Ministry for the Environment
Manatū Mō Te Taiao

1 September 2021

OIAD-106

Jon Muller
Secretary
GE Free NZ
secretary@gefree.org.nz

Dear Jon Muller

Thank you for your email of 12 August 2021 requesting the following under the Official Information Act 1982 (the Act):

> *GE Free NZ understand that there has been a release under the Official Information Act to media organisations. These relate to Ministry for the Environment (MfE) briefs given to the Minister in relation to new advanced genome edited organisms, namely CRISPR, TALENs and ZNFNs.*
>
> *Please can we have -*
>
> *1. All correspondence, Ministerial briefs and documents relating to the advice given to the Minister regarding the regulation of genome-edited organisms in the HSNO Act?*
>
> *2. All MfE correspondence with CRI's and organisations regarding the regulation of genome-edited organisms in the HSNO Act?*
>
> *3. All MfE documents from January 2017 – June 2021*
>
> *We understand that this information has previously been requested and provided to NewsHub and has been the basis for a number of media pieces.*
>
> *https://www.newshub.co.nz/home/new-zealand/2021/05/revealed-archaic-genetic-modification-law-stifles-progress-on-new-zealand-s-own-covid-19-vaccine.html*

The Ministry for the Environment (the Ministry) contacted you on 17 August to clarify your request and to confirm whether you were after all the material which was previously released in the Newshub OIA. The Ministry followed up with you again on 24 August. As no response was received, we have identified five documents in scope of your request.

The material being released to you is the same as the documents which were released in the Newshub OIA. Two of the briefings are released to you in full.

The remaining three documents are released to you in part, with some information removed as being out of scope, in accordance with section 16(1)(e) of the Act - where the information requested by any person is comprised in a document, that information may be made available in 1 or more of the following ways: by giving an excerpt or summary of the contents.

In terms of section 9(1) of the Act, I am satisfied that, in the circumstances, the withholding of this information is not outweighed by other considerations that render it desirable to make the information available in the public interest.

You have the right to seek an investigation and review by the Office of the Ombudsman of my decision to withhold information relating to this request, in accordance with section 28(3) of the Act. The relevant details can be found on their website at: www.ombudsman.parliament.nz.

Please note that due to the public interest in our work the Ministry for the Environment publishes responses to requests for official information on our OIA responses page shortly after the response has been sent. If you have any queries about this, please feel free to contact our Ministerial Services team: ministerials@mfe.govt.nz.

Yours sincerely

Glenn Wigley
Director - Policy and Regulatory
Waste and Resource Efficiency

Document schedule

Document no.	Document date	Content	Decisions	OIA sections applied
1	18 November 2019	2019-B-06162 Advice on simplifying regulation for simple modification in containment and for medical uses	Release in full	
2	17 February 2021	2021-B-07485 Update on the regulation of genetically modified organisms in New Zealand	Release in full	
3	26 January 2021	Final Environment weekly update week starting 26 January 2021	Release in part Some out of scope information has been removed	16(1)(e)
4	16 December 2019	Final Hon Parker Environment weekly update week starting 16 December 2019	Release in part Some out of scope information has been removed	16(1)(e)
5	2 March 2020	Final Hon Parker Environment weekly update week starting 2 March 2020	Release in part Some out of scope information has been removed	16(1)(e)

2019-B-06162 Advice on simplifying regulation for genetic modification in containment and for medical uses

Date Submitted:	18 November 2019	Tracking #: 2019-B-06162	
Security Level	In confidence	MfE Priority:	Non-Urgent

	Action sought:	**Response by:**
To Hon David Parker, Minister for the Environment	**Note/agree** to the recommendations	2 December 2019

Actions for Minister's Office Staff	**Forward** this report for noting to Hon Damien O'Connor, Minister for Biosecurity and to Hon Dr David Clark, Minister of Health **Return** the signed report to MfE
Number of appendices and attachments 5	Titles of appendices and attachments (i.e. separate attached documents): 1. Material considered in preparing this briefing 2. Regulation 3 of Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 3. Risk-tiering for medical uses and contained research 4. Operational improvements for contained research 5. Qualifying medicines and Malaghan's CAR-T cell trial
Note any feedback on the quality of the report	

Ministry for the Environment contacts

Position	Name	Cell phone	1st contact
Principal Author	Simon Lamping / Dianna Caird		
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Director	Glenn Wigley	027 491 7806	✓

2019-B-06162 Advice on simplifying regulation for genetic modification in containment and for medical uses

1. Following the release of the final report by the Royal Society Te Apārangi in their inquiry on Gene Editing in Aotearoa called *Gene editing – Legal and regulatory implications*, you asked for specific advice on gene editing.

2. New Zealand's regulatory framework draws no distinction between gene editing and other genetic modification techniques that are used to develop genetically modified organisms. Therefore, this briefing advises on the regulation of genetic modification and genetically modified organisms rather than just gene editing (Appendix 1 provides a list of materials we considered in preparing our advice). Key definitions are provided below [refer 18-B-04195]:

   - A **Genetically Modified Organism (GMO)** under the Hazardous Substance and New Organisms Act 1996 means: any organism in which any of the genes or other genetic material—

     (a) have been modified by *in vitro*[1] techniques; or

     (b) are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques

   - **Genetic modification (GM)** is a broad range of technologies that manipulate DNA to enhance or change the characteristics of an individual organism. It can refer to both editing within the genome and material brought in from outside the genome

   - **Gene editing** or genome editing is considered to be a precise and efficient way of making specific changes to the DNA of a cell or organism. It can be used to add, remove or alter DNA in the genome.

3. The three questions you requested advice on are[2]:

   - where lower regulatory hurdles ought to be considered to enable medical uses that would result in no inheritable traits
   - where lower regulatory hurdles ought to be considered to enable laboratory tests where any risk is mitigated by containment
   - whether conflicting or inconsistent definitions across the regulatory framework need to be clarified.

4. In New Zealand, genetic modification is primarily regulated under the Hazardous Substances and New Organisms 1996 (HSNO), although other legislation may also play a role depending on the application of the GM technique.

   The Hazardous Substances and New Organisms Act 1996

5. The HSNO Act emphasises precaution in the regulation of organisms that meet the definition of a GMO. The Environmental Protection Authority (EPA) is the regulator responsible for issuing 'new organism'[3] approvals to use GMOs in containment, or for release.

6. The HSNO Act has never had a full review and the legislation therefore has not evolved since 1998 (apart from minor changes). The Act sets regulatory requirements based on the GM

[1] *In vitro* means taking place in a test tube. This in contract to *in vivo* modification, which occurs inside an organism.

[2] http://www.scoop.co.nz/stories/PA1908/S00129/government-responds-to-report-on-gene-editing.htm

[3] A new organism is defined under HSNO and includes, but is not limited to, organisms that were not present in New Zealand prior to 1998 and genetically modified organisms.

technique used to create an organism. Technique is not correlated with risk, so the framework can result in organisms being regulated disproportionately to the risk they actually pose (an issue raised by the Royal Society and many other parties). Our June 2018 briefing provides further background on New Zealand's regulatory framework [refer 18-B-04195].

The regulation of GM in medical uses

7. The existing regulatory framework does not provide simple options to reduce regulatory approval processes for the use of gene editing in medical uses that results in no inheritable traits (referred to as *non-hereditary traits* in the following paragraphs).

8. The Hazardous Substances (Organisms Not Genetically Modified) Regulations 1998 (Not-GM Regulations) provide a mechanism for exempting GMOs from regulation under HSNO. The regulations list organisms derived from specific GM techniques in use prior to 1998 as **not** genetically modified and, therefore, not subject to any form of regulatory control (see Appendix 2). The regulations do not distinguish by the type of organism modified (eg. human cell), the purpose of the modification (medical uses), or by the outcome of a modification (eg. non-hereditary modifications that cannot be passed down between generations). Adding techniques to the Not-GM regulations, specifically for medical uses, is not well aligned with the regulations as currently framed, as the regulations are focussed on the type of GM technique. They are agnostic on use and outcome.

9. Reducing, or streamlining, approval processes under HSNO to enable the use of GMOs for medical purposes (including those that result in *non-hereditary* changes) would require fundamental change to the HSNO Act and its associated regulations. Options to enable such a change may include:

   - a framework that considers the outcome of a modification (eg. the GMO that is produced and the traits/risk that it possesses)[4] rather than an approval process that is triggered purely because a particular type of genetic technique has been used (as is currently the case)
   - a risk–tiered approach[5] for the use of GM in medical research through the introduction of regulations that prescribe circumstances in which a HSNO approval to undertake a clinical trial involving a GMO is not required, for example, where the environmental risk is negligible (more information on risk-tiering is in Appendix 3).

The regulation of GM in contained research

10. The Prime Minister's Chief Science Advisor (PMCSA) suggested there were concerns amongst the science community about the level of reporting required in relation to the use of GM in contained laboratories. On her recommendation, we spoke to scientists that carry out research in laboratories.

11. Based on our conversations with researchers, and other government departments, we consider the regulatory framework for GM in contained facilities is generally working. Researchers we spoke to acknowledged recent improvements in EPA processes, and did not identify major barriers to the use of gene editing and other novel techniques in containment.

12. We consider some duplication exists where organism-focussed approvals under HSNO, and

[4] For example, the Australian system describes GMOs that are generally exempt from regulation (not just in containment) based on the outcome of the modification - Schedule 1 of Australia's Gene Technology Regulations 2001 describes Organisms that are not genetically modified organisms

[5] The Royal Society advocated a risk-tiered approach in its August 2019 report (see rec 4 making regulation proportionate to risk) although this was not specific to medical uses.

facility-based containment standards[6] (under HSNO or the Biosecurity Act 1993), both prescribe measures to prevent the escape of organisms, including GMOs, to the environment. This duplication may be behind comments concerning regulatory reporting requirements. However, work is underway to streamline approval processes (see Appendix 4), and to reduce the administrative burden on researchers:

- the EPA has issued generic 'institutional low-risk approvals' to two of our largest research institutes that have significantly reduced the need for new HSNO approvals
- the Ministry for Primary Industries (MPI) and the EPA are modernising facility containment standards to ensure a level of consistency between different standards and the requirements of HSNO approvals.

