Deregulation? Biotechnology & gene editing: New Zealand context.

2023

PSGR

Physicians and Scientists for Global Responsibility

PSGR

"Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed, it is the only thing that ever has."

Margaret Mead.

www.psgr.org.nz

Physicians and Scientists for Global Responsibility Charitable Trust New Zealand
PO Box 16164
Bethlehem
Tauranga 3147
New Zealand

Primary Author: JR Bruning

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

Introduction

This 2023 report summarises key issues relating to science, stewardship and risk of biotechnologies in New Zealand.

In Aotearoa New Zealand there are gaps and barriers to effective stewardship, science and regulation regarding biotechnology, including regulation of newer technologies such as gene editing and penetrator technologies.[1] The barriers arise from governance structures, political cultures, science policy and lack of funding pathways which deter independent research and science and expert knowledge.

GMOs and gene edited organisms, together with chemicals and increased use of trace or heavy metals, are known as novel entities:

> "new substances, new forms of existing substances and modified life forms that have the potential for unwanted geophysical and/or biological effects… These potentially include chemicals and other new types of engineered materials or organisms not previously known to the Earth system as well as naturally occurring elements (for example, heavy metals) mobilized by anthropogenic activities".

Stockholm Environment Institute scientists recently proposed that

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

Current regulatory protocols fail to require independent reviews of the changing scientific literature which might contradict biotechnology-as-safe narratives; and the absence of funding ensure appropriate feedback loops are not established which could funnel monitoring and research information back into the regulatory environment concerning novel entities that are currently released into the environment and into human bodies.

The effect is that the government can neither predict risk or harm, nor steward these technologies precautionarily, in order to ensure that the principles of the Treaty of Waitangi are upheld.

REGULATING *PROCESS*

Despite media rhetoric, our legislation is good, as it recognises the simple fact that scientists, lawmakers and the public simply do not know what new *techniques* lie around the corner.

New Zealand's existing legislation augmented with local government involvement in key regions of genetically modified organisms (GMOs), including newer gene editing technologies, is robust and fit for purpose.

This is where New Zealand stands:

1. Gene editing processes trigger regulation. Regulation of technology in relation to airlines, chemicals, cars etc is common[2] and important.
2. Our regulation aligns with a recent European Union court decision. It has been held that newer gene editing technologies require regulation, just like the older techniques of genetic modification.
3. Our legislation is precautionary which thus does not permit automatic releases into the environment. As many unanticipated problems continue to arise with both the older techniques and with new techniques, the precautionary principle continues to be the best mechanism to protect human and environmental health.
4. Our oversight can improve – to recognise the risk from the potential for technologies to quickly scale up.

By regulating the *process* (as opposed to a product or novelty), New Zealand should have across the board transparency as we regulate all genetic engineering processes – as do the majority of countries in the world which are united under the Cartagena Protocol for Biosafety.

As our monitoring is limited, public discussions are often weighted to industry-based perspectives, bioethics issues remain out in the cold. Similarly, our regulation can be improved, and take into account the scalability of technologies.

THE SCALABILITY IMPACT

Biotechnologies continue to require regulation and oversight because of their potential to be emitted or deployed at scale, whether in medicine, personal care, agriculture in pest control or for other applications. However, current regulatory triggers don't allow for risk from release or deployment at scale, and scientists have proposed that a scale trigger can be embedded in regulation. [3] Scale is explained here:

> 'Scale is a complex concept that differs in meaning across disciplines. It is not exclusively a measure of distance, area, volume, and time but also a mixture of these and their relationship with human activity. Where human activity intersects with the environment, there is risk, putting the intersection at the place where we may best control risks of our own making. The highest priority for technology regulation, after deciding to adopt a technology, are harmful or beneficial effects that scale up quickly and/or widely as a result of human activity.'[4]

However, as the 'scale of control afforded by science advances, so does the domain of uncertainty and potential risk.'[5] The rationale for continued oversight of biotechnology was outlined by Professor Jack Heinemann, from the Centre for Integrated Research in Biosafety, in a 2021 submission[6] which looked at definitions of gene technology:

> 'Describing techniques of gene technology by their biochemistry, whether it be the reactions that lead to the insertion of a 'transgene' and the reactions that lead to genome editing, provides little clarity for technology governance.

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

Heinemann's work on scalability and uncertainty complements Dr Jan Wright's criteria[7] for judging the potential for an environmental threat to cause harm, which stems from the degree to which the harm might be:

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

Another problem when it comes to ensuring the safe regulation of biotechnology is the persistent dilemma (with all environmental harms) that harm and risk are difficult to predict. In such an environment, decision-making using the precautionary principle can aide officials. However, in New Zealand, implementation of the precautionary principle is inconsistent and poor, and there has been little work undertaken to develop frameworks and understandings that might support officials.

With this in mind, this report focusses on the following governance and public interest issues:

1. Our Independent Oversight Problem

New Zealand has few experts outside biotechnology research and development, where intellectual property and patents, and the associated royalties, accumulate as assets and income sources for the institutions where they work.

New Zealand doesn't provide an independent research space, with block funding, where experts are funded to independently undertake long term safety research to identify hazards and risks from manmade technologies, otherwise known as novel entities.

The effect of the science and research gap – from the regulatory environment to the laboratory, and to New Zealand's flora and fauna - is that New Zealand civil society is broadly ignorant about the potential risk from genetic technologies.

As a result, officials in Ministries and the Environmental Protection Agency are poorly informed about risk from manmade technologies in the New Zealand environment. However, if society cannot understand the risk from manmade technologies including GMOs and new gene editing techniques, society cannot steward them.

Science policy is not stewarded by high level principles that require officials to ensure that scientific research should overall protect human and environmental health.

Science policy instead focuses on *innovation* and *excellence* (research in a single discipline is more easily identified as excellent, as compared to basic science or interdisciplinary research). Interdisciplinary research exploring risk from manmade technologies is therefore, frequently outside the scope for funding.

As a result of science policy which steers science towards innovation[1], most expert scientists in the field of genetic modification in Aotearoa New Zealand are reliant on the development of gene editing technologies. New Zealand therefore has very few expert scientists who are in a neutral position to discuss deregulation, where owners of a biotechnology do not have to disclose the tech to the regulator. Expert scientists who are paid to consider ethics, and risk, are scarce.

These gaps mean that there are no scientists feeding back knowledge into the regulatory environment that might demonstrate harm or risk for these manmade technologies.

The science and research gap grows all the greater if the absence of resourcing for environmental monitoring, research and reporting is considered. As New Zealand's Parliamentary Commissioner for the Environment stated:

> New Zealand's broader environmental system also suffers from significant data and knowledge gaps which bedevil our understanding. This is in stark contrast to areas such as the economy, where we are much more reliably informed. While measuring a vast and complex natural environment is challenging, it is also true that historically, measuring economic indicators has been viewed as a higher priority. People have felt less urgency about measuring the environment and natural resources that have appeared to be 'free' and seemingly unlimited.

[1] "the implementation of a new or significantly improved product (good or service) or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations" (OECD 2005)

Stewardship is hampered by regulatory protocols that look to industry data to provide evidence of safety. Conventionally regulators rely on industry data to approve novel entities, which include GMOs and newer edited products. However, as the evidence in the scientific literature changes, regulators rarely conduct methodological literature reviews to identify new challenges and risks (and triangulate back to industry safety claims).

Rather than resorting to formal risk assessments and review of the literature, regulatory agencies tend to call for information from civil society. What this inevitably does is delegate the sourcing of weight of evidence information to the public. It pits industry paid scientists against publics. When public sector scientists do not have funding and direction to research risk from biotechnology, it means that there will be disproportionately less independent expert scientists to weigh these matters independently. In these environments regulators then weigh up who said what. This is neither scientific, independent nor accountable.

Therefore, when officials consider the weight of evidence, if it is only industry producing the 'evidence' with no independent science funded, the outcome will inevitably be distorted or biased to industry claims. Reviews of scientific literature consistently demonstrate that industry funded scientific research persistently favours outcomes that present their technologies in a positive light.

With these issues in mind, the capacity for Ministry and agency officials to honour the principles of the Treaty of Waitangi and safely steward Aotearoa New Zealand into the future is weak - not only due to the absence of resourcing for scientists to do this work -but because there is no independent body which can traverse the complex social, legal, cultural and scientific issues and draw attention to long-term risk.

The Royal Commission on Genetic Modification[8] in 2001 was already aware of the problem, as were submitters to the Royal Commission (p.347):

> 'I ask the ethical issue ... who watches who? That is a key, Ko wai ma e ata tino titiro ki nga tangata, wahine e mahi ana nga mahi ara te ira tangata? (Who is examining the works of the people who are doing genetic modification?) Mahara Okeroa (Taranaki) MP at Waiwhetu Marae, Wellington regional hui.

The Royal Commission attempted to remedy this governance problem with a three-pronged approach. It recommended the establishment of a Parliamentary Commissioner on Biotechnology, a Bioethics Council and a biotechnology strategy (p.342). None of these are in effect in 2020.

The McGuinness Institute released a report[9] in 2008 that revealed that only seventeen recommendations of the 2001 Royal Commission had been implemented. In such a climate, safeguards to protect against the potential downstream risks of innovation, including planetary boundaries, may be unlikely to be put in place and instead considered undue "red tape".

In July 2022, PSGR and GE Free trustee Jon Carapiet published an Open Letter to all Green Party members and MP's. The letter requested that Toi Te Taiao – The Bioethics Council be reinstated

and expanded to include other emerging technologies including synthetic biology, artificial intelligence, nanotechnology and geo-engineering.

The absence of a Bioethics Council impairs good judgement as there is no institution equipped to talk to complex socio-technical dilemmas. The courts struggle to deal with questions of science.

Anticipating when a new technology might create irreversible harm, and acting before harm occurs involves balancing complex multidisciplinary concepts; and navigating overlapping questions and dilemmas of social, legal, cultural and scientific nature, that can stretch into the future. An independent entity that can parse complex issues of ethics, the potential for off-target and unanticipated effects and consider the impact on future generations, at arm's length from political or financial interests would assist decision-making in the public interest.

