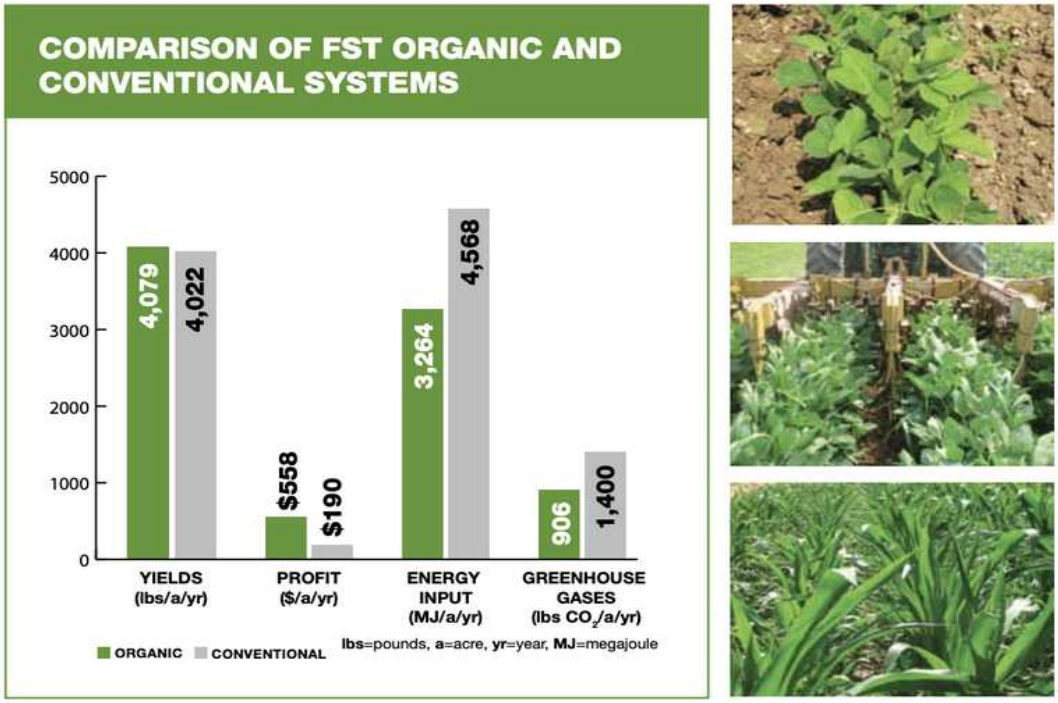
These solutions are also aligned with the market-appeal of Non-GMO food that advantages ALL New Zealand exporters.

The 30 year Rodale Farm System Trial[15] (FST) (1983-2013) found that organic systems out performed conventional /GMO farming systems both environmentally and economically in years for extreme weather events.

It also found that yields were affected in times of drought. GMOs were introduced into the farming trial in 2008 to reflect the growth in GMO planting and to assess its outcomes. (See below).

FST FACTS

- **Organic yields match conventional yields.**
- **Organic outperforms conventional in years of drought.**
- **Organic farming systems build rather than deplete soil organic matter, making it a more sustainable system.**
- **Organic farming uses 45% less energy and is more efficient.**
- **Conventional systems produce 40% more greenhouse gases.**
- **Organic farming systems are more profitable than conventional.**



(FST, p. 4)

15 *https://rodaleinstitute.org/wp-content/uploads/fst-30-year-report.pdf*

GENETICALLY MODIFIED CROPS

According to the Department of Agriculture, 94% of all soybeans and 72% of all corn currently grown in the United States are genetically modified to be herbicide-tolerant or express pesticides within the crop. So, in 2008, genetically modified (GM) corn and soybeans were introduced to FST to better represent agriculture in America. GM varieties were incorporated into all the conventional plots.

We incorporated the GM crops to reflect current American agriculture, rather than to specifically study their performance. Our data only encompasses three years, but the research being done in the community at large highlights some of the clear weaknesses of GM crops:

- **Farmers who cultivated GM varieties earned less money** over a 14-year period than those who continued to grow non-GM crops according to a study from the University of Minnesota.
- **Traditional plant breeding and farming methods have increased yields of major grain crops three to four times more than GM varieties** despite huge investments of public and private dollars in biotech research.
- **There are 197 species of herbicide-resistant weeds, many of which can be linked directly back to GM crops**, and the list keeps growing.

Pesticides commonly used in agriculture have been found in drinking water, sometimes at levels above regulatory thresholds.

- **GM crops have led to an explosion in herbicide-use** as resistant crops continue to emerge. In particular, the EPA approved a 20-fold increase in how much glyphosate (Roundup®) residue is allowed in our food in response to escalating concentrations.

11

The Rodale 30 year Farming System Trial (FST) conducted by Rodale Institute printed in 2014, and recently updated 40 year trial (2024) did not find any change to the GMO outcomes except a growth and increase in the type and use of pesticides used on the crops due to insect and weed resistance.

The 40 year Farm Trial Report [16](FST) found that organic systems in times of weather extremes outperformed conventional and GMO systems.

Yields were comparable between organic and conventional systems. However, organic grains surpassed conventional yields in years of drought or excess rainfall. Overall, organic corn yields have been 31 percent higher than conventional/GMO production in drought years. (Rodale 40 yr Farm Trial, p. 18-19). They say -

> *"Organic corn yields were 31% higher than conventional in years of drought. These drought yields are remarkable when compared to genetically engineered "drought tolerant" varieties which saw increases of only 6.7% to 13.3% over conventional (non-drought resistant) varieties." (FST, p.8)*

INCREASE IN PESTICIDES WITH GE PLANTS

Pesticides and Tolerant GE Plants that have increased use of industrial chemicals on food crops.

The rise in superweeds and super pests are reasons why there has been a drop in appeal and a downturn in demand for GE variants.

The recent USDA statistics (January 2025) on GE crops were varied

- Corn for grain production in 2024 was estimated at 14.9 billion bushels, down 3 percent from the 2023 estimate.
- Soybean production in 2024 totalled 4.37 billion bushels, up 5 percent from 2023. The average yield per acre was estimated at 50.7 bushels, up 0.1 bushel from 2023.
- All cotton production in 2024 is estimated at 836 pounds per acre, down 63 pounds from last year.

Virtually all the GE crop plants that have been released have herbicide tolerance and insect resistance traits, often stacked genes for multiple herbicides or insecticides.

This has caused a rise in multiple applications of proprietary herbicide applications on crops, increased residues in foods, as well as a rise in weed and insect resistance.

There has been concern over the years of herbicide resistance and where GE crops are grown there is documented rise in super weeds and pest resistance from GE.

The report by Jeffrey McNeely, Chief scientist for the ICUN[17] details the invasive nature of GMO and pest as "alien species" or plants that are not in their native ecosystems.

16 *https://rodaleinstitute.org/wp-content/uploads/FST_40YearReport_RodaleInstitute-1.pdf*

17 *https://www.icgeb.org/wp-content/uploads/2019/01/2-The-problems-with-invasive-alien-species-and-implications-for-GMOs-Jeffrey-A.-McNeely.pdf*

In 2005, the paper found the herbicide tolerant genes in principle could “escape” from GM plants to weedy relatives through pollen transfer, which in turn would cause “superweeds” that might turn out to be highly invasive (McNeely, p. 25).

Professor John Paull, University of Tasmania, details in his publication “Genetically Modified Organisms (GMO) as Invasive Species”[18] that GE/GMO are not similar to non-GM plants (as they are patented) and have become invasive pest species and harbour invasive species that have disrupted the social license of agriculture. (Paull J, 2018)

In the past 20 years the invasion of the “superweeds" has become a reality.

The proliferation of invasive super weeds now occupy 60 million acres of US farmland. This is causing economic loss and serious depression to farmers. (Union of Concerned Scientists, 2023)

The Scientific Dossier on GE corn[19] by Felipe Carrillo Puerto (2024) has documented the resistance to the endotoxin Cry proteins causing a rise in “super pests.

