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Genetic technologies– The next steps for modernising New Zealand’s policy framework

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Executive Summary

New Zealand stands at a pivotal crossroads, amidst growing calls from various stakeholders, to reevaluate its approach to how genetic modification technology is regulated. This report serves as a resource for policymakers tasked with the responsibility of reevaluating New Zealand's biotechnology regulations. It offers historical context, explains the current situation, and outlines the fundamental principles that should guide the development of a new approach. Key recommendations are provided for developing a bespoke policy framework that addresses the values and priorities of all New Zealanders while leveraging international best practices.

The HSNO Act of 1996, which forms the basis of New Zealand's current regulatory framework, was enacted over 20 years ago. Since then, there have been substantial technological advancements that present new opportunities for New Zealand, but also new concerns. The existing approach is viewed by some researchers as overly cautious and cost prohibitive to engage with, and there is concern that New Zealand is falling behind trading partners and competitors.

Genetic modification has historically been a controversial topic in New Zealand, resulting in a lack of comprehensive national discourse since the Royal Commission on Genetic Modification report in 2001. Concerns have focussed on the potential impact on the environment, health, and agricultural exports, while the effect on cultural values holds special significance for Māori. However, with growing understanding of the potential benefits for genetic technologies, New Zealand has a fresh opportunity to engage in this essential conversation and ensure that it leads to a modern, fit-for-purpose approach.

The methodology for writing this report began by identifying a primary research question – Is New Zealand's current policy settings for the regulation of genetic technologies fit for purpose? Finding that it wasn't led onto secondary questions of what a modern approach would look like for New Zealand and how this should be developed.

A wide range of sources were used to research these questions, from academic papers, primary sources such as government legislation, and publicly available reports written by scientific organisations and government departments. This research was supported by eight semi-structured interviews which aimed to gain a deeper understanding of the topic, test assumptions, and provide a range of expert views.

Key areas were identified for deeper research using peer reviewed papers. This included a focus on understanding Māori views towards genetic technologies and comparison of international regimes. Of particular interest for this report was international partners who had recently reviewed and updated their policies and the public views on this change.

New Zealand has the opportunity to develop a New Zealand-specific approach to genetic modification regulation, by taking learnings from the international context and incorporating key New Zealand values. This report outlines the principles that should underpin the development of a new regulatory regime and provides suggestions on how to proceed. It is crucial to understand that these are not exhaustive recommendations; the objective is to outline a process that should be followed and principles that should be included in any updated policy.

The initial step in this process should be gaining a deep understanding of the core values of New Zealanders. By creating a draft regulatory framework that aligns with these values, the Government can foster constructive discussions and develop a distinctively New Zealand approach that effectively balances both risks and opportunities.

This report recommends that the New Zealand Government:

- Review in detail the international context, taking learnings from what works well and what doesn't and use these findings to develop a draft policy for consultation.
- Build on and test the work that has already done to understand the values that are important to New Zealanders with special regard to Māori views.
- Develop a New Zealand-centric policy towards the use of genetic technologies that address the priorities and incorporates the values of all New Zealanders.
- Explain how these values have been incorporated into any draft policy for consultation.
- Communicate clearly what risks have been identified and how they have been addressed, as well as the opportunities a new approach would provide.
- Develop a strong engagement package that aims to minimise the contentious nature of previous engagements. This includes the use of communicators trusted by the sector of society that you are aiming to reach.
- **A new regulatory regime should:**
 - Ensure New Zealand's exports are not negatively impacted.
 - Be clear on what technology is regulated or deregulated and why.
 - Support New Zealand firms to develop solutions for New Zealand-specific issues.
 - Respect and enhance Māori values.
 - Be risk-based rather than focussing on process.
 - Be future-proofed through regular monitoring and review.

A report on the future of genetic modification in New Zealand

1. Project Overview

E ngaki ana a mua, e tōtō mai ana a muri

First clear the weeds, then plant.

1.1. Introduction

New Zealand prides itself as a technologically advanced agricultural nation. New Zealand's legislation is outcomes focussed, meaning that it allows farmers and businesses to innovate and achieve the purpose of the legislation in a way that best suits that farming system and land use. New Zealand has also historically reduced its agricultural subsidies to the lowest level in the OECD (making up only 0.64 percent of gross farm receipts), which has removed market distortions and meant that farm businesses are structured in a way that maximises productivity and efficiency – with regulation setting bottom lines and assurance programmes providing customer verification. New Zealanders consider that their farmers are among the best in the world when measured on sustainability, animal welfare, and production and that through Kiwi ingenuity any challenge can be overcome.

New Zealand farmers have among the lowest greenhouse gas emissions per unit of milk solids, sheepmeat, and beef, in the world. They have also improved production, increased native vegetation and leading the world in agricultural productivity on many other metrics (Ledgard, Falconer, & Mazzetto, 2021) (Ledgard, Falconer, & Mazzetto, Updating the carbon footprint for selected New Zealand agricultural products: an update for milk, 2021). However, there are challenges and risks to New Zealand agriculture that have not yet been addressed including adapting to climate change impacts and further reducing greenhouse gas emissions to satisfy both government and international consumer requirements. A changing climate brings increased risks of biosecurity incursions and negative animal welfare through higher temperatures, while pest control remains a significant problem both for conservation and productivity, with introduced species preying on and out-competing indigenous flora and fauna. To keep at the forefront of innovation it is important that there is a regulatory framework in place that allows for innovation while mitigating any risks associated with new technologies.

Genetic technologies have a checkered history in New Zealand, with significant public concern regarding genetically modified organisms since regulation in New Zealand under the HSNO Act 1998. Despite there being dramatic advancements in these technologies since that time, only one minor update in 2003 has been made to the regulations. It is unclear what level of support there currently is for their use from the New Zealand public, however a range of civil service organisations, NGOs, and government departments have called for a review of current policy settings.

“...there are many factors that we don't control, but one thing we can control is whether we release GMOs or not.” – Interview participant

With New Zealand reliant on trade and export markets for continued farm profitability, the risk of losing market access has been a significant driver to the opposition of their use by growers and farmers. Recently, however, views have changed in comparable jurisdictions such as Australia and in New Zealand's export markets, with both the United Kingdom and the European Union recently reevaluating their approaches to genetic modification.

In New Zealand, there has been a raft of reports, white papers, and government briefings that have examined the issue in greater detail, with a view to consider how genetic technologies could be used for different purposes in different industries. Scientists have also been calling for

change, with 150 young New Zealanders recently writing to ask the Green Party to revisit its position on genetic modification (Manhire, 2019).

For such a historically sensitive issue however, change will need to come at a political level, by elected representatives rather than by government officials. Reviewing the use of genetic technologies will need to be done in a way that is transparent, science based and clearly recognises any risks associated with their use. Importantly, obligations under the Treaty of Waitangi and views of Māori are a uniquely New Zealand factor that must also be considered, meaning that overseas approaches cannot simply be replicated.

There is appetite for change in New Zealand, with the Labour Government launching a review of genetic modification technology in July 2023, albeit for limited purposes in laboratories and biomedical research. The National and Act parties both stated they would end the ban on genetic technologies in New Zealand should they form the next government. Recent reports from the Productivity Commission, the Royal Society Te Apārangi, and the Prime Minister's Chief Science Advisor have also called for modernisation of New Zealand's regulations for genetic technologies.

This report does not seek to duplicate the work looking at potential uses of the technology in New Zealand but aims to look at what a uniquely New Zealand approach to the use of genetic technologies would look like. It will do this through analysis of what is happening overseas and reviewing work that has already been done in New Zealand. The report aims to provide a blueprint for New Zealand government policy analysts tasked with implementing such a change by examining the international context and factors unique to New Zealand before proposing a solution for next steps.

1.2. Project objectives

This project aims to review the current situation in New Zealand regarding the use of genetic technologies and provide recommendations for the next steps that should be taken.

My research question was – **Is New Zealand's current approach towards the regulation of genetic technologies fit for purpose?**

Underneath this primary question sat two sub-questions:

- 1. What should a modern biotechnology technology regime for New Zealand include?**
- 2. How should New Zealand approach regulatory change when updating its policy?**

This project does not seek to evaluate in detail the pros and cons of genetic technologies or look at what they may be used for in New Zealand, as this has been covered extensively in numerous reports and studies. This literature has provided a solid basis for this report and has been summarised to provide an overview of New Zealand's historical and current approach to genetic technology regulation. From there, the international context will be reviewed to understand the regulatory regimes for the use of genetic technologies overseas, whether they have changed over time, and whether there is anything New Zealand can learn from them. This will be contrasted with the New Zealand situation and whether the changing international context means that New Zealand should also review its approach, and if so what can be learnt from international jurisdictions.

This report will conclude with recommendations for next steps that New Zealand could take regarding a review of its approach to genetic technologies in a way that reflects the New Zealand context, before discussing what principles should underpin any regulatory review.

1.3. Definition of genetic technologies

There are many different types of genetic technologies and different terminologies for them. In essence, this report discusses genetic technologies that provide the ability to accelerate the

uptake of new traits in organisms. While these technologies have existed historically, this report focuses on the ones that are currently regulated in New Zealand and are commonly known as 'genetic modification' or 'gene editing' and their use results in 'genetically modified organisms' as defined by the Hazardous Substances and New Organisms (HSNO) Act 1996. This does not cover random mutagenesis technology which was developed in the 1920's and is regulated in the same way as traditional selective breeding.

Genetic technologies is used in this report to refer to both genetic modification and gene editing technologies.

'New Breeding Techniques' (NBTs), cover a range of new genetic technologies, including New Genomic Techniques, Precision Breeding, genome editing, gene editing, New Precision Breeding Techniques (NPBTs), Precision Breeding Techniques (PBTs), and New Plant Engineering Techniques.

Gene editing refers to methods such as CRISPR-Cas9, TALE nucleases, and zinc-finger nucleases, that are used to selectively edit a genome through the addition or removal of genetic material at a particular location in the genome.

Genetic modification refers to older technologies used for modifying genetic material but does not cover random mutagenesis.

Random mutagenesis is a process where an organism's DNA is altered through a mutagen (either chemical or radiation). This can happen naturally (such as from the sun) or can be initiated by a scientist.

Site Site-directed mutagenesis like random mutagenesis but more precise than random mutagenesis. Developed in the 1990's these encompass many of what is considered gene editing.

2. Methodology of project

Tē tōia, tē haumatia

Nothing can be achieved without a plan, a workforce, and a way of doing things

2.1. Literature review

In order to understand and gather information on this topic a literature review was undertaken before a series of semi-structured interviews.

This first part of the literature review aimed to collate the significant amount of information already published on this topic from government departments, think tanks, academia, and industry organisations within New Zealand. It aimed to provide background and a deeper understanding of the topic and the range of views on it. It also focussed the project by highlighting what has already been done in order to avoid duplication.