13. Addressing this issue to further reduce regulatory processes for research in containment would require significant amendments to the HSNO framework. This could follow a risk-tiered approach to contained GM research similar to the Australian system[7], which exempts certain 'low-risk' contained research from requiring a specific approval from the Australian Gene Technology Regulator (see Appendix 3).

Definition of organism – human cell

14. We focus on definitional issues relating to the use of GM in medical uses in response to the Royal Society's reports that question the role of HSNO in regulating the genetic modification of human cells for medical purposes. Anybody wishing to genetically modify human cells for medical purposes requires an approval from the EPA - approvals are required for GMOs in containment, clinical release trials, and for use in medicines.
15. Clinical trials involving GMOs (including modified human cells), including the Malaghan Institute's CAR-T[8] cell trial, take place outside containment and require approvals from the EPA and Medsafe (Appendix 5 provides information on the CAR-T cell application). These regulators perform two separate functions:
    - the EPA assesses risks to the environment and the wider population (ie. the patient's family, the community) under HSNO.
    - Medsafe considers impacts on a patient and the quality, safety and efficacy of medicines under the Medicines Act 1981[9].
16. Researchers have questioned the need for a dual approval process, particularly where a medical trial involves a GMO that poses a low-risk to the community and the environment. This has led to a suggestion that human cells should be removed from the definition of organism under HSNO.
17. Removing human cell from the definition of an organism would exempt any GM research (contained research or release) involving human cells from the EPA's process. This would treat the modification of human cells differently to GM research involving other organisms

[6] There are facility standards for plants, invertebrates, farm animals, microorganisms, zoo standards. Indoor containment facilities such as laboratories, glasshouses, and animal facilities, are approved to specific physical containment levels.

[7] The Australian regulatory system incorporates a risk-tiered approach to contained GM research by categorising dealings according to their level of risk (dealings that are exempt, dealings that must be notified, and dealings that require approval). Dealings essentially refer to any activities that involve GMOs, for example conducting experiments, breeding GMOs, importing GMOs et

[8] Chimeric antigen receptor T-cell therapy or CAR-T cell therapy in short.

[9] Depending on the application, Medsafe's approval process is supported by, for example, the Health and Disability Ethics Committee, and/or the Health Research Council Gene Technology Advisory Committee

including plants, animals, and microorganisms. Such a change would require a review of several Acts[10] to ensure that any potential risks and unintended consequences are carefully managed.

18. We consider definitional issues, including those affecting human cells, should be addressed as part of a broader review of the regulatory system. The HSNO definition of a GMO represents a more than thirty-year old understanding of GM technology (it refers to genetic material modified *in vitro*). In some cases, the definition of GMO may be unnecessarily restrictive, in others it may not capture new GM techniques that do not rely on *in vitro* modification. Definitions should be broad enough to capture all organisms and techniques that pose a risk, while distinguishing those changes that have negligible risks.

Conclusion – we recommend a broader discussion on New Zealand's regulatory framework

19. Due to the nature of the regulatory framework, fundamental changes to HSNO would be required to streamline, or reduce, regulatory processes for the use of GM in medical research or in containment. Such changes are likely to attract a high level of public interest. The recent release of the final Royal Society report has received significant media attention and attracted commentary from various scientists and political parties.

20. Changes focussed solely on medical applications, and contained research, will not address broader issues with our regulatory settings [refer 18-B-04195]. It would also create a level of disparity between the regulation of medical uses, and other applications of GM that would likely continue to operate under older aspects of the HSNO framework (for example, if a risk-tiered approach was only considered for medical uses).

21. A comprehensive review of New Zealand's approach to regulating genetic technologies is likely to offer greater benefits than one focussed solely on research in containment, or the use of GM technology for medical purposes. This is the approach taken by Australia, which has recently conducted the third review of its Gene Technology Scheme. A regulatory review has also been advocated by the Royal Society, the PMCSA, and other members of the research community. A similar assessment in New Zealand could identify areas where changes to regulation may be required.

22. We consider a regulatory review could be framed within:

    - a context that not only considers the risks posed by these technologies but also the opportunities that emerging technology may offer for medical uses, New Zealand's primary sector in the context of a changing climate, and continued threats to our native species (*our preferred approach*), **OR**
    - a narrower context within the existing HSNO risk-management framework to ensure regulation adequately manages new technologies in a risk proportionate manner, and to ensure it is flexible enough to deal with changing technologies.

23. A review would be initiated by a public conversation and must take into account the moral and ethical issues, including societal preferences (not just western science), Mātauranga Māori and other factors that are important to New Zealand including our economic reliance on the primary sector and tourism. The Royal Society considers that regulations should be informed by wide public engagement (see rec 5 community engagement principles and education)[11], and we concur that such engagement should occur as part of a policy review prior to proposing changes to our regulatory regime.

[10] Including, but not limited to, Human Assisted Reproductive Technology Act 2004, Medicines Act 1981, the HSNO Act 1996, and the Human Tissues Act 2008

[11] https://www.royalsociety.org.nz/assets/Uploads/Gene-Editing-Legal-and-regulatory-implications-DIGITAL.pdf

Consultation and Collaboration

24. Input into this briefing has been received from the following agencies the Ministry for Primary Industries, Medsafe, and the Ministry of Health.
25. The EPA has undertaken an operational and factual review of the material.
26. We also approached a number of researchers to informally seek their input into the above analysis relating to containment approvals.

Risks and mitigations

27. The above analysis is high-level only based on the information available to us in the timeframe. The 'findings' are therefore presented as a basis for potential future analysis.

Legal issues

28. No legal issues have been identified.

Financial, regulatory and legislative implications

29. A number of the approaches raised would have regulatory and legislative implications.
30. If further analysis is required there will also be financial implications for the Ministry (and other agencies), as a new work programme will need to be put in place.

Recommendations

31. We recommend that you:

a. **Note** in the short-term:

i. The Not-GM Regulations, as currently constructed, do not provide a simple option to reduce approval processes for the use of GMOs in medical research that would result in no inheritable traits, including GMOs developed by gene-editing.

ii. The regulatory framework for GM research in containment is generally working. Operational improvements have been initiated to streamline approval processes for GM research in containment where appropriate.

iii. Changing the definition of organism, by removing human cell, is likely to have unintended consequences because it would remove the EPA's assessment of risks to the environment and wider population.

b. **Note** fundamental changes to HSNO are required to streamline, or reduce, regulatory processes for the use of GM in medical research or in containment. This would require amendments to existing regulation and/or the development of new regulations and changes to HSNO.

c. **Note** we recommend a broader review of New Zealand's regulatory framework that not only considers the risk posed by emerging technologies, but also the opportunities that such technology may offer for medical uses, New Zealand's primary industries, the protection of our environment, and our ability to adapt to climate change.

d. **Note** a public conversation should occur before proposing changes to our regulatory regime. Initially, the Ministry will work to identify the benefits and risks posed by emerging GM technologies, and the gaps and limitations of our regulatory framework. This work, in conjunction with information produced by the Royal Society and other parties, will provide context to inform wider public engagement.

e. **Agree** to provide Ministry for the Environmental officials with direction on the next steps.

Yes/No

f. **Refer** this briefing for noting to the Hon Damien O'Connor, Minister of Biosecurity and to Hon Dr David Clark, Minister of Health.

Yes/No

g. **Meet** with officials from the Ministry for the Environment, the Environmental Protection Authority, Medsafe, the Ministry of Health, the Ministry for Primary Industries, and the Office of the Prime Minister's Chief Science Advisor for further discussion.

Yes/No

h. **Agree** that this briefing and appendices will be released proactively on the Ministry for the Environment's website within the next eight weeks.

Yes/No

Signature

Glenn Wigley
Director
Natural and Built System

Hon David Parker
Minister for the Environment **Date**

Appendix 1: Material considered in preparing this briefing

1. Your request follows the release of the final report by the Royal Society Te Apārangi in their inquiry on Gene Editing in Aotearoa called *Gene editing – Legal and regulatory implications*[12]. Relevant to this briefing the report notes that:
   - the development of a shared set of definitions across the regulatory system would be a useful first step to enabling a constructive debate and determining the degree of public support for use of genetic technologies for different applications
   - issues such as definitions, complexity and inconsistency in the current legislation, and accommodating the advances in gene technologies, would be more effectively achieved with a risk-tiered approach commensurate with risk
   - the purpose of the HSNO Act is to protect the environment and health and safety of people and communities, and that it was never intended for new organisms to include human beings.
2. An academic paper, *Gene editing in Aotearoa – Legal considerations for policy makers*[13], associated with the Royal Society's report states that human gene edited tissue is classified as genetically modified and would thus be a new organism according to HSNO. It argues that this is an oversight following the removal of transitional provisions in 2004 and that therefore the term 'human cell' should be deleted from the definition of organism in HSNO, and dealt with in the Human Tissues Act 2008.
3. The PMCSA wrote a briefing to the Prime Minister to accompany the Royal Society's report in which she made a number of observations. In relation to the topic of this briefing, she suggests that there is a large consensus for a reduction in regulatory reporting requirements for GM technology used in the laboratory where any risk is mitigated by containment. Her briefing also notes that definitions of key concepts are inconsistent across acts. She suggests that, at the intersection of the Medicines Act and HSNO, there is confusion about whether modifying human cells creates a legally defined 'new organism', and whether a human being receiving modified cells could then not leave containment ("is Granny a GMO?")[14].
4. Following your visit to the Malaghan Institute, you received a letter from its Director which raises the following issues:
   - CAR-T cell therapies should not be regulated as GMOs (or at least not as 'non-low risk' GMOs) under HSNO as a somatic cell[15] such as a CAR-T cell is not a life form, they carry no environmental risk, and the modification cannot be passed onto other people (except in the rarest of circumstances)
   - In the meantime, applications to the EPA for the use of GMOs for clinical trials or clinical uses should be handled expeditiously
   - Regulatory activities should not be duplicated between EPA, Medsafe, Health and Disability Ethics Committees and the Gene Technology Advisory Committee.
5. We have also considered related issues being considered by the Australian Department of

[12] https://www.royalsociety.org.nz/what-we-do/our-expert-advice/all-expert-advice-papers/gene-editing-legal-and-regulatory-implications/

[13] Everett-Hincks, J.M. and Henaghan, R.M., Gene Editing in Aotearoa – Legal considerations for policy makers

[14] The HSNO Act explicitly excludes human beings from the definition of organism under the HSNO Act. Therefore, humans receiving medical treatments containing GMOs are **not** themselves considered GMOs

[15] Any biological cell forming the body of an organism that is not a reproductive cell.