There are now:

- Seven species of Lepidoptera and one of Coleoptera which have developed resistance to GM plants that produce insecticidal Bt proteins.
- The corn earworm, *Spodoptera frugiperda*, has developed resistance mechanisms to organophosphate, pyrethroid and diamide insecticides, as well as to the Cry1F protein;

South America – Evidence of Bt insect resistance

- Cross-resistance, selected with GM corn, to Cry2Ab2, causing resistance to Bt crops expressing similar proteins;
- Resistance to Cry1Fa and Cry1A proteins
- Resistance to Cry1 insecticidal proteins;
- Resistance to Vip3Aa20 protein from Bt corn;
- Resistance to the Cry1F protein from GM corn event TC1507 with some strains showing high levels of cross-resistance to Cry1A.105 and Cry1Ab;
- Resistance to the Cry1Fa2 protein, as well as cross-resistance to other Cry1A proteins

North America - Evidence of Bt insect resistance

- The African corn stem borer has developed resistance, particularly in GM Bt corn expressing the Cry1Ab protein.
- The European corn borer, *Ostrinia nubilalis*, is resistant to Bt proteins.1120,1121
- Resistance of *Diabrotica barberi* to corn expressing the Cry3Bb and Cry34/35Ab1 proteins.
- Field populations of *Diabrotica virgifera virgifera* have resistance to the Cry3Bb1 and mCry3A proteins of GM corn, and cross-resistance between these two types of Bt corn. Also, resistance to eCry3.1Ab corn and cross-resistance between Cry3Bb1, mCry3A and eCry3.1Ab.
- The bollworm, *Helicoverpa zea*, has shown to be resistant to Cry1 and Cry2 proteins, with different levels of dominance and recessiveness depending on protein concentration. The same species has developed resistance to Bt proteins, with up to 1,000-fold levels of resistance to Cry1Ac;

18 *https://orgprints.org/id/eprint/33327/1/Paull2018GMInvasiveSpeciesJEPSD.pdf*

19 *https://usrtk.org/wp-content/uploads/2024/11/DOSSIER-MAIZ-2024-ENGfinal-5.pdf*

- Dominant resistance to Cry1Ac and minimal cross-resistance to Cry2Ab;
- Resistance to Cry1A.105 and Cry2Ab2 among 22 field populations collected on Bt corn;
- High levels of resistance to the Vip3Aa protein used in GM Bt corn and cotton, pyramided with Cry1 and Cry2 proteins, in the United States;1 and developed resistance to the Vip3Aa protein.

Australian - Evidence of Bt insect resistance

- Populations of *Helicoverpa punctigera*, developed resistance to Bt proteins has been observed, specifically to the Cry2Ab protein of Bollgard II cotton;
- Resistance to Vip3 proteins has been observed in populations of *H. armigera* and *H.punctigera.*

India - Evidence of Bt insect resistance

- The pink bollworm, *Pectinophora gossypiella*, has developed resistance to the Cry2Ab toxin, associated with mutations in the ABCA2 gene; and resistance to Cry1Ac and Cry2Ab2 proteins from GM cotton.
- There is resistance to Cry1Ac in Trichoplusia sp. due to multigene mutations.

Super weeds - Evidence of emergence after GMO crops commercialised

Some resistant varieties have emerged as a result of a gradual evolution of herbicide-exposed weed species, while others have emerged due to gene flow from glyphosate-tolerant GM crops to their wild relatives.

The platform of the International Survey of Herbicide Resistant Weeds recently reported 317 cases of 47 species with glyphosate resistance in 29 countries, and the list shows a growing trend with new resistant species identified every year.

The overuse of a cocktail of herbicides will accelerate weeds resistant.

The main ones include:

- *Amaranthus tuberculatus, Amaranthus spinosus, Amaranthus rudis, Amaranthus palmeri,*
- *Ambrosia artemisiifolia, Ambrosia trifida,*
- *Bassia scoparia,*
- *Chloris virgata, Chloris truncata,*
- *Conyza bonariensis,*
- *Digitaria insularis,*
- *Echinochloa colona,*
- *Eleusine indica,*
- *Erigeron canadensis,*
- *Lolium multiflorum, Lolium rigidum,*
- *Poa annua and*
- *Sorghum halepense*.

Mexico - Evidence of resistance in weeds

- *Amaranthus palmeri, Aster squamatus*
- *Bidens pilosa,*
- *Leptochloa virgata* and
- *Steinchisma laxum,*

RECOMMENDATIONS:

The Bill:

1 Require the Regulator to prevent and manage risks, both
2 Ensure that those responsible for introducing economically harmful GE practices that create a rise in super weeds or super pests are liable for the costs they impose.
3 Ensure that those responsible for introducing GE are responsible for clean-up of genetic contamination of non-GE producers and districts.
4 Require developers and those owning the patents, importing, planting and commercialising GE to be liable and have commercial insurance to cover any spread to non-GE production areas or contamination of non-GE seed, plants or animals.

Forestry

Issues of risks to biodiversity from GE tree monocultures have been discussed internationally.
No one knows the effects on biodiversity, flora, fauna and soil health.
In addition to biosafety risks, fire hazards have also been identified.

Risks arise if gene edited organisms are exempt without regulatory oversight as seen in the blight resistant GE American Chestnut.

The American Chestnut Foundation withdrew its support for the "GE Darling 58 Chestnut" engineered for blight after they were informed that:

> *"academic colleagues brought to our attention their newest findings suggesting a significant identity error in the propagation materials supplied to TACF. Independent confirmation now shows all pollen and trees used for this research was derived not from Darling 58, but from a different prototype, one which contains a deletion in a known gene .. That deletion, along with the discouraging field performance collectively renders these trees, … unsuitable as the basis for species restoration."* (TACF, 2023)[20]

Recent reports from Canada on the spread of wild fires has seen that plantation trees sprayed with herbicides fuel wild fires.

This is caused by herbicides that remove the shrubs and other trees, which in turn dries out the soil, kills the protection and diversity and triggers the spread of wild fires. This has serious consequences if GE pine plantations are planted to offset carbon credits for the increased coal and gas mining that is being proposed.

Fire burning in a pine plantation (North of Amberly) about 80ha but has spread further today.

20 https://tacf.org/tacf-discontinues-development-of-darling-58/

In the four years (2018 -2022) New Zealand Fire and Emergency[21] reported a total of 4100 fires in the forestry sector.

The Canterbury wild fires in pine plantations[22] is an example for the wind and incendiary trees being a risk to New Zealand communities. This is of serious concern and consideration if New Zealand is to develop herbicide resistant Pine Trees, especially when there are already dry soil conditions and winds.
As the Canadian article shows the diversity of shrubs and trees in forests help protect the ground and other flora from the ravages of fires and droughts.

RECOMMENDATIONS:

1 Any application for release of genetically engineered trees that are resistant to herbicides must have a detailed fire policy that addresses the protection of the surrounding communities and native forests.
2 The Regulator is required to prevent and manage risks to natural ecosystems, including soil, and to protect bees and pollinators

SUBPART 7 - RECOGNISED OVERSEAS AUTHORITIES - SECTION 57 :

Recognising international authorities expertise is a defacto method that removes effective regulation and sovereignty.

Efficiency and alignment must not be at the cost of clinical standards, or effective prevention and managing of risks from gene technologies. The Bill's focus to enable commercial biotechnology effectively undermines this balance of competing interests in favour of commercial enterprise.

The Bill includes mandatory emergency medical approvals AND automatic acceptance of GE technology approved by two agreed overseas regulators.

Both pose a risk to the public and National Interest.

> *The Bill provides the Regulator with the ability to recognise overseas Gene Technology Regulators that operate within a comparable legislative framework. The Regulator can develop an agreement with another regulator for the purposes of undertaking joint risk assessments to increase the efficiency of decision-making.*

This departure from New Zealand sovereignty with the requirement - not just ability - to defer to overseas regulatory decisions on gene technology releases is unacceptable.

Each country has differing criteria on their assessment process. Any seed contamination will also put all conventional GE-free and Organic farming systems at risk.

The Organics Products and Production Act regulatory[23] standards expressly prohibits GMOs in the farming system.