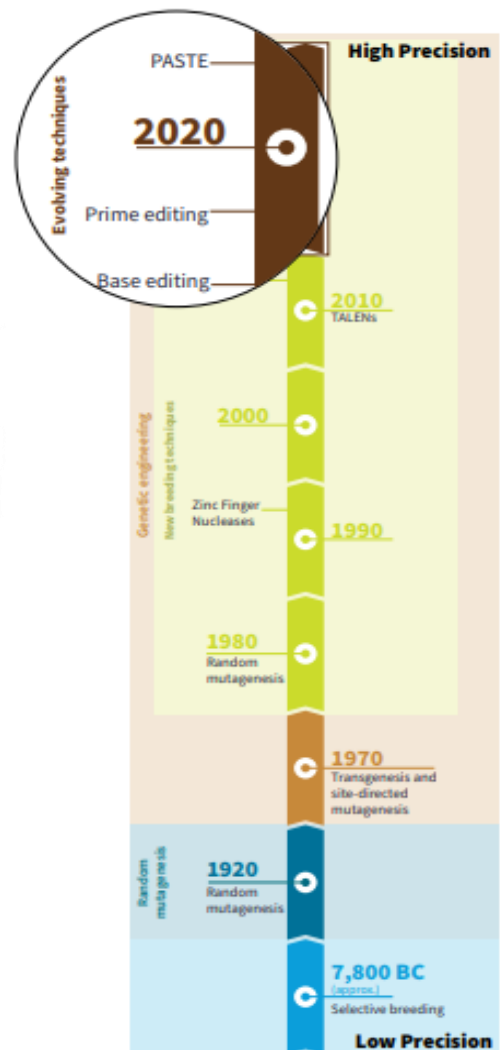


Figure 1 Development history of breeding (Te Puna Whakaaronui, 2023)

The literature review began by seeking to understand the historical context of the use of genetic technologies in New Zealand. Following this, reports were identified that had reviewed the current approach to regulating genetic technologies in New Zealand. These provided the basis for this report and identified areas for further research. Where possible, New Zealand literature and resources were prioritised over international resources as this report focusses on the New Zealand context. A key aspect was to understand what had already been done and avoid duplicating previous work while providing guidance for future areas of focus.

To understand the values of New Zealanders, research was identified that had either conducted studies on the New Zealand-specific context or had reviewed and collated previous papers on this topic. This was synthesised by analysing the findings and understanding what was common across the research and where there were gaps. This report then provides an overview of these findings.

There was a wealth of information on the international context, due to the countries analysed having a long history of using genetic technologies. In some cases, their regulatory regime had been updated at least once already. In these cases, particular focus was on what changes had been made and why. This provided valuable information on what has worked overseas and what hasn't and was then reviewed for relevancy to the New Zealand context.

The literature review was conducted by identifying key questions that needed to be answered and sorting information into those themes. Academic literature was then crosschecked to ensure information was current by using primary sources such as government legislation. The interviews helped test theories that had been developed through the literature review and research, and provided personal viewpoints on issues where finding relevant literature was challenging. An example of this was the interviewee's opinions on what an updated regulatory system for the use of genetic technologies in New Zealand should look like.

2.2. Interviews

Eight people were interviewed over Microsoft Teams with interviews lasting 45 minutes to 1.5 hours and one person responded in writing to the questions.

A wide range of interviewees were selected to provide a range of views. This is a complex topic, and the aim was not to provide a representative sample but to understand differing perspectives. Some were scientists, some represented views from industry or scientific organisations, and one was political. As interviews were conducted, recommendations were sought for additional interviewees. A list of interviewees, and the organisations they work for is provided in Appendix Three.

The interviews aimed to test hypotheses and views that had been formulated through the literature review. As some of the people interviewed were also authors of the reviewed literature, interviews provided an opportunity to discuss their findings in greater detail. Some represented organisations, while others spoke from personal experience and expertise on the topic.

A set of questions was provided beforehand, with some questions omitted or adapted due to their relevance for that particular interviewee. This helped provide structure for the interview, although it was noted that the questions were meant to guide the conversation and there was flexibility to further discuss specific areas of interest and where interviewees had specific experience or expertise. The interview questions are attached in Appendix One.

Once completed, interview responses were collated and cross-checked against each other to find areas where they agreed or conflicted. Understanding where there was disagreement highlighted the need for additional research and what aspects of an updated policy may be controversial. Due to the more naturally roving form of the interviews, however, many answers

were less easily compared. These answers tended to provide insight into the complexity of the issue and have been included throughout this report where appropriate.

2.3. Joint analysis method

The literature review provided the scientific and background context, while the interviews highlight both the complexities and the range of concerns of actual NZ people. Together they resulted in a comprehensive view of New Zealand's current regulatory system for genetic technologies and identified where they did not feel it was functioning well.

Many of the interviewees provided further literature to support their views, as well as recommending additional sources of information and people to talk to. They were all passionate, articulate, and cared deeply about New Zealand approaching this topic in a mature way. As experts in their field, their generous donation of time has greatly contributed to the end quality of this report.

3. Findings on the use of genetic technologies in New Zealand

Nā te iahia kia tīfiro, ā, ka kite ai tātou te mutunga.

You must understand the beginning if you wish to see the end.

3.1. History of genetic technologies

Humans have utilised selective breeding to select for desired genes for around 10,000 years. (Te Puna Whakaaronui, 2023) Selective breeding resulted in significant changes to both plants and animals and has provided humans with the crop and animal species that are used for modern agriculture. This has resulted in new species that have benefits such as increased resistance to pests, improved productivity and nutritional content, longer shelf lives, and that are better adapted to a range of ecological conditions. (Te Puna Whakaaronui, 2023) Almost all of the crops and animals used in agriculture today are a result of selective breeding.

It wasn't until 1920 that scientists figured out how to induce random mutagenesis where DNA is broken by the introduction of mutagens (which may be chemical or radiative). (Te Puna Whakaaronui, 2023) When this broken DNA is repaired by the cell, it causes new traits to appear in the organism. This method creates multiple new mutations, not all of which may be desirable, and requires further screening to remove any unwanted mutations. (Te Puna Whakaaronui, 2023)

In the 1970's the first 'New Breeding Techniques' (NBTs) were developed which allowed scientists to target specific traits within an organism and therefore make changes to it much more quickly and precisely. These NBTs cover transgenesis, cisgenesis, and intragenesis which are outlined in the table below:

Name	Process	Result from breeding?	possible selective breeding?	Foreign DNA
Transgenesis	A foreign gene is introduced into an organism with the aim of producing a new characteristic that is not possible through selective breeding due to a reproductive barrier	No		Yes
Cisgenesis	DNA from the same or closely related species is introduced into the organism without changing the DNA sequence or arrangement	Yes		No
Intragenesis	Similar to cisgenesis but the DNA to be inserted is changed from its original form to include additional pieces of DNA from the same or closely related	Not always		No

	species and/or is rearranged in some way before being inserted.		
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Table 1 Description of different Genetic Technologies, reproduced from Well_NZ: Modern genetic technology – what it is and how it is regulated (Te Puna Whakaaronui, 2023)

Within these NBTs, there are a range of techniques that have become more precise over time, with scientists able to determine where changes would be made and what these changes would be. These have been developed and improved over the last 30 years and have been used in a wide variety of applications, with a study finding that 41 plants have been developed for commercial purposes. (Te Puna Whakaaronui, 2023) Its use in animal breeding is less common, although there have been examples of its use for animal health and welfare. (USDA Agricultural Research Service , 2023) (Nature Biotechnology, 2022)

3.2. Historical backdrop of GMO management in New Zealand.

In 1978, in response to the development of a new tool for genetic modification, the New Zealand Government created the Advisory Committee on Novel Genetic Techniques (ACNGT) to provide oversight on laboratory work, with a moratorium on the release of the technology. Following this, New Zealand began using NBTs in the 1980s mainly for biological and medical research purposes. (Sustainable Future, 2008)

In 1987, a Field Release Working Party recommended that the Ministry for the Environment establish an Interim Assessment Group (IAG) for field testing and release of GMOs. This recommendation was accepted and the moratorium on field releases was lifted, while the ACNGT continued to have responsibility for experiments in laboratories. During this period, the IAG approved applications for field tests which began to attract public attention. (Sustainable Future, 2008)

Neither of these bodies had any legislative authority and from 1988 the government began moving towards the creation of what is now known as the Hazardous Substances and New Organisms Act (HSNO). The HSNO Act became law in 1996 and only came into effect in 1998 while methodologies were being developed for GMO management. This aimed to provide an approach that managed risk and was both precautionary and consultative. The Environmental Risk Management Authority (ERMA) was established with the responsibility of managing the GMOs imported and developed in New Zealand. Consultation with other government agencies was required, but once a release was approved, ERMA had no further involvement, with the GMO being treated like any other organism. (Sustainable Future, 2008)

The ERMA (later to become the Environmental Protection Authority (EPA)) had the key aims of preventing or managing any adverse effects of new organisms by granting or withholding approval and setting controls for importing and developing GMOs, conducting field tests, and releasing any contained or imported GMOs. It was a quasi-judicial decision-making body made of up to eight individuals appointed by the Minister for the Environment and was supported by Ngā Kaihautū Tikanga Taiao, a body that advised the ERMA on how the principles of the Treaty of Waitangi should be incorporated into decision making. (Sustainable Future, 2008)

3.3. Historic perception

By the late 1990s, there was growing public interest in GMOs and how they were managed in New Zealand, spurred on by the rapid advancement of the technology internationally and its applications. These were fuelled by high-profile cases that demonstrated what was possible with new advancements that had not



Figure 2 Greenpeace and local activists protesting a field trial near Oamaru in 1996 (Greenpeace, 2023)

been contemplated when the HSNO Act was developed. While the agricultural industry and Crown Research Institutes were promoting rapid uptake and application of the technology, concerns were raised by other scientists, iwi, industry organisations promoting organics, NGOs, and the general public who wanted a pause on field tests until risks and opportunities could be fully identified. (Sustainable Future, 2008) Māori opposition to GMOs was strong as it was considered to negatively impact cultural values. (Te Rūnanga o Ngāi Tahu, 2021)

Over time, this opposition grew until it cumulated in a petition signed by 92,000 people calling for a Royal Commission into Genetic Modification. This was presented to parliament by the Green Party in 1999. In December 1999 the new Labour Government announced its intention to establish a Royal Commission on Genetic Modification and a voluntary moratorium on the release of new organisms was implemented. (Sustainable Future, 2008)

The Royal Commission released its report a year later, recommending a middle option called 'preserving opportunities' that sat between a total ban on the technology and completely unrestricted use. The Commission also identified seven shared values of New Zealand society that underpinned the report's 49 recommendations which are outlined below. Essentially, this left the regulatory regime as the status quo for research, food, and medicine but recommended that the release of GMO crops would require a national strategic decision, as this would change the status of New Zealand's non-GMO status. A bioethics commission, a parliamentary commissioner on biotechnology, and a biotechnology strategy were also recommended for institutional change. (The Royal Commission on Genetic Modification, 2001)]

Summary of the Royal Commission's seven values that underpinned the report

Value	Overview
The uniqueness of New Zealand	Recognising the uniqueness of New Zealand's environment due to geographical isolation, native ecosystems, and flora and fauna.
The uniqueness of our cultural heritage	The Treaty of Waitangi created a special relationship between tangata whenua (people of the land) and tangata tiriti (the settlers who came later).
Sustainability	The need to sustain New Zealand's unique but fragile environment for generations yet to come was central to the Royal Commission's consultation. Any estimate of benefits and costs must include sustainability as a central criterion.
Being part of a global family	While New Zealand is isolated geographically, we are connected to the world through travel and partnerships. We must recognize that we are part of an interconnected world.
The well-being of all	Economic and social goals must be considered together and New Zealand must work to improve both society and the economy.
Freedom of choice	People must be free to make their own choices, but at the same time, their freedom of choice must not impact on others. Everyone's freedom of choice must be maintained in a flexible and cooperative way.
Participation	People must be empowered to participate in decision making on important issues.

Table 2 Summary of the Royal Commission's seven values underpinning the final report (The Royal Commission on Genetic Modification, 2001)

Many of the recommendations were accepted by the Government in 2001 and provide the basis for how GMOs are regulated in New Zealand today. This included conducting research, establishing a bioethics council, amending the HSNO Act and developing a biotechnology strategy, but did not set up a parliamentary commissioner for biotechnology as it was felt the functions could be implemented in other ways. While this was considered world-leading at the time by the international scientific community, (Sustainable Future, 2008) significant public opposition remained. This concern culminated in two separate hikoī from Northland to Parliament in Wellington with participants protesting the findings of the Royal Commission and the Government's response. While both hikoī were organised and participated in by Māori, people of other concerned groups also took part. (Sustainable Future, 2008)

This left New Zealand in a position where the use of GMOs was highly regulated and contested, with two opposing sides: those who were against its use, broadly made up of concerned Māori and environmentalists; and those who were for more liberal use, mainly from the agricultural sector and pro-business organisations.