There is no place for this to occur in New Zealand.

And of course, somewhat uniquely, New Zealand's science policy and science funding is held within the Ministry of Business, Innovation and Employment. Most nations situate the scientific enterprise independently or align the science and research with the education sector. However New Zealand's science enterprise is under the umbrella of the Ministry most concerned with economic growth.

These stewardship deficits occur in a policy and media climate that is transparently lobbying for deregulation of biotechnologies, and in particular gene editing technologies.

2. Politics of Advocacy: the deregulatory push

There is persistent pressure to deregulate, and in particular, to deregulate new genomic techniques (NGTs), such as for organisms engineered with 'gene scissors' such as CRISPR/Cas. Lobbying by both industry and government representatives, continues, largely out of the public eye, and there is fear that deregulation clauses may be sequestered in international trade agreements.[10] [11]

UNITED KINGDOM

In May 2022 in the UK, a Genetic Technology (Precision Breeding) Bill was introduced. In June/July 2022, the UK House of Commons Public Bill Committee heard oral evidence on a new Genetic Technology (Precision Breeding) Bill. QC Dr Michael Edenborough drew attention to the problem of deregulation and the challenge of identifying a biotechnology once released into the environment, the issue of burden of proof, the unequal power-relationship between the developer and, in the example cited, the farmer, and difficulty in ascertaining damages.

Following this, two reports were released, one by the Delegated Powers and Regulatory Reform Committee (DPRRC), and one by the Constitution Committee. NGO GMWatch noted:

> Both reports voice concern about the excessive powers that the bill confers on ministers to do what they want without the scrutiny of Parliament – powers that a legal briefing called "Henry VIII powers", after that monarch's style of ruling by proclamation.

> For instance, the DPRRC points out that the bill leaves it up to ministers alone to decide what information the applicant has to give to the Secretary of State before they can market or release a "precision bred" GMO and whether the applicant has to do an environmental risk assessment.

EUROPE

In October 2022 the European Food Safety Authority (EFSA) released a Criteria for risk assessment paper. The EFSA paper suggests that all future risk assessment would only take the intended characteristics of the plants into account, and set aside any unintended genetic changes caused by the genetic engineering processes. As a result, many plants derived from new genome techniques (NGT) could be released without undergoing detailed risk assessment. However, this reduces the capacity to not only anticipate harm, but identify drivers of harm post-release.

Germany-based *Institute for Independent Impact Assessment of Biotechnology*, TestBiotech stated in response:

> ‘future risk assessment would, in most cases, not assess the unintended genetic changes resulting from NGT processes, and only assess the intended biological characteristics of the plants. In effect this means that the only criteria to be applied would be the similarity to already known breeding characteristics (‘history of safe use’) and the genetic functions of the target genes.
>
> Many publications show that the multi-step processes of NGTs may be associated with unintended genetic changes that are very different to those resulting from conventional breeding methods. The same is true for intended changes. This is especially relevant for plants engineered with ‘molecular scissors’ such as CRISPR/Cas. Such differences between conventional breeding and NGTs can be easily overlooked, but can have serious consequences: if hazardous, unintended genetic changes go unnoticed, they can quickly spread within large populations.
>
> The EFSA position fundamentally denies all these differences, claiming instead that the unintended genetic changes could not be distinguished from genetic changes arising from conventional breeding. Inadequate data is one of the causes for this flawed assumption: in its previous opinions, the authority stated several times that it does not have a mandate to comprehensively assess all relevant publications.’

In December 2022 TestBiotech released a related report.[12] Their report found that the EFSA Criteria neglected to consider, or was based on a presumption that unintended changes following NGT processes could be distinguished from those resulting from conventional breeding. The report proposed that the EFSA assumptions were made on the basis of inadequate data, following the EFSA statements that that it did not have a mandate to comprehensively assess all relevant scientific publications. TestBiotech contested this position, stating

> ‘many publications show that the multi-step processes of NGTs are associated with intended and unintended genetic changes that can be different to those resulting from conventional breeding methods. This is especially relevant for organisms engineered with ‘gene scissors’ such as CRISPR/Cas.

TestBiotech concluded that based on the EFSA overlooking a substantial body of science, the EFSAs claim was not sufficiently backed by science.

AUSTRALIA NEW ZEALAND - FSANZ AND THE DRIVE TO DEREGULATE

As a party to the Food Standards Australia New Zealand (FSANZ), New Zealand is vulnerable to changes made by the authority, that inherently reflects the perspective of the Australian government.

In December 2021 the PSGR submitted to the FSANZ (consultation P1055) that the PSGR:

- Disagreed with the proposal to adopt the United States Department of Agriculture (USDA) revised definition for ‘genetic engineering’ and submits that the definition should not be limited to nucleic acids.
- Agreed that it is important to regulate gene-edited foods in a manner that recognises their risk. Risk arises from biological and chemical characteristics and via the rapid take-up and application of NBT foods throughout the global food chain.
- Proposed that ALL gene-edited food and refined ingredients should remain designated as GM food for Code purposes.
- Proposed that the new definition includes all technology that can alter a pathway or molecule of an organism, that then changes/has potential to change chemical, biological traits of organisms, viruses or related replicating element.

A total of 1734 submissions were received from stakeholders and a Proposal P1055 – Stakeholder feedback summary report was released.

New Zealand’s Ministry for Primary Industries preferred deregulation, supporting specific exclusions:

> “MPI supports Option 3: Amend the definitions in the Code to revise the process-based definition for ‘gene technology’ to capture all methods for genetic modification other than conventional breeding, and to revise the definition for ‘food produced using gene technology’ to include specific product-based criteria for excluding certain foods from pre-market safety assessment and approval as GM food.” – New Zealand Ministry for Primary Industries

The FSANZ concluded (p.6):

> 'that NBT food and refined ingredients should not be GM food for Code purposes (i.e. not require an application to FSANZ for pre-market approval as GM foods) if they are equivalent in characteristics and risk to conventional food with a history of safe use.
>
> Based on this assessment, FSANZ proposed:
>
> - expanding the existing process-based definition for 'gene technology' to capture all methods for genetic modification other than conventional breeding, and
> - revising the definition for 'food produced using gene technology' to exclude foods that are equivalent in risk to conventional food from pre-market safety assessment and approval as GM food. Exclusions would be based on specific product-based criteria. Food not meeting all exclusion criteria would require an application to FSANZ for approval as a GM food.

A second call for submission (CFS) round will be held in the first quarter of 2023.

DEREGULATION PRESSURE IN NEW ZEALAND

The New Zealand media repeatedly noted in 2022 that genetic modification legislation is 'outdated' or 'old and tired' and we will be 'left behind'. However, such media soundbytes did not disclose the financial return from biotechnology royalties that large institutions are increasingly dependent upon, nor the relationships of the commentators.

Funding environments shepherd research to favour innovation solutions (an innovation being a product or process (see OECD 2005), rather than interdisciplinary scientific research unpicking pollution or disease drivers).

Scientists must not only contend with precarious funding environments; these environments directly favour patent-related development. Funding for applied science (such as biotechnology) is favoured over basic science (which shows drivers of harm). This inevitably distorts which science can and will be selected for funding.[13]

In innovation/patent environments (patent numbers are a proxy for GDP), scientists which produce IP will be favoured over scientists which attempt to untangle complex environmental and health related problems. This environment fundamentally benefits biotechnology over long-term monitoring and interdisciplinary research. It produces a 'technophilic orientation' which produces a technology-push environment, while complex and less patent-friendly issues remain unaddressed.

Inevitably, quorums of scientists working in biotech will support deregulated environments, while the scientists that might suggest more complex solutions remain fewer and with less resources to take part in submissions processes.

As Heinemann and Hiscox have noted in relation to climate-change:

> ' technology still reigns supreme in discussions of how to adapt to or mitigate it. Technology investment is dependent on the promises it makes. Promises, the fuel of technology-push, drive the cycle even after a technology has been shown to underachieve or cause unintended harm. Emerging technologies and products are especially prone to disappoint. After all, it is dependent upon a developing underlying science which takes time to distinguish itself from the science that is not reproducible.'[14]

Therefore technology developers may not be the best placed for understanding the potential payoffs and trade-offs of technology centric solutionism.

Four examples of how biotechnology is favoured, without any over-riding scientific or policy brief that requires that first and foremostly, human and environmental health must be protected, follow.

(a) The Productivity Commissioner

The New Zealand Productivity Commission's primary purpose is to support well-being

> 'The principal purpose of the Commission is to provide advice to the Government on improving productivity in a way that is directed to supporting the overall well-being of New Zealanders, having regard to a wide range of communities of interest and population groups in New Zealand society.'[15]

The New Zealand productivity Commissioner has recently called to reopen the HSNO Act, citing that it is out of date. In a report New Zealand firms: reaching for the frontier, investment in biotechnology development was discussed at length with the report stating: 'The regulatory framework for GM tools was last reviewed in 2001 and does not reflect technological advances since that time.'

However of the 81 submissions, biotechnology was only raised by three entities, two with a relationship to medical and patent development, rather than agriculture, and one, the Sustainability Council, urging caution. In addition the Reaching for the Frontier enquiry included one discussion with Zac Hanley from Plant and Food, as an Official Information Act request identified. 'Other meetings with single outside participants that touched on GM were with Malcolm Bailey, Simon Tucker and Peter McBride.

In a later Radio New Zealand interview, the Productivity Commissioner called current approach to regulation a bureaucratic approach that can stifle regulation, and emphasised the benefits to agriculture. Somewhat paradoxically, none of the big agriculture submitters raised the issue of biotechnology in their submissions, yet this was the Commissioner's focus following the release of the report. Many of the claims to benefits in the interview are problematic, for example, the claim to golden rice continues to be plagued by issues that include the fact that other foods are much higher in vitamin A, and that the patenting of core crops in low-income nations can result not only in additional input costs for farmers, but result in the erosion of different varieties, and risk from horizontal gene transfer.