Health, in their current issues paper setting out implementing recommendations of the Third Review of the National Gene Technology Scheme[16]. This paper considers the regulatory oversight of the technology to genetically modify humans, either in ways that are not able to be passed on to offspring (somatic changes), or those that are heritable (germline changes).

6. The Australian Gene Technology Scheme was not designed to regulate humans, including those who receive germline or somatic therapies and those who inherit modified traits. The issues paper notes, however, that while scientific advances in gene technology provide potential opportunities to treat significant medical conditions and genetic diseases, there are ongoing moral and ethical debates which must be considered. This includes consideration of regulatory oversight of the technology to genetically modify humans, either in ways that are notable to be passed on to offspring (somatic changes), or those that are heritable (germline changes). The paper also states such considerations also need to take account of the changing international environment, as well as the benefits of national collaboration across the health sector, to identify appropriate mechanisms for managing human genetic treatments.

[16] https://consultations.health.gov.au/best-practice-regulation/implementing-recommendations-of-the-third-review-o/supporting_documents/September%202019%20GT%20Issues%20Paper%20Phase%201.pdf

Appendix 2: Regulation 3 of Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998

3 Organisms not genetically modified

(1) For the purposes of the Act, the following organisms are not to be regarded as genetically modified:

(a) organisms that result solely from selection or natural regeneration, hand pollination, or other managed, controlled pollination:

(b) organisms that are regenerated from organs, tissues, or cell culture, including those produced through selection and propagation of somaclonal variants, embryo rescue, and cell fusion (including protoplast fusion):

(ba) organisms that result from mutagenesis that uses chemical or radiation treatments that were in use on or before 29 July 1998:

(c) organisms that result solely from artificial insemination, superovulation, embryo transfer, or embryo splitting:

(d) organisms modified solely by—

(i) the movement of nucleic acids using physiological processes, including conjugation, transduction, and transformation; and

(ii) plasmid loss or spontaneous deletion:

(e) organisms resulting from spontaneous deletions, rearrangements, and amplifications within a single genome, including its extrachromosomal elements.

(2) Despite anything in subclause (1)(d), if nucleic acid molecules produced using *in vitro* manipulation are transferred using any of the techniques referred to in subparagraph (i) or subparagraph (ii) of subclause (1)(d), the resulting organism is a genetically modified organism for the purposes of the Act.

Appendix 3: Risk-tiering for medical uses and contained research

Medical uses

1. The Australian system also describes GMOs that are generally exempt from regulation (not just in containment) based on the outcome of the modification. Australia recently updated its list of exempt GMOs to include organisms produced using some new gene editing approaches[17]. From 8 October 2019, organisms modified through unguided repair of site-directed nuclease activity, also known as SDN-1 organisms, were excluded from regulation as GMOs. Unguided repair means that no nucleic acid template was added to cells to guide genome repair following SDN application.
2. HSNO Act approvals are required for all GMOs with the exception of those made using techniques specifically listed in the Organisms Not Genetically Modified Regulations 1998 (Not GM regulations). This creates a disparity in the regulatory approval process where new genetic technologies, not listed in the 'Not GM' Regulations, are subject to a high level of regulation regardless of the risk a modification may pose. This is a key point of difference from the Australian approach that exempts GMOs primarily on the basis of outcome (rather than on the technique alone).
3. The Ministry of Health has been leading consultation on the draft Therapeutic Products Bill (TPB), intended to replace the Medicines Act 1981. The aim of the Bill is to modernise the regulatory arrangements for medicines, and to provide regulation of all therapeutic products[18]. This includes medical devices and cell and tissue therapies which are currently not fully regulated in New Zealand. The new regime is expected to be flexible enough to ensure effective control over the quickly evolving technology used in therapeutic products, while also being as efficient and cost-effective as possible.
4. Medsafe also has a working group looking at the regulation of cell and tissue therapies under the Medicines Act 1981, and are using the Malaghan Institute's work on CAR-T cells as a case-study.
5. The Therapeutic Products Bill proposes to regulate the cell and tissue sector using the European approach, which distinguishes between cells and tissues that are minimally manipulated and those that are engineered. The European approach generally mirrors a global approach.
6. The policy intent of the Bill is to continue the interface with HSNO and to allow[19]:
   - The therapeutic products regulator to give HSNO approval for qualifying new medicines with low-risk new organisms (HSNO regulates GMOs as new organisms).
   - A parallel process involving both the HSNO and therapeutic products regulator for qualifying new medicines with higher-risk new organisms.
7. The Bill may offer an opportunity to shift to a more risk-tiered approach to the consideration of GMOs in medicines, therapeutic products[20], and clinical trials. However, the policy intent of the Bill (as stated in the TPB consultation document) proposes a risk-tiered approach only for medicines and therapeutic products, and not for the use of GMOs in clinical trials.

[17] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/amendments+to+the+regs+2019

[18] Therapeutic products are defined in the Therapeutics Products Bill.

[19] Note the interface between HSNO and the TPB has not yet been drafted.

[20] Therapeutic products are those that are prescribed for clinical use after a pre-market approval by the therapeutic products regulator.

Contained research

8. The Australian regulatory framework includes three levels of contained research that must not result in the release of a GMO to the environment (described as 'dealings'[21]):
   - *Exempt dealings* set out in regulations – very low risk GMO research, with no requirement for approval or reporting
   - *Notifiable low risk dealings*, assessed by Institutional Biosafety Sub-Committees[22] and reported annually to the regulator
   - *Dealings not involving intentional research*, need to be approved (90 working days).
9. Research using GMOs requiring specific approval from the Australian Gene Technology Regulator is generally higher risk, and includes research with pathogenic organisms, or GMOs that contain genes from pathogens or genes that produce toxins. This type of research is undertaken in containment facilities certified by the regulator. The regulator also maintains a GMO register that provides information on all GMOs notified or licensed by the regulator. Exempt dealings are not listed on the register.
10. The HSNO Act does not provide powers to exempt low risk GMO containment research from an approval process. However, low risk genetic modifications that meet the criteria listed in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003 (Low-Risk GM regulations) may undergo a rapid approval process. For these modifications, the EPA typically makes a decision on an application within 10 working days of formal receipt, with a notification of the decision no later than 30 working days after consideration of the application.
11. The Low-Risk GM Regulations, as they are framed currently, do not provide a mechanism to exempt low risk GMOs from an approval process. The regulations are simply a framework for establishing when a rapid assessment is allowed under the HSNO Act.
12. MPI is also beginning a review of the Biosecurity Act 1993 which will include consideration of the relationship between the HSNO Act and the Biosecurity Act 1993. MfE will work with MPI to identify issues we may want to take into this review process, for example the regulation of new organisms (including GMOs) under both Acts.

[21] Dealings refer to the definition of 'deal with' under Australia's Gene Technology Act 2000. Dealings essentially refer to any activities that involve GMOs, for example conducting experiments, breeding GMOs, importing GMOs etc.

[22] In New Zealand, the EPA has moved away from authorising IBSCs, in part due to interpretation issues regarding what is and isn't defined as a GMO under HSNO. Researchers we spoke to also commented on a shift away from the use of IBSCs in New Zealand universities.

Appendix 4: Operational improvements for contained research

1. The importation and development of GMOs in containment requires EPA approval under HSNO. The approval process requires the EPA to assess an organism's specific risks to the environment and to the health and safety of people and communities.
2. Facilities, where GM research occurs, must also be approved by MPI to specific containment standards under the Biosecurity Act 1993 or HSNO. These standards aim to ensure the overall integrity of a facility.
3. Researchers questioned the value in requiring specific HSNO approvals for low risk genetic modifications[23] (including during medical experiments in containment24), when research takes place in facilities approved to MPI-approved containment standards. In some cases the approval process for contained GM research may be disproportionate to the level of risk, especially where the use of approved containment facilities appropriately mitigates the risk of GMO release
4. A single research facility may hold dozens of HSNO approvals, and these may also need to be approved under multiple facility containment standards (where research occurs on different types of organisms). Many of the requirements under containment standards are also listed as conditions in GMO containment approvals issued under HSNO. HSNO Act approvals can also vary in their level of prescription or detail, because approvals do not expire and techniques used for experimentation evolve over time. This creates administrative burden for facility operators and MPI as the enforcement agency under both regimes.
5. The EPA has already made operational changes that have the effect of reducing regulatory burden on the research community, in particular the introduction of generic approvals for larger institutes. Two of our largest universities (Auckland and Otago) already hold generic HSNO approvals, which cover the vast majority of GM research undertaken at these locations. For these institutes, new HSNO approvals are rarely required. In our conversations with researchers, we heard that these 'institutional low-risk approvals' have eased the application burden. To date, there have been no negative effects as a result of these operational changes from a risk management perspective.
6. Large-scale generic approvals do not remove the requirement to comply with HSNO controls and the conditions set through the facilities standards, although they do reduce the number of approvals a facility must comply with. The value of the multi-approval approach (an organism requiring HSNO approval and a facility meeting containment standards) could be questionable, if containment standards effectively mitigate the risk of the organism.
7. EPA and MPI are undertaking work to modernise facility containment standards by shifting to a more performance-based approach (that focuses on achieving outcomes rather than prescribing methods), which may reduce some of the paperwork that scientists have expressed frustration with. This is likely to streamline laboratory approval processes further, and ensure a level of standardisation between HSNO approval conditions (which are generally more outcome based) and containment standards.