3.4. What is and what isn't currently allowed in New Zealand?

Creation of new organisms in New Zealand is currently allowed using traditional techniques such as selective breeding, and random mutagenesis using chemical and radiative methods. The use of newer site directed mutagenesis genetic technologies is allowed but heavily regulated.

Some interview participants felt that the current regulatory regime amounted to a ban in practice as it was so prescriptive that it was almost impossible to comply with, and the regulations limited the usefulness of any data that could be collected from a field trial. Because of this, those wanting to conduct trials in New Zealand had not been able to and had done so in regulatory regimes that were more permissive. (Rolleston & Mills, 2023) The EPA has not received an application for a field trial in the last 10 years, although supporters of the current regime say this level of precaution is acceptable and the lack of applications demonstrates that the safety requirements can't be met. (Morton, 2023)

While the breeding and release of new organisms is highly regulated, genetically modified food is allowed to be imported into New Zealand and sold once it has been approved by Food Safety Australia New Zealand (FSANZ). Once a GM crop has been approved by FSANZ, any ingredient made from that crop can be sold in New Zealand, with nine crops currently approved. (Food Standards Australia New Zealand, 2021) FSANZ does not consider that genetically modified crops carry any additional risk compared to conventional crops due to their genetic modification. (Food Standards Australia New Zealand, 2021)



Figure 3 Impossible Burger made with GM soy and yeast (Morton, 2023)

In New Zealand, genetic editing (cisgenesis) is regulated in the same way as genetic modification (transgenesis), although this was tested in a 2014 High Court case. (The Sustainability Council of New Zealand Trust v The Environmental Protection Authority, 2014)

3.4.1 High Court Case

In 2014 the High Court of New Zealand ruled on a case bought by the Sustainability Council of New Zealand against the EPA. The EPA had previously determined that two gene editing technologies (ZFN-1 and TALEs) fell within an exception in the HSNO Act and therefore organisms resulting from their use would not fall within the definition of a genetically modified organism (GMO). This would have opened the door for their use in New Zealand as they would

not fall within the regulations of the HSNO Act. (The Sustainability Council of New Zealand Trust v The Environmental Protection Authority , 2014)

The High Court disagreed with the EPA's interpretation. The decision in this case meant that new genetic techniques were considered to fall under the HSNO Act's definition and are regulated in the same way as traditional GMOs. Any change in this approach will therefore require legislative change from parliament rather than novel interpretation of current regulations.

3.5. Regulatory environment in 2023

In 2019 New Zealand's peak science body, The Royal Society Te Apārangi produced a series of reports examining whether New Zealand's position on gene editing technologies was still fit for purpose. These reports considered the implications of the technology in three separate sectors – agriculture, healthcare, and environmental pest management with an overarching report analysing the legal and regulatory implications.

This report found that New Zealand's statutory environment had not kept up with technological change and was not currently fit for purpose. The report produced six findings that it considered would improve the regulation of genetic technologies in New Zealand. (Royal Society Te Apārangi , 2019) These are:

- better defining terms to describe the range of technology and support public discussion.
- developing consistent definitions across the regulatory system.
- considering international approaches.
- making regulation proportionate to risk.
- engaging with the community and improving capacity; and
- improving capability for engagement and decision making within communities, the research sector, and government.

Woven through this was the recognition that in the New Zealand context special consideration needed to be given to Māori views.

A key finding by was that advances in genetic technologies had surpassed New Zealand's current regulatory environment by creating situations that the original regulations had not anticipated. Importantly, it found that it is not possible to class organisms as GMO or non-GMO and that a more nuanced view is needed to capture the range of situations that are now possible. (Royal Society Te Apārangi , 2019)

This is contrasted with the views of some academics who view the regulations as adequately covering the range of genetic technologies currently developed and that differentiation between newer and older technologies is unhelpful. They argue that the increased speed at which breeders can develop new organisms presents a higher risk of unintended consequences if they are released into the environment. For this view, it is the larger scale use of genetic technologies that present risk, and they therefore advocate for a precautionary approach that limits the chance of them entering the environment. (Heinemann, Paull, Walker , & Kurenbach, 2021)

“You change the scale of what you're doing when you take it out of containment because you change the geographical scale from a contained laboratory to a field.”

(Heinemann, Kellogg interview regarding genetic technologies , 2023)

The Royal Society paper argued that if the regulatory environment is not updated it runs the risk of allowing uses of the technology that are not aligned with public views and/or restricting its use in situations where the risk does not outweigh the benefit. (Royal Society Te Apārangi , 2019)

From the reports, the Royal Society argued that a review and update of the regulatory system is needed in order to reflect the New Zealand public's current view towards GMOs. Regardless of whether one considers that the current regime adequately covers the range of technologies available to scientists, it has been over 20 years since the regulations were drafted and a review would provide useful information on the New Zealand public's appetite for use of this technology and under what circumstances.

3.6. The Treaty of Waitangi

Treaty of Waitangi obligations require the Crown, to incorporate Māori values, and therefore any change to genetic technology policy must be done in a way that respects Māori values and incorporates them into the regulatory regime.

This is further bolstered by claims under the Waitangi Tribunal. For example, the Wai262 claim recognises that Māori have special interests in GMOs regarding mātauranga Māori, taonga, and cultural and spiritual values and has provided a best practice guide for science partnerships with kaitiaki for research involving taonga. (Potter & Māngai, 2022)

4. Findings on the differing views on genetic technologies within New Zealand

***Mā te rongo, ka mōhio, Mā te mōhio, ka mārama,
Mā te mārama, ka mātau, Mā te mātau, ka ora.***

*From listening comes knowledge, from knowledge comes understanding,
From understanding comes wisdom, from wisdom comes well-being.*

4.1. Findings from literature review and research

4.1.1 Views of the New Zealand public

There are a range of views on genetic technologies within New Zealand ranging from very against to very pro. Within this spectrum, there are also views on specific uses of genetic technologies related to certain industries or uses.

Gauging the true view of the New Zealand public is difficult, as many views are based on historic understandings of the technologies and have not progressed as technologies have advanced. The science around genetic technologies is not well understood by the public and therefore views are based on general perceptions, rather than hard data. This is compounded by academic research as many studies look at their use for a specific purpose, such as conservation or in food, and therefore obtain the views of a limited section of the public (MacDonald, me ētahi atu, 2020) (Fritsche, Poovaiah, MacRae, & Thorlby, 2018).

Conversely, there are areas where the public may be more receptive to the use of genetic technologies. These include issues such as animal welfare or conservation, where the desire to find solutions to the issue may be higher than the concern regarding the use of genetic technologies. Consumers may also perceive the use of genetic technology as providing benefits to them directly, through food or products that are healthier, cheaper, or more sustainable. Studies have found that in those cases, consumers were more willing to purchase genetically modified foods. (Knight, Mather, Holdsworth, & Ermen, 2007)

This highlights the fact that the views on the use of genetic technologies shift depending on their use and what the perceived benefits are.

4.1.2 Government organisation views

Government agencies have published reports discussing how genetic technologies could be utilised in their area of responsibility but have not gone as far as recommending a regulatory change, preferring to leave this up to elected politicians. The Department of Conservation

(DoC) and Toitū te Whenua (LINZ)'s Long Term Insights Briefing provides examples of how genetic technologies could be used for conservation and land management. (Department of Conservation and Toitū te Whenua, 2023) The Ministry for Primary Industries' (MPI) think tank Te Puna Whakaaronui has also published a report on genetic technologies, recommending an inclusive, informed national conversation about genetic technologies. MPI's report notes that the Royal Society Te Apārangi, the Prime Minister's Science Advisor, the Productivity Commission, and Food Safety Australia New Zealand are unanimous that there is "a need to recalibrate regulatory settings with technology and that existing regulations are no longer fit-for-purpose" and that they suggest a risk proportionate response over the current precautionary approach. (Te Puna Whakaaronui, 2023)

4.1.3 Political party views

The previous Labour Government recently announced a limited review into improving GMO regulations for laboratory and biomedical research. The proposed 10 policy changes would streamline and simplify laboratory work with GMOs by moving to an outcomes based/risk assessment regime but does not extend to releases of the technology into the environment or for field trials. (Ministry for the Environment, 2023)

The Green Party's Research, Science and Technology Policy is stricter than the status quo, as it requires all organisms to be kept in an indoor laboratory and prohibits the release of any viable organism into water, air, land, or soil ecosystems. (Green Party, 2023) It has been criticised by over 150 young New Zealand scientists who requested that the Green Party reconsider its position on genetic technology regulation in order to allow the development of tools that could be used to address climate change. (Multiple, 2019)

It is unclear whether New Zealand First or Te Pati Māori have policies on genetic technologies from reading their available policy statements.

Both ACT and National support the use of genetic technologies and have policies that will allow for their use in agriculture.

The ACT party does not have detailed policy information but have said that they want to liberalise New Zealand's GE legislation in a press release. (ACT Party, 2023)

National's Spokesperson for Science, Research and Technology Judith Collins responded to questions for this report saying that National would create a biotech regulator based on the Australian model that would "Streamline the approvals process for trials and use of non-GE/GM biotech for emissions reduction and other purposes. The biotech regulator will be tasked with reducing delays for the safe introduction of biotechnologies into New Zealand" and that "the biotech regulator will approve trials or use of non-GE/GM products that have already been approved for trial or use by at least two other OECD countries (or the EU and at least one OECD country outside the EU)." (Collins, 2023)

Analysis of whether National's policy is an appropriate way of regulating genetic technology in New Zealand is provided in the analysis section of this report, however it should be noted that there are 37 OECD member countries with a wide variety of approaches towards biotechnology. Some of these are outlined in the following section.

4.1.4 Māori views

Throughout this research there has consistently been the recognition that Māori have unique views towards the use of genetic technologies. This has been enshrined in law, through the requirement for the EPA to take into account Māori perspectives through the advisory body Ngā Kaihautu Tikanga Taiao. In the 1990's there were significant concerns from Māori regarding the potential impact of genetically modified organisms on cultural values. (Sustainable Future, 2008) It is unclear to what extent this view has changed although some iwi

are increasingly open to a conversation on how genetic technologies could be used to support Māori values, such as through pest control to protect taonga species. (Brankin, 2021)

While there is not one Māori view, some literature has identified underlying themes that can be drawn out. Indigenous Perspectives and Gene Editing in Aotearoa New Zealand (2019) examines Māori perspectives towards gene editing and found key concepts and values that were relevant to genetic technologies. Following a literature review that identified four key values of whakapapa, mauri, mana, and kaitiakitanga, preliminary discussions with agencies with expertise and experience in Māori biotechnology were held. (A table with an overview of these key values is provided in Appendix Two). This was followed by in depth interviews with Māori with experience in plant, environmental and human health, business, research, public communication, and policy and was supported by an additional written survey. What emerged was a comprehensive summary regarding Māori attitudes towards gene editing. (Hudson, me ētahi atu, 2019)

It is clear that there are a range of opinions within broader New Zealand on genetic technologies and Māori are no different, although views are influenced by a uniquely Te Āo Māori worldview. While some are strongly for or against, most people sit on a spectrum somewhere in between. A key result from the paper found that for Māori this view was more about the application of the technology, rather than the process itself. Generally, there is not opposition to new technologies per se and if they are used in a way that supports core values such as whanaungatanga then their use is more likely to be supported compared to a use that diminishes this value (Hudson, me ētahi atu, 2019).