However, as an Official Information Act request has revealed, the Productivity Commissioner has not invested time detailing, analysing or assessing returns or environment (or other) risks relating to genetic modification (GM). Rather, their office has 'looked at reports that have been written by others about the current GM regulations and their benefits and costs considering the current state of knowledge about GM.'

In addition, many of the small advanced economies cited by the Product Commissioner as having higher labour productivity than New Zealand strictly regulate biotechnologies. For example, Sweden, Denmark, Northern Ireland and the Netherlands operate under European regulations – like New Zealand, their regulation is processed based, the difference is that New Zealand does not release organisms into the environment.

The Productivity Commissioner has not spent, for example, equivalent time exploring the potential for the organics sector to contribute to productivity in such a way that benefits all of New Zealand. The Productivity Commissioner in his *Reaching for the Frontier* report, did not review the perspective of industries that trade on a basis that New Zealand tightly regulates biotechnology.

Therefore, potential impact to the organic sector was not considered, when the Productivity Commissioner discussed agriculture and the 'updating' of biotechnology regulation in New Zealand. For decades, established organic principles, which include health, ecology , fairness and care, have guided the global organic sector. These principles exclude genetic modification, and recognition of this is built into European Commission legislation.

One of the key ethical challenges for the biotechnology food sector, concerns the question of biopiracy. Current biotechnology initiatives include drives to produce drought tolerant crops. However, if the biotechnology industry selects ancient strains that have been bred by generations of indigenous farmers, and use, for example, flood or drought tolerant attributes to produce patented drought tolerant varieties for which farmers must pay a premium, this is a form of biopiracy.[16]

The European Commission meanwhile has explored the benefit of organic agriculture, and has developed a Farm to Fork policy which includes increasing organic land farmed, due in part to the low pollutant emissions from this form of agriculture.

(b) Crown Research Institutes

While the Crown Research Institutes Act requires CRIs to work for the betterment of New Zealand, and to exhibit 'a sense of social responsibility by having regard to the interests of the community' there is no requirement to *prioritise* their resources to address challenging issues such as the nutritional and environmental drivers of disease, or to research that might provide knowledge, solutions and technology to address escalating pollution (outside of greenhouse gas emissions).

CRIs are incentivised to direct their resources to research and development that results in the development of IP because that income can be 'reinvested' back into more research. The returns from the commercialisation of intellectual property back into New Zealand Crown Research

Institutes (CRIs) are significant. This distorts their capacity to select long term public good research that addresses transdisciplinary and complex issues (such as the environmental and nutritional drivers of disease in humans and agriculture) that help inform policy and public sector knowledge.

In 2021 return from royalty revenues to Plant and Food was NZ$58 million. Plant and Food have stated that the objectives of their research in relation to genetic modification include:

- To undertake research on the development and function of plants, pests and diseases.
- To accelerate and/or improve the development of new non-GM cultivars.
- To develop and maintain sufficient capability to enable New Zealand to utilise genetic modification technology more widely in the event of widespread adoption and acceptance of genetically modified crops in New Zealand or in our export markets.
- To gain knowledge of the potential risks and benefits of the wider use of genetic modification technologies, to inform public consideration of these issues in New Zealand.

PSGR would welcome a review of the risk and benefits of biotechnology as this relates to the regulatory environment, and stewardship of human and environmental health in New Zealand.

AgResearch's income is reinvested into AgResearch. In 2021 income from royalties exceeded NZ$11 million.

As noted, New Zealand experts with practical laboratory experience in gene editing tend to be connected to development and commercialisation of new technologies. Because these hardworking scientists have a vested interest in the development of new technologies, they cannot claim to be independent.

New Zealand needs to be cautious in adopting rules, guidelines and definitions from offshore agencies, as these have been found to weaken or diffuse understanding around technologies.

(c) Royal Society Te Apārangi

The data supporting many of the claims regarding GM development have been drawn from a major campaign produced by the Royal Society Te Apārangi.[17] However there are gaps in the Royal Society Te Apārangi papers that indicate that the Society's position relating to GM and the development of new technologies is not neutral.

In such an environment, the Soil & Health Association express concern that the Royal Society Te Apārangi campaign has downplayed the uncertainties and the continued risks associated with both GM and newer technologies. The Royal Society plays an important role in advancing and promoting science, technology and the humanities. Their values and objectives are laudable, but they do not have a legal obligation to protect health and the environment.

New Zealand media has relied on information drawn from the Society's campaign. Science is often tricky and uncertain, but there are no public sector agencies the media can go to, to understand the

problems from risk assessment technical experts or ethicists, or to help the media understand the veracity of claims from a the public interest viewpoint..

The Royal Society's Gene Editing in Aotearoa campaign refers to a significant body of supporting literature. However, the literature produced often skimmed over the potential for off target, adverse effects, or the consequences of intellectual property rights, for example, regarding the ownership of a gene-edited manuka plant material.

Resource and time- poor journalists with pressure to publish are increasingly relying on press releases supplied by the industry advancing the technology or innovation. There has been little frank discussion drawing attention to the economic incentive of patent ownership across Crown Research Institutes and Universities – who will own the patent and profit from potential royalties, and how this will impact future generations, particularly in relation to indigenous plant varieties.

(d) Te Papa Atawhai Department of Conservation (DOC) and Toitū Te Whenua Land Information New Zealand (Toitū Te Whenua). Long Term Insights Briefing.

In considering the use of information and technology in a December 2022/January 2023 consultation to 'help biodiversity thrive' non-greenhouse gas emissions as a risk to biodiversity were downplayed. This reinforced political narratives which persistently (as we have previously discussed) shepherd policy and potential funding away from pollutant (i.e. novel entities) drivers which fundamentally drive risk degradation and species decline in natural environments.

In this context information and emerging technologies becomes a narrowly framed set of technologies that favour biotechnology.

The consultation by DOC and Toitū Te Whenua Land Information New Zealand (LINZ) asks whether respondents

> 'think the draft Long-term Insights Briefing covers the key components needed to support a national conversation about potential tools for biodiversity management in the future.'

The draft briefing:

- considers how new and improved information and emerging technologies could support Aotearoa New Zealand's long-term vision for a thriving biodiversity;
- demonstrates the opportunities for biodiversity presented by innovation, information and emerging technology by exploring;
- satellite imagery and remote sensing;
- artificial intelligence and data-driven technologies,
- and genetic technologies.
- considers options to support the safe and effective use of emerging technologies that could help address biodiversity decline.

Earlier, in November 2021 the focus was on:

- new and improved information
- the use of biotechnology

The Summary of Consultation[2], released following the 18 October to 14 November 2021 consultation showed that many submitters were opposed and the majority were hesitant and cautious with a strong awareness of the risk of biotechnology. Of the 47 submissions, fifteen responses were 'strongly opposed' only one submission only supported the biotechnology 'aspect', while ten submission did not agree (and seven submissions did not specify). The summary document noted:

> Fifteen responses were strongly opposed to the use of biotechnology, but there was mixed opinion on whether biotechnology could be explored as a topic in the Long-term Insights Briefing. The majority of submissions strongly opposing the use of biotechnology were from individuals. Some submitters noted there was limited or no social license for either a conversation about, or action on, biotechnology. A number of other submitters indicated that the topic created risks to social license. Some noted that the two topic areas – information and biotechnology – had different levels of established social license, which should be accommodated when developing the Long-term Insights Briefing itself.
>
> There was a strong message that there are risks associated with biotechnology.

Indeed, it appears that there was no review of the risk and harm in any documents leading up to the November 2021 consultation.

A backgrounder document for the November 2021 How we developed this draft Long-term Insights Briefing [3] explained that information was drawn from:

- ✓ IPBES 2019. Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services
- ✓ Department of Conservation. (2020). Biodiversity in Aotearoa: An overview of state, trends and pressures.

Other documents referenced included documents from the

> ***World Economic Forum,*** a global lobbyist alliance of industry partnerships. The WEF' imaginary of 'strategic intelligence' does not encompass protection of human and environmental health. The WEF does not promote closed loop, low chemical emissions agriculture, the local provision of safe and nourishing food. It's idea of strategic intelligence does not extend to digital tracking and biomarker assays of wildlife or humans to survey harms from non-greenhouse gas anthropogenic emissions. The WEF is concerned with dual-

[2] Long-term Insights Briefing. Summary of Consultation from 18 October to 14 November 2021. https://www.doc.govt.nz/contentassets/4a6414ec062949aaaaa998ae59163d04/summary-of-submissions.pdf
[3] How we developed this draft Long-term Insights Briefing. Long-term Insights Briefing supplementary notes https://www.doc.govt.nz/contentassets/8bb2214f37aa47ffbbba17af76fd5e46/supplementary-document---process-of-ltib.pdf

purpose surveillance, digital architecture and biomedical and biotechnological solutions that predominantly benefit WEF partner organisations. The only NGO's that can participate are globally financed. Grass-roots and indigenous and local agriculture movements do not participate.

A September 2020 UN Economist Network white paper[4] where the conversation revolves around megatrends, digital technology solutionism and inequalities. Pollution from industry, urban runoff and agriculture, as a driver of biodiversity loss was ignored. The content on inequalities failed to address pervasive and ongoing harms from pollution, nutrient deprivation and disproportionate industry power and the failure of governments resource local communities. These imagined harms are unlikely to be fixed by IMF injections and increasing digital technology instruments.

EY. (2020). Megatrends 2020 and beyond. EY is a partner organisation of the WEF. EY's consultancy work, as a 'multinational professional services partnership' predominantly concerns transformational business opportunities for the private sector, as well as contract work in policy development with consultant nation states. EY is a partner of the WEF. EY is not an environmental science organisation and is predominantly concerned with the deployment of technologies in such a way that will benefit clients and partners.

OXFAM Global Megatrends discussion paper. This paper predominantly concerned poverty and technological innovation, not the management of the natural environment. The focus on 'environmental pressures' concerned climate change and resource scarcity.

United Kingdom Government. (2021). Trend Deck Spring 2021. This series of papers included one paper which considered Natural Resources Trends. Again there was no discussion of non-greenhouse gas emissions. For example, the document mentioned pollinator decline but did not focus on the demonstrable drivers of intensive pesticidal use which has been demonstrated to drive these declines.