21 *https://www.ruralfireresearch.co.nz/__data/assets/pdf_file/0006/73959/FireSeasonWrap_2019-20.pdf*
22 *https://www.nzherald.co.nz/nz/canterbury-wildfire-scorches-pine-plantation-overnight-concerns-it-will-spread-today/WVN3Q7YL2NCJTOQ6E3V52AFKCA/#google_vignette*
23 *https://legislation.govt.nz/act/public/2023/0014/latest/LMS312665.html*

The Bill unfairly transfers industry risk and imposes costs on affected parties with increased costs of securing the supply chain for Non-GMO food imposed on the food industry and consumers.

Commercial risk is being socialised on taxpayers and ratepayers.

In the US, the patent holder, applicant takes all responsibility for risk and harm and can be sued by the farmer (etc) if harm is found.

In Aotearoa New Zealand risk effects are put on the person contaminated and costs are borne by the affected party.

ACC covers any health impact that might occur, e.g. the depression and anxiety related to loss of income or over use of pesticides. Dr Debra Strauss, Fairfield University, document on the Legal liability Risks of Genetically Modified Food[24] highlights the litigation dangers to seed companies, farmers, and businesses.

Also, the document highlights the aggressive patent holders ability to litigate non-GE farmers who grow patented GE contaminated crops.

In particular there is concern that through exemption of gene editing, natural traits may be captured and patented by biotechnology companies, charging fees and reducing access to natural varieties for farmers and growers. The Regulator and Committees have a duty to protect our farmers and seeds from GE contamination.

RECOMMENDATIONS:

1. Remove overseas regulator mandatory release approvals of any type from the Bill.
2. Prohibit Patents on natural traits. These should not be allowed or they will limit access and increase costs for grower and producers.
3. Include Liability on Users of Gene Technology and the requirement for commercial insurance
4. Require proof of financial fitness for companies to pay fines and for payment for remediation, for repair, replacement and any unforseen impacts of their product.

GM Results From New Zealand

NZ Scientific Research outcomes GM Field Trials

Important science and useful research has been conducted by the Crown Research Institutes on genetically modified organisms.

Annual reports to ERMA (now the EPA) document the risks faced by this technology when extrapolated to the larger field trials and open environment.

There have been 20 field trials in New Zealand, conducted by CRI scientists. Not one has reached commercial viability. There have been repeated breaches of GM trial conditions despite our current robust regulatory controls.

24 *https://digitalcommons.fairfield.edu/cgi/viewcontent.cgi?article=1158&context=business-facultypubs*

Lessons from the scientific failures make it clear why precaution, ethics and long term research into an unknown, unproven technology must be included (as it is in HSNO Act now,) in the Gene Technology Bill.

Below is an overview of the various documented breaches and field trial outcomes:

Import Breaches –
The Corn Gate incident in 2000 was discovered when Japan returned a consignment of GM Free corn saying they detected GM presence. Ministry of Agriculture and Fisheries (MAF) now Ministry of Primary Industries (MPI) tested the consignment and found multiple varieties of GM corn[25] in the consignment mostly positive for the NoS3 gene and the CAM35S gene. The Star link corn found was only approved for animal consumption due to its risk profile. Continued monitoring of the site, until 2003 did not find any volunteers but still found presence of GM contamination[26]

Laboratory breaches
Arabidopsis thaliani[27] found growing outside containment facility. Plants and Food leased their facilities to an outside person. GM material illegally sent out of New Zealand.

GM apples trees filter faulty[28].
Un approved GM organisms[29] and other material illegally exported from Auckland University

Field Trial outcomes

GM Allium – this was a field trial on five different species of onions. It was conducted in partnership with Monsanto and the trial was closed down early. GM onions were found growing outside the contained facility.

Scion GM Trees – Facility badly maintained, animals entering and eating the saplings. Large breach where GM Tree were cut down. Trees were allowed to grow taller that specified in controls.

Pine trees[30] Breach of controls relating to the laboratory containment with a disease

Plant and Food GM Brassica field Trial (GMF 06001) – four different species of Brassica were trialled in Lincoln. Breaches of conditions from the start by letting field trial brassicas flower instead of moving them to the glass house. A black bacteria rotted the stems[31] that was not tested for possibility of GM nature. Cutting the GM plants to 6 inches from the ground at the end of the trial season instead of removing the whole stalks. Not monitoring them to check on any new growth or flowering. The trial was closed down after one year when a flowering re growth GM plant was found, threatening the seed growers in the area.

25 *https://www.mpi.govt.nz/dmsdocument/13044-Test-results-on-seed-grown-and-harvested-at-sites-in-Gisborne-during-2003*
26 *https://www.mpi.govt.nz/dmsdocument/13041-Periodic-updates-to-officials-on-Gisborne-sweetcorn-June-July-2003*
27 *https://www.gefree.org.nz/assets/doc/GE-breaches/OIA-Arabidopsis-Investigation-Offence-Summary.pdf*
28 *https://www.gefree.org.nz/assets/Uploads/OIA16-0146-Release.pdf*
29 *https://www.nzherald.co.nz/nz/gm-material-sent-out-of-nz-illegally/ZWJDXJLXO2VRBK3VDO5BQ46524/*
30 *https://www.nzherald.co.nz/nz/gm-pine-trees-in-disease-probe/HG62UPDGAAHZKOLITOEEEP35AQ/*
31 *https://www.gefree.org.nz/assets/pdf/BrassicaRot.pdf*

AgResearch GM Animal Trial partnership with Genzyme (GMF98009, ERMA20223) - Ethics and prevention of cruelty to animals from gene technology

In 2000 the GM animals experimental trials commenced which were engineered to produce pharmaceuticals in their milk. The trial caused unexpected outcomes that ended in the deaths of the 3 FSH GM calves[32] after extreme animal suffering.

Animals were born with fused organs, bone deformities. Abortions and deaths of surrogate animals was high. Live births ranged from 0-7%.

The GM progeny were sterile and unexpected sudden deaths in animals was found. The milks from GM animals were found to be not viable. The trials on goats and sheep have similar failures and problems. (GE Animals in New Zealand the First 15 years) [33]

These adverse outcomes have also been observed in Germany where an experiment to create hornless cows was conducted. The experiment had no success and the findings printed in the British Medical Journal scientific reports wrote -

> *"70 clones were generated in the lab, of which only nine developed into embryos that were then implanted into surrogate mother cows. Three of those embryos did not result in pregnancy, they died in the uterus. Four cows had serious complications due to the pregnancy and lost their calves. One calf was killed prematurely for further examination. Only one calf was born alive via caesarean section, but died the same day. Its pathological examination on the calf revealed malformations of some internal organs including the liver, heart, diaphragm, lungs and skull, finally resulting in acute cardio-vascular failure." (BMJ. 2020)*[34].

AgResearch GM HME Rye grass was conducted overseas in a five year field trial 2017-2022, costing $25 million dollars.

After two years the trial went on to conduct animal feeding trials. The final trial outcome was poor. The grass did not perform to expectation and the expected yield was not sufficient to produce enough ensilage to conduct the first ever animal nutrition trials for the project.

> *"… preparing commercial-ready HME forages for New Zealand-based field and animal nutrition trials scheduled for the spring of 2021."* (AgResearch, Statement of Intent, 2018, p.20)

The HME rye grass died back when temperatures reached 26C, the grass did not grow well with competition, and yield was poor.

The Australian Authorities turned down a trial application voicing concerns over the allergenicity of the transgenic sesame oil construct.

32 *https://www.gefree.org.nz/assets/pdf/Gluckmanreportoncattledeaths-.pdf*

33 *https://www.gefree.org.nz/assets/pdf/GE-Animals-in-New-Zealand.pdf*

34 *Schuster, F., Aldag, P., Frenzel, A. et al. CRISPR/Cas12a mediated knock-in of the Polled Celtic variant to produce a polled genotype in dairy cattle. Sci Rep* ***10****, 13570 (2020). https://doi.org/10.1038/s41598-020-70531-y*

In the USA Gene Edited Hornless Cows (TALENs technology) escaped regulation as gene editing was deemed exempt. A new detection method found they had genes conferring resistance to antibiotics inserted unintentionally into the genome of the cattle. This did not stop Recombinetics from exporting semen to Australia where 8 cows were born and 5 were euthanised, in 2019.