The paper expanded on the original four values, adding eight more for a total of 12, outlining how they could be enhanced or diminished by genetic editing. These provide a solid framework for analysing on a case-by-case basis potential new uses of genetic technologies and provides guidance for future applications of the technology. While the paper focussed on the use of gene editing (using CRISPR-Cas9) compared to older technologies, a key aspect was that the focus was on the end use of the technology rather than the method used. (Hudson, me ētahi atu, 2019)

Key Māori concepts regarding genetic technologies		
Value	Explanation	Relation to genetic technologies
Whakapapa	Genealogy	“the foundation for how Māori construct their identities and their relationships with other species”
Mauri	Life Essence	“the distinctive and special nature of an organism including its right to life”
Kaitiakitanga	Gaurdianship	“ that Māori have authority over their lands and resources and that the use of gene technologies is done in ways that supports these outcomes”
Mana	Authority	“a responsibility to act in the interests of the broader community”

Table 3 Key Māori concepts regarding genetic technologies (Hudson, me ētahi atu, 2019)

The Department of Conservation (DoC) and Toitū te Whenua - Land Information New Zealand (LINZ) produced a long-term insight briefing in 2023, which included analysis of how new genetic technologies could be used to support Māori values. This briefing also recognised that while there are concerns from Māori regarding genetic technologies, they could be used in a way that supports other Māori priorities, such as the conservation of taonga species. (Department of Conservation and Toitū te Whenua, 2023)

A study in 2019 surveyed New Zealanders' views towards genetic technologies and genetic modification and used the results to understand different positions between Māori and non-Māori. This research found that non-Māori did not see the importance of including Māori values in policymaking on gene editing. (Kathlene , Munshi, Kurian, & Morrison, 2022) This suggests that any consultation on Māori values will need to demonstrate to non-Māori why this is important.

"... a widespread social license for the use of gene-based technology is unlikely in the short term. Generally, Māori do not oppose new and emerging gene technologies a priori, but instead raise concerns about how the technologies should be used and the rationale, objectives, and consequences of choosing them." (Hudson, me ētahi atu, 2019)

4.1.5 Interviews as part of this project

As part of this research, a range of people were interviewed that had expertise regarding the use of and regulation of genetic technologies in New Zealand. The purpose of the interviews was to further explore topics of interest arising from the literature review and better understand the range of views on this issue. Many of the people interviewed had written papers on the topic and some had experience engaging with regulatory systems in New Zealand and in other jurisdictions. The interviews provided an opportunity to discuss the topic with experts and sense test findings obtained through the literature review.

The aim was not to provide a representative sample of views on the use of genetic technologies in New Zealand and should not be seen as such. This can only be done with in-depth public surveys, such as those found in the literature review. The interviews were invaluable for understanding where there are positions of agreement and disagreement between those in favour and those against the use of genetic technologies in New Zealand.

Based on the literature review it was assumed that there would be strong views both for and against the use of genetic technologies in New Zealand. It was less clear what the views would be relating to the efficacy of the current regulatory system, New Zealand's international GMO-free status, and whether an overhaul of the system was timely or even needed.

These unclear areas were what framed and directed the development of interview questions. These are attached in Appendix One and the summarised results are as follows:

Views common to all interviewees

Across the interviews, there was a general consensus that New Zealand's current regulatory regime was not fit for purpose. The reasoning behind this differed between each interviewee and there were a range of views as to how it should be improved, with some seeking a relaxation of the rules and some feeling that they should be tightened. There was a general view across interviewees that New Zealand's regulatory regime did not adequately cover genetic techniques that had been developed since it was implemented, although there was a dissenting opinion from one scientist, who felt that it did.

Regarding New Zealand's current laws for genetic technologies:

"So they seemed like a good idea at the time, but they are massively out of date, and they've been patched so many times that it's just craziness." (Slim, 2023)

Within the interviewees that wanted to see New Zealand's regulatory approach updated to allow for the use of genetic technologies, there was a general feeling of frustration that New

Zealand was missing out on utilising scientific techniques that could provide benefits across multiple areas, whether this was conservation, production, or animal welfare.

While some interviewees felt that the use of new genetic technologies would result in significant new opportunities, there were others who felt that they would be more muted, and New Zealand wasn't missing out on much by taking a precautionary approach. There was a general sense across all interviewees that it was the regulatory barriers that were the issue, and that if they were removed New Zealand would quickly be able to utilise the technology. It was noted however that genetic technologies would face the same challenges as uptake of any other new technology in terms of implementation and behaviour change.

Interestingly, there was also a general view that change was coming and it was important to get right. For some, this meant having a detailed public conversation about what a change would mean, while others felt that New Zealand could develop a regime by looking at what other countries were doing internationally.

Across all interviewees there was also recognition that Māori interests needed to be incorporated into any biotechnology regime, although some felt this was done adequately through the EPA's current advisory board Ngā Kaihautū Tikanga Taiao and others thought that there could be better ways to ensure the principles of the Treaty of Waitangi were recognised.

Those who were for increased use of genetic technologies in New Zealand

Of the people interviewed who thought that New Zealand should allow the use of genetic technologies there was also general consensus that an approach that balanced the risks and opportunities associated with the release of any new organism was better than one that focused on the technology itself. There was some recognition that organisms where foreign genes had been introduced (transgenesis) were less acceptable to the general public than ones that had genes from the same species, however this was seen as an ethical view rather than one based on scientific evidence. It was felt that a properly designed risk-based regime could adequately cover both transgenesis and cisgenesis organisms.

There was a view from those in favour of their use that opposition to the use of genetic technologies was values rather than science based and any risks were overstated - whether they were environmental or commercial (e.g., organic certification). Generally, it was felt by those in favour that opposition was restricted to a small minority and the majority of New Zealanders didn't have strong opinions on the issue.

Regarding how change should happen there was a general view that people against the use of genetic technologies could make a lot of noise and derail public consultation with misinformation. In order to combat this, two suggestions were put forward, however only the second was seen as realistic. Firstly, the government could move quickly and change the legislation without providing opportunities for disinformation campaigns after which it was felt most opposition would die down. Secondly, a comprehensive consultation process would be needed with significant investment into public outreach. COVID was seen as a good example of effective communication with trusted sources providing information to different groups and the media fact checking information.

Views of those against

Of those interviewed who were against the use of genetic technologies, it was felt that a precautionary approach should be taken, as there were significant risks associated with their release for the environment and commercially, particularly regarding New Zealand's image and ability to obtain a premium for agricultural products in export markets. There was concern that genetic technologies were seen as a silver bullet and there were other solutions already available for the issues they aimed to solve.

On deregulation:

"The solution has always been and not that it's a perfect solution, but the regulatory framework that came up in the 70s is to use containment... It ensures that the only thing that could ever exit a properly contained laboratory is the organism you intended to change."

(Heinemann, Kellogg interview regarding genetic technologies , 2023)

There was also the view that the risks associated with genetic technologies were not fully understood and therefore a precautionary approach should be taken, as once they were released they would be difficult if not impossible to control. This view applied to both transgenesis and cisgenesis organisms. Regarding the current regulatory regime, it was felt that the EPA was under resourced and not a particularly open process to the public. That the current controls on genetic technologies were viewed as very difficult for people to prove that risk could be managed was seen as demonstrating they were set at the appropriate level and this approach should be kept in any updated policy.

There was also concern that organisms produced with genetic technologies could be patented more easily than

those using traditional techniques and this represented a concerning trend of corporatisation in agriculture that should be rejected. Looking around the world it was accepted that while other countries were changing their regulatory procedures New Zealand should not look to follow these trends as the current approach provided a point of difference. Of particular concern was many countries not requiring gene edited products to be labelled as this limited consumer and farmer ability to choose non-genetically edited products.

5. Findings on the international context

"He maurea kai whiria"

Ignore small matters and direct effort toward important projects

As noted earlier, NZ's trading partners and competitors have been reconsidering and updating the use of genetic technologies within their jurisdictions. This has implications for both New Zealand's trade and GMO-free status and has given cause for many to look to a review here in NZ. The following is a review of the approaches being taken in other jurisdictions where NZ may find different insights and learnings. These have been split into different groups: those that are comparable jurisdictions to New Zealand and those that are important export markets for New Zealand agricultural products. Some countries fall into both categories.

5.1 Comparable Jurisdictions

Australia

Australian policy on GMOs is devolved to the state level. As of 1 July 2021, when New South Wales lifted an 18-year moratorium, GM crops can be grown in every Australian state except for Tasmania. (United States Department of Agriculture , 2021)

Genetic technologies are regulated through 'The National Gene Technology Scheme' which provides a nationally consistent regulatory system for gene technology in Australia in the states where its use is approved. It is established through the Gene Technology Act 2000 and is regulated through the Office of the Gene Technology Regulator (OTGR) which consults with other Australian agencies, state and territory governments, the Environment Minister, the public, and local councils. The OTGR is advised by technical and ethics committees. A diagram providing an overview of the system is included here. (Office of the Gene Technology Regulator , 2022)

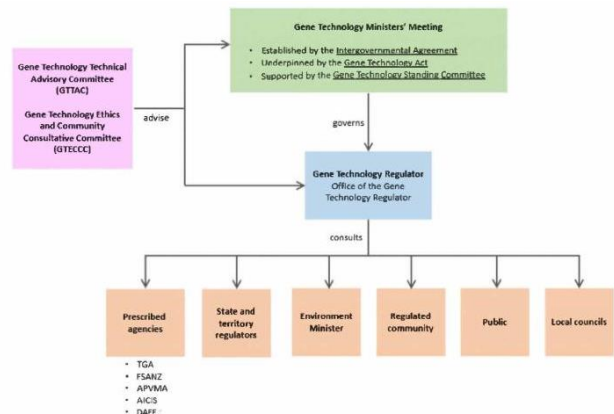


Figure 4: Diagram of Australian Gene Technology Regulation (Office of the Gene Technology Regulator , 2022)

Several interviewees saw the Australian system as a model that New Zealand should be following, as it is perceived to be balancing risks in an appropriate way and focusing on outcomes rather than the technology itself. Another key aspect was that it is a low-cost system for applicants meaning that smaller organisations could afford to do trials, whereas other jurisdictions had prohibitive costs associated with applications. New Zealand companies are already successfully using the Australian regime to conduct field trials of organisms that could eventually be released in New Zealand. (Rolleston & Mills, 2023) (Caradus, 2023) US companies have also used the Australian regime, stating that it is less confusing than the US approach. (Langford, 2019)

From 2019 Site Directed Nucleases (SDN-1) such as CRISPR-Cas, Zinc-Finger Nucleases, TALENs, and Meganucleases where no foreign genes are introduced into the new organism are not considered GMOs by the Australian approach. (Genetic Literacy Project , 2020)

A wide range of research has been conducted in Australia using genetic modification for human health, animal welfare, pest control, and conservation. (Genetic Literacy Project , 2020)

Interviewee response who had used the Australian system: "They asked some tough questions, but they asked reasonable, tough questions." (Rolleston & Mills, 2023)

Argentina

Argentina has a long history of growing genetically modified crops, with the first commercial release approved in 1996, and the country is now the third largest producer of genetically modified crops. The regulatory framework was created in 1991 (CONABIA), with the United Nations Food and Agriculture Organisation (FAO) recognising it as the Center of Reference for Biosafety of Genetically Modified Organisms. This highlights the Argentina regulatory system as one that is experienced in safety assessment practice, commercial adoption of agricultural biotechnology, and leadership in developing regulatory criteria. (Entine, me ētahi atu, 2021)

Following the recognition in 2012 that new technologies required an update to Argentina's approach, a review of the regulations was initiated. This culminated in a new decision-making process for deciding whether new products should be regulated as GMOs or not on a case-by-case basis. This new approach required significant public consultation, with workshops for both citizens and communicators where genetic technologies were debated. This resulted in high public confidence in the national regulatory agencies, mainly because of national pride

in the development of new products and opportunities for new traits addressing consumer concerns and providing environmental benefits. (Entine, me ētahi atu, 2021)