[23] Low-risk genetic modification is defined in regulation 4 of the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003

[24] The Malaghan Institute suggested that HSNO approval for 'low-risk' GMOs should be waived, including all modifications to alter the normal expression of cellular genes (e.g. gene inactivation or loss of expression, constitutive expression, dysregulated or ectopic expression, etc) to include oncogenes and tumor suppressor.

Appendix 5: Qualifying medicines and Malaghan's CAR-T cell trial

1. The HSNO Act does not distinguish new organisms, including GMOs on the basis of purpose/use, except for certain qualifying medicines (human and veterinary).
2. A qualifying medicine is a medicine or new medicine, defined in section 3 of the Medicines Act, that is or contains a new organism (including GMOs) and meets the release criteria in of the HSNO Act s38I(3). The EPA can approve qualifying medicines for release if it is highly improbable that:
   - the dose and routes of administration of the medicine (human or veterinary) would have significant adverse effects on the health of the public or any valued species, and
   - the qualifying organism (the GMO contained in the medicine) could form an undesirable self-sustaining population and would have significant adverse effects on the health and safety of the public, or any valued species, or natural habitats, or the environment.
3. The EPA has approved five qualifying medicine applications[25].These qualifying medicines must all also be approved by Medsafe under the Medicines Act 1981.
4. Medsafe and the EPA have an established process for approvals relating to qualifying medicines. Medsafe is aware of the need to continue streamlining the regulatory approval process to enable innovation (i.e., not create regulatory barriers through inefficiency).
5. The most recent qualifying medicine approval was issued to the Malaghan institute for its application to use live genetically modified autologous[26] human chimaeric antigen receptor T cells (CAR-T cells) as an experimental medicine. The Malaghan Institute expressed concern that the approval process under the HSNO Act duplicated other approval processes, that it was unduly lengthy, and that the HSNO Act should not regulate CAR-T cells on the basis that they carry no environmental risk and the modification cannot be passed onto other people.
6. The decision on the application was made in ten calendar days. The application was received on 16 September 2019 and the decision to release with controls was notified on September 26 2019. The official application process was indeed rapid. We understand that the pre-application stage (which is not a formal step under the HSNO Act) was lengthy. Applicants tend to consider the pre-application and formal stages of a process as part of the overall time taken to obtain an approval.
7. During the pre-application process, EPA staff worked with the applicant to enable Malaghan to submit a comprehensive application, to ensure that facilities were adequate, and that the laboratory and researchers had the required systems in place or were able to put them in place. Time was also taken to assess technical material in the application documents, and in awaiting further information from the applicant. The EPA also considered other legislation, standards and accreditations that applied to Malaghan's trial to ensure there was no duplication in the controls imposed by the EPA.[27]
8. Malaghan's CAR-T cell trail was the first of its kind in New Zealand, and it is expected that future CAR-T cell applications for experimental medicines can be progressed faster.

[25] Note a veterinary medicine that met all the qualifying organism criteria was approved instead under section 38A of the HSNO Act in 2008. The qualifying medicine sections of the Act were not used until 2016, despite being added by amendment in 2003.

[26] Autologous cells are those that were obtained from the same individual that receives the treatment.

[27] See EPA Staff Assessment Report on application APP203750: To release genetically modified live Chimaeric Antigen Receptor T-cells for use in a Phase 1 dose escalation clinical trial to examine safety and efficacy in patients with relapsed and refractory B-cell lymphomas.

Update on the regulation of genetically modified organisms in New Zealand

Date Submitted:	17/2/2021	Tracking #: 2021-B-07485	
Security Level	In confidence	MfE Priority:	Non-Urgent

	Action sought:	Response by:
To Hon David Parker, Minister for the Environment	Forward to Minister Twyford and note this briefing	3/3/2021
Forward to Hon Phil Twyford, Associate Minister for the Environment	Note this briefing	

Actions for Minister's Office Staff	**Return** the signed report to MfE.
Number of appendices and attachments 4	Titles of appendices and attachments (ie separate attached documents): 1. A brief introduction to genetics and genetic modification 2. GM strategies of relevance to New Zealand that rely on the use of gene technologies and their approximate stage of development 3. 2018-B-04195 - Genetic Technology – Overview and Next Steps 4. 2019-B-06162 - Advice on simplifying regulation for genetic modification in containment and for medical uses

Ministry for the Environment contacts

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Director	Glenn Wigley	027 491 7806	

Update on the regulation of genetically modified organisms in New Zealand

Key Messages

1. As requested, this briefing updates Minister Twyford on the regulation of genetically modified organisms (GMOs) in New Zealand. This briefing includes an outline of New Zealand's GMO legislative framework, stakeholder views, recent domestic and international developments, and high-level issues with current legislation.
2. In comparison to most other countries New Zealand strictly regulates the importation, development and release of GMOs. Similarly, while many countries have updated their regulations in light of recent technological developments, New Zealand's GMO legislative framework has not been reviewed for nearly 20 years.
3. According to the most recent BioTech New Zealand survey, a large number of companies and research groups in the biotechnology space consider New Zealand's GMO legislation to be unduly restrictive. In their view this restrictiveness is holding back innovation and potentially causing New Zealand companies to fall behind their overseas competitors.
4. In contrast, a number of groups are opposed to changes to New Zealand's GMO legislation due to a number of reasons. These reasons include potential impacts to New Zealand export revenues, effects on New Zealand organic producers, and potential risks to human health and the environment. In regards to Māori viewpoints, there is no one Māori view on genetic modification and the views expressed by Māori are often nuanced, taking into account a range of considerations and concepts.
5. There was increased media interest in genetic modification (and gene editing more specifically) in 2019 following the release of reports by the Interim Climate Change Committee and the Royal Society Te Apārangi. The draft report from the Interim Climate Change Committee noted that our GMO legislation may be acting as a barrier to reducing our agricultural emissions. The Royal Society reports also increased calls to review our GMO legislation. COVID-19 has increased media coverage of genetic technologies, such as genetic sequencing and innovative vaccines.
6. The Climate Change Commission's recently released draft report included a number of recommendations to the Government to reduce biogenic agricultural emissions. In particular, under 'Time-critical necessary action 4', the report recommend that in the first budget period (2022 - 2025) the Government:
    a. Review current arrangements and develop a long-term plan for targeted research and development of technologies (including evaluating the role of emerging technologies such as genetic engineering) and practices to reduce biogenic emissions from agriculture.
    b. Review and update processes and regulatory regimes to ensure that new emissions reducing technologies and practices can be rapidly deployed as and when they are developed.
7. Additionally, as part of this time-critical necessary action, the Climate Change Commission recommended as a progress indicator that the:
    a. Government to have, by 31 December 2022, reviewed and amended processes and regulatory regimes for new emissions reducing technologies and practices.

8. There is a growing recognition of utilising GMOs to address environmental issues, including in the areas of climate change and biodiversity. A number of technologies have recently been developed that have direct relevance to specific environmental issues in New Zealand, including Kauri dieback disease and plastic waste. Our stringent legislation may mean that we miss out on these and other future opportunities.
9. It is the Ministry for the Environment's view that a suite of tools will be required to address the complex environmental issues faced by New Zealand. It is also the Ministry for the Environment's view that there is no fundamental reason, based on the evidence available, for excluding genetic modification from this future suite of tools.
10. A review of the current GMO legislative framework is not a part of the Government's manifesto for this term. Additionally, the Ministry for the Environment (the Ministry) is currently not resourcing a proactive work programme to review New Zealand's GMO legislative framework.

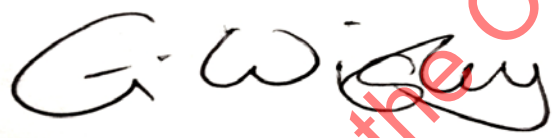
Recommendations

11. We recommend that you:

    a. **Forward** this briefing to the Associate Minister for the Environment.

Yes/No

Signature



15 February 2021

Glenn Wigley
Director, Waste and Resource Efficiency **Date**

Hon David Parker
Minister for the Environment **Date**

Update on the regulation of genetically modified organisms in New Zealand

Supporting material

Purpose

1. As requested, this briefing provides the Associate Minister for the Environment with an update on the regulation of genetically modified organisms (GMOs) in New Zealand. This briefing includes an outline of New Zealand's GMO legislation, stakeholder views, recent domestic and international developments, and high-level issues with current legislation. Also included for the Associate Minister's reference are two briefings previously provided to you relating to genetic modification and our GMO legislation.
2. This briefing is one of a number of briefings requested by the Associate Minister for the Environment on topics relating to the Associate Minister's delegated responsibilities. The information provided in this briefing is intended to support the Associate Minister's work with you on policy development and other matters relating to the Hazardous Substances and New Organisms Act 1996 (the HSNO Act), as per his Associate Minister Delegation.
3. This briefing focuses on environmental issues and gene technologies that may address these issues, in line with the Ministry's area of focus and expertise. As such, this briefing does not cover applications of gene technology in areas such as healthcare and fundamental science research, which are likely to far exceed the number of environmental applications.[1]

Context

An overview of New Zealand's GMO legislative framework

4. GMOs are regulated in New Zealand under the HSNO Act. Under the HSNO Act, a GMO is defined as any organism in which any of the genes or other genetic material have been modified by *in vitro* techniques.[2] This definition also covers any organisms that have inherited similarly modified genes or genetic material.[3]
5. Broadly, genetic modification refers to a range of technologies that manipulate an organism's genetic material (generally DNA), but doesn't include techniques such as conventional breeding techniques. Because some conventional breeding techniques would be captured by the aforementioned GMO definition, the HSNO (Organisms Not Genetically Modified) Regulations 1998 (the Not-GM regulations) sets out an exhaustive list of techniques that are exempt from regulation. A brief explanation of genetic modification,

[1] There are several thousand genetic disorders and many more diseases that have a fundamental genetic cause. For more information see: Jackson, M., Marks, L., May, G. H., & Wilson, J. B. (2018). The genetic basis of disease. *Essays in biochemistry*, *62*(5), 643-723.

[2] *In vitro* generally refers to occurring outside of an organism's natural environment, such as in a test tube or petri dish.