There are further experiments being carried out with CRISPR/ Cas on species, such as cattle and[35] pigs, whereby unintended genetic changes and health problems are a regular occurrence. (TestBiotech, 2023) See further information on this in INBI submission).

All the breaches occurred under the auspices of respected researchers and staff at Crown research Institutes (CRI) or Universities. Human error is a major risk and by exempting organisms this risk is increased. Future errors of "paper work" or mis-labelling could see a wider range of problems, including from exempt organisms that will escape labelling.

RECOMMENDATIONS:

1. GM/GE of sentient animals is prohibited.
2. No pest animals in the environment are to be genetically modified/gene edited.

MBIE REGULATORY REPORT

The Ministry of Business, Innovation and Employment (MBIE) Regulation of Gene Technologies-Policy Decision[36] recently released on 10 December 2024 outlines the intent of the Gene Technology Bill. It is ambiguous to exempt low risk organisms from regulation without specifying whether they will be open to release into the environment or just not regulated so that they can be used by researchers in laboratories without regulation.

Any organism that has been manipulated by in vitro gene editing techniques and had their DNA altered by bacterial splicing should be considered as needing regulation. The removal or addition of template modifications, though they don't introduce new material they are open to repair mutations that have effects on other parts of the chromosome or genome, **"off target effects"**. It cannot be considered the same as natural selective breeding. Two gametes have a preselected set of DNA in their makeup and a vulnerability or just one gene extra can cause serious rare diseases or predispositions to disease. The deleting and inserting of genes without proper oversight and long term research is open to the same possibilities and heritable risks and failures as seen in New Zealand trials.

RECOMMENDATIONS:

1 All exempt organisms from regulation should only be used in laboratory research and must be registered with the EPA and open to transparency under the Official Information Act.

2 Exempt organisms cannot be released into the environment without public notification

3 Exempt organisms cannot be patented at commercialisation.

35 *https://www.testbiotech.org/en/news/dubious-crispr-experiments-calves/*

36 https://www.mbie.govt.nz/dmsdocument/29938-regulation-of-gene-technologies-policy-decisions-proactiverelease-pdf#:~:text=39%20In%20line%20with%20international,not%20introduce%20new%20genetic%20material.

SUBPART 4 - NON-NOTIFIABLE AND NOTIFIABLE ACTIVITIES CLAUSES 47 AND 48

The Gene Technology Bill General Provisions - the activity tiers are very open ended. They state that:

- *The non-notifiable, very low risk activities need no monitoring or approval, but cannot be released into the environment.*
- *The notifiable low risk extends to animal laboratory research and must be notified to the regulator.*

Exempt Activities

No Gene Edited/GMO organisms should be exempted from regulation

The range of GE plants, animals, fungi and micro-organisms to be exempted is far more permissive than our trading countries.

The EU is considering some deregulation for plants only and to date, is maintaining traceability and labelling.

The UK allows precision breeding of plants and animals but requires an application, proof of gene sequence, animal welfare reports , and registration of all PBT organisms.

We have serious concerns over the large range of Gene Edited foods that will be made exempt . Dr Kawall paper, The Generic Risks and the Potential of SDN-1 Applications in Crop Plants (2021) [37] found that even in the exempted site-directed nuclease 1 (SDN-1) technology there are serious unexpected deleterious outcomes. The paper found

> *that nearly half of plants with so-called market-oriented traits contain complex genomic alterations induced by SDN-1 applications, which may also pose new types of risks. (*Kawall K. *et al, 2021)* [38]

The gene editing technologies like CRISPR are multiplied in specific culture media (Culture media is a gel or liquid that contains nutrients and is used to grow bacteria or microorganisms). In the research paper Arakawa et al (2024) Cross-contamination of CRISPR guides and other unrelated nucleotide sequences among commercial oligonucleotides[39]. They tested CRISPR batches from suppliers. They detected a variety of contaminants in all batches. Though the cross contamination varied. This contamination could lead to the unexpected outcomes from the simplest of GE techniques.

Exempted organisms does not allow the Māori Advisory Committee kaitiaki to evaluate whether there will be an environmental risk to the indigenous flora and fauna, moana or awa and taonga species now endemic to Aotearoa. The Treaty of Waitangi principles allow for this in the HSNO Act

37 https://pmc.ncbi.nlm.nih.gov/articles/PMC8622673/

38 Kawall K. The Generic Risks and the Potential of SDN-1 Applications in Crop Plants. Plants (Basel). 2021 Oct 22;10(11):2259. doi: 10.3390/plants10112259. PMID: 34834620; PMCID: PMC8622673.

39 https://academic.oup.com/nar/article/52/6/3137/7602849?login=false

Exempting selected GE organism categories from the Bill creates vulnerability in the food chain, undermining trust, losing traceability and denying consumers the right to choose.

The absence of any method of identification for exempted GE organisms removes the ability to choose and could be considered misleading conduct in relation to goods and in contravention of the Fair-Trading Act. (Fair Trading Act sec: 10)[40]

RECOMMENDATIONS:

1 All exempt organisms from regulation should only be used in laboratory research and must be registered with the EPA and open to transparency under the Official Information Act.

2 Exempt organisms cannot be released into the environment without long term studies on risk. They must be publicly notified, and considered by The Regulator within a framework requiring prevention and managing of risks, precaution, and protection for GE-free producers and natural environments

3 Exempt organisms cannot be patented at commercialisation.

Non-notifiable and notifiable low risk activities

The non-notifiable and notifiable low risk activities are contained laboratory developments do not require public notification.

The experience of the breaches of conditions in CRI laboratories and ability of unlicenced people able to use the premises for GE regulated organism research shows this is inadequate to meet the purposes of the Bill.

Unless there is strict monitoring and knowledge of what is being tested, escape to the environment is a strong probability and without monitoring and inspection there is no ability to know what and how the escape occurred or what the effects will be.

RECOMMENDATIONS:

1 Notification to the Regulator, even of what are considered very low risk organisms, and monitoring of facilities to be specified in all GE research.

2 Annual Reports on the progress of the experimental organisms.

3 Contained laboratory facilities must be registered PC facilities specifically tailored to microorganisms, animals, plants.

4 No products from new gene editing are to be exempted from registration, traceability, labelling, or from consideration of ethical issues including animal welfare.

40 *https://www.legislation.govt.nz/act/public/1986/0121/latest/DLM96904.html*

Licensed Pre-assessed Activity

The licensed pre-assessed activity category is not specified whether it is still undertaken in a contained facility.

If allowed outdoors it is a risk to the environment and farming community unless it is in a contained dedicated monitored facility with strict controls.

This is because the Regulator may have advice from Industry, Māori and Technology Committee that is narrow. It does not take into account the full scientific data as a basis for concerns nor the different regions business agricultural activities.

RECOMMENDATIONS:

1 All GE experimentation must be fully notifiable to councils and open to public submissions.

2 It must be in a contained dedicated monitored outdoor facility with strict controls.

Licensed - Expedited assessment –

At no stage should any GE organism whether exempt or not, should be given a licensed expediated assessment without there first being comprehensive environmental and human safety studies and full public notification is undertaken.

RECOMMENDATIONS:

1 There should be no Regulator discretion as to who can be consulted. The tailored licence conditions / controls must be clearly specified and monitored in a dedicated open air facility of limited size.

2 A public register of where the licensed activity is undertaken.

3 Expediated activities must be carried out in only one region and must be inspected and monitored against the conditions the Regulator has placed on them.

4 There should full public notification.

5 Consultation with overseas regulators can only inform the Regulator but not be used as an acceptable substitute for New Zealand conditions. This is a significant breach of transparency for the public of New Zealand.

Licensed - Full assessment –

This indicates a full release of a new breeding technology regulated GE organism.

RECOMMENDATIONS:

There must be:

1. Full public consultation into risk factors that have been conducted in New Zealand, including prior licensed activities that address environmental and human health safety outcomes.
2. No GE release activity can be carried out in regions where organic and regenerative, non-GE businesses are situated unless at least 120 km apart. This is because New Zealand areas often have 120km winds and any GE pollen would be blown across these existing dedicated farming systems affecting their productivity and livelihoods.
3. Dedicated depot facilities that only accept GE seeds and produce and all transportation vehicles and equipment.