This new approach aims to balance the needs of researchers for early certainty on the regulatory stance of new products, with a case-by-case assessment. Developers can submit a new product to the regulators to understand whether it is classed as a GMO and needs to be regulated as such, or if it goes through the conventional plant breeding path. The definition of GMO was taken from the Cartagena Protocol on Biosafety, which is the international agreement on plant biotechnology and essentially means that new genomic techniques (gene editing) are not classed as GMOs and are not subject to the more rigorous GMO regulatory processes. (Entine, me ētahi atu, 2021) (United States Department of Agriculture , 2016)

This approach was subsequently promoted by the Argentine government at the World Trade Organisation, G-20, OECD, and bilaterally. This led to other Latin American countries such as Chile, Brazil, Colombia, Paraguay, Ecuador, Honduras, and Guatemala using the Argentina regulations as a basis for their own, although with some local differences. (Entine, me ētahi atu, 2021)

Brazil

Brazil's regulations follow Argentina's, with the National Biosafety Technical Commission (CTNBio) responsible for establishing guidelines around their use. These guidelines require CTNBio to consider the impact on the environment and human health before proposing regulations for new technology. (Entine, me ētahi atu, 2021)

It was recognised that the cost of new applications was deterring smaller operators from engaging with the process and that the regulatory requirements were not proportional to the risk, therefore creating a costly and time intensive process. This was inhibiting the development of products by publicly funded research bodies and small/medium companies. When the CTNBio was originally developed in 2005, many of the new genetic technologies were still in development and weren't considered so in 2014 the rules were reviewed, culminating in a new approach in 2018. This new approach evaluates on a case-by-case basis whether a product created through new genomic technologies is considered a conventional or transgenic organism. (Entine, me ētahi atu, 2021)

If the product is considered non-GMO, it goes through the conventional pathway for new products making the process significantly faster and cheaper and encouraging development of new products by smaller companies. It has resulted in smaller companies playing a larger role in the development of new products and provided a pathway for young scientists to build their own companies with innovative products designed for Brazilian agribusinesses. This approach covers the use of genetic technologies for plants, animals, and microorganisms and for human and animal health, industrial applications, and for agriculture. (Entine, me ētahi atu, 2021)

Canada

Canada has one of the longest histories with genetic technologies, with field trials beginning in 1986, and the first crops receiving regulatory approval for release in 1995. (Entine, me ētahi atu, 2021) Since then, Canada has approved 123 crop varieties, with no risk proven to differ from conventionally bred crop varieties. Nearly all of the canola and corn planted in Canada is genetically engineered, with the most common traits for herbicide tolerance and insect resistance. (Entine, me ētahi atu, 2021)

Canada has a regulatory framework that is permissive and product-based. According to guidance released by the Canadian Food Inspection Agency (2023), plants with novel traits

are defined as those that have traits new to cultivated populations of the same species in Canada, and they must have the potential to have significant negative effects on the environment. This means plants that do not contain new genetic material from outside their species are not subject to the regulatory regime and may be released. If the criteria are met, then the Canadian Food Inspection Agency must carry out a health and environmental risk assessment, after which the new plant may be released. (Krinke, 2023) (Canadian Food Inspection Agency , 2023)

This regulatory regime does not discriminate between methods used and is risk-based, meaning new scientific methods can be utilised without a change in the regulations. This however has been criticised by anti-GMO groups who consider that the regulations leave it up to the companies to decide whether a new variety is novel or could cause risk to the environment. (Krinke, 2023)

5.2 Countries that are both comparable jurisdictions and export destinations

The United Kingdom (UK)

In March 2023 the UK passed the Precision Breeding Act into law. This Act provides a streamlined regulatory system and allows the use of precision breeding technologies in England. Wales, Scotland, and Northern Ireland have not permitted the commercial use of gene editing. Previously when the UK was part of the European Union, this technology was banned for commercial (non-laboratory uses).

The new approach only allows cisgenesis (from the same species) and genetic changes that could have also been produced naturally or through traditional cross-breeding programmes. Transgenics (or using genes from other species) will not be permitted. The new regulation applies to agricultural uses of the technology for products for both human consumption and animal feed and will also apply to animal breeding. (Department for Environment, Food & Rural Affairs , 2023)

The new regulations are open to the use of new techniques that may be developed as they focus on whether the new organism could be developed through traditional methods. While the regulatory regime is still in development, it is much more permissive than what was previously allowed under European rules. The Food Standards Agency is currently developing the framework that will regulate crops for human and animal feed produced through precision breeding, although it looks as though this will be risk-based and will require products to be at least as safe as conventional counterparts. (United Kingdom Food Standards Agency , 2023)

There seems to be a relatively high level of support for genetically modified products in the UK, with a Department for Environment, Food and Rural Affairs study finding that 57 percent of people thought gene editing of crops was acceptable. (Cookson & Cameron-Chileshe, 2022) Another study by the United Kingdom Royal Society found that 24 percent of respondents were very interested in genetic technologies, while 46 percent were fairly interested, demonstrating relatively strong support for their use. (van Mil, Hopkins , & Kinsella, 2017)

European Union

The European Union is currently updating its approach to allow for commercial use of plants produced through new genomic techniques, with the European Food Safety Authority (EFSA) concluding that there are no new hazards linked to targeted mutagenesis and cisgenesis. The reason given for the change was to support the 'green transition of the agrifood system'. (European Commission, 2023)

Like the UK, the EU framework is still in development, however, it will likely mean that based on certain criteria plants produced with new genomic technologies that could be created

through traditional breeding will not be subject to a verification procedure. If this criterion is met, then the plants will be treated like conventional plants and will be exempted from the EU's GMO regulation. This would mean that no risk assessment needs to be made and they can be labelled in the same way as ordinary plants.

Under this proposed approach the EU would not consider new breeding techniques such as targeted mutagenesis and cisgenesis to be GMO's. For plants with traits that could not be obtained through traditional breeding (such as those utilising genes from other species), they will be subject to GMO legislation and are subject to risk assessments, and can only enter the market if they have gone through the authorisation procedure.

The EU was driven to change its approach after recognising that previous legislation developed in 2001 did not adequately cover advances in genetic technologies. To understand the current science significant research was conducted by the European Commission Joint Research Centre as well as consulting with a range of stakeholders and experts. (European Commission, 2023)

The proposed EU regime aims to balance public concern around transgenic organisms with allowing farmers to use the latest technology to improve yields, address environmental challenges such as climate change, pest resistance, and reduce the need for fertilisers and pesticides. It does not, however, include animals.

USA

The United States has a long history of regulating genetic technologies, beginning with the 'Coordinated Framework for Regulation of Biotechnology' in 1986. This was risk-based and focused on the characteristics of the new product rather than the process. It was updated in 2017 to better incorporate new technologies that had been developed. (Entine, me ētahi atu, 2021)

Genetic technologies are administered in the United States by three agencies, the US Department of Agriculture, the Food and Drug Administration, and the Environmental Protection Agency. This ensures that products placed on the market do not negatively impact agricultural production, are safe for human and animal consumption, and do not harm the environment. (U.S. Food and Drug Administration, 2023)

Gene-edited crops are regulated in the same way as traditionally bred plants if the new trait could have been obtained by traditional breeding techniques. This aims to streamline regulatory procedures and focus on risk rather than the method used to obtain the new product. There are still regulatory requirements for if the new organism may be a plant pest and those placing new products on the market must ensure that they are safe for human consumption. Plants produced through genetic modification that have traits that could not be obtained through traditional breeding are required to be labelled with a US Department of Agriculture approved logo.

Genetically modified animals including cattle, pigs, and salmon have also been approved for human consumption in the USA. (American Veterinary Medical Association, 2022)

5.3 Export markets

China

Until recently, China allowed the import of transgenic crops, but did not allow their planting except in very limited cases. Only two cisgenic crops of papaya and cotton had been previously approved for use and have been used in China since 1997. (Genetic Literacy Project , 2023)

However, in 2022, following a law change in 2021, China's Ministry of Rural Affairs published updated guidelines for the use of gene-edited crops, providing approval for their use in Chinese Agriculture. (Patton, 2021) (Patton, China to allow gene-edited crops in push for food security, 2022) (United States Department of Agriculture, 2022) This provides a faster path for commercial use, as previously lengthy field trials were required before a crop was approved for commercial use. This is expected to reduce the approval time for CRISPR-Cas 9 crops from up to six years to one or two. (Genetic Literacy Project , 2023) In 2023, the first gene-edited corn crops were planted, although this was a smaller land area than expected, making up only 1% of China's corn plantings and signifying that while regulations had changed, a cautionary approach was being taken. (Patton, Exclusive: China rolls out GMO corn planting, starts small, 2023) Livestock are also covered by the updated regulation and while research has also included animals it seems the major focus is on crops. (United States Department of Agriculture, 2022)

Alongside regulatory change, there is significant research into gene-edited crops, with Chinese scientists publishing more papers on gene editing than any other country over the last five years. This increase in investment has been driven by the Chinese government which has spent close to US\$ 10 billion on agricultural research over the last decade with the aim to improve food security through increased yields, resilience against climate change, improved fertiliser response, and for consumer health benefits. A further aim was to revitalise China's seed industry which has been struggling with intellectual property challenges and overcapacity. (Genetic Literacy Project , 2023)

Japan

Japan is a significant importer of genetically modified food and animal feed, and genetically modified crops are allowed to be grown provided they are not significantly different from existing foods and there is no health risk (such as allergies). (Goda, 2017) Not many genetically modified crops are grown domestically, mainly due to consumer concern which has meant farmers have not seen value in growing them. Genetically edited foods are required to be labelled in Japan. (Neo, 2022)

Japan has a robust regulatory regime for the approval of genetically edited products, with oversight from three different ministries. In 2019 the Ministry of Health, Labour and Welfare published a report recommending that no safety screening is required if the genetic technologies leave no foreign genes in the new organism, and in 2022, the Ministry of Agriculture, Forestry and Fisheries concluded that cultivation of certain crops provided no risk to biodiversity. (Neo, Japan GM food: New data 'further supports' the case for genetically modified ingredients – government study, 2022)

There is significant investment in research for gene-edited crops and in fish for human consumption, but a strict regulatory framework and little public demand has meant that uptake remains slow. While the Japanese public does not appear to be that concerned about the use of gene editing technology for production, and they are happy to eat animals that have consumed genetically modified feed, they do not seem to want to consume it directly. (Goda, 2017)

5.4 Summary of what is happening internationally.

While GMO (transgenesis) remains highly regulated in many countries there has been a shift towards more permissive regulation for gene editing technologies using cisgenesis. In many countries, targeted cisgenesis technologies are not viewed as GMO, meaning that they are deregulated and fall under the same categorisation as traditional breeding methods, therefore not requiring additional regulatory procedures for use. This includes any labelling for products entering the supply chain for human consumption.

It therefore seems unlikely that New Zealand would have to go through any additional hurdles to export products produced through targeted cisgenesis technologies to the markets discussed in the section above. However, for protectionist markets there is always a risk that restrictions could be placed on imported products to restrict trade. This would depend on the use of the technology, and if it is similar to what is already happening domestically it would be unlikely.

6. Risks and opportunities for genetic technologies in New Zealand

He moana pukepuke e ekengia e te waka
A rough ocean can be overcome by the waka

Genetic technologies could provide opportunities for New Zealand across a range of areas. This report does not seek to analyse the likelihood of any particular use in New Zealand, but instead provides some general areas that they may be used for in a New Zealand situation.