[3] The full statutory definition of a genetically modified organism is: "any organism in which any of the genes or other genetic material have been modified by *in vitro* techniques; or are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques" (HSNO Act s2(1)).

genetics and new technologies such as gene editing have been included in Appendix 1 for your reference.

6. The Ministry for the Environment administers the HSNO Act, including making regulatory amendments to the Act. The Environmental Protection Authority (EPA) is the regulator tasked with the operational aspects of the HSNO Act, including the assessment and approval of applications to import, develop, field test and release GMOs in New Zealand. The Ministry for Primary Industries (MPI), as the official enforcement agency, also assesses, approves and enforces applications relating to the proper containment of GMOs under the Biosecurity Act 1993.

7. New Zealand also has a number of international obligations relating to GMOs. Chief among these is the Cartagena Protocol on Biosafety (the Protocol) to the Convention on Biological Diversity. The Protocol aims to ensure the safe handling, transport and use of living modified organisms between countries. New Zealand is one of 171 parties to the Protocol and has implemented its obligations through the HSNO Act and other legislation and regulations.

8. The HSNO Act sets out specific provisions for assessment and decision-making processes relating to hazardous substances and new organisms (which include GMOs). In practice, GMO applications must meet minimum standards in regards to adverse effects and evidence-based risk/benefit assessments are used in the decision-making processes applied by the EPA.

9. Those exercising functions and powers under the Act are also directed by the Act to take a precautionary approach when managing adverse effects from GMOs. However, this is only applicable where there is scientific and technical uncertainty about those adverse effects.[4]

10. New Zealand's regulation of GMOs is generally considered to be highly restrictive in comparison to other countries and jurisdictions. A number of countries more lightly regulate GMOs than New Zealand. These countries include Australia, Canada, Japan, South Africa, Argentina and the United States. In contrast, a number of countries and jurisdictions highly regulate GMOs like New Zealand, including the European Union (the EU), Russia and Norway.

11. There are a number of reasons why New Zealand's GMO legislation is considered highly restrictive. These include, in general, the administrative and financial requirements to obtain approval for GMOs across all application types, and more specifically, the high assessment thresholds for the full or contained release of GMOs and the application requirements for contained research using low-risk GMOs.

Stakeholder views in favour of changes to GMO legislation

12. Many groups and companies in the New Zealand biotechnology industry, and those in industries that directly benefit from biotechnology, consider New Zealand's GMO legislation to be unduly stringent. In their view this stringency is holding back innovation and potentially causing New Zealand companies to fall behind their overseas competitors.

13. BioTech New Zealand recently released a report on New Zealand's growing biotechnology sector in 2020.[5] New Zealand's biotechnology sector includes 211 companies with an

[4] Section 7 of the HSNO Act outlines how a precautionary approach is to be applied: 'All persons exercising functions, powers, and duties under this Act including, but not limited to, functions, powers, and duties under sections 28A, 29, 32, 38, 45, and 48, shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.'

[5] BioTech New Zealand is a membership-funded organisation whose aim is to 'maximise New Zealand's bioscience and technology capability to create a strong New Zealand bioeconomy.' Its members currently include

estimated $2.7 billion in annual revenue that support a bioeconomy worth an estimated $49.4 billion.

14. This report surveyed the biotechnology sector on opportunities and challenges in the New Zealand context. New Zealand biotechnology companies surveyed considered the current GMO legislation as the second most significant constraint to biotechnology research and development in New Zealand, second to access to capital.

15. In addition, current GMO legislation was considered the third most significant constraint to biotechnology commercialisation in New Zealand, behind access to capital and lack of distribution and marketing channels. Of relevance, LanzaTech have cited New Zealand's GMO legislation as one of the reasons they relocated overseas.[6]

16. In addition to industry groups, researchers and representatives of New Zealand universities, research institutes and Crown Research Institutes (CRIs) have previously expressed the view that our GMO legislation is likely to be constraining innovative research. In their view low-risk GMO research conducted in containment and through field trials are regulated at a higher level than justified by the risks entailed. A number of researchers have argued that containment facility approval provided by MPI is sufficient to manage risks, and additional EPA approval processes merely function as an unnecessary administrative burden.

17. Similarly, research and industry stakeholders suggest the high level of regulation is likely to be discouraging potential applicants from submitting an application to the EPA for field trials in containment or the release of a GMO. The perception, however accurate, is that applications are unlikely to be successful or will take too much time, effort and financial backing. Similarly, according to a variety of stakeholders, our assessment framework sets a very high threshold for the full or contained release of GMOs. Currently, no application for a full environmental release has ever been received by the EPA.

18. CRIs such as AgResearch and Scion have highlighted issues in the current legislation that are likely to be holding back research in the field. As an example, due to the constraints of our GMO legislation, in 2017 AgResearch decided to conduct field trials on genetically modified High Metabolisable Energy (HME) ryegrass overseas rather than in New Zealand. Representatives of Scion have commented that current legislation would place significant constraints on potential future field trials of pines gene edited to be sterile.[7] Due to New Zealand's unique environment and weather conditions, field trials are of particular importance to New Zealand biotechnology research.

Stakeholder views not in favour of changes to GMO legislation

19. In contrast to New Zealand's biotechnology industry, researchers and research organisations, a number of organisations, local government bodies and individuals are supportive of New Zealand's strict GMO legislation. These groups include GE Free New Zealand, the Sustainability Council, and the McGuinness Institute. These organisations are opposed to regulatory change that would more lightly regulate GMOs. Their view is that GMOs pose a risk to human health and New Zealand's environment and economy.

AgResearch, BLIS Technologies, Callaghan Innovation, LanzaTech, Malaghan Institute, Mint Innovation, New Zealand Trade & Enterprise, Plant & Food Research, Scion, and five New Zealand universities. The 2020 report can be found at: https://biotechnz.org.nz/wp-content/uploads/sites/16/2020/11/Biotech-Report-2020_online.pdf

[6] One News. (March 2020). Is it time to have a national conversation about genetic engineering? Retrieved from: https://www.tvnz.co.nz/one-news/new-zealand/time-have-national-conversation-genetic-engineering

[7] Sterile pines would reduce future wilding events and potentially increase growth rates by diverting energy from reproduction to wood growth.

20. In particular, the Sustainability Council is opposed to changes to New Zealand's GMO legislation as they view this as a risk to New Zealand's export revenues.[8] In their view, New Zealand exporters benefit from the country's current 'GM free' (genetically modified free) status.

21. GE Free New Zealand advocate for stricter labelling requirements for genetically modified food, a moratorium on genetic modification in New Zealand and restrictions on genetic modification releases at a regional council level. In addition, in their view GMOs pose a risk to human health and the environment.

22. The McGuinness Institute, through correspondence and OIA requests to government agencies, Ministers and MPs, has raised the potential risk of pandemics as a result of genetically modified animals in New Zealand, and has proposed a moratorium on any GMO releases and a systemic review of New Zealand's GMO legislation. Their recommended changes to our GMO legislation would further restrict the development, field testing and release of GMOs in New Zealand.[9]

23. Since 2015, a number of local government authorities have introduced district or regional by-laws prohibiting or limiting the release and/or field trials of GMOs, excluding medical therapies. These authorities include the Hastings District Council, Auckland Council, Whangarei District Council, Far North District Council and Northland Regional Council.

24. New Zealand organic growers have also expressed opposition to the release of GMOs in New Zealand and have supported regional and district by-laws restricting GMO release. Additionally, a number of submissions on the Organic Products Bill, currently in Select Committee, requested that the Bill specifically prohibit the use of GMOs in organic production. Submitters that opposed the use of GMOs in organic production included Organic Farm New Zealand, the Soil and Health Association, Biodynamics New Zealand and GE Free New Zealand.

Māori views on GMO legislation

25. A significant amount of academic research has been conducted on Māori views of genetic modification. This research has shown that there is no one 'Māori view', any more than there is one 'Pakeha view' or 'Pasifika view'. A range of views are held by Māori, ranging from acceptance of genetic modification to rejection.

26. In particular, the views expressed by Māori are often nuanced and take into account a range of considerations and concepts. Te Ao Māori concepts such as *kaitiakitanga* (guardianship), *manaakitanga* (caring or support, an imperative to help those who are sick for instance), *kaupapa* (purpose, of research for instance), *whakapapa* (geneology) and *mauri* (life essence) allow for both ethical and practical considerations relevant to the use of genetic modification.

27. In 2011, the Waitangi Tribunal released its report, *Ko Aotearoa Tēnei*, into the Wai 262 Treaty claim relating to Māori culture, identity and traditional knowledge in New Zealand laws and policies. A number of the key recommendations made in the report that relate to GMOs have subsequently been implemented. The report also highlighted the diverse range of Māori views in regards to GMOs.

[8] Sustainability Council of New Zealand. (January 2021). GM Free Food Producer. Retrieved from http://www.sustainabilitynz.org/genetic-modification/gm-free-food-producer/

[9] McGuinness Institute. (January 2021). Correspondence/OIAs. Retrieved from https://www.mcguinnessinstitute.org/publications/correspondence-oias/

28. In addition, a whole-of-government plan of action to address issues raised in the *Ko Aotearoa Tēnei* report is currently being led by Te Puni Kōkiri. The Ministry will keep you informed should this plan of action have relevance to our GMO legislation.

Need for broad public conversation

29. The Ministry considers there to be a need for a broad public conversation on GMOs in New Zealand for a number of reasons. This year it will be 20 years since the Royal Commission on Genetic Modification released its findings after hearing New Zealander's views on genetic modification. There is a lack of data on the New Zealand public's views on genetic modification and its uses, and the public conversation has in large part been driven by a relatively small number of groups in the space.

30. A broad public conversation on GMOs would deliver value in two respects. It would allow the Ministry and the Government to hear and gauge the views of a range of individuals, groups and organisations in New Zealand. Additionally, a public conversation would also clarify whether there exists a public mandate for changing New Zealand's GMO legislation.