THE CARTAGENA PROTOCOL ON BIOSAFETY (CPBS)

The Gene Technology Bill must consider the Cartagena and Convention on Biological Diversity.

> *"The Regulator and every other person who carries out a function or duty or exercises a power under this Act, must when doing so, have regard to the provisions of—*
> ***(a)*** *the Convention on Biological Diversity ; and*
> ***(b)*** *the Cartagena Protocol. (*Gene Technology Bill, clause 5)

By deregulation and enabling legislation, New Zealand as a signatory to The Cartagena Protocol on Biosafety (CPBS)[41] is undermining the safe trans boundary movements of Living Modified organisms created with modern biotechnology.

The CPBS definition of terms state -

> *"Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;* and
>
> *"Modern biotechnology" means the application of:*
>
> *a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or*
>
> *b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;" (Cartagena Protocol, Use of Terms, p.4)*

The Gene Technology bill removes all references and definitions of genetically modified organisms (GE) replacing the definition with "regulated organism".

This is obscuring the true nature and scope of exempted GE organisms though they are all still GE organisms, and contrary to the international terminology around GE.

41 *https://www.legislation.govt.nz/bill/government/2024/0110/latest/whole.html#LMS1011631*

The CPBS allows a decision-maker to take both socio-economic issues and a scientific risk assessment into account. –

> *"… consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities." (Cartagena Protocol, Article 26, p.19)*

RECOMMENDATIONS:

1 Ensure interpretation and definitions on genetically modified/gene edited organisms are consistent with International Convention on Biological Diversity (CBD) terminology.

2 Ensure science (not unscientific concepts or terminology) defines and validates all products of new genomic techniques, with no pre exemptions or mandatory approvals either.

AMENDMENTS TO OTHER LEGISLATION

SUBPART 6 - AMENDMENTS TO HAZARDOUS SUBSTANCES AND NEW ORGANISMS ACT 1996

Subpart 6—
The removal of the term genetic modified organism as specified in the HSNO interpretation section 2–

> *genetic modified organism means, unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material—*
> *(a) have been modified by in vitro techniques; or*
> *(b) are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques.*

We strongly oppose the non-scientific reinterpretation of that genetically modified/ engineered/gene edited organisms are reinterpreted to mean "regulated organisms".

Regulated Organisms is a confusing and misleading term as it predetermines 'non-regulated' without a scientific basis or system to assess what they actually are.

The Bill removes the accurate definition and identification a genetically modified/ gene edited organism (GE) created by new breeding techniques involving laboratory manipulations of genes. The term "regulated"[42] infers that it has undergone consideration by a constituted authority with rules and regulations as specified under the law.

42 *https://www.merriam-webster.com/dictionary/regulate*

The term regulated organism also misleads consumers in assuming that GE has undergone oversight by a Regulatory body thereby assuming that safety has been tested and assured. By contrast, the HSNO Act states a genetically modified organism even if released does not cease to be a genetically modified organism. This is clear for consumers and businesses alike.

There are distinct and defined areas of jurisdiction for the RMA in the HSNO Act. These are being dismantled without any known reason.

The Biotech industry have been integral in advising the writing of the Gene Technology Bill and have now been able to forward their agenda by overruling existing laws for their own benefit. (see page 33)

SUBPART 9 - AMENDMENTS TO RESOURCE MANAGEMENT ACT 1991 -

This relates to 248 -253 Functions of regional, territorial and district councils[43] of the Gene Technology Bill.

The rural communities are an essential contributor to the economic viability of New Zealand. All Unitary, Regional and district Councils must be able to set rules that protect their community.

The removal, under the amendments to the RMA, of ability for councils and territorial and unitary authorities to regulate the district's activities is an overreach into an area that the Gene Technology Bill has no jurisdiction nor expertise.

The EPA regulatory hearing committees are focused on the scientific data that a specific organism has, e.g. risk benefit of a GMO, Treaty principles and any precautionary safety issues.

But the EPA committee does not consider the nature of differing environmental weather patterns like cyclones, droughts, tornados, floods between regions.

It is unrealistic and self-serving to say that Councils protecting their rural economy by declaring restrictions on GMOs are redundant and "a dual approval system".
There are no grounds for this statement - it is erroneous and without merit.

Removing precaution from the Bill is against the public interest.

The Bill denies Councils their capacity to apply the precautionary principle, also with no compensation for imposed costs, nor requirement for bonds and commercial insurance required of developers.

The Gene Technology Regulator can only consider mitigating risk but existing legislation allows local district communities to ask the Councils to consider any avoidance or mitigation that is a threat to their community.

Regional developments as GE-free producers with an export marketing advantage must continue to be allowed.

Councils can be sued if any contamination in areas under their control spreads to neighbouring land and this not addressed in the Bill.

43 *https://www.legislation.govt.nz/bill/government/2024/0110/7.0/LMS1010272.html*

It undermines the integrity of the food supply to have patented GE organisms un labelled, unregulated, with unknown risks being deemed the same as non-GE conventionally bred organisms.

A GE progeny will always be from a gene altered organism parent. A precautionary approach to any business growing /using GE organisms must be able to be taken by councils and territorial and unitary authorities if their community wants it.

RECOMMENDATIONS:

1. Section 248-253 must be rescinded, and councils and territorial and unitary authorities be allowed to continue to consider local needs and to place precautionary principles and rules around GE organisms.

2. Each Council and community has its own character and challenges. The rural regions are an essential contributor to the economic viability of New Zealand and they must be able to set rules that protect their community.

INTERFACE OF HSNO, GENE TECHNOLOGY BILL AND RMA AND ECONOMICS

The High Court has ruled on the distinct differing areas of jurisdiction between the Environmental Protection Authority (HSNO) and Local Bodies (RMA).

The RMA allows communities to set rules that embody community determined outcomes, including the level of risk it is willing to accept with respect to activities such as the management of GMOs.

This right will be taken away by the Gene Technology Bill, yet there is no rationale for this change as the Environmental and High Courts have both determined that there are differences in the responsibilities of HSNO and the RMA to communities.

This allows communities to protect their land use and livelihoods from any risk, effects of spray drift and spread of GE organisms,including heavy metals and industrial pollutants.

The proposed Gene Technology Bill removes the right of communities to have a say on GE organisms but allows prospective benefits to be considered in isolation of risks, ethics , economics or societal value.

This "cherry picking" excludes wider considerations and only serve to financially benefit protected biotech investors, pushing risk and costs onto citizens of Aotearoa.

It is difficult to understand how the HSNO Act guidelines regarding GMOs and existing tort law will stand in relation to the Gene Technology Bill.

It is unusual and deeply concerning that a new Bill will negate the understanding of existing precautionary law established over many years. Especially when there are no studies on human health or animal health of any food from new biotechnologies or Gene Edited foods.

Normally safety precautions are introduced once a product has undergone clinical or field/environmental or ingestion testing. MBIE and advisors writing the law have not addressed the lack of safety studies on new exempt biotechnologies to the detriment of society.

There should be no removal of the ability of local and regional authorities to apply the precautionary principle in their land use, especially when the High Court has deemed under HSNO, any escape from containment is the jurisdiction of Regional and District bodies.

The Royal Commission on Genetic Modification (RCGM) found that it was important to preserve opportunities by ensuring rigorous assessment of future use of GM with assurance of safety, and prevention and management of risk.

The Bill's exemption of certain categories of gene edited and genetically modified organisms does not allow for the agricultural sector to maintain systems integrity with traceability and controls on GE contamination.

It stifles regional development for GE-free Zones to reach their full economic potential. The release of GE unlabelled and unregulated threatens both the organic sector and the conventional Non-GMO export sector for which global export demand is growing by +12% annually.

The RCGM found that future uses of genetic modification will continue to require rigorous assessment by ERMA [now EPA] before approval. One detail whereby the RCGM considers the existing processes could be improved is an addition to the approval types now available.

> *"We are recommending a new category, conditional release, where the use of a genetically modified organism can be made subject to terms and reporting back, as a further assurance of safety and to enhance the management of risk." (Executive Summary* p.3)

The RCGM wrote about the considerations that they took in Preserving Opportunities and reporting of results.