6.1. Opportunities

6.1.1. Agriculture

Gene editing offers significant opportunities for the primary sector, with the Royal Society Report on Gene editing Scenarios in the Primary Industries finding that gene editing technology could speed up innovation, reduce costs associated with pests, mitigate the impact of climate change, and create higher value products. (Royal Society Te Apārangi, 2019) There are also applications for animal health and welfare regarding heat tolerance, reducing the incidence of painful procedures, and providing protection against disease. (American Veterinary Medical Association, 2022) (USDA Agricultural Research Service , 2023) (Brier, 2023)



Figure 5 Bovine viral diarrhoea resistant calf (USDA Agricultural Research Service , 2023)

6.1.2. Conservation

New Zealand has a substantial challenge with pests causing significant damage to native ecosystems and impacting agricultural productivity. A report by MPI in 2020 estimated that pest control in New Zealand for both conservation and agricultural productivity cost around \$1.5 billion, while the total economic costs of pests to New Zealand was \$9.2 billion. (Ministry for Primary Industries , 2021) This does not consider the environmental and cultural impact from the continued loss of native New Zealand biodiversity from introduced species.

Pest-control is currently carried out by a range of methods such as poisoning, shooting, trapping, fencing, and others including biological control. This comes at significant cost and is required on an ongoing basis to ensure areas stay free of pests. They can also be controversial for cultural, personal, and ethical reasons and to date have not solved the pest problem in New Zealand. This also creates an ongoing and significant economic cost to ensure areas stay pest free.

One potential solution is to gene edit an organism to reduce its reproductive capability and use a gene drive to increase the chance that this trait is inherited to reduce pest populations over time. (Guthrie, 2019) While gene editing an organism may also be controversial, this should be weighed up against other pest control methods and their downsides. Deciding not to use these technologies also has consequences, and so the choice is less about genetic engineering or not, but balancing the current approach with what could be achieved with genetic technologies. Having this conversation is supported by both Forest and Bird and the SPCA, who recognise the role genetic technologies could play a role in pest management for

protecting ecosystems (Forest and Bird) and animal welfare (SPCA). (Forest & Bird , 2020) (SPCA, 2023)

6.2. Risks of using genetic technologies

It is also argued that the use of genetic technologies presents risks to New Zealand, and that these risks outweigh the potential benefits. Like the section above, this report does not aim to analyse the likelihood or severity of the risks but presents some of the common arguments against their use.

6.2.1. Market access and returns.

New Zealand is an exporting nation, with food and fibre exports making up 81.4 percent of goods export revenue in 2022. (O'Connor, `2022) Because of this, there is significant concern that the introduction of genetic technologies could impact market access and consumer returns. There is also concern that separating out GMO and non-GMO products could also impose significant verification costs on suppliers to demonstrate that their products are GMO-free.

Market access is negotiated between governments and includes bans and restrictions on food produced with genetic technologies.
Consumer returns come from the value that customers are willing to pay for products.

The use of genetic technologies in New Zealand does not necessarily mean they will enter the food chain, however there is concern that the use of the technologies for other uses such as gene drives in conservation could impact New Zealand's country wide GMO status. This has been put forward as a reason for caution when considering their introduction into New Zealand, along with concerns around the impact on human and environmental health.

6.2.2. Increased scale of potential risk

The scale and speed at which genetic technologies are used is also seen as a significant risk. With genetic technology advancing at a rapid pace and the technology becoming easier to use, the potential for any negative consequences to be amplified increases. Professor Jack Heinemann at the University of Canterbury argues that because genetic technologies have become more precise, the cost has fallen, and more frequent use increases the chance of unintended outcomes. It is this increased scale of the use of genetic technologies that creates additional risk.

“You look at where scale changes occur for any technology in which scale increases risk, but doesn't increase safety at the same time, regulation is our only instrument for containing that potential harm.” (Heinemann, Kellogg interview regarding genetic technologies , 2023)

Due to the wide application of genetic technology to both animals and plants, the potential for unintended consequences is both significant and unknown. Its use outside of the laboratory, (including field trials) where there is a possibility that it may escape into the wild is therefore an argument for a cautious approach requiring strict controls on the containment of any new organisms. (Heinemann, Kellogg interview regarding genetic technologies , 2023)

The fact that any organism can be modified in any number of ways means that it is difficult to balance risks and opportunities at a general scale. To fully understand any trade-offs a case-by-case approach is therefore needed. Like any tool it can be both dangerous and beneficial depending on its use.

6.3. The risk of not using genetic technologies in New Zealand

While there are risks associated with any new technology, the decision not to use it also comes with trade-offs. In some cases, alternative methods to address the issue may have negative consequences and so the decision not to use genetic technologies means they continue. The SPCA for example supports innovation and research into humane alternatives to using poison

for pest control, including genetic technologies, while Forest & Bird advocates a case-by-case analysis for its use in controlling predators. (SPCA, 2023) (Forest & Bird, 2020)

Other negative trade-offs may be environmental, through the use of increased pesticides or reputational, where New Zealand is not able to utilise alternative options offered by genetic technologies and is forced to continue with traditional practices that do not align with changing public morals in export markets. (Brier, 2023)

7. Analysis: Where to from here?

I orea te tuatara ka patu ki waho

A problem is solved by continuing to find solutions.

Research and interviews as part of this report have highlighted that the current system doesn't appear to be fulfilling the needs of the scientific community and that New Zealand is currently unable to utilise genetic technologies to address local challenges. The current regulatory regime is viewed as unfit for purpose and imposing significant costs on applicants. Countries that New Zealand competes with internationally are using these technologies, and it seems unlikely that there would be any market access issues at a government level for exports.

There also seems to be recognition within New Zealand government, iwi, and NGO's that genetic technologies could be used in certain circumstances for challenges that have been unable to be addressed by current methods. This is not saying that genetic technologies are the only answer, but rather that they should be investigated, and the risks and benefits weighed up on a case-by-case basis.

The view of the public is unknown and needs to be further investigated as part of any regulatory change, however it is possible that attitudes may have shifted since the Royal Commission report in 2001. Understanding this will be a key part of any review. There are people with strong views for and against the use of genetic technologies in New Zealand, however the wealth of literature on this topic indicates that there is an appetite to have this discussion.

The barrier to having this conversation has been the lack of motivation by politicians to tackle such a historically controversial topic, however this may have changed with the recent election of the National and Act parties who both included it as part of their election manifestos.

A well-managed review process provides an opportunity to understand the public's views towards genetic technologies and build a modern biotechnology approach that reflects New Zealand's unique situation. For this to happen, a comprehensive national conversation is needed that seeks to understand the range of views across different sectors of society and then provides recommendations for an updated and modern approach to genetic technology.

7.1. Reason for review

Therefore, based on the analysis above, it is clear that it is time for regulatory reform/review.

New Zealand's current approach to genetic technologies is risk averse and has precluded conversations about their application across a range of different situations. Any new technology has risks, and it is important to recognise that and mitigate where possible, however regulation is needed that considers risk on a case-by-case basis for each possible application of the technology.

New Zealand has been unable to have this conversation, as regulatory barriers and the costs imposed by them have had a chilling effect on new science developments. As a country, New Zealand needs to move past a focus on the method, and towards one where the risks and benefits can be weighed up regarding the use of new technology. Genetic modification is not a silver bullet and will not solve all problems, however it is a tool that should be considered for certain cases alongside the ones already being used.

A regulatory regime should allow these questions to be asked, as not doing so risks precluding options that could be used to address some of the environmental, animal welfare, and productivity challenges the country is facing. There needs to be a balance between risk and opportunity and an understanding that a regulatory regime that precludes investigation of these possibilities risks locking New Zealand into the status quo. This status quo also carries risk, and it is up to the New Zealand public to consider what level of risk they are comfortable with and where it lies.

“So yes, we have some significant challenges in front of us, but let's start the discussion and see whether we can find some not so much common ground, but space where we have the ability to make choices as to what's the best way forward.”

(Caradus, Kellogg interview regarding genetic technologies, 2023)

Understanding this will provide the basis for a modern New Zealand's policy towards the use of genetic technologies.

7.2. A framework for regulatory review

There is recognition by political parties, government departments, industry bodies, NGOs, and scientists that New Zealand's current regulatory regime for genetic technologies is not fit for purpose. (Gerrard, 2023) The HSNO Act was enacted in 1996 and has had some minor updates and court cases have clarified some aspects in relation to advances in technology, however it has not kept up with scientific advances and changes in the international context. Because of this, it will not be enough to update the HSNO Act and a new regime will need to be created that effectively manages the use of genetic technologies.

Since the last time New Zealand had a public discussion about the use of genetic technologies there have been scientific advances and new opportunities for agricultural production, conservation and environmental issues, and medical advances. Because of this, it is worth understanding current public views and what a modern New Zealand approach to the regulation of biotechnologies would look like.

Unique New Zealand factors such as unique biodiversity, Treaty of Waitangi obligations and previous public concern about genetic modification suggest a New Zealand specific approach should be designed, rather than copying and pasting a regulatory regime from overseas.

This report puts forward a two-step process for reviewing the current system. Firstly, testing a set of shared values with the New Zealand public; secondly, developing a proposed system based on these values for consultation. The following section expands on the process outlined in the table below.

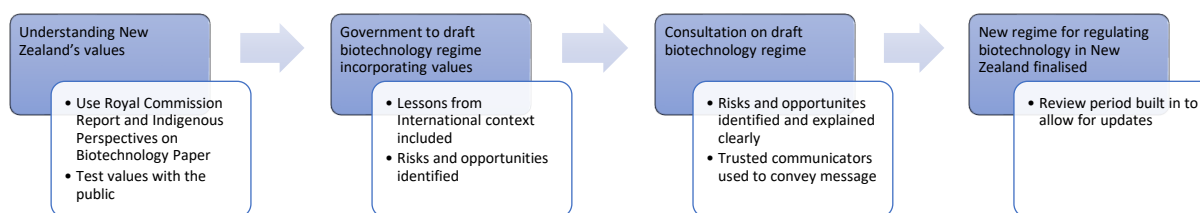


Table 4 Process for developing a New Zealand specific approach to the regulation of genetic technologies (Author's own work)

7.3. Initiating a review of New Zealand's genetic technology policy

The National and Act parties have stated that they intend to modernise New Zealand's regulatory approach to genetic technologies and 'end their effective ban'. (Collins, 2023) There is broad consensus from the Royal Society Te Āparangi and the current and previous Prime Minister's Chief Science Advisors that a review is needed. (Royal Society Te Apārangi, 2019) (Office of the Prime Minister's Chief Science Advisor, 2019)

Likewise, the decision to continue with New Zealand's current approach where there has been little use of these technologies due to a regulatory regime that is seen as overly prescriptive and difficult to work with also presents risks. It means that genetic technologies have not been investigated as potential solutions to challenges and in some cases, this has perpetuated other methods with negative side effects to address these issues.

7.4. National Party's approach

The National Party, recently elected into Government alongside the Act party has stated that they plan to modernise and update New Zealand's biotech policy. Under this approach, a biotech regulator will be created following the Australian Model that will:

- Streamline the approvals process for trials and use of non-GE/GM biotech for emissions reduction and other purposes. The biotech regulator will be tasked with reducing delays for the safe introduction of biotechnologies into New Zealand.
- The biotech regulator will approve trials or use of non-GE/GM products that have already been approved for trial or use by at least two other OECD countries (or the EU and at least one OECD country outside the EU). (Collins, 2023)

While there are arguments for aligning New Zealand's approach with other countries, it has been consistently recognised through the interviews for this report and the literature review that a New Zealand-centric approach must be developed that incorporates Māori views. National's policy states that this will be included in the formulation of the biotech regulator which will incorporate obligations arising under the Treaty of Waitangi. (Collins, 2023) The principles of the Treaty of Waitangi include partnership, participation, and protection and have been interpreted by New Zealand Courts to require the Crown to engage in good faith with Māori, however they do not provide direction for how to approach specific issues such as the use of genetic technologies. (Te Puni Kōkiri, 2002) To adhere to these principles, the Government must work in partnership with Māori and must not predetermine the result of the

consultation. To do so would jeopardise the process and lose trust in what has been a previously controversial topic.