The papers that informed this process were inappropriate for the purposes of the DOC consultation to 'help biodiversity thrive' as they did not provide a scientific overview of the dominant pressures on soil, water and air, as well as flora and fauna from anthropogenic activity.

There was no review, at all, on pressures from non-greenhouse gas emissions.

The information concerning the adoption of technology focused on a select range of Emerging Technologies.

This narrow selection poorly represents new and emerging technologies that can be strategically engaged by global governments for the protection of human and environmental health. They are narrowly technical in nature and do not appropriately reflect the complex, interdisciplinary

[4] Report of the UN Economist Network for the UN 75th Anniversary Shaping the Trends of Our Time. 20-124-UNEN-75Report-2-1.pdf

scientific work required to understand, and inform both policy-makers and the New Zealand public, of the drivers of human and environmental harm from anthropogenic activities.

By exclusively drawing attention to these narrow technologies, officials rhetorically frame, and manufacture consent for dedicated investment for these particular technologies. The technologies and interdisciplinary scientific research – including monitoring, such as has been raised by the Parliamentary Commissioner for the Environment, then remains ignored as there is no policy platform to support meaningful, and persistent investment in broader research.

The 'Emerging technologies'[5] papers used as the underpinning rationale were therefore cherry picked by officials in support of a predetermined focus on AI and biotechnology:

- Chui, M., Roberts, R., Lareina Yee. McKinsey Technology Trends Outlook 2022.
- AI Forum New Zealand. (2022). Artificial Intelligence for the Environment in Aotearoa New Zealand
- European Policy Centre. (2020). Improving biodiversity: How can digitalisation help?
- Royal Society Te Apārangi. (2022). Gene editing in Aotearoa.
- Segelbacher, G., Bosse, M., Burger, P. et al.(2022). New developments in the field of genomic technologies and their relevance to conservation management. Conserv Genet 23, 217–242
- Hudson, M., et al. (2019). Indigenous Perspectives and Gene Editing in Aotearoa New Zealand. Frontiers in bioengineering and biotechnology, 7, 70.
- OECD AI Policy Observatory. (n.d). Policies, data and analysis for trustworthy artificial intelligence
- Global partnership on Artificial Intelligence (GPAI)

No white papers which looked critically at biotechnology or AI were explored, and no review of the scientific literature was undertaken to draw attention to this issue.

Following the 2021 consultation, in 2022 another Long Term Insight Briefing[6] which asked

> *How can we help biodiversity thrive through the innovative use of information and emerging technologies?*

However, once again, no review was undertaken of the dominant drivers of biodiversity decline, which would then inform policy makers, and help guide decision-making to steward resources into science, so that biodiversity (and the environments which are increasingly degraded and exposed to pollution) may be protected.

The 2022 submission paper once again highlighted the central focus of government and officials on genetic and digital technologies. The 'areas of transformation' (Section 3) focussed on

[5] Links available at: https://www.doc.govt.nz/contentassets/8bb2214f37aa47ffbbba17af76fd5e46/supplementary-document---process-of-ltib.pdf
[6] November 2022Long-term Insights Briefing. See also: https://www.doc.govt.nz/ltib-consult

- Satellite imagery and remote sensing
- Artificial intelligence and data-driven technologies
- Genetic technologies.

There was no discussion of 'transformational' science to implement large scale monitoring and interdisciplinary research to identify the drivers of anthropogenic (non-greenhouse gas) pollution, despite (particularly chemical) pollution being a major driver of biodiversity decline and freshwater degradation.

3. Gene-editing: Potential for off-target, unanticipated, adverse effects – and off target exposures.

The gene-editing technology known as CRISPR/Cas is claimed by the Royal Society to be 'more precise'. However, many studies indicating risk were excluded from its campaign literature. For example, The European Network of Scientists for Social and Environmental Responsibility 'ENSSER '[18] produced a major white paper in 2019 which cited studies that demonstrate that CRISPR/Cas editing not only resulted in intended on-target effects, but in unintended off-target effects such as deletions at the DNA breakage site, mutations including deletions, and rearrangements and insertions away from the target site. ENSSNER is not the only organisation expressing concern at the potential risk of new gene editing technologies.[19] As new opportunities arise it is not only off-target effects from registered laboratories that pose a risk, but off-target exposures from easily accessible, scalable penetrator technologies that modify in real time as they are being applied. If under-regulated, these could create heritable intergenerational changes which cannot be confined.[20] [21]

(It is clear that scientists want a moratorium and/ or a strict regulation around germline editing that changes heritable DNA in humans.)

Since ENSSER report was released other peer-reviewed scientific papers have been published which reveal new and different problems with the technology.

Scientists are finding that CRISPR/Cas is not precise; it is extremely difficult to estimate the complexity of genetic function; off-target, unintended effects may have greater ramifications if released into the environment; for example:

- *Cross-contamination with antibiotic-resistance genes in laboratory material.*[22] Scientists took years to detect unanticipated problems from molecular scissors. For example, non-bovine DNA was used in a process designed to make cattle hornless and was introduced into the genetic material of the cattle. This went undetected by the developers. The DNA-fragments which entered the cells however carried antibiotic resistance genes. [23]
- *Mutations can occur that might not be picked up.* Unintended mutations can result from unintended 'nicking' by eg the CRISPR-Cas12a tool. The tool was prone to making off-target cuts or 'nicks' which did not reflect the intended sequence. A paper revealed computer programs designed to predict off-target DNA cuts were unlikely to detect this;[24]

- Instead of mice pups carrying a correct insertion, 'the rest carried deletions of the gene or had unaltered genomes'. The paper revealed that unwanted duplications can occur that are almost impossible to detect during standard analysis;[25]
- Editing that intends to 'knock out' gene expression, often fails to happen;[26]

Papers such as these, are appearing regularly - yet receive scant local media attention. Anecdotal evidence suggests it is difficult to get articles into mainstream media that criticise new biotechnologies. There is increasing concern from civil society groups in Europe that campaigns and events can be geared towards marginalising criticism.[27]

GENE DRIVE TECHNOLOGY – PREDATOR FREE NEW ZEALAND

New Zealand's Predator Free Vision 2050[28] has correctly excluded GM and new gene-editing techniques including CRISPR/Cas. Gene-drive technologies aim to alter the genome so that a specific trait (such as infertility) will be transmitted to offspring. At least for now.

The possibility of success with gene-drive technology remains largely speculative, uncertain and hypothetical as the ENSSER paper discussed. In 2018 the Sustainability Council drew attention to the significant governance and stewardship challenges regarding these technologies in a major report A Constitutional Moment – Gene Drive and International Governance. The paper stressed that current international governance of genetically modified organisms was inadequate to regulate gene drives and that in effect, gene drive technology is a biosecurity threat. The authors drew attention to the fact that while Hazardous Substances and New Organisms Act (HSNO) legislation could regulate gene drive technology,

> 'there are three important deficiencies: the exercise of precaution is optional rather than required, there are significant gaps in the liability arrangements, and it is unclear to what extent effects beyond New Zealand are to be counted in an assessment.'[29]

Due to the ability for gene drive technology to spread through populations, resulting in likely loss of control, and the lack of knowledge regarding long term, intergenerational consequences, scientists advocate a strong precautionary approach to gene drive technologies.[30] When the risk is viewed alongside with Aotearoa's governance gaps arising from the failure to adopt Royal Commission recommendations, the Predator Free Vision demonstrates that current officials are keenly aware that such activities have the potential to produce a significant and incalculable level of risk to biodiversity in New Zealand.

4. European and New Zealand legislation harmonise – does the public know this?

In 2014 the New Zealand High Court ruled[31] [32] that the new gene editing techniques are techniques of genetic modification. In 2018, the European Court of Justice[33] effectively confirmed this finding. The European Court decided that:

> 'under the EU regulation on genetically modified organisms, modern techniques and methods of directed alteration of genetic material (genome editing) constitute a genetic modification and do not fall under the mutagenesis exemption.'[34]

There was severe criticism of the European ruling, referred to above, from industry-connected groups who misrepresented that the ruling would result on a ban on research.[35] These claims are misleading. Regulation is not a ban. Many technologies are regulated. There is considerable international pressure on Europe to deregulate GM technologies.

What the European Court ruling in effect ensures, is transparency and accountability. This legislation requires that new technologies *must be risk assessed and authorised for safety* to ensure that human and environmental health is not put at risk. A number of technological products have already been released into the environment before the risk has been truly understood.

The Soil & Health Association consider that New Zealand is too small to reinvent the wheel. In order to secure trust in premium international markets for our premium food, it is important that New Zealand aligns with international best practice regulation. Alignment with European Union decisions sends a message to international markets. The European Commission must take the precautionary principle into account in decision-making when there is risk of harm, and the risk is scientifically plausible but uncertain. It is increasingly apparent the precautionary principle has assisted the Europe Union to make rulings that are protective of human and environmental health.

5. New Zealand: A lax approach to monitoring and regulation

Despite New Zealand's up to date precautionary legislation, responsible agencies and authorities, first, have not monitored products to establish the levels of GM in animal feed and in the human food chain, and secondly, have only loosely interpreted the legislation that requires that GM and gene editing technologies should not be released into the environment.[36]

As Professor Jack Heinemann, of the University of Canterbury Centre for Integrated Research in Biosafety has discussed,

> Aotearoa has an immature regulatory system for the oversight of biotechnology when it is used as a tool of intervention in Aotearoa mauri. As the recall and revision of the 2018 Environmental Protection Authority decision on the outdoor use of gene silencing tools illustrated, there is a fundamental need for an increase in regulatory capacity and a decrease in the effort required for external informed views to participate in regulatory decision- making. A change in focus from tools such as information and biotechnology to improved governance and cooperation between agencies and non-state actors, would be welcome.
>
> The responsible use of any biotechnology involves a holistic appraisal of its ability to scale and an ability to anticipate how harm is caused at application scale. The dimensions of harm can be on biodiversity and human health, but also on socio-economic systems. Likewise, various social systems, not just ecosystems, can be modalities that amplify harm. [37]

Our legislation requires that if food has more than 1% of content that is GM, this must be declared on the label.[38] Many processed and ultra-processed foods contain a large number of ingredients that are commonly derived from GM corn, soy, sugar beet or canola, as well as developed from microbial and enzyme GM processes. Contamination is increasing.[39] However there is no testing process that transparently tests and publishes this in the public interest. So, it must be optimal to retain transparent, precautionary legislation.