Renewed media and public interest – Interim Climate Change Committee report

31. In July 2019, the Government's Interim Climate Change Committee (the Committee) released its report, *Action on agricultural emissions*. In their report, the Committee raised concerns that our current GMO legislation could be a barrier to lowering agricultural emissions.

32. In response to the Committee's report, the Minister of Agriculture Damien O'Connor commented that it was time to review the current legislation and to have a sensible, mature conversation about genetic modification. In addition, in light of the report's findings, both Climate Change Minister James Shaw and the then-Regional Economic Development Minister Shane Jones agreed that changes to the legislation should be considered.[10] A review of the current GMO legislative framework is not a part of the Government's manifesto for this term.

The question of a market advantage from New Zealand remaining GM free

33. The Minister of Agriculture also highlighted concerns about potential risks to the market advantage New Zealand products receive from New Zealand being GM free. High-end New Zealand GM free products, but not low-end or non-food products, may receive a market advantage if, at the product level, they are GM free.

34. However, research and data that the Ministry has reviewed does not support the claim that products receive a market advantage as a result of New Zealand as a country being GM free. An example of this claim would be that a GM free apple from a GM free New Zealand would receive a market advantage over a GM free apple from New Zealand.

35. Given the potential productivity increases from the use of genetic modification technologies, New Zealand may be missing out on positive effects to GDP and increased export revenue for our primary sectors based on unsupported assumptions regarding a GM free market advantage.[11]

Renewed media and public interest – Royal Society Te Apārangi reports

36. In August 2019, the Royal Society Te Apārangi released four reports on gene editing in New Zealand. Three of these reports considered potential applications of gene editing

[10] However, it should be noted that the Climate Change Minister also argued that consideration should be given to New Zealand's GM-free brand and that there are non-GM solutions that will do the job.

[11] Harris Consulting. Unpublished. "Assessing the Economic Impact of Cisgenic Technologies in Ryegrass" – Report prepared for Pastoral Genomics Ltd, Final Report, December 2009.

within the contexts of healthcare, the primary industries and pest control. In addition, a fourth report was produced on the legal and regulatory environment for genetic technology in New Zealand.

37. These reports generated a moderate amount of media coverage on the topic of gene editing and New Zealand's regulatory framework for GMOs. Renewed calls were made for a review of New Zealand's legislation and a public conversation on genetic modification. This included calls from the former Prime Minister's Chief Science Advisor (PMCSA), Professor Sir Peter Gluckman and the current PMCSA, Professor Dame Juliet Gerrard.

38. Professor Dame Juliet Gerrard subsequently provided a briefing to the Prime Minister on the Royal Society's reports.[12] In addition to arguing for more nuanced thinking than that used in previous debates, Prof. Gerrard supported the view that the current legal and regulatory frameworks are not fit for purpose. In addition, in her view conversations with stakeholders suggest a large consensus for a reduction in regulatory reporting requirements for GMO research conducted in contained laboratories.

Work by the Ministry for the Environment following the Royal Society's reports

39. Following the Royal Society's gene editing reports, the Ministry commissioned research into genetic modification technologies with the potential to address New Zealand's environmental issues. Because genetic modification is a suite of tools that varying in maturity and potential, the purpose of this research was to establish the real state-of-play of these technologies.

40. In the areas of climate change, biodiversity, waste and freshwater, researchers from the University of Auckland identified over 21 technologies and assessed each technology's potential, time-to-market and technical hurdles. These technologies ranged from those that have a long history of use overseas, such as pesticide-free crops, to technologies that are decades away from being usable, such as de-extinction.

41. There were a number of key insights from the research. Carbon capture and recycling technologies that utilise genetic modification are rapidly developing, and some have been successfully commercialised overseas. Genetic modification of endangered species has been successfully applied to the creation of pathogen-resistant species overseas, which has direct relevance for efforts to combat Kauri dieback disease and myrtle rust. A table outlining the current maturity of these and a number of other gene technologies has been included in Appendix 2.

42. A major challenge identified by commercialisation experts interviewed for the research report was the risk of operating in the genetic modification space in New Zealand, owing to the local regulatory environment. However, this risk differed depending on the nature of the technology. The experts also commented that public-good research would be unlikely to be undertaken commercially unless there was investment from the public sector.

43. It is the Ministry's view that a suite of tools will be required to address the complex environmental issues the Government has prioritised addressing, including climate change, biodiversity loss and moving towards a circular economy. It is also the Ministry's view that there is no fundamental reason, based on the evidence available, for excluding genetic modification from a future suite of tools.

COVID-19 has increased media coverage of genetic technology applications

44. Although not a genetic modification technique, genomic sequencing of SARS-CoV-2 has become a highly valuable COVID-19 surveillance tool in New Zealand. Rapid sequencing

[12] A copy of *Briefing to the Prime Minister on the Report on Gene Editing from Royal Society Te Apārangi* can be found at: https://www.pmcsa.ac.nz/archives/

and analysis by the Institute of Environmental Science and Research (commonly known as ESR) has meant probable sources of infection can be established quickly, enabling more effective responses.

45. Similarly, the use of genetic technologies has enabled the rapid development of multiple COVID-19 vaccines overseas. Vaccines developed by Pfizer/BioNTech and Moderna use mRNA (messenger RNA) to trigger a response from the body's immune system. While these vaccines do not use a genetically modified organism nor genetically modify the body's cells, they do utilise the body's internal genetic machinery.[13]

46. Unlike these mRNA vaccines, the vaccines developed by AstraZeneca/University of Oxford and Janssen/Johnson & Johnson do contain genetically modified organisms. These vaccines utilise a genetically modified chimpanzee adenovirus (cold virus) and a genetically modified human adenovirus, respectively. Like other viruses, these adenoviruses insert DNA into the body's cells, providing the instructions to make the SARS-CoV-2 spike protein, which are expressed on the outside of those cells.

47. The production of these vaccines also utilizes genetically modified human cells. These human cells ensure the modified viruses can be produced on mass without the viruses themselves having the ability to replicate.[14]

48. The protein subunit vaccine developed by Novavax also uses a genetically modified baculovirus in its production.[15] This modified virus is used to infect moth cells which then express the SARS-CoV-2 spike protein. These spike proteins are then harvested from these cells and then mixed with synthetic particles in which the spikes embed.

49. Media coverage of these technologies has likely increased the public visibility of positive applications of genetic technologies. The EPA will likely keep the Associate Minister Hon Phil Twyford informed of progress on any COVID-19 vaccine applications.

Climate Change Commission report and recommendations

50. On 31 January 2021, the Climate Change Commission (the Commission), which superseded the Interim Climate Change Committee, released its first draft advice to the Government. As part of this advice, the Commission recommended a number of sector specific policies and time-critical actions to reduce biogenic agricultural emissions. In particular, under 'Time-critical necessary action 4', the report recommend that in the first budget period (2022 - 2025) the Government:

    a. Review current arrangements and develop a long-term plan for targeted research and development of technologies (including evaluating the role of emerging technologies such as genetic engineering) and practices to reduce biogenic emissions from agriculture.

    b. Review and update processes and regulatory regimes to ensure that new emissions reducing technologies and practices can be rapidly deployed as and when they are developed.

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[13] The sequence to translate genes into proteins or enzymes proceed as follows: DNA is transcribed into mRNA (messenger RNA), this mRNA is then translated into an amino acid sequence that forms a protein or enzyme. By delivering mRNA directly into the body's cells, these vaccines skip the first part of the sequence. Other DNA vaccines are also in development overseas but have not been developed as rapidly. DNA vaccines may, however, be more stable than RNA vaccines due to their chemical properties.

[14] Science Translational Medicine. (8 February 2021). How You Make an Adenovirus Vaccine. Retrieved from: https://blogs.sciencemag.org/pipeline/archives/2021/02/08/how-you-make-an-adenovirus-vaccine

[15] Baculoviruses are viruses that infect insect cells.

51. As part of this time-critical necessary action, the Commission recommended as a progress indicator that the:

    a. Government to have, by 31 December 2022, reviewed and amended processes and regulatory regimes for new emissions reducing technologies and practices.

Issues

Technology and knowledge has evolved considerably since the HSNO Act was last reviewed

52. It has been nearly 20 years since the HSNO Act was last reviewed. As such, the HSNO Act has not evolved since the early 2000s when the common view of what genetic modification entailed was the creation of transgenic organisms.[16] In the time since the HSNO Act was last reviewed, biotechnology and genetic modification technology has evolved substantially, in particular with the advent of new forms of gene editing in the last decade.

53. This has meant that organisms developed using new and more precise technologies receive the same level of scrutiny as earlier transgenic technology, as they are not listed in the Not-GM regulations. This level of scrutiny may be an unnecessarily high threshold, particularly when these new technologies are being used to create organisms that are not transgenic, are indistinguishable from organisms produced from a technique listed under the Not-GM regulations, and in some cases could occur through slower natural processes.

54. This has likely resulted in organisms being regulated at a level not proportionate to the risk they pose and New Zealand missing out on the benefits they could provide. In particular, the unique qualities of gene-editing technologies like CRISPR-Cas9 has increased the possibilities available to researchers in the biotechnology sector.

55. Compared to previous genetic modification technologies, gene-editing technologies are precise, cheap and easy to use. They also bypass several of the problems associated with previous genetic modification techniques, including the number of unintentional changes to genetic material. All of these features combine to increase the ability of researchers to create new products, therapies, and solutions in less time and at less expense.

56. The collective evidence on the risks of GMOs has also grown substantially since the early 2000s. Large national and international organisations have assessed the evidence on the environmental and health safety of GMOs, concluding that, to date, plants and foods produced through biotechnology are no more risky than those produced through conventional means.

57. These organisations include the World Health Organisation (WHO), Food Standards Australia New Zealand (FSANZ), the American Medical Association, the National Academies of Sciences, Engineering, and Medicine (United States) and the European Commission. On the topic of genetically modified foods that have passed safety assessments, the WHO stated that “no effects on human health have been shown as a result of the consumption of such foods by the general population in the countries where they have been approved.”[17]

[16] Transgenic organisms are those that have a gene or genetic material from a sexually incompatible species inserted to achieve a desirable trait.