7.5. Understanding New Zealand's values

Table 5 Summary of inherent New Zealand values from the Report of the Royal Commission on Genetic Modification (The Royal Commission on Genetic Modification, 2001)

The Royal Commission into Genetic Modification in 2001 was a result of significant public concern regarding the use of genetic technologies. While other countries have seen this concern diminish over time, and the same may have also occurred in New Zealand there remains significant public interest in genetic technologies and their use. Because of this historical interest, any reopening of the conversation is likely to reopen these previous fault lines.

Any review should begin by understanding the New Zealand public's values before consulting on a proposal. Understanding these underlying values and using them to draft a legislative proposal for consultation may allow discussion of the issue in good faith. Using the seven values outlined in the Royal Commission report would build on the significant work already done through this process. (The Royal Commission on Genetic Modification, 2001) They should however be tested through public consultation to ensure their relevance 22 years on, and to see if updates are needed.

While the Royal Commission also looked at Māori values, the excellent work done in the paper "Indigenous Perspectives and Gene Editing in Aotearoa New Zealand" is more recent and goes into greater depth and could provide a solid base for engaging with Māori on specific Māori values. (Hudson, me ētahi atu, 2019) These are attached at Appendix Two.

Following consultation, the two sets of values would provide the basis for any change in regulation. Using these values means that the public can be consulted without requiring detailed knowledge of the science. This would also provide an opportunity to bring New Zealand together and demonstrate that while different sectors of the public have different views on how genetic technologies should be regulated, there are shared values that underpin these differing views.

7.6. Incorporating Māori values

A key part of any review process will be working in partnership with Māori to understand Māori specific values and designing a regime that enhances, rather than diminishes them. (Hudson, me ētahi atu, 2019)

This could provide the basis for a modern regulatory regime that is outcomes-focused, rather than regulating the method used to achieve such outcomes. While the requirement to utilise genetic technologies in a way that aligns with Māori values may be unfamiliar to non-Māori, using the values outlined in the "Indigenous Perspectives and Gene Editing in Aotearoa New Zealand" paper could provide guidance. Future work expanding on these values through wider consultation with Māori should be used to create a framework to help researchers understand whether proposed uses of genetic technologies are aligned with Māori values.

The Wai262 claim recognises that Māori have special interests in GMOs regarding mātauranga Māori, taonga, and cultural and spiritual values and has provided a best practice guide for science partnerships with kaitiaki for research involving taonga. (Potter & Māngai, 2022)

Royal Commission Seven Values Inherent to New Zealanders
The uniqueness of New Zealand
The uniqueness of our cultural heritage
Sustainability
Being part of a global family
The wellbeing of all
Freedom of choice
Participation

Utilising these resources and values to create a framework for the use of genetic technologies could provide more certainty for commercial applications of the technology while ensuring that Māori values are respected.

This would suggest an outcomes-based approach, where the use of the technology is assessed on a case-by-case basis, with approval granted if alignment with Māori values could be demonstrated. A proposed approach for this is included in Section 7.9.4 of this report.

7.7. Drafting a proposal

Following this consultation on values, a draft regulatory regime can be designed that incorporates both Māori and the general public's values. Discussion of these values and how they have been used to create the draft legislation would ensure that people feel that they have been listened to and their concerns reflected. This means that when it is consulted on, it is clear what is being proposed and there can be no confusion to what the final legislation will be.

While it is a noble concept that policy making can be evidence-based, different sides will point to evidence to support their viewpoint. Evidence will need to be reviewed to ensure it is factual and a policy developed that recognises different viewpoints and values. Expert opinion from comparable jurisdictions should also be sought, as well as discussing with export markets any potential impact on trade. Following this a clear and comprehensive legislative proposal should be drafted that does not allow for ambiguity, and for bad faith actors to create confusion by spreading misinformation.

7.8. Communication

Alongside any consultation a significant communication piece will be needed to provide context to the consultation. This should seek to use communicators that are trusted by the community they are engaging with to ensure information is conveyed clearly.

Detailed analysis and investigation should be conducted into major concerns to understand their validity and likelihood of occurring. This analysis should be presented alongside a proposed bill by trusted sources to provide assurance to those who have concerns.

There should be a significant investment into education regarding genetic technologies, including a thorough discussion on what the changed regulatory approach would mean for New Zealand. This will require a detailed analysis of both the benefits and the risks of genetic technologies.

Communication should also address the opportunities and risks of keeping the current approach, as this also has implications for New Zealand. As well as a discussion with the general public, consultation should also seek to understand specific Māori values and views towards genetic technologies and how they should be incorporated into any regulatory change.

It will be particularly important for concerns to be addressed by reputable and trusted sources of information to ensure a factual message is conveyed and there is limited opportunity for misinformation. Messages need to be tailored to individual communities and clearly address any concerns while explaining opportunities. This will require a coordinated messaging and could look at previous communication on issues important to New Zealand for inspiration such as the COVID-19 response.

7.9. Principles for regulatory development

An updated policy for regulating genetic technologies in New Zealand needs to consider circumstances unique to New Zealand such as economic reliance on export markets, its

unique biodiversity, the history of public interest and concern, and obligations under the Treaty of Waitangi.

This section looks at factors that should be considered when designing a regulatory regime for biotechnology in New Zealand.

7.9.1 Trade

Any change in approach to genetic technologies must not negatively impact New Zealand's ability to trade.

New Zealand needs to be clear about any risks to export markets. New Zealand's primary sector, responsible for 81.4 percent of goods revenue, is the engine of the economy and access to international consumers is critical for the country's economic prosperity. Understanding risks for trade comes in two components – the first being market access through rules made at a government level, and the second consumer perception and willingness to purchase New Zealand products.

A New Zealand specific regulatory scheme must take this into account and ensure that any risk to exports is balanced with opportunities in other areas. Any risk to export markets must be well understood and mitigated. This will likely be different for different uses – with products that are for human consumption having the highest risk profile, where ones that are used for animal feed or for conservation having less risk.

The following questions should be considered to understand the impact on New Zealand's exports following any change of approach.

1. What technologies are considered GMO and required to be labelled in export markets?
2. Does New Zealand receive premiums for its GMO status?
3. What technologies would impact this status, and how could any risks be mitigated?
4. What costs are associated with retaining GMO-free status within supply chains?

7.9.2 Coverage

Any regulatory regime must be clear about what is covered and any change to this must be publicly consulted on. Shifting coverage by stealth will lose public trust in the system.

Another important consideration will be to define what is covered by any GMO regulation in New Zealand. Overseas, there is a general trend to deem processes that do not introduce genes from other species as non-GMO, and therefore putting it in the same class as traditional breeding techniques. Most countries overseas have moved to deregulate organisms created through cisgenesis, such as the UK, EU, Canada, USA, Argentina, Brazil, and Australia. While they have their differences in how this is applied, they essentially look at the risks associated with the new organism rather than the process it was created by.

This leaves GMO regulation to focus on transgenesis products (where genes have been introduced that could not be obtained through traditional breeding techniques) and sets out a separate process for approvals for those organisms.

Moving to such a hybrid regime may address some of the concerns that were raised in 2001 regarding transgenesis organisms and would allow for the use of new breeding techniques to create new organisms that could be obtained through traditional breeding.

7.9.3 New Zealand technology for New Zealand

A regulatory regime should be set up to benefit New Zealand, rather than for multinational companies.

One challenge of a regulatory regime that provides for the use of genetic technologies but is highly regulated is the cost associated with interacting with the regulatory process. Brazil recognised that their regulatory regime imposed significant costs applicants which impacted the ability of small medium enterprises (SMEs) and universities to engage with it. Because of this, the majority of applications received, and new products developed were by large, multinational companies. Brazil made a conscious decision to streamline the regulatory process and make it easier for smaller organisations to participate. This resulted in a risk-based regime that facilitated Brazilian companies developing technologies uniquely suited for Brazilian needs.

A New Zealand approach should adopt a similar position, encouraging New Zealand based companies to develop solutions that address New Zealand challenges and opportunities. This would facilitate an environment that encourages genetic technology development for New Zealand situations. It would also encourage research that benefits New Zealand, rather than by multinationals for use overseas. Some interviewees raised concerns that the use of genetic technologies was heavily corporatised and served company interests rather than those of local communities. For people to support new technologies, they must recognise the benefits and a regime that encouraged local companies to invest in research for New Zealand specific issues may go some way towards addressing these concerns.

7.9.4 Engagement with Māori

The regulatory body should set up in a way to enhance Māori participation and trust in the regulatory regime.

Incorporating Māori participation into the design of any new regulatory regime, as well as having ongoing input into the approval process will be key to fulfilling obligations under the Treaty of Waitangi. The current EPA approval process includes this through Nga Kaihautu Tikanga Taiao, the body that advises the EPA on Māori issues. (Environmental Protection Authority, 2023)

The Wai262 claim recognises that Māori have special interests in GMOs regarding mātauranga Māori, taonga, and cultural and spiritual values and has provided a best practice guide for science partnerships with kaitiaki for research involving taonga. (Potter & Māngai, 2022). Along with the principles outlined in the “Indigenous Perspectives and Gene Editing in Aotearoa New Zealand” paper this provides a solid foundation for understanding how genetic technologies can enhance, rather than diminish Māori values. (Hudson, me ētahi atu, 2019)

Setting out guidance for applications to use genetic technology would provide clarity for applicants and ensure that the level of consultation is appropriate to the outcome desired. For example, greater levels of consultation would be required for taonga species than commercial applications of agricultural technology. A scientist in one of the interviews noted that Māori participation was very helpful in a previous application for release of genetically modified organisms, however the challenge was understanding who to engage with.

“Ngai Tahu from the South Island actually came along to one of the public hearings and they were great. They were excellent. They were not strongly for or against. They just wanted to say their piece and I found it very constructive and useful.”

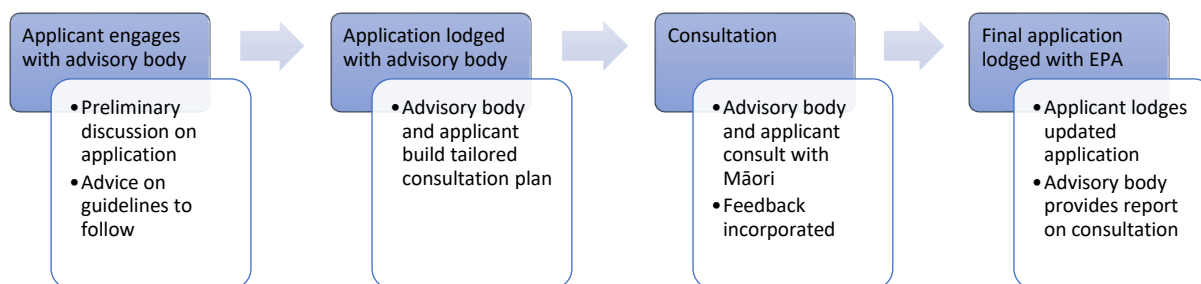
(Caradus, Kellogg interview regarding genetic technologies, 2023)

A trusted body, potentially an expansion of Nga Kaihautu Tikanga Taiao's role, that worked with applicants to consult with Māori could improve the quality of consultation and could provide preliminary guidance on applications. This body could also facilitate consultation and ensure that it is reaching the right people, and they are fully informed on what they are being consulted, therefore improving outcomes for both the applicant and Māori interests. Following

the consultation process, the advisory body could provide an additional report outlining what was covered and the range of views.

The regulator could then be confident that final applications had consulted with the appropriate Māori representatives and their views had been incorporated. A draft process is set out below:

Figure 6 Draft process for engaging with Māori on genetic technologies



7.9.5 Risk management

Managing risk is more important than focusing on the process used to obtain the organism.

A key aspect of any new approach to genetic technologies must be whether it is based on process or outcomes or a hybrid of the two.

A process-based approach regulates the technology used to create the new organism whereas an outcomes-based approach looks at the new trait, and balances this with any new risk.