In contradiction to the exemptions from regulation in The Gene Technology Bill today, the Royal Commission gave its thoughts explicitly rejecting the unrestricted use of genetic modification. This position still stands today.

> *"We also reject the option that New Zealand allows completely unrestricted use of genetic modification technology. Unregulated use would involve taking unacceptable risks with human and environmental health and with our cultural heritage. It would also compromise consumer choice and our export market options. In the event, no submitters suggested such an approach to us."*
>
> *and*
>
> "*In short, either of the extreme options [of GE] would significantly restrict New Zealand's future choices and has the potential to impose considerable costs. All sectors of our economy should remain viable and be able to expand to their full potential within the constraints of a competitive environment".*
> *(Chapter 13: Major Conclusion cl14 &15. p. 333)*

ECONOMIC IMPACT OF GE ON PRIMARY PRODUCERS ARE INDICATIVELY NEGATIVE.

The MBIE Regulatory Impact Statement[44] (July 2024) on impacts writes -

> *"Unquantified costs to organic/non-GMO primary producers. At present this sector operates without risk of inadvertent contamination to their products from GMOs, because under the status quo there have not been any environmental releases of GMO products that could cause such contamination.*
>
> *Under the proposal, it is expected that eventually GMO products will be released into the environment which would require new supply chain management approaches to avoid contamination of non-GMO products. There would also be additional costs for organic and other certified non-GMO supply chains to meet assurance" (MBIE, 2024, p.6)*

With this finding MBIE did not undertake an economic regulatory impact report as it was deemed out of scope.

In the absence of such an economic impact assessment Organic Aotearoa New Zealand (OANZ) commissioned The New Zealand Institute of Economic Research (NZIER) to do an economic report on the Economic Assessments on MBIE proposal.

The NZIER report, Potential Costs of Regulatory Changes for Gene Technology, (Attachment 2) projected a $10-$20 billion dollar drop in demand for New Zealand primary sector exports if GE was introduced.

This would have a massive impact on the rural communities' economy.

Contamination in the Organic sector is not the sole concern. The organic sector, is only 1.5% of the market. However, the finanical risk is to the entire food sector. Contamination and loss of trust in New Zealand produce would affect 98.5% of the rural agriculture who a not organic but also currently benefit from a Non-GMO status in export markets.

The 360,000 people employed by the agricultural sector would be severely affected as the total food and fibre sector exports comes to $54 billion (increasing to $57 billion by July 2025) with a potential loss of 45% of export income. This could collapse the regional rural economy, raise costs, increase mental health problems, push families further into poverty and affect jobs, schools and Councils.

The Ministry of Primary Industries (MPI) 2024 Situation and Outlook report [45] sole focus is on the excellent growth in demand for our GE Free agricultural produce.

Minister Todd McLay foreword forecasts that the food and fibre export revenue will reach $56.9 billion in the year to 30 June 2025, and projected as $58.3 billion in the year to 30 June 2026 based

44 *https://www.mbie.govt.nz/dmsdocument/29936-regulatory-impact-statement-reform-of-gene-technology-regulation-pdf*

45 *https://www.mpi.govt.nz/dmsdocument/66648-Situation-and-Outlook-for-Primary-Industries-SOPI-December-2024*

on the previous non-GE market data. The current HSNO legislation preserves this opportunity to grow the economy.

The MPI report on projected growth in income is to be tempered with the fact that there has been no regulatory impact statement on the economic risk of adopting GE.
It is a frightening realisation that no feasibility study has been undertaken into the risks to our exports from adopting unregulated, exempted GE organisms. The NZIER report projected the economic outcomes of the proposed Bill would be deleterious to the whole agricultural sector.

RECOMMENDATIONS:

1. The Gene technology Bill is withdrawn, and appropriate economic, environmental, and social impact reports are conducted.
2. The Regulator is required to protect non-GMO production (conventional GE-free and organic) in decision making.

CONTAMINATION IS REAL

Control of Genetic drift is needed to protect our primary industry.

There is a cavalier attitude by some of the Technology Committee researchers who believe that co-existence is possible. Examples cited from overseas typically ignore compromises in food purity that require acceptance of levels of cross-contamination. Unlike New Zealand, much of the honey from the USA can no longer be guaranteed to be GE-free because of the widespreadof GM crops.

It will be too late to recall a GE organism if contamination of the seed supply is found.
Their philosophy is – "Do it now - apologise later".

The 2014 GM Contamination Register[46] report detected illegal GE trial escapees and GE commercial crops contaminating the seed supply. In every GM commercialised crop a level of contamination was found.

The authors report:

> *"As of 31 December 2013, the Register had recorded 396 incidents since 1997 (i.e. over a period of 17 years) and across 63 different countries (Additional file 1). Since 2000, there have been more than 10 incidents per year and, since 2005, more than 20 incidents per year (Figure 1). For 2006, there is a sharp spike in the number of incidents to nearly 60. "*
> (International Journal of Food Contamination, 2014). [47]

The EU's Rapid Alert System for Food and Feed (RASFF) reported that between 2002 -2023 that –

> *"over the 22-year period, the total number of notifications for GM food reached 724, while those for feed were considerably lower, at 103."*
> (Journal of Food Composition and Analysis, 2024) [48]

46 *https://foodsafetyandrisk.biomedcentral.com/articles/10.1186/s40550-014-0005-8#:~:text=The%20GM%20Contamination%20Register%20is,provides%20alerts%20to%20these%20incidents.*
47 *https://foodsafetyandrisk.biomedcentral.com/articles/10.1186/s40550-014-0005-8*
48 *https://www.sciencedirect.com/science/article/abs/pii/S0889157524008354*

In 1999 the finding of the Aventis GM star link corn[49] unapproved for human consumption caused a rejection of overseas markets and serous economic problems for the growers. Costs included a buyback programm, test kits, costs of cleaning, transport and storage of the contamination. The estimated program cleanup by Aventis were from $100M to $1Billion.

Dr Allison Snow published findings in molecular Biology on the illegal gene flow from an unapproved field trial of GE Bentgrass created by Scotts Company found that despite efforts to restrict gene flow wind dispersal carried pollen 14 km away and to sentinel plants up to 21kms. The grass could not be killed and feral populations are now introgressing with other grass varieties. (Molecular Ecology, 2012)[50] Scotts Company were required to pay compensation of US$500,000.

Recently the contamination of GM rice[51] was found in a shipment of organic rice. Rice is also a wind pollinated crop. There was a suggestion that it was due to loosened regulatory checks.

The documentation of GM contamination of vital corn land races in Mexico and South American countries have shown the GMO genes have introgressed/[52] transferred into their landrace varieties. Corn is again, another wind pollinated crop.

Due to contamination of the seed supply or pesticide drift the commercial American crops like corn, canola, soy are 95% GMO. However, 80% of these crops end up in refined oils, industrial uses, animal feed.

This is because there is growing consumer resistance and changing the name of a GMO will not make it any safer or more trustworthy.

The threat to the indigenous flora and fauna are unknown and have not been tested. The projected rhetoric for the gains that might be made from biotechnology GE organisms is based on "modelling" without allowance for negative impacts such as harm to biodiversity or market rejection.

In Canada, there have been extensive contamination reports of the seed supply of wheat, canola, flax (linseed), alfalfa as well as GE experimental pigs entering the food system.

There have been loss of access to markets export, lower crop prices and loss of farm saved seed. The widespread GE contamination of the canola seed has impacted non-GE farmers who have lost the option of growing canola and the inability to save their seeds. (Canadian Biotechnology Action Network, 2024[53]) an earlier CBAN report (2019)[54] goes into detail the impacts of GE contamination.

Modelling of situations, especially if it only considers imagined benefits, is not realistic.

Such "modelling" gives unsupported assurances of the possibility of co-existence and ability to avoid contamination is not reliable as overseas data sets results show.