[17] World Health Organisation. (May 2014). Frequently asked questions on genetically modified foods. Retrieved from https://www.who.int/news-room/q-a-detail/FAQ-genetically-modified-foods

58. Similarly, FSANZ has concluded that "gene technology has not been shown to introduce any new or altered hazards into the food supply, therefore the potential for long term health risks associated with genetically modified foods is considered to be no different to that for conventional foods already in the food supply."[18]

59. A large review by the European Commission conducted between 2001 and 2010 observed that the "main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not *per se* more risky than e.g. conventional plant breeding technologies."[19]

Public attitudes are changing, with a growing recognition of the benefits of genetic modification for environmental issues

60. As environmental issues such as climate change and biodiversity loss have grown in importance to New Zealander's, there has been a growing number of calls in recent years to investigate and utilise genetic modification to address these issues. Recent polling conducted by Pew Research shows that younger generations globally are more accepting of genetic modification applications compared to older generations.[20] Two notable examples shows that this is also likely to be the case in New Zealand.

61. In an open letter in 2019, 150 young scientists urged the Green Party to take a lead in changing New Zealand's GMO legislation, arguing that "climate change is one of the greatest crises in human history, and our current law severely restricts the development of technologies that could make a vital difference."[21]

62. Similarly, School Strike 4 Climate activist Mia Sutherland has advocated for changes to our GMO legislation, writing in 2019 that "If this coalition government is serious about tackling climate change and ensuring future generations are left with a prosperous planet, GMO law reform must be considered."[22]

63. In contrast to the public opposition to GMOs in the early 2000s, recent surveys conducted by market research firm Ipsos show that genetic modification is not a top issue for the New Zealand public, but environmental pollution/water concerns and climate change rank in the top 20.[23] No surveys have been conducted in recent years to gauge the New Zealand public's acceptance of genetic modification applications in a wide range of areas, however

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[18] Food Standards Australia New Zealand. (August 2019). Safety assessments of GM foods. Retrieved from https://www.foodstandards.gov.au/consumer/gmfood/safety/Pages/default.aspx

[19] European Commission. (2010). A Decade of EU-Funded GMO Research 2001–2010. *Directorate-General for Research and Innovation, Biotechnologies, Agriculture, Food*.

[20] Pew Research Center. (December 2020). Biotechnology Research Viewed With Caution Globally, but Most Support Gene Editing for Babies To Treat Disease. Retrieved from https://www.pewresearch.org/science/2020/12/10/biotechnology-research-viewed-with-caution-globally-but-most-support-gene-editing-for-babies-to-treat-disease/

[21] The Spinoff. (October 2019). GM could be decisive: An open letter to the Green Party from young NZ scientists. Retrieved from https://thespinoff.co.nz/science/29-10-2019/genetic-modification-open-letter-green-party-young-scientists/

[22] Stuff. (October 2019). New Zealand's anti-science GMO laws need to change to tackle climate change. Retrieved from https://www.stuff.co.nz/environment/climate-news/116739646/new-zealands-antiscience-gmo-laws-need-to-change-to-tackle-climate-change

[23] IPSOS. (July 2020). The IPSOS New Zealand Issues Monitor. Retrieved from https://www.ipsos.com/sites/default/files/9th-ipsos-new-zealand-issues-monitor-090720.pdf

a recent survey showed that there was high approval from New Zealanders surveyed for using gene editing to address certain environmental issues.

Other countries are responding to developments through regulatory changes and we may end up out of step

64. In response to changes to genetic modification technology and the growing scientific evidence base, countries and jurisdictions have updated their GMO legislation, or are exploring options to. Countries that have recently updated their regulations include Australia, Japan, Argentina and the United States.

65. In 2019, Australia excluded from regulation organisms created using a type of gene editing called SDN-1. This means that these SDN-1 organisms are not considered GMOs provided a number of conditions are met.[24] SDN-1, a type of site-directed nuclease, introduces base-pair changes or small insertions/deletions to the genetic material of an organism without the addition of foreign DNA.[25]

66. Similarly, Japan, Argentina and the United States do not regulate gene-edited organisms if no foreign DNA is introduced into that organism. Discussions are currently ongoing in the United Kingdom (UK), Switzerland and Norway as to whether to not regulate gene-edited organisms where no foreign DNA is introduced.[26] On 7 January 2021, the UK's Environment Secretary announced that a consultation on gene editing would be launched. This is a break from the EU's policy following Brexit and would "focus on stopping certain gene editing organisms from being regulated in the same way as genetic modification".[27]

67. The EU and New Zealand are the only jurisdictions that regulate gene-edited organisms – where no foreign DNA is introduced – as GMOs, and where no discussion is ongoing regarding the regulation of gene editing.[28] The decision to regulate gene-edited organisms as GMOs both came about as the result of court decisions in New Zealand and the EU.

68. Despite the varying approaches, major players appear to be moving towards less regulation of organisms created using these new technologies. This is based on their country's own scientific risk assessment and regulatory framework concluding that these organisms do not pose added risks compared to organisms developed through conventional breeding.

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[24] These conditions include: 1) no nucleic acid template was added to cells to guide genome repair following site-directed nuclease application, and 2) the organism has no other traits from gene technology. Office of the Gene Technology Regulator. (November 2020). 2019 Amendments to the Regulations. Retrieved from: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/amendments+to+the+regs+2019

[25] Bases are the letters (A, C, G and T) in a DNA sequence that encode the instructions to make proteins in an organism's cell. Because DNA is double-stranded each base has a corresponding pair (A with T and C with G). Base-pair gene editing changes both the specific letter and its corresponding pair.

[26] Schmidt, S. M., Belisle, M., & Frommer, W. B. (2020). The evolving landscape around genome editing in agriculture: Many countries have exempted or move to exempt forms of genome editing from GMO regulation of crop plants. EMBO reports, e50680.

[27] Gov.uk. (January 2021). Press release - Gene editing creates potential to protect the nation's environment, pollinators and wildlife. Retrieved from https://www.gov.uk/government/news/gene-editing-creates-potential-to-protect-the-nations-environment-pollinators-and-wildlife

[28] Schmidt, S. M., Belisle, M., & Frommer, W. B. (2020). The evolving landscape around genome editing in agriculture: Many countries have exempted or move to exempt forms of genome editing from GMO regulation of crop plants. EMBO reports, e50680.

Our regulatory settings may mean we will miss out on present and future opportunities and may not appropriately manage future risks

69. Due to our current regulatory settings, New Zealand may be missing out on tools that could positively contribute to achieving goals in the Government's priority areas. Based on forecasts by the Biological Emissions Reference Group (BERG), the genetically modified ryegrass developed by AgResearch is one of a number of mitigation tools that would be required for New Zealand to reach its agricultural Zero Carbon goals.[29] These forecasts now form part of the December 2020 Emissions Reduction Plan for the Agricultural Sector developed by MPI.

70. Technology being developed overseas also has direct relevance to the Government's commitments to combating Kauri dieback disease and reducing plastic waste to enable a circular economy. Researchers in 2014 developed late blight resistant potatoes by introducing genes into those potatoes from wild relatives.[30] The microorganism that causes late blight, *Phytophthora infestans*, is a member of the group that includes *Phytophthora agathidicida*, the microorganism that causes Kauri dieback disease.

71. Enzymes created using genetically modified organisms have been developed by French company Carbios, to breakdown and recycle PET. PET is the most common type of plastic and is commonly used in plastic bottles. According to Carbios' research, this modified enzyme is likely to be more cost-effective at producing recycled PET, which is generally sold at a premium, and could potentially match the cost of virgin PET.[31] Breakdown and recycling of PET waste would better enable a circular economy for plastics in New Zealand.

72. The ease with which gene technologies can be researched and tested domestically and used in New Zealand is likely to be important for two reasons. The first is that our biodiversity and climate is unique. Similarly, a number of the environmental issues faced by New Zealand are also high by international standards. New Zealand has the highest methane emissions per capita in the OECD and the fifth highest per capita rate of plastic waste generation in the OECD.[32]

73. New Zealand's exports are also heavily concentrated in primary industry products.[33] This means any measures to lower environmental impacts from agricultural production while not simultaneously increasing on-farm productivity or export prices risks negative impacts to export revenues and producer incomes.

74. A restrictive legislative framework for GMOs may also not effectively manage emerging future risks and may impact on New Zealand's resiliency to these risks. Discussion of New Zealand's GMO legislation has centred on the appropriate level of GMO risk management for present, domestic risks. What is likely missing from this discussion is the appropriate legislative settings to increase the ability for New Zealand to respond to future non-GMO

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[29] Ministry for Primary Industries. (December 2018). Report of the Biological Emissions Reference Group. Retrieved from: https://www.mpi.govt.nz/funding-rural-support/environment-and-natural-resources/biological-emissions-reference-group/

[30] Jo, K. R., Kim, C. J., Kim, S. J., Kim, T. Y., Bergervoet, M., Jongsma, M. A., ... & Vossen, J. H. (2014). Development of late blight resistant potatoes by cisgene stacking. *BMC biotechnology*, *14*(1), 50.

[31] Tournier, V., Topham, C. M., Gilles, A., David, B., Folgoas, C., Moya-Leclair, E., ... & Cot, M. (2020). An engineered PET depolymerase to break down and recycle plastic bottles. *Nature*, *580* (7802), 216-219.

[32] Our World in Data. (December 2020). New Zealand: CO_2 Profile. Retrieved from: https://ourworldindata.org/co2/country/new-zealand; Our World in Data. (December 2020). Plastic Pollution. Retrieved from: https://ourworldindata.org/plastic-pollution

[33] Observatory of Economic Complexity. (December 2020). Country Profile: New Zealand. Retrieved from: https://oec.world/en/profile/country/nzl/

and GMO risks, with domestic or global origins, that have relevance to our GMO legislation. Climate change and the SARS-CoV-2 pandemic illustrate what may be the overly narrow focus of New Zealand's GMO legislation.