The monitoring and managing of GM trials has been controversial. A report by GE Free New Zealand documented the now disbanded Ruakura trials which appeared to be plagued by animal health issues including genetic abnormalities and 'unacceptable death rates'.[40] Neither the Ministry for Primary Industries, nor the Environmental Protection Authority engaged in hazard monitoring at the Ruakura trials.[41]

Farmers importing animal feed, particularly those containing commonly modified crops (soy, corn, canola, sugar beet, alfalafa/lucerne) cannot assume the feed is GM free as there is no testing or labelling. Most of the GM ingredients in processed foods and animal feed will be derived from GM crops that are herbicide tolerant.

If regulators lack specific molecular markers, it is possible to identify GMOs using a matrix approach.[42] Biological organisms , whether GMO or non-GMO have specific molecular markers which can be used to identify a specimen. Groups of markers can form a 'reference matrix' – constituting a fingerprint, or signature of that variety. A guidance document has been produced to protect industry assets. This same protocol could be used to enforce and uphold New Zealand legislation.

As we have previously discussed in our submission to the Food Standards Australia and New Zealand (FSANZ) regarding A1186 Soy Leghemoglobin, it is not evident that the FSANZ can fulfil the requirements of its own legislation, which include a requirement to protect public health, prevent misleading conduct and take advantage of the best available scientific evidence.[43] As we stated in our submission, 'The narrow scope of consideration retains important scientific knowledge and data outside consideration, limiting data that may inform the public in the matter of the potential health risk … This narrow scope may undermine the objectives of the Act s.3(c).'[44]

The next section addresses the weak regulation regarding herbicide tolerant GMO foods.

6. Case Study: Herbicide Tolerance, risk assessment for health effects 'insufficient'

Longstanding 'knowledge gaps' in GMO risk assessment are well known.[45] Similarly, an increasing body of studies demonstrate that the industry and regulatory claim of substantial equivalence is incorrect. These studies continue to be ignored, despite the increasing body of evidence.[46] [47] [48] [49] New research continues to draw attention to the inconsistency (or rather, hypocrisy) of a system that permits a biological organism to be uniquely patented, then - in the same breath - refuses to

acknowledge that that organism displays different characteristics as a result of the process for which the patent was derived.

A recent paper drew more light on how the risks have been underestimated, revealing that current risk assessment practices cannot ensure that these crops are safe for public consumption. In a European trial, Juliana Miyazak and colleagues demonstrated that application of herbicides on plant material not only influenced 'the presence, amount and composition of their residues, but can also impact gene expression, agronomic performance and plant composition.'[50] The scientists observed that field trials carried out for risk assessment purposes do not match common agronomic conditions, and in particular, that the applied dose and the number of herbicide applications did not appear to match real conditions. Recommended dosages are often much higher than the dose applied in the field trials.

The scientists considered that risk assessment processes ignore the problems of 'indirect, cumulative and combinatorial effects as well as the assessment of mixed toxicity.'

Herbicide tolerance is the most common GM trait. Many herbicide tolerant food and feed crops contain multiple applications of herbicides and agricultural chemicals. However, issues of 'risk' are not restricted to the consequence of DNA or RNA (ribonucleic acid) change. Many GM crops are 'stacked'?– triple or double stacked so that many different applications of herbicides can be applied to the one crop. This is because resistance to herbicides is a major problem, and weeds, like the modified crop, develop traits that ensure they become resistant to the herbicide mixtures sprayed on the crop. This has led to the 'arms race' of multiple stacked traits in GM herbicide tolerant crops. Spraying one crop with multiple herbicides increases the probability that all resident weeds will be killed. In New Zealand and Australia, FSANZ chooses not to consider formulation toxicity, nor the different ingredients in formulations that may leave residues on food; nor do they consider mixture toxicity, such as the additive or synergistic effects from different herbicides.

Example 1. In 2020 the Food Standards Australia New Zealand (FSANZ) conducted 'a full safety assessment' of a new corn line (MON87429) - intended to be used in 'starch, grits, meal, flour, oil and sweeteners (corn syrups)'. FSANZ CEO in a press release dated March 26, claimed 'the corn derived from this GM line is as safe as traditional non-GM corn'. The herbicide-tolerant corn line MON87429, is genetically modified to provide resistance to dicamba, glufosinate, 2,4-D and the aryloxyphenoxypropionate group of herbicides ('FOPs'). When applied to a crop the active ingredients, eg. dicamba, are applied as a commercial formulation. In effect, multiple formulations, containing multiple formulant ingredients are applied on a single crop. According to current processes, there is no requirement to consider the total toxicity of the end product that becomes an ingredient in supermarket or take-away or restaurant food. The synergistic effects of multiple herbicide residues in combination with the modified plant are never considered in risk assessment.

Example 2. GM Bt crops containing Bt toxins that kill target insects and damage non-target populations. Scientists are revealing that short term laboratory trials do not reflect real life conditions. Nor do they reflect the long-term sub-lethal risk of ongoing population exposures.[1] In addition, while the public consider Bt crops reduce synthetic insecticide use, this is not always correct. GM Bt corn is conventionally treated with one to two neonicotinoid insecticide seed treatments. In the early phase of growth, the young plants do not express enough Bt toxin to prevent insect damage. Without these seed treatments (which include an innovative slow release polymer) the GM Bt corn plants would not survive.

Miyazak and colleagues made recommendations to improve risk assessment of herbicide tolerant GM plants in order to fill current regulatory safety gaps:

- All residues of active substances must be assessed, including taking various practical conditions into consideration (e.g. dosage and frequency of herbicide application, PHIs).
- All applied additives/adjuvants and their residues must be assessed.
- Combinatorial effects of the applied herbicides must be investigated, i.e. both herbicide and/or herbicide interactions, but also herbicide and /or plant (constituent) interactions. • Potential changes in plant composition due to various herbicide applications must be investigated.
- Long-term effects of consumption of HT GM soybeans must be investigated, including potential effects on the endocrine system, reproduction and the intestinal microbiome.
- In a separate paper the authors noted that the current risk assessment system bases toxicity on field trials where HT soybeans were sprayed at lower than normal (contemporary commercial) conditions, creating further knowledge gaps.[51]

Earlier, in 2013, Jack Heinemann and colleagues published recommendations aimed to protect health and environment from potential adverse effects from GMO derived dsRNA molecules.[52] Heinemann and colleagues have also drawn attention to the potential for many of the pesticides

used on HT GMO crops to make bacteria resistant to higher concentrations of antibiotics and to hasten antibiotic resistance.[53]

Without including recommendations such as these (and others), an agency can conduct a risk assessment, and claim the potential product to be authorised is safe (and substantially equivalent), ignoring downstream and cumulative risks. As a final note, the scientific data is selected and supplied by the GM industry organisation seeking the approval and it is usually unpublished and unavailable for independent scientific scrutiny.

7. New Zealand: Court cases, co-existence & product development

CAN REGIONAL COUNCIL RESTRICT GMOS?

The courts have been a battleground in New Zealand for some time, with industry related organisations including Federated Farmers and Life Sciences Network seeking to keep precautionary requirements and GM free policies out of regional plans. A series of decisions have been appealed by the parties seeking deregulation. The decisions have been upheld. In 2018 this prompted Environment Court Judge Laurie Newhook to remark that it was 'quite remarkable' that Federated Farmers was trying its hand at yet another appeal, even though it had lost a string of similar cases. [54]

These court cases have exerted a heavy toll on an increasingly eroded group of civil society organisations and groups, (and the often pro-bono lawyers that have supported them) such as GE Free New Zealand and GE Free Northland, who have laboured to protect the GM free status established pursuant to the findings of the Royal Commission. The absence of a public body to support civil society actions has resulted in fewer parties financially able to support court cases, and the erosion of fiscal stability in these organisations. In 2016 the Soil and Health Association stated it appeared as if Federated Farmers was attempting to 'bleed it dry'.[55]

In submissions to councils and court cases in New Zealand the Life Sciences Network, Federated Farmers, and Biotech NZ (NZBIO) are frequently major players, maintaining that councils do not need precautionary regulation to restrict GMOs in New Zealand regions. There has been concern that cases may have been financially supported by offshore funding from powerful organisations such as from the International Life Sciences Institute (ILSI). ILSI is an industry-funded lobby group whose role is to support research and promote industry- friendly policy positions.[56] [57] [58] Academic and research work could explore the long-term effect of power differentials in relation to the capacity for local groups to contest industry funded claims in a court of law, and the potential for such activities to erode protective and precautionary environmental regulation.

Over the longer term, there is also the potential for large entities with powerful resources to dominate ownership of life forms through the sustained acquisition of biotechnology patents. Thus, while a local developer may own a particular patent now, this may not necessarily be true in ten or twenty years. Again, lacking the governing bodies recommended by the Royal Commission, there remains no public interest authority mandated to explore issues such as these.

CO-EXISTENCE

Local court cases frequently concern the question of whether modified crops can co-exist with organic management.[59] Discussion concerning co-existence that relies on the authority of individuals who promote deregulation of biotechnology and advance arguments for co-existence without supporting data is unhelpful. A recent European forum drew attention to the lack of meaningful policy debate and discussion around co-existence. This is also a stewardship gap in New Zealand.

In European organics legislation, GMO's are considered incompatible with organic agriculture see: Article 9 p.188. Organic food standards require product to be GMO free. This transparent and easy to understand boundary ensures consumer trust.