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49 *https://biosecurity.fas.org/education/dualuse-agriculture/2.-agricultural-biotechnology/starlink-corn.html*

50 *https://onlinelibrary.wiley.com/doi/10.1111/j.1365-294X.2012.05695.x*

51 *https://profit.pakistantoday.com.pk/2024/08/08/gmo-contamination-in-pakistani-rice-shipment-alarms-export-circles/*

52 https://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S2007-90282023000200018&lang=es

53 *https://cban.ca/gmos/issues/contamination/*

54 *https://cban.ca/wp-content/uploads/GM-contamination-in-canada-2019.pdf*

It is not proven that GE contamination in NZ will not be a major risk to farming systems that rely on GE Free/ non-GE production. However, what is proven is the growing global demand for GE-free food from consumers in our premium export markets.

RECOMMENDATIONS:

1 No release of GE organisms, plants or animals into the environment until contained long term field trials in NZ have been conducted.

2 Liability for contamination cleanup costs and loss of livelihood must rest with the GE grower and patent holder.

3 Modelling data for GE can not be relied on, and full environmental and health trials must be undertaken before release from containment, with public notification

4 A prohibition on GE plants containing pharmaceutical genes.

5 A prohibition on release of any GE microorganisms outside containment that could sustain in the environment

HEALTH THREATS TO INSECT AND AQUATIC LIFE AND SMALL ANIMALS

There has been no research into the effects on indigenous fauna.

New Zealand has 28 species of native bees[55] (Ngaro Huruhuru). Of those 28, 27 are endemic – meaning they occur only in New Zealand. Dr Ngaire Hart[56]s interview in Waatea news research has found that native bees are small and nest in the bare undisturbed soil. They feed their larvae with the pollen and nectar from surrounding flowers. They are including critically the main pollinators of the indigenous flora like mānuka, kānuka and Pohutukawa, which over the millennia have adapted too. The risk to the taonga species from gene edited organisms have never been tested.

New Zealand has 51 species of native freshwater fish, 79% are threatened or at risk of extinction. The Ministry for the Environment (MfE)[57] in 2020 documented threatened or at risk of taonga species include - five species of mudfish, four whitebait species (shortjaw kōkopu, giant kōkopu, kōaro, and īnanga), lamprey (kanakana/piharau), longfin eel (tuna), and Stokell's smelt. One freshwater fish, the once common and widespread New Zealand grayling, is extinct. South Island freshwater crayfish (kēkēwai/wai kōura) and two of three species of freshwater mussel (kākahi/kaaeo),and one tadpole shrimp.

The rivers and lakes have many threatened aquatic organisms which could be further threatened from the environmental release of any organisms derived from genetic engineering (GE). Linn M.D. and Moore P.A. (2014) study in Archives of Environmental contamination and Toxicology found that:

55 *https://www.fortheloveofbees.co.nz/native-bees*

56 *https://waateanews.com/2023/05/04/dr-ngaire-hart-native-bee-expert/*

57 *https://environment.govt.nz/publications/our-freshwater-2020/issue-1-our-native-freshwater-species-and-ecosystems-are-under-threat/*

"after 8 weeks there was no statistically significant difference in growth between crayfish in Bt and isogenic treatments. However, survival was 31 % lower in the Bt treatment compared with the isogenic treatment. These results suggest that the Bt corn and isogenic corn were of equivalent nutritional value but that Bt corn does have a toxic effect on rusty crayfish during long-term exposure. (Linn and Moore, The Effects of Bt Corn on Rusty Crayfish (*Orconectes Rusticus*) Growth[58] 2014)

RECOMMENDATIONS:

1. The Regulator must be required to protect indigenous flora and fauna.
2. The Regulator must be required to protect bees and other pollinators.
3. The Regulator must be required to protect soil and aquatic natural ecosystems.

TECHNICAL ADVISORY COMMITTEE (TAC)

The Regulator under the Environmental Protection Authority (EPA) will rely on a Technical Advisory Committee[59] existing members directly benefit from the commercialisation of GE as they own patents or are involved in the creation of commercial GE biotechnology products. As such, the Committee has industry bias.

The TAC in the Act is limited in scope and responsibilities (GTB clause 113 & 114), it has no power to require precaution or ethical considerations from the Regulator, or be heeded, and is being given immunity from prosecution.

The required expertise specified in the Gene Technology Bill for the TAC has potential for enabling conflicts of interest and working against the Crown Entities Act 2004 whose board members' and committee's duty is to act with '*honesty and integrity' and not to pursue their interests 'at the expense of the entity's [NZ Inc] interests'*. (Crown Entities Act sec: 54 and 55)

The Gene technology Bill has already been guided by the TAC who are Crown employees (including a Minister of the Crown) who will stand to benefit by this Bill in their working and private life.

If they are going to also be the Technical Committee who advises the Regulator the bias toward pursuing their own interests will be hard to navigate between their duty of care to the New Zealand public (entities interest) when advising the Regulator on GE.

The Technical Advisory Committee[60] members that provided advice to the government in the formation of the Gene Technology Bill and associated policy work:

- Professor Emily Parker (Chair), Ferrier Research Institute, Departmental Science Advisor MBIE research techniques including small molecule synthesis, protein engineering, and molecular and structural biology.
- Associate Professor Tim Hore, University of Otago | Ōtākou Whakaihu Waka School of Biomedical Sciences

58 *https://link.springer.com/article/10.1007/s00244-014-0061-3*

59 *New Zealand patent applications to the EPO with foreign co-inventors https://figure.nz/chart/v1LueWKXD1kfmHJD*

60 *https://www.mbie.govt.nz/science-and-technology/science-and-innovation/agencies-policies-and-budget-initiatives/gene-technology-regulation*

- Dr Richard Scott, AgResearch | *āta mātai, mātai whetū* Science team leader – Climate change and forage innovations, AgResearch work on research in New Zealand that uses genetic technologies;

- Professor David Ackerley, Victoria University of Wellington | Te Herenga Waka Biotechnology Programme Director. Microbiologist and enzyme engineer, with a primary focus on discovery, characterisation, engineering and application of useful bacterial enzymes, and of novel antibiotics

- Dr Hillary (Billy) Sheppard, University of Auckland | Waipapa Taumata Rau Senior Lecturer Biological Sciences – gene and molecular therapy, animal and cell molecular biology antibody engineering, xenotransplantation and T-cell therapies.

- Dr Andrew Allan, Principal Scientist at Plant & Food Research; and Professor in the School of Biological Sciences at the University of Auckland, gene editing of plants, IP red apple,

- Dr Alec Foster, Portfolio Leader – Bioproducts and Packaging, Scion, *Part* of the MBIE Technical advisory group for Gene Technologies, executive member of BiotechNZ and also oversee several projects at Scion which leverage gene technologies

- Professor Jasna Rakonjac, Massey University | Te Kunenga ki Pūrehuroa research into biology of bacterial viruses (bacteriophages or phages) and their biotechnology applications in medicine and agriculture.

- Associate Professor Maui Hudson, University of Waikato | Te Whare Wānanga o Waikato Māori genomics and ethics

- Dr Nicole (Nikki) Freed, Daisy Lab founder precision fermentation. Molecular Biology, Synthetic Biology, Microbiology, Genomics, Auckland Genomics.

- Dr Rachel Perret, Malaghan Institute of Medical Research. Work on engineering and redirecting gene-therapy of T-cells working with chimeric antigen receptors (CAR),

- Ariana Estoras, AgResearch | āta mātai, mātai whetū Suporting the growth of Māori agribusiness and nurturing Māori participation in Science.

- Professor Neil Gemmell, Neil Gemmel Laboratory University of Otago | Ōtākou Whakaihu Waka. Work on gene drives, genetic fertility, genetic analysis Service

- William Rolleston, ex Lifesciences Chair, Genomics Aotearoa, South Pacific Sera Limited, biotech and vaccine manufacturing company

One member of the Technology committee[61] stated that "the cost of the GM moratorium to South Australian canola farmers was $33 million." However, the latest data (January 2025) market report shows that GM Free canola prices are consistently improved compared to their GM counterpart and farmers are moving back to conventional canola, because of the increase in the premium of non-GM.

In Australia, over a two year period (2024 -25) canola prices fluctuated between $40 - $150 NZD per tonne higher for non-GM (GM Free) canola in individual states.