75. Climate change is a global issue that has generated, and will continue to generate, risks to New Zealand. Climate change and its risks are non-GMO in nature but our GMO legislation may still impact on the ability of New Zealand to respond to climate change and its risks. This resiliency may come in the form of New Zealand's ability to further lower greenhouse emissions, produce food in changing climate conditions, and address biosecurity incursions that threaten food production and indigenous species.

76. Responses to the SARS-CoV-2 pandemic overseas and in New Zealand have relied heavily on the knowledge and resourcing of each country's scientific communities. Well-resourced scientific communities have quickly responded to the pandemic in a number of ways, including in the form of sophisticated diagnostic analysis and the rapid development of GMO and non-GMO vaccines. Regulations have an impact on what research is pursued, financed and resourced, which in turn has implications for the development of scientific communities, both broadly and specifically. As things like genome sequencing, big data in the biological sciences and medical gene technology become more ubiquitous, regulations that impact GMO research will have greater significance to how New Zealand is able to respond to future issues and risks.

Next Steps

77. We recommend that you forward this briefing to the Associate Minister for the Environment.

Appendix 1: A brief introduction to genetics and genetic modification

1. **Genetics** is a field of biology that studies how traits are passed from parents to their offspring. With the exclusion of certain types of viruses, genetics is built around molecules called **DNA**. DNA molecules provide cells with the information they need to perform tasks that allow an organism to grow, survive and reproduce.
2. A **chromosome** is a structure made from tightly packed strands of DNA.[34] The collective chromosomes in a cell make up an organism's **genome**.[35] Genomic testing then means the testing of an organism's entire genetic information.
3. A **gene** is a specific segment of a DNA molecule that holds the information for one specific protein. DNA molecules have a unique code for each gene which codes for their specific protein. The DNA code for a gene is made up of four units called **nucleotides**, which are represented in DNA sequences by the letters A, G, C and T. These nucleotides are also known as bases.
4. To encode a protein, a gene is first transcribed from DNA to **RNA**. RNA is also a chain of nucleotides like DNA, albeit slightly different.[36] Once transcribed, RNA is then translated into a sequence of **amino acids**. This long chain of amino acids then forms a **protein**. Proteins then perform the various functions of an organism's cell.
5. **Genetic modification** involves the modification of an organism's DNA in order to change the proteins expressed by an organism. For example, using a variety of techniques, genes can be inserted or deleted from an organism's DNA, or specific changes can be made to nucleotides to modify the subsequent protein created.
6. Forms of genetic modification such as **chemically induced mutagenesis** or **radiation induced mutagenesis** that were in use before 29 July 1998 are unregulated in New Zealand.[37] These forms of genetic modification introduce a number of random changes (mutations) to an organism's DNA.
7. **Transgenic organisms** are organisms in which genes from other sexually incompatible organisms have been inserted into their DNA sequence via genetic modification techniques (eg. inserting a flounder gene into a potato). In contrast, **cisgenic organisms** are organisms in which genes from sexually compatible organisms have been inserted into their DNA sequence via genetic modification techniques (eg. inserting a gene from a wild variety of wheat into a commercial variety of wheat). Cisgenic organisms can also be created through conventional breeding techniques.
8. In addition, the transfer of genes between organisms also occurs regularly in nature, in what is referred to as **horizontal gene transfer**. A notable example of this is a horizontal gene transfer event between a species of bacteria and the ancestors of domesticated kumara some ~8,000-10,000 years ago. The natural genetic modification occurred early during domestication in South America, and may have contributed to its development as a crop plant.
9. **Gene editing** typically refers to a type of genetic modification that can make precise and targeted changes to an organism's DNA. The best known example of gene editing is **CRISPR/Cas9** editing. Older forms of genetic modification (excluding mutagenesis) result

[34] A chromosome also includes special proteins called histones.

[35] Technically, an organism's genome is contained in a cell compartment called a nucleus.

[36] When a DNA sequence is transcribed into RNA, the T nucleotide is replaced by a U nucleotide.

[37] These technologies are considered genetic modification but their use does not result in a genetically modified organism, according to our Not-GM regulations.

in changes to an organism's DNA in an untargeted fashion, and typically involve the insertion of foreign DNA.

Figure 1: Genetic modification compared to gene-editing

10. As such, gene-editing has a number of unique characteristics including:
    a. producing organisms indistinguishable from those that occur naturally
    b. mimicking what a technique exempt from regulations can do
    c. turning genes 'on' and 'off' without the addition of foreign DNA
11. Genetic tools then can be divided into **low precision tools** and **high precision tools**. Unregulated tools such as chemically induced mutagenesis may introduce a desired change (mutation) in a gene of interest but with many other changes in off target genes. In contrast, high precision tools, such CRISPR/Cas9 editing are much more likely to introduce only the desired change in the gene of interest.

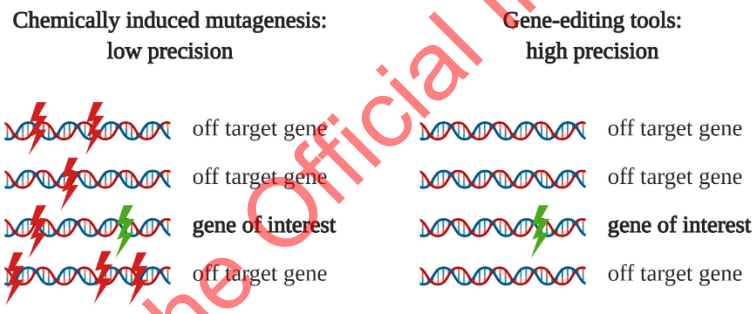

Figure 2: Low precision compared to high precision genetic tools

Appendix 2: GM strategies of relevance to New Zealand that rely on the use of gene technologies and their approximate stage of development

	Stage of development							
Gene technology and type of strategy	**NZ ready**	**Overseas ready**	**Near to market**		**Proof of principle**		**Early concept**	
			NZ	**OS**	**NZ**	**OS**	**NZ**	**OS**
Mitigation strategies								
Microbial CO2 capture	x							
Microbial mining of waste	x							
Pesticide free plants		x						
Self-limiting sterile insects				x				
Low fertiliser requiring plants				x				
PET recycling				x				
Low methane feedstock					x			
Methane vaccination of livestock					x			
Protein-stimulated N uptake by plants					x			
Low P excreting livestock						x		
Other plastic recycling								x
Gene drive predator elimination								x
GE animals for reduced methane								x
Adaptation Strategies								
High yield, low N crops				x				
Facilitated adaptation vulnerable species				x				
High N uptake plants						x		
Alternative Technologies								
Synthetic meat - plant-based		x						
Protein-stimulated resistance in plants					x			
Synthetic meat - animal-cell based						x		
Algae biofuels						x		
De-extinction								x

Note: OS = Overseas.

Environment Weekly Update

For the week starting 26 January 2021

Hon David Parker, Minister for the Environment

Hon Kiritapu Allan, Associate Minister for the Environment

Hon Phil Twyford, Associate Minister for the Environment

2.7. Australia's Office of the Gene Technology Regulator opens consultation on proposed regulatory framework

Australia's Office of the Gene Technology Regulator has recently opened consultation on a new proposed regulatory framework for gene technology. This proposed regulatory framework would implement recommendations of the comprehensive Third Review of the National Gene Technology Scheme. Conducted in 2017 and 2018, the Third Review included substantial public consultation over three phases.

The framework would take the form of a 'proportionate' model, in which legislation would contain a mix of principles and prescriptive rules to provide sufficient flexibility for the regulatory system. This flexibility is intended to allow the system to respond to scientific advances and emerging technology in a timely manner, while ensuring that risks to public health and the environment continue to be suitably managed.

Weekly Update

Hon David Parker, Minister for the Environment

For the week starting 16 December 2019

Out of Scope

Out of Scope

2.3. Food Standards Australia New Zealand Report on genetically modified food

On 10 December 2019, Food Standards Australia New Zealand (FSANZ) released its review on how the Australia New Zealand Food Standards Code (the Code) applies to food derived using new genetic techniques. The Code is implemented in New Zealand by the Ministry for Primary Industries (New Zealand Food Safety).

Under the Code, foods produced using 'gene technology' are subject to a pre-market safety assessment and approval process before they are allowed for sale. The Code contains definitions to determine what foods are considered genetically modified, and therefore subject to a pre-market safety assessment.

The FSANZ review concluded that some key definitions in the Code that relate to genetically modified food are no longer fit for purpose given the emergence of new gene technologies. The report recommends that definitions under the Code should be amended to improve clarity, and to that ensure foods are regulated in a way that is commensurate with the risks that gene technologies pose.

In 2020, FSANZ will prepare a proposal to amend definitions relating to gene technology. Ministry officials will stay up to date with this work, and engage with FSANZ and MPI as appropriate, given the similar situation we face in the regulation of genetically modified organisms under the HSNO Act.

Out of Scope

Weekly Update

Hon David Parker, Minister for the Environment

For the week starting 2 March 2020

Out of Scope

Out of Scope

1.6. Food Standards Australia New Zealand proposal to amend definitions for gene technology

In December 2019, Food Standards Australia New Zealand (FSANZ) released its review on how the Australia New Zealand Food Standards Code (the Code) applies to food derived using new genetic techniques. FSANZ has notified the Ministry of the commencement of a new proposal entitled 'Definitions for gene technology and new breeding techniques.' The commencement of the proposal will be publicly notified on 28 February 2020.

The aim of the proposal is to revise and update the definitions in the Code for 'food produced using gene technology' and 'gene technology' to better reflect existing and emerging gene technologies including new breeding techniques. Currently, under the Code, foods produced using 'gene technology' are subject to a pre-market safety assessment and approval process before they are allowed for sale.

The proposal aims to provide clarity around which foods require a pre-market safety assessment and whether there is a case, based on risk, for foods produced using some gene technologies to be excluded from this requirement. It will also consider whether to retain a process based definitional trigger or to adopt an outcomes based approach.

The timeframe for the proposal is approximately 18 months, with the first call for submissions report anticipated to be released in June 2020. Initial work on the proposal will involve targeted consultation with a range of stakeholders and the development of communications material. The Ministry will stay up to date with this work and engage with FSANZ as appropriate.