Biotechnology representatives in New Zealand argue that this is not practical.[60] Instead, biotechnology industry lobby group ILSI appear to conduct workshops for regulators to normalise 'Low Level Presence' in agricultural biotechnology, and encourage regulatory acceptance of co-existence. There are no well-funded groups with an equally sophisticated communications and marketing presence, for example, to present on the precautionary principle and off-target or adverse effects, particularly, long-term unanticipated ones.

There is substantial evidence that the co-existence of modified crops with organics is not supported by the public, and that claims that co-existence poses no risk to the environment are false. To date, regulators have been reluctant to value (or place weight on) data outside of studies supplied by industry when authorising new food ingredients to enter the food chain. However, because risk assessment practices lack independent rigour[61], and often do not consider downstream risk. The FSANZ risk framing skirts around known pathways of harm, such as for example the potential for leaky gut[62], or the cumulative consequence of stacked herbicide traits discussed above. These gaps impact public trust. Claims food containing GMOs is safe and beneficial, remains fragile.

As trust in regulators decline, trust in the organic sector as regulator is increasing:

- There is evidence that gene flow into the environment may be greater than estimated, [63]
- There is no legal remedy for farmers who lose organic status due to contamination[64]
- There is a price penalty for organic farmers when their product is contaminated;[65] [66]
- Consumers consider GMOs to be worse for health than foods which do not contain GMO ingredients;[67]
- Organics may represent 'safe' food as risk assessment processes and decisions may be ignoring cautionary objectives in guiding legislation;[68]
- The organics industry is booming[69], and organics production confers multiple environmental benefits including emitting fewer toxic chemicals into surrounding ecosystems.[70]
- Organic consumers expect organic food free from contamination[71]
- Ongoing release of publications revealing unexpected, unintended and uncertain effects from genetic modification and gene editing processes.

OUR LIMITED FUNDING POOL

One of the reasons why the issue of co-existence has been a focus in recent court cases, may be that AgResearch scientists are developing genetically modified ryegrass and apples. In order to sell them in New Zealand, councils must permit genetically modified products into regional environments. Ryegrass, a common pasture species, is a highly out-crossed, wind-pollinated stock-feed and subject to extensive gene flow. While it is claimed the *bulk* of ryegrass gene flow is limited to 10 metres, this is optimistically conservative. Drift can occur from 35 metres[72] to up to 1 kilometre away.[73] In addition, Professor Jack Heinemann, in court testimony has stated that gene flow can be greater than estimated when animal movement and machinery are taken into account.[74]

Current funding for genetically modified forages, - predominantly concerning a genetically modified 'high metabolisable energy' ryegrass that is claimed will reduce methane emissions and nitrate discharges - is over $25 million and as much as $50 million. Benefits are speculative, as despite the majority of funding coming from the public sector, the results of early trials have not been published. A raft of media releases have supported the ongoing research, and few have questioned issues such as palatability, drought tolerance, digestibility and the results of dietary exposure to multiple generations of stock. The question of gene flow and the potential for the ryegrass to contaminate non-GMO or organic pastures has not been explored. Ironically, just as millions of dollars are committed to mitigate fertiliser-related pollution, the $25 million patented ryegrass appears to require higher fertiliser inputs than conventional species.

It is questionable whether policy analysts and funding bodies have the capacity to assess value from complex farming approaches that offer greater domestic, social and environmental benefits. The issue may be that funding for projects such as genetically modified ryegrass tick exciting 'innovation' boxes and provide a black and white path to commercial revenue via ownership of the consequent biological organism. It is also easier to categorise biotechnology development in 'applied science' boxes required in funding rounds – while multi-year trials to understand potential outcomes from soil regeneration, integrated pest management, and mixed forage pasture management are said to be too 'basic'. Issues merge and overlap and are not sufficiently 'innovative'.

This may explain why groups such as Landcare have struggled to obtain funding for trials in organic and/or regenerative agriculture. Funding for assessing the potential for carbon sequestration, reduced fertiliser use, improved soil health or stock health and increased nutrition and moisture retention (as drought tolerance) from mixed pasture and low synthetic-input regenerative strategies is lacking. Farmers in New Zealand are applying these methods, and scientists want to understand the potential over time, but funding for trials and research is difficult to access.

8. Global Governance: We're only as strong as our borders

New Zealand spends millions ensuring that unwanted organisms, in the form of insects, pests or infections, do not threaten agriculture. The Sustainability Council white paper, A Constitutional

Moment: Gene Drive and International Governance drew attention to the potential threat of regulated and unregulated GM (including gene edited) organisms entering New Zealand.[75] As the evidence suggests, the potential for adverse and downstream effects that may cause biological harm is real – once in the environment this technology cannot be controlled and the long term consequences cannot be reliably estimated.

There are no international conventions that have teeth or that are binding There are no mechanisms that integrate the transparent and accountable measures required to adequately steward these technologies in the public interest. Despite having a regulatory infrastructure in place that should be identifying and regulating all new GMOs, an Australian company has recently bred dairy cows[76] from gene edited bulls. Friends of the Earth have now reported that 'genomes have since been found to unintentionally contain bacterial DNA'.[77] Unfortunately, and unreported by the ABC, is that the bacterial DNA confers resistance to three different antibiotics. It is unlikely that New Zealand would welcome genetic material being introduced into the New Zealand dairy herd that hastens antibiotic resistance, particularly if it was due to poor regulation by the agencies that are meant to protect the food chain.

9. Scalability: Beyond current gene-editing techniques.

Deregulation of newer techniques appears to carry with it the assumption that all future techniques will be precise, safe, and carry no risk. This optimism cannot serve the public interest, because we cannot forecast future development or the accompanying challenges such as environmental or human vulnerabilities. Technology regulation must be anticipatory, which means that black and white definitions will quickly become out-of-date, or unfit for purpose. This is why principles often allow greater flexibility in shifting technology environments. Nor can we assume there will be political will to support long term oversight to ensure a GMO technology or its process will not pose a hazard.

In many cases off-target effects are not detected in the laboratory but are found after release of an organism. The release of the organism, and the potential for a technology to be rapidly deployed at scale changes the nature of risk. As Jack Heinemann and colleagues have outlined:

> Whereas all technologies have risks of creating unintended hazards, the focus of a governance system should not fail to respond when safety and risk diverge as the scale of use changes. We argue risk and use scale together at critical control points, which make them useful for regulation and could serve either an RRI or distributed governance model. [78]

The authors go on to state:

> 'precision is the efficiency at achieving changes at a desired location in a DNA molecule. Increases in precision make "on-target" outcomes scalable. However, with increased use, "off-target" effects also are scalable. Because off-target effects are associated with risk, risk increases with use, while safety increases incrementally with slow improvements to target specificity (precision) built into the tools over time.' [79]

In order to cope with such challenges, Heineman et al. suggest that that

Biotechnology has increased our existential risk[80] and much of this is due to the fact that biotechnologies can be rapidly scaled out and released. Unforeseen events can and will arise, from insect releases to pandemics. Many technologies have dual uses, and not just the end product, but the *scientific knowledge* has the potential to open the door to applications by bad actors, individuals or organisations with malicious intent, and increase the potential for bioterrorism or international industrial sabotage.[81] It is difficult to estimate when a new technology or process is sufficiently risky that the knowledge itself should be regulated – because the information itself is a hazard.[82]

New 'penetration' technologies are currently being developed that could be rapidly deployed into the open environment for pest control, in food production or for other preservation applications. These technologies create genetically modified organisms just by spraying them. This new emerging technology has low barriers to entry. It is potentially simple and inexpensive to apply yet as with existing technologies, continues to carry the potential for adverse and unintended effects.[83]

The use of penetration technologies without strict regulation is alarming. A review of penetration technology by Jack Heinemann and Sophie Walker stressed that it was important for regulators to 'separate the discussion of promised benefits from a strict evaluation of potential hazards as part of a risk assessment' – noting that benefits were not the 'opposite of hazards and do not negate them'. The authors offered suggestions for risk assessment and regulation, and due to risk that these technologies could be easily accessible, cautioned:

> 'Based on the scalability and potential to re-task or create non-commercial vehicles and combine them with biological active ingredients, a risk assessment should also consider malicious, criminal and military uses of methods and apparati, particularly those that may be widely available as commercial products in the future'.[84]

10. Conclusion

The problems addressed above are not exclusively restricted to biotechnology. A broad variety of industries are engaged in defending hazardous substances that have initially appeared beneficial or benign. Many of them have scaled up rapidly, with emissions that have been found to be persistent, toxic and bioaccumulative long after the products were in common use. Time after time, these technologies have been found to be damaging to human and/or to environmental health. This includes, but is not restricted to tobacco products, sugar, fire retardants, ultra-processed food and non-stick cookware. When found to be damaging, the producers of the harms rarely self-regulate to protect environmental or human health. Instead, these organisations commonly apply extensive and complex tactics to delay regulation and ensure consensus is not achieved to ban or restrict the substance.

This is why it is critical to have independent oversight and regulators with resources to operate at arms-length from industry influence.

If society cannot understand the risk posed by modern technologies, society cannot steward them and the principles of the Treaty of Waitangi cannot be honoured. This is why the public require a science system that is not driven by an innovation dogma, but that is stewarded by high level principles of protection. Principles that provide a pathway for scientists, ensuring that scientists have permissions, capability and resourcing to explore the potential for off-target and unanticipated harms that arise from the technologies industry and civil society produce and consume, and the non-greenhouse gas pollutants that are then emitted.

Currently the structure of science policy and science funding does not provide scope for these activities, which often involve non-orthodox interdisciplinary research. This research can traverse genetics, epidemiology, data mining, machine learning and predictive modelling. Scientists wishing to explore the potential for unintended changes from new breeding techniques, including the potential for deletions, duplications or scrambling of chromosomal sequences proximate to the genomic site that was edited – would struggle to secure not only the financial resources, but the political will to do this research.