An outcomes-based system, where the new trait is assessed on its risk profile would mean that regulation is able to move with technological advances and moves focus away from how that trait is obtained. This is the approach that is being taken in Australia, Canada, the UK, the USA, and South American countries and has resulted in streamlined systems that address concerns about new organisms while providing a pathway for technological development.

The way regulations should be drafted depends on the underlying values of society and their tolerance for risk. The precautionary principle of regulation provides a higher degree of protection at the expense of innovation. A risk-based approach on the other hand balances the likelihood of any harm with the magnitude or severity of the harm on a case-by-case basis. Risk based regulation therefore looks at the potential outcomes rather than the process used to obtain those outcomes. The OECD recognises that regulation that is risk focused and risk proportional is essential to improving efficiency, strengthening effectiveness, and reducing administrative burden (OECD, 2021).

The Prime Minister's Chief Science Advisor in her briefing to the Prime Minister on the Royal Society Te Apārangi report notes, however, that the debate regarding product versus process is unhelpful and overly simplistic. For a technology such as gene editing that can be used for an extremely wide range of purposes, there is a more nuanced conversation that is needed to ensure the New Zealand public's views are represented in any new approach. (Office of the Prime Minister's Chief Science Advisor, 2019) There will be organisations that will remain opposed to the use of genetic technologies. A transparent and well-communicated consultation process will ensure that these views can be carefully considered and publicly addressed.

7.9.6 Monitoring and review

Building in a review period will ensure that regulation stays relevant.

Any regulation should be written in a way that is futureproof, however the speed that genetic technology develops may mean that additional review periods need to be built into the legislation. Building a review process into the law at the beginning would ensure that the law can keep pace with technological development. It would also lessen politicisation of the issue, as review processes monitor the effectiveness of regulatory frameworks and policies rather than broader ethical concerns.

The current consultation on GMOs for laboratory and medical use initiated by the previous Labour Government suggests a five-year review period. This would encompass horizon scanning and would also include a summary of relevant changes in other jurisdictions to ensure regulations don't become outdated and encourages proactive planning for future biotechnology developments. (Ministry for the Environment , 2023)

Reviews are expensive and time consuming and this needs to be balanced with the objectives of doing one. For an issue such as the use of genetic technologies, where there is high public interest in ensuring policy settings are correct, a review could provide assurance to people and organisations that regulations are adaptive and remain fit for purpose.

8. Conclusion

He waka eke noa

We are all in this together.

New Zealand sits as an outlier with comparable jurisdictions and its export markets regarding the regulation of genetic technologies, however any review of the regulations should not be based upon this alone. Any change in policy must be because it has significant public backing and is right for New Zealand circumstances.

There is significant interest from a range of organisations to review New Zealand's current approach, however they does not say what change is needed, only that there is recognition that technologies have changed since there was last a national conversation on the issue. This also does not necessarily mean that there is widespread support for the use of genetic technologies, but it does signify that there is recognition that they could provide benefits in certain areas, whether this is environmental, agricultural, animal welfare, or medical. Technological change since the HSNO Act 1996 was developed will have resulted in new risks and new opportunities that must be considered with any updated policy. In order to update the regulations it will be important to clearly articulate what these risks and opportunities are and ensure that they are recognised and addressed in any change.

New Zealand is unique in many ways. Obligations under the Treaty of Waitangi to consider Māori views, rare native species, and heavy dependence on agricultural trade for national prosperity all point to designing a system that is unique to New Zealand. While New Zealand should consider what is happening around the world and how it could be applied to a New Zealand situation, at the end of the day a regime must be constructed that is relevant for New Zealand circumstances.

This will require wide consultation and communication on exactly what is being proposed. Risks must be considered and mitigated where possible in order to ensure that benefits are not outweighed by risks.

Genetic technologies have a controversial history in New Zealand, and present both risks and opportunities due to their wide variety of applications. This should not prevent a conversation on their use, as the decision to continue with the current approach also has consequences.

This report aims to help policy makers understand the international and New Zealand context to the use of genetic technologies. It builds on the significant amount of work already done in New Zealand by a range of different organisations on this topic and sets out what should be considered in any new rule change. It now requires elected politicians to direct officials to conduct a process that consults widely, works in partnership with Māori, and results in a modern policy for biotechnology that works for New Zealand. It is up to New Zealanders to participate in the process and ensure that their voices are heard.

9. Recommendations

Waiho i te toipoto, kaua i te toiroa.

Let us all keep close together, not wide apart.

These recommendations summarise next steps for developing a New Zealand approach for the management of genetic technologies.

This report recommends that the New Zealand Government:

- Review in detail the international context, taking learnings from what works well and what doesn't and use these findings to develop a draft policy for consultation.
- Build on and test the work that has already done to understand the values that are important to New Zealanders with special regard to Māori views.
- Develop a New Zealand-centric policy towards the use of genetic technologies that address the priorities and incorporates the values of all New Zealanders.
- Explain how these values have been incorporated into any draft policy for consultation.
- Communicate clearly what risks have been identified and how they have been addressed, as well as the opportunities a new approach would provide.
- Develop a strong engagement package that aims to minimise the contentious nature of previous engagements. This includes the use of communicators trusted by the sector of society that you are aiming to reach.
- **A new regulatory regime should:**
 - Ensure New Zealand's exports are not negatively impacted.
 - Be clear on what technology is regulated or deregulated and why.
 - Support New Zealand firms to develop solutions for New Zealand-specific issues.
 - Respect and enhance Māori values.
 - Be risk-based rather than focussing on process.
 - Be future-proofed through regular monitoring and review.

Limitations

This report aims to provide a base for policy makers to work from regarding an updated policy for the regulation of genetic technologies. While comprehensive research was undertaken using both academic and public sources, and interviews with subject matter experts were conducted, to fully understand the New Zealand public's views and values, extensive consultation will need to be done as part of any review.

For an understanding of Māori concepts and values, this research relied on previous studies that had synthesised available literature and conducted interviews with experts to provide qualitative views. While I read deeply, consultation with a range of Māori people and organisations should be undertaken to properly understand the range of views towards genetic technologies. The information related to international contexts was gathered through a literature review and from publicly available information on government websites. Likewise, discussions with those operating in other jurisdictions should also be sought to better understand the nuances of each regime.

This report's author does not have a scientific background and at the end of the day, the evaluation of risk and opportunity regarding the use of genetic technologies is a moral choice rather than one that can be decided by science alone. Evidence submitted during a consultation process will inevitably support one view over another. Care should be taken to understand what is realistic, and all evidence presented during any consultation should be analysed thoroughly.

There is both compelling and passionate views on both sides of the debate and this report did not seek to evaluate the evidence presented beyond a basic level, and therefore was unable to conclude whether New Zealand should allow increased use of Genetic technologies. Holding this conversation is now a matter for the New Zealand Government to have with the New Zealand public.

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Appendix One – Interview questions

Name

Contact details

Organisation:

Position

1. What are your views on New Zealand's current biotech policy?
2. Where do you see the main opportunities for genetic technologies in New Zealand?
 - Agriculture
 - Conservation/Environment
 - Healthcare
 - Other
3. Where do you see the risks?
 - Consumers?
 - Markets?
4. Could these risks be managed in order to negate any negative effects?
5. Do you know of any barriers to the adoption of GE/GM in NZ that are not regulatory?
6. Do you have any views on other countries approaches to biotech policy around GM/GE products and what works well and what doesn't?
7. How should we balance precautionary and risk based approaches?
8. How could we learn from previous change in policy be influenced by previous experience regarding controversial topics in NZ? e.g., combatting disinformation around COVID? Are there any other like situations that can be used as a comparison? Cannabis/end of life referendums?
9. How could a communication strategy address public concerns around the use of genetic technologies?
10. How could Māori views and Treaty obligations be incorporated into an updated policy?
11. Is there anyone else that you recommend I should be talking to?
12. Any further comments?

Appendix Two – Māori values

Reproduced from the paper “Indigenous Perspectives and Gene Editing in Aotearoa New Zealand” (Hudson, me ētahi atu, 2019)

Value/Concept	Value enhancement	Value diminishment
Whakapapa	Gene Editing does not involve the transfer of genes between species— whakapapa can be maintained and enhanced through the continued well-being of the species	Gene Editing introduces foreign DNA or involves changing the genome inter-generationally with negative consequences— whakapapa is diminished
Mauri	Gene Editing is being used to support human or environmental health— mauri is enhanced	Gene Editing is used for inappropriate purposes— mauri is diminished
Kaitiakitanga	Gene Editing may support or enhance resilience of ecosystems— kaitiakitanga is enhanced	Gene editing has unknown effects on the well-being of organisms and the ecosystem— kaitiakitanga is diminished
Mana	Māori are able to choose how gene editing is applied— mana is enhanced	Māori have no say in discussions about how gene-editing is used— mana is diminished
Taonga	Gene-editing supports commercial and cultural interests as identified by Māori— Taonga status is enhanced	Gene-Editing is used in ways that negatively affect taonga species— Taonga is diminished
Tapu	The use of gene editing is restricted and subject to a precautionary principle— Tapu is enhanced	The use of gene editing is widely approved for any purpose— Tapu is diminished
Wairua	Māori are involved in decision-making and are comfortable with the uses of the biotechnology— Wairua is enhanced	Māori are not involved in decision-making and don't know what's going on— Wairua is diminished
Kawa	Robust consultation and decision-making processes are developed, and Māori values inform the use of gene editing— Kawa is enhanced	Māori values are excluded from policy development and decision making processes— Kawa are diminished
Tika	Benefits of the research are shared equitably across the community— Tika is enhanced	Benefits are captured by commercial or special interest groups— Tika is diminished
Manaakitanga	Cultural protocols are developed to support the use of gene-editing— Manaakitanga is enhanced	No cultural support for Māori participation in gene editing activities— Manaakitanga is diminished
Tākoha	Recognition of Māori rights and interests to genome sequences and responsibilities associated with this— Tākoha is enhanced	No recognition of Māori rights, interests or responsibilities— Tākoha is diminished
Whanaungatanga	The use of gene editing supports a strengthening of whanau by addressing a key issue or concern— Whanaungatanga is enhanced	The use of gene editing does not contribute to addressing whanau issues or creates disruption in the whanau— Whanaungatanga is diminished
Whakapapa	Gene Editing does not involve the transfer of genes between species— whakapapa can be maintained and enhanced through the continued well-being of the species	Gene Editing introduces foreign DNA or involves changing the genome inter-generationally with negative consequences— whakapapa is diminished

Mauri	Gene Editing is being used to support human or environmental health— mauri is enhanced	Gene Editing is used for inappropriate purposes— mauri is diminished
Kaitiakitanga	Gene Editing may support or enhance resilience of ecosystems— kaitiakitanga is enhanced	Gene editing has unknown effects on the well-being of organisms and the ecosystem— kaitiakitanga is diminished

Appendix Three – List of interviewees

The following people contributed to the report through interviews. They spoke as individuals rather than representing the organisations where they worked, however their roles and organisations are included to provide context and to illustrate the range of experience that they brought to the interviews.

Their kindly donated time provided invaluable context and expertise on a complex topic. Their honesty and willingness to be involved speaks to the desire for a regulatory approach that works for all New Zealanders.

Interviewees:

Distinguished Professor Caroline Saunders ONZM – Director, Lincoln University Agribusiness & Economics Research Unit

David Hume – Senior Scientist, AgResearch

John Caradus – CEO, Grasslanz Technology

George Slim – Consultant, Rhadegund Life Sciences

Jenny Lux – Farmer and Chair, Soil & Health Association

Barry Wards – Principal Advisor, Ministry for Primary Industries

William Rolleston CNZM – Chair, Geonomics Aotearoa

Nathan Mills – Executive Director, Life Sciences Network

Dan Brier – General Manager Farming Excellence, Beef + Lamb New Zealand

Professor Jack Heinemann – Professor, University of Canterbury

Written responses to interview questions were received by:

Hon Judith Collins – National Party, Science, Innovation, and Technology Spokesperson