61 *https://www.farmersweekly.co.nz/opinion/genetic-technologies-an-economic-choice-is-for-farmers/*

To the the contrary, we would be committing to undermining our NZ premium.

This error in advice could be misleading for Regulators licensing decisions if the Technology committee members have a bias toward information given that will favour the biotechnology industry and overlook and are not even required to consider information related risk to society, to the public, to animal welfare and natural world systems.

RECOMMENDATIONS:

1. The Technical Committee who advises the Regulator must have independent expertise with no link to biotech industry or potential to benefit personal financial interests.

2. Officials should not have exemption from liability or immunity from prosecution. In the absence off precaution which is being removed in the Blll both nationally and locally, the risk of unacceptable industry bias is even greater.

ENDING THE "BAN" OF GENETIC MODIFIED ORGANISMS.

The Gene Technology Bill Purpose (cl: 15) of the Gene Technology Bill does not specify how or what type of avoidance, mitigation, liability, accountability that the applicant has. Many exempt organisms will bypass the Regulator and there will be no public notification or right of appeal. If there is no ability for the public to be able to interact and place their concerns in front of the Regulator, the Gene Technology Committee advisors will have an extraordinary power and influence on the term “safety”.

The Treaty of Waitangi (cl: 20) does not allow for the exempted organisms to have any Māori Advisory Committee kaitiaki evaluation nor ability to evaluate whether there will be an environmental risk to the indigenous flora and fauna, moana or awa and taonga species now endemic to Aotearoa.

This Bill is a direct assault on the environmental and economic livelihoods of the citizens of New Zealand. There is no ban of GE, only the accountable requirement to show the risk and benefit outcomes through the staged application process of the Hazardous substances and New Organisms Act (HSNO).

The HSNO Act is fit for purpose and has allowed regular, safe and progressive transfer of living modified organism (LMOs) microbes, seeds, plants and animals across to collaborating partners and countries through the Cartagena Protocol Biological Clearing House.[62]

The EPA has delegated to Institutional Biological Safety Committees (IBSC) and approved hundreds of genetically modified[63] organisms laboratory experiments under their HSNO rapid assessment process.

62 https://www.gefree.org.nz/assets/Uploads/Appendix-One-10.pdf
63 *https://www.gefree.org.nz/assets/Uploads/All-s42B+s45-GMC-approvals.pdf*

REINTERPRETATION OF ALL GENETICALLY MODIFIED/ ENGINEERED/GENE EDITED ORGANISMS

This Bill will require a total dismantling of the New Zealand sovereignty laws that protect in a precautionary way our export markets and citizens rights.

The most used and common gene editing technology is CRISPR (clustered, regularly interspaced short palindromic repeats) are bacterial in origin and have been shown to have unexpected and deleterious off **"target effects".** Technically the whole process of gene editing used transgenes from **bacterial** origin and **should always be regulated** to ensure that the changes expected are the changes able to be proven without any adverse risk.

The move to deregulate and exempt gene technologies SDN1 and SDN2 when there are no scientific studies to show any long term safety is a dereliction of duty to the people of Aotearoa/New Zealand. In 2024 The Centre for Food Safety[64] challenged the FDA Aphis regulator about the lax way they saw GE. This case was upheld and Aphis is required to consider the scientific aspects of GE.

The rising problem of superweeds and insect resistance from the overuse of insecticides and herbicides is a growing problem in the countries that grow GE crops. The ever continuing

The existing legislation, Hazardous Substances and New Organisms Act (HSNO) is fit for purpose and guarantees that the precautionary principle and Treaty of Waitangi issues must be considered and the risks and benefits weighed up. The Gene Technology Bill must be amended to include these principles.

Exempting GE removes all protection for a GE Free nation. Markets will seek out GE Free produce because consumers demand it. New Zealand is still GE Free in its agricultural growing sector. We must maintain that advantage and protect 100% of our farming sector, and retain our alignment with the 100% PURE tourism brand.

RECOMMENDATIONS:

1. No Exemptions from regulation should be made for new Gene Editing breeding techniques.
2. Self-Regulation by Industry is Not Likely to Protect People or the Environment.
3. There are a large range of Gene Edited foods that will be made exempt.
4. The range of plants, animals, fungi and micro-organisms to be exempted is far more permissive than our trading countries.
5. The EU is considering some deregulation for plants only, and to date, is **maintaining traceability and labelling.**
6. The UK allows precision breeding of planets and animals but requires an application, proof of gene sequence, **animal welfare reports , and registration of all NBT organisms.**

64 *https://www.centerforfoodsafety.org/files/2024-12-02--ecf-81--order-re-summary-judgment_44232.pdf*

In Summary

We recommend that:

The Gene technology Bill is withdrawn and re written to address these points:

1 The HSNO Act is fit for purpose and is retained with no alterations to interpretation, but with potential for adjustment to enable safe, contained controlled and ethical applications as the government desires.

2 Ensure HSNO's continued regular, safe and progressive transfer of living modified organism (LMOs) microbes, seeds, plants and animals across to collaborating partners and countries through the Cartagena Protocol Biological Clearing House.[65]

3 Retain the Precautionary Principle and definitions from The HSNO Act

4 Economic, environmental, and social impact reports are required of the Regulator for all gene technology applications.

5 A prohibition on GE plants containing pharmaceutical genes.

6 Remove *exempt activities* as a risk tier.

7 Require that all GE /GMO activities, including exempt and non-notifiable, be conducted inside certified containment facilities.

8 Require that **all** outcomes of gene technology are assessed for risk on a case-by-case basis.

9 Introduce a specific obligation of the proposed Regulator to require that evidence provided to prove that an organism meets the exemption criteria or satisfies the risk assessment is of the highest scientific standards and is current with the most recent scientific techniques.

10 No release of GE organisms, microbes, plants or animals into the environment until contained long term field trials in NZ have been conducted.

11 Liability for contamination cleanup costs and loss of livelihood must be on the GE grower and patent holder.

12 No modelling data for GE can be relied on, and full environmental and health trials must be undertaken before release from containment, with public notification

13 A prohibition on GE plants containing pharmaceutical genes.

14 The Regulator must be required to protect indigenous flora and fauna.

15 The Regulator must be required to protect bees and other pollinators.

16 The Regulator must be required to protect soil and aquatic natural ecosystems

17 All gene therapy trials are approved with conditions by a recognised independent Authority.

18 All exempt organisms from regulation should only be used in laboratory research and must be registered with the EPA and open to transparency under the Official Information Act.

19 Exempt organisms cannot be released into the environment without long term studies on risk and must be publically notified

20 Exempt organisms and natural traits cannot be patented at commercialisation.

21 Section 248-253 must be rescinded and allow councils and territorial and unitary authorities to place precautionary principles and rules around GE organisms.

65 *https://www.gefree.org.nz/assets/Uploads/Appendix-One-10.pdf*

22 All GE experimentation must be fully notifiable to councils and open to public submissions.

23 There must be a contained dedicated monitored outdoor facility with strict controls.

24 There should be no Regulator discretion as to who can be consulted. The tailored license conditions / controls must be clearly specified and monitored in a dedicated open air facility of limited size.

25 A public register of where the licensed activity is undertaken.

26 Expediated activities must be carried out in only one region, must be inspected and monitored against the conditions the Regulator has placed on them.

27 There should be full public notification and the right of submitters to challenge the Regulator's decisions

28 No Mandatory approvals in legislation. Consultation with overseas regulators can only inform the Regulator but not be used as an acceptable substitute for New Zealand conditions. This is a significant breach of transparency for the public of New Zealand.

29 The Technical Committee who advises the Regulator must have independent expertise with no link to biotech industry and personal benefit.

30 Officials should not have exemption from liability and immunity from prosecution, especially if precaution, liability on users, and commercial insurance are not in place, and there is risk of vested industry interests being promoted over safety or the public interest.

31 Establish a Gene Technology Ethics and Community Consultative Committee (GTECCC).

32 Require the Regulator maintain engagement and consultation with the community, Tangata Whenua, farmers and growers, and the Food and Fibre sector.

ATTACHMENTS:

1. Food Standards Australia New Zealand (FSANZ) Survey Results
2. NZIER report, Potential Costs of Regulatory Changes for Gene Technology