However, scientific feedback loops are an important part of the regulatory apparatus. As Professor David Michaels has written:

> 'Our regulatory system is the response to these market failures. The objectives of the new laws and the agencies empowered to enforce them is not only to stop the damage and prevent future harm; it is to maintain and strengthen the free market system. Although many advocates of free market economics refuse to acknowledge this dynamic, law and regulations are the underpinnings of our economic system. They define market structure and property rights while attempting to ensure that property rights don't intrude on our civil liberties. Without the regulatory apparatus of the state, our modern economy could not exist. The state fosters a safe space for market growth.'[85]

Our current media environment is terrific at promoting positive hypothetical scenarios for biotechnology, but not so good at considering adverse, unintended or irreversible consequences and communicating this to the public. Public knowledge of biotechnology risk is largely shaped by the industries and interests promoting deregulation, and the few people that have the capacity to respond at an expert level are easily marginalised.

Yet this is occurring in a world where the planetary boundary for novel entities, which includes biotechnology, has been found to have been exceeded, simply because the release of these technologies have exceeded societies' ability to conduct safety related assessments and monitoring. (It is possible to monitor the new technologies). It is the scalability of these technologies that compound risk, and it is the scalability potential that is a key reason for ongoing regulation of biotechnologies. Regulation promotes transparency and, ideally, publicly accessible deliberation to ensure actions precautionarily prevent harm, should a known, or unanticipated error or off-target effect arise.

Our regulatory framework is weak and has exhibited scant interest in scaling up control as new understandings of risk are reached. Neither is it strong at preventing the problems of bias arising from industry selecting and supplying its own data to gain market approval.

There is no assembly of independent experts with interdisciplinary expertise to navigate sufficiently ethical issues of intergenerational risk and scientific uncertainty, or to assist the public to draw a social and value laden line in the sand about what we wish to protect or promote. Further, New Zealand is a small country, and the absence of regulation to date suggests that there is little capacity to manage *future* threats to protect health and environment.

It is increasingly evident that these biotechnologies have the potential to create profound hazards for humans and the environment and that they contribute to global risk. Our current legislation, which aligns with European regulation, requires that all techniques of genetic modification are regulated. This represents a critical and necessary measure of protection, helping us to navigate what Donald Rumsfield[86] termed the 'known unknowns' and the 'unknown unknowns'. However, it should not be surprising that industry interests wish to deregulate this legislation, because if we do not know what is being released into the environment, we cannot stop it, nor anticipate its effects.

Critically, our legislation which prohibits releases into the environment, is essential to protect the public interest and compensate for our otherwise weak and under-resourced regulatory environment. It is these safeguards, weak though they are, that represent our best chance to ensure that principles of the Treaty of Waitangi are upheld, and to protect human and environmental health for future generations. Our governing legislation is not 'outdated' – it is foundational.

Bibliography

[1] Described in this new paper from the University of Canterbury the New Zealand Defence Agency Heinemann, J.A.; Walker, S. Environmentally applied nucleic acids and proteins for purposes of engineering changes to genes and other genetic material. Biosafety Health 2019;1:113-123

[2] Heinemann, JA. Is product-based regulation of biotechnology code for no regulation? Rightbiotech. https://rightbiotech.tumblr.com/post/178959072080/is-product-based-regulation-of-biotechnology-code

[3] Heinemann, JA, Paull DJ, Walker S, Kurenbach B. 2021. Differentiated impacts of human interventions on nature: Scaling the conversation on regulation of gene technologies. *Elem Sci Anth*, 9: 1. https://doi.org/10.1525/elementa.2021.00086

[4] Heinemann, JA, Paull DJ, Walker S, Kurenbach B. 2021. Differentiated impacts of human interventions on nature: Scaling the conversation on regulation of gene technologies. *Elem Sci Anth*, 9: 1. https://doi.org/10.1525/elementa.2021.00086

[5] Montenegro de Wit, M. 2020. Democratizing CRISPR? Stories, practices, and politics of science and governance on the agricultural gene editing frontier. Elementa: Science of the Anthropocene 8: 9. DOI: http:// dx.doi.org/10.1525/elementa.405.

[6] Heinemann JA. 2021. Submission on Proposal P1055 Definitions of Gene Technology. November 2021. Technical Report. DOI:10.13140/RG.2.2.26196.32647

[7] Parliamentary Commissioner for the Environment (2010). How clean is New Zealand? Measuring and reporting on the health of our environment https://pce.parliament.nz/media/kcvdylib/how-clean-is-new-zealand3.pdf

[8] Ministry for the Environment. Report of the Royal Commission on Genetic Modification. 2001 https://www.mfe.govt.nz/publications/hazards/report-royal-commission-genetic-modification

[9] McGuiness W., Versteed S., White W. Review of the Forty-Nine Recommendations of the Royal Commission on Genetic Modification. Sustainable Future Limited, April 2008

[10]CEO. US pressure on EU to de-regulate new GM. Corporate Europe Observatory. July 24 2019. https://corporateeurope.org/en/2019/07/us-pressure-eu-de-regulate-new-gm

[11] Food & Water Watch. Biotech Ambassadors: How the U.S. State Department Promotes the Seed Industry's Global Agenda. 2013. https://www.foodandwaterwatch.org/sites/default/files/Biotech%20Ambassadors%20Report%20May%202013.pdf

[12] TestBiotech (2022) New Genomic Techniques and unintended genetic changes: EFSA 'overlooked' most of the relevant publications. Background 12-12-2022 https://www.testbiotech.org/sites/default/files/EFSA%20%E2%80%98overlooked%E2%80%99%20relevant%20publications.pdf

[13] See PSGR's submissions to:
PSGR (2022) Te Ara Paerangi - Future Pathways Green Paper
https://psgr.org.nz/component/jdownloads/send/1-root/88-nzscience
PSGR (2021) Inquiry on the Natural and Built Environments Bill: Parliamentary Paper
https://psgr.org.nz/component/jdownloads/send/1-root/72-21nba

[14] Heinemann JA & Hiscox TC (2022) Rethinking the drivers of biotechnologies: a paradigm for holistic climate change solutions. *Curr Op Env Sust.* 59:101222 https://doi.org/10.1016/j.cosust.2022.101222

[15] Parliamentary Counsel Office. New Zealand Productivity Commission Act 2010 Part 2, Sn 7. https://www.legislation.govt.nz/act/public/2010/0136/latest/whole.html#DLM3104312

[16] Navdanya (2020). Biopiracy of Climate Resilient Seeds. https://navdanyainternational.org/wp-content/uploads/2020/10/BIOPIRACY-OF-CLIMATE-RESILIENT-SEEDS.pdf

[17] The Royal Society Te Apārangi. Gene Editing. Compilation of Documents. https://www.royalsociety.org.nz/assets/Uploads/Gene-Editing-FINAL-COMPILATION-compressed.pdf

[18] ENSSNER 2019. Gene Drives: A report on their science, applications, social aspects, ethics and regulations. 2019. Critical Scientists Switzerland, European Network of Scientists for Social and Environmental Responsibility and Vereinigung Deutscher Wissenschaftler (VDW). ISBN: 978-3-00-062389-9

[19] Cotter J and Perls D. Gene-edited organisms in agriculture: Risks and unexpected consequences. Friends of the Earth U.S.

[20] Heinemann, J.A.; Walker, S. Environmentally applied nucleic acids and proteins for purposes of engineering changes to genes and other genetic material. Biosafety Health 2019;1:113-123

[21] Heinemann, J.A. Should dsRNA treatments applied in outdoor environments be regulated? Environ Int 2019;132:104856

[22] Bloch, S. FDA finds a surprise in gene-edited cattle: antibiotic-resistant, non-bovine DNA. The Counter. August 15, 2019. https://thecounter.org/fda-gene-edited-cattle-antibiotic-resistant-crispr-dna/

[23] Norris et al. (2020) Template plasmid integration in germline genome-edited cattle, Nature Biotechnology

[24] Murugan K. et al 2020. CRISPR-Cas12a has widespread off-target and dsDNA-nicking effects. Journal of Biological Chemistry. doi: 10.1074/jbc.RA120.012933

[25] Skryabin BV et al 2020 Pervasive head-to-tail insertions of DNA templates mask desired CRISPR-Cas9–mediated genome editing events. Science Advances. 6:7:DOI 10.1126/sciadv.aax2941 https://advances.sciencemag.org/content/6/7/eaax2941

[26] Smits AH et al 2019. Biological plasticity rescues target activity in CRISPR knock outs. Nature Methods volume 16, pages1087–1093. https://www.nature.com/articles/s41592-019-0614-5

[27] Arora et al 2019. Choreographed Consensus: The stifling of dissent at CRISPRCon 2019. https://steps-centre.org/blog/choreographed-consensus-the-stifling-of-dissent-at-crisprcon-2019/

[28] Predator Free NZ https://predatorfreenz.org/big-picture/pf-2050-vision/

[29] Sustainability Council 2018. A Constitutional Moment: Gene Drive and International Governance. P.9 http://www.sustainabilitynz.org/a-constitutional-moment-gene-drive-and-international-governance/

[30] Von Gleich A & Schröder, W. 2020. Gene Drives at Tipping Points. Precautionary Technology Assessment and Governance of New Approaches to Genetically Modify Animal and Plant Populations. Springer. DOI https://doi.org/10.1007/978-3-030-38934-5

[31] The Sustainability Council of New Zealand Trust v The Environmental Protection Authority [2014] NZHC 1067, (2014) 18 ELRNZ 33.

[32] Sustainability Council 2014. Key Background to the High Court Ruling. http://www.sustainabilitynz.org/wp-content/uploads/2014/05/Backgrounder_ZFN-1HighCourtDecision.pdf

[33] Judgement of the Court (Grand Chamber), 25 July 2018 in Case C-528/16. Accessed 11/02/2020 http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d0f130dcd5adc6577ba74dc9b5acf2530b87e485.e34KaxiLc3eQc40LaxqMbN4Pb3yRe0?text=&docid=204387&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=72898

[34] IUCN. European Court of Justice Ruling on genome editing. August 14 2018. https://www.iucn.org/news/world-commission-environmental-law/201808/european-court-justice-ruling-genome-editing

[35] Gelinsky E and Hilbeck A. 2018. European Court of Justice ruling regarding new genetic engineering methods scientifically justified: a commentary on the biased reporting about the recent ruling. *Environmental Sciences Europe.* 31:1;52. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6302053/

[36] see for example Heinemann, J.A. Should dsRNA treatments applied in outdoor environments be regulated? Environ Int 2019;132:104856

[37] Heinemann JA 2021. INBI submission to New Zealand Department of Conservation consultation on innovation and biotechnology. Technical Report · October 2021. DOI: 10.13140/RG.2.2.27823.25764

[38] Food Standards Australia New Zealand. Genetically modified (GM) food labelling. Do GM foods have to be labelled? August 2019 http://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx

[39] Price B & Cotter J. The GM Contamination Register: a review of recorded contamination incidents associated with genetically modified organisms (GMOs), 1997–2013. International Journal of Food Contamination. 2014:5

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

[41] Heinemann, J.A., Kurenbach, B. and Bleyendaal, N. 2011. Evaluation of horizontal gene transfer monitoring experiments conducted in New Zealand between 2004-2009. Journal of Organic Systems 6, 3-16.

[42] Meunier, E. UPOV : Indeed, new GMOs can be accurately identified. 25 March 2020. Infogm.org

[43] Food Standards Australia New Zealand Act 1991. S.18

[44] Submission: Soil & Health Association, dated February 13, 2020 Application A1186 Soy Leghemoglobin.

[45] Nordgård et al 2015 Uncertainty and Knowledge Gaps related to Environmental Risk Assessment of GMOs. Biosafety Report 2015/03. GenØk – Centre for Biosafety, Tromsø, Norway October 2015

[46] GMOScience. A GMO Corn and Its Non-GMO Parent Are Not Substantially Equivalent. February 20, 2020. https://www.gmoscience.org/gmo-corn-non-gmo-parent-not-substantially-equivalent-part1/

[47] Heinemann J. GM crops and herbicides: time to reassess risk assessment methods. *Sciblogs.* 11/01/2017

[48] Poirier F, et al 2017Proteomic analysis of the soil filamentous fungus Aspergillus nidulans exposed to a Roundup formulation at a dose causing no macroscopic effect: a functional study. *Environ Sci Pollut Res Int*. 2017 Sep 23. doi: 10.1007/s11356-017-0217-6.

[49] Hernández-Terán et al 2017. Domesticated, Genetically Engineered, and Wild Plant Relatives Exhibit Unintended Phenotypic Differences: A Comparative Meta-Analysis Profiling Rice, Canola, Maize, Sunflower, and Pumpkin. *Plant Science*. https://www.frontiersin.org/articles/10.3389/fpls.2017.02030/full#B24

[50] Miyazaki J et al 2019. Insufficient risk assessment of herbicide-tolerant genetically engineered soybeans intended for import into the EU. Environmental Sciences Europe 92:2019

[51] Bøhn T, Millstone E. The introduction of thousands of tonnes of glyphosate in the food chain - An evaluation of glyphosate tolerant soybeans *Foods.* 2019 Dec 11;8(12). pii: E669. doi: 10.3390/foods8120669.

[52] Heinemann et al 2013. A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments. *Environment International. 55:43-55*

[53] Kurenbach et al. (2018), Agrichemicals and antibiotics in combination increase antibiotic resistance evolution. PeerJ 6:e5801; DOI 10.7717/peerj.5801

[54] Bradley, A. Federated Farmers slammed by judge for blocking GMO bans. April 16 2018. RNZ. https://www.rnz.co.nz/news/national/355238/federated-farmers-slammed-by-judge-for-blocking-gmo-bans

[55] Bradley, A. Federated Farmers slammed by judge for blocking GMO bans. April 16 2018. RNZ. https://www.rnz.co.nz/news/national/355238/federated-farmers-slammed-by-judge-for-blocking-gmo-bans

[56] Steel S et al 2019. Are industry-funded charities promoting “advocacy-led studies” or “evidence-based science”?: a case study of the International Life Sciences Institute. *Globalization and Health.* 15:36

[57] CEO 2012 The International Life Sciences Institute (ILSI), a corporate lobby group. Corporate Europe Observatory. https://corporateeurope.org/sites/default/files/ilsi-article-final.pdf

[58] Sourcewatch International Life Sciences Institute. https://www.sourcewatch.org/index.php/International_Life_Sciences_Institute

[59] See Waikato District Council Proposed District Plan. Hearing 8B: GMO. Submitter evidence and Rebuttal Evidence https://www.waikatodistrict.govt.nz/your-council/plans-policies-and-bylaws/plans/waikato-district-plan/district-plan-review/stage-1/hearings/hearing-8b

[60] See Waikato District Council Proposed District Plan. Hearing 8B: GMO. Submitter evidence and Rebuttal Evidence Life Sciences Network. W. Rolleston. https://www.waikatodistrict.govt.nz/your-council/plans-policies-and-bylaws/plans/waikato-district-plan/district-plan-review/stage-1/hearings/hearing-8b

[61] Miyazaki J et al 2019. Insufficient risk assessment of herbicide-tolerant genetically engineered soybeans intended for import into the EU. Environmental Sciences Europe 92:2019

[63] Centre for Integrated Research in Biosafety, University of Canterbury. Statement to the Whangerei and Far North District Councils Hearing Panel. June 2016. http://www.wdc.govt.nz/PlansPoliciesandBylaws/Plans/DistrictPlan/DistrictPlanChanges/Documents/PC-131-GMO/5-Hearing/6-Statement-of-Evidence-Professor-Jack-Heinemann-UOC.pdf

[64] Paull, J. 2019 The Failures of Genetically Modified Organisms (GMOs): Resistance, regulation and rejection. https://hal.archives-ouvertes.fr/hal-02450467/document

[65] Paull, J. Contamination of Farms by Genetically Modified Organisms (GMOs): Options for Compensation Journal of Organics, 6(1), 2019 https://www.researchgate.net/publication/335463907_Contamination_of_Farms_by_Genetically_Modified_Organisms_GMOs_Options_for_Compensation

[66] IFOAM and FiBL. 2017. Report: Socio-Economic Impacts of GMOs on European Agriculture. https://www.ifoam-eu.org/sites/default/files/ifoam_eu_project_keeping_gmos_socioeconomic_study_final.pdf

[67] GMWatch. Surveys make unsettling reading for GMO proponents. April 2020. https://gmwatch.org/en/news/latest-news/19385-surveys-make-unsettling-reading-for-gmo-proponents

[68] Soil & Health Association submission. Application A1186 Soy Leghemoglobin. 2020. https://organicnz.org.nz/wp-content/uploads/2019/10/2020-A1186-Soil-and-Health-LegH-Prep-soy-leghemoglobin.pdf

[69] OANZ. New Zealand Organic Market Report 2018 http://www.oanz.org/publications/reports.html

[70] Soil & Health Association & PSGR NZ. Aotearoa New Zealand Policy Proposals on healthy waterways. 2020 https://organicnz.org.nz/submissions/submission-on-healthy-waterway-proposals/

[71] Organics Aotearoa New Zealand. 2018 New Zealand Organic Sector Market Report. https://nzkgi.org.nz/wp-content/uploads/2018/07/OANZ_Market-Report_2018_F.pdf

[72] Yanniccari M et al 2018 Dynamics of Glyphosate Resistance in Lolium perenne: Pollen-Mediated Gene Flow under Field Conditions in Argentina. *Agronomy.* 8:286

[73] Giddings GD (2000) Modelling the spread of pollen from Lolium perenne. The implications for the release of wind-pollinated transgenics. Theor Appl Genet 100:971–974

[74] Centre for Integrated Research in Biosafety, University of Canterbury. Statement to the Whangerei and Far North District Councils Hearing Panel. June 2016. http://www.wdc.govt.nz/PlansPoliciesandBylaws/Plans/DistrictPlan/DistrictPlanChanges/Documents/PC-131-GMO/5-Hearing/6-Statement-of-Evidence-Professor-Jack-Heinemann-UOC.pdf

[75] Sustainability Council 2018. A Constitutional Moment: Gene Drive and International Governance. http://www.sustainabilitynz.org/a-constitutional-moment-gene-drive-and-international-governance/

[76] Slezak M & Timms P. Mutants or Miracles? 15 March 2020. https://www.abc.net.au/news/2020-03-14/genetically-modified-cows-no-horns-in-australia/12018078

[77] GE Free NZ. Are Australian GE Regulators Threatening New Zealand's Food Chain? 13 March 2020. Scoop.

[78] Heinemann, JA, Paull DJ, Walker S, Kurenbach B. 2021. Differentiated impacts of human interventions on nature: Scaling the conversation on regulation of gene technologies. *Elem Sci Anth*, 9: 1. https://doi.org/10.1525/elementa.2021.00086

[79] Heinemann, JA, Paull DJ, Walker S, Kurenbach B. 2021. Differentiated impacts of human interventions on nature: Scaling the conversation on regulation of gene technologies. *Elem Sci Anth*, 9: 1. https://doi.org/10.1525/elementa.2021.00086

[80] Bostrom, N. Existential Risk Prevention as Global Priority. *Global Policy.* 4:1;15-31

[81] Mueller, S. Are market GM plants an unrecognized platform for bioterrorism and biocrime? Front Bioeng Biotechnol 2019;7:121

[82] Lewis, G, Millet et al 2019 Information Hazards in Biotechnology. *Risk Perspective.* 39:5;2019

[83] Sirinathsinghji E. 2019. Transferring the laboratory to the wild: An emerging era of environmental genetic engineering. TWN Biosafety Briefing. November 2019. https://biosafety-info.net/wp-content/uploads/2019/11/Biosafety-briefing_From-lab-to-wild.pdf

[84] Heinemann, J.A.; Walker, S. Environmentally applied nucleic acids and proteins for purposes of engineering changes to genes and other genetic material. Biosafety Health 2019;1:113-123

[85] Michaels, D. The Triumph of Doubt: Dark Money and the Science of Deception. Oxford University Press p271

[86] Shermer M. Rumsfield's Wisdom. Scientific American. September 1, 2005. https://www.scientificamerican.com/article/rumsfelds-wisdom/