



19-D-00633

s 9(2)(a)

Dear

s 9(2)(a)

Thank you for your email of 13 April 2019 requesting the following under the Official Information Act 1982 (the Act):

In relation to the responsibilities of the Ministry for the Environment, I would be grateful if you would provide me with copies or transcripts of all communications or reports made or received regarding the use of genetically modified organisms and technologies (such as gene editing) for predator / invasive species control:

- by David Parker;
- by Nanaia Mahuta;
- by Eugenie Sage; and
- by the Ministry for the Environment.

I would further be grateful if you would ensure the information includes copies or transcripts of:

- any advice the Minister or Associate Ministers or the Ministry has received or given regarding the use of such genetically modified organisms and technologies; and
- any communications or reports made or received regarding public or expert consultation on the use of such genetically modified organisms or technologies.

On 24 April 2019, Adam Houppermans, Executive Relations Senior Advisor at the Ministry for the Environment (MfE), called you and discussed refining the request given its wide scope. Executive Relations followed up by email the same day, and you confirmed a refinement on 26 April 2019 to the following:

From 1 November 2017 onwards

- Any advice (including by email or contained in briefings and weekly reports) on GM pest control from the Ministry for the Environment to Minister Parker, Minister Mahuta or Minister Sage.
- Any Ministry documents that discuss our outline expert advice or consultation on GM pest control.

There have been eight documents identified in scope of your request, as listed in the attached table. Some information within these documents has been withheld under the following sections of the Act:

- 6(a) to avoid prejudice to the NZ Government's international relations
- 9(2)(a) to protect privacy
- 9(2)(f)(iv) to protect the confidentiality of advice given by officials.

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.

Some out of scope information has also been removed from the documents being released to you.

The work referred to in the June 2018 MfE briefing *Genetic Technology – Overview and Next Steps* to be undertaken by MfE in 2018 as part of our work programme has been modified and is no longer accurately reflected by this briefing. We will continue to monitor international developments but will not be putting resource into analysis of opportunities and challenges for New Zealand, monitoring public views or exploration of approaches to a participatory public process.

The briefing was not sent on to other Ministers as suggested.

The briefing was produced after the Advocate-General's (A-G) report to the European Court of Justice (ECJ) was published but prior to the ECJ's final decision, so the briefing does not accurately reflect the ECJ's final position (we had indicated what we thought the position was likely to be based on the A-G opinion but were incorrect).

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 contact our Executive Relations team (email address ministerials@mfe.govt.nz), if you have any queries about this response.

Yours sincerely



Glenn Wigley
Director, Natural and Built System

List of documents

Document no.	Document date	Content	Decisions	OIA sections applied
1	19 December 2017	Email from MfE to Minister Parker's office "Royal Society's gene editing papers - some background for info and/or responding to questions"	Release in full	N/A
2	26 January 2018	Email from MfE to Minister Parker's office "Productivity Commission suggestions"	Release in full (except for out of scope parts of email)	N/A
3	16 February 2018	EPA-hosted visit by Prof Kevin Esvelt: Internal MfE note prepared for MfE Deputy Secretary Penny Nelson prior to her meeting with Prof Esvelt	Release in full	N/A
4	7 June 2018	MfE Briefing on GM to Minister Parker - "2018-B-04195 - Genetic Technology - Overview and Next Steps"	Release in full	N/A
5	11 June 2018	MFAT briefing "Convention on Biological Diversity Negotiating Position"	Release in part	S6(a) S9(2)(a) S9(2)(f)(iv)
6	7 November 2018	Email from MfE to Minister Parker's office "FW: Min Sage ask for advice on gene drives in CBD - for comment by COP 7 November" attaching document: "Gene drive technology and the Convention on Biological Diversity" (advice provided by MFAT (supported by MfE and EPA) to Minister Sage)	Release in part	S6(a) S9(2)(a) S9(2)(f)(iv)
7	28 November 2018	Email from MfE to Minister Parker's office: "RE: Letter for Hon David Parker: Sustainability Council on GE and CBD Meeting - COR6623"	Release in part	S6(a) S9(2)(a)
8	28 February 2019	Advice to Minister Parker "In support of a media interview on genetic modification"	Release in full	N/A

From: [Brian Hallinan](#)
To: [Joe Beaglehole \(Parliament\)](#)
Cc: [Penny Nelson](#); [Laurie Edwards](#); [Rachel White](#); [Alison Collins](#); [Glenn Wigley](#); [Mariska Wouters](#); [Olivia Chamberlain](#)
Subject: Royal Society's gene editing papers - some background for info and/or responding to questions
Date: Tuesday, 19 December 2017 11:59:25 AM
Attachments: [image001.png](#)

Hi Joe

As discussed with Penny, please find attached some information on the Royal Society's gene editing papers, for your info and/or if the Minister gets any further media questions

Lines for media

- The Ministry for the Environment (MFE) is supportive of the Royal Society's efforts in raising awareness and discussion of genetic technology.
- MFE is working with other agencies to actively monitor international developments in genetic technology, including considering how well-placed New Zealand's current policy and regulatory framework, which dates from 1996, is to deal with new technology.
- I expect to receive further information from the Ministry for the Environment about developments in genetic technology. This will help inform how the government considers genetic technology developments, including how we discuss opportunities and risk with the public.

Background

- The Royal Society Te Aparangi is an independent, statutory not-for-profit organisation constituted under an Act, for the purpose of advancing and promoting science, technology and the humanities in New Zealand.
- The Royal Society Te Aparangi has released (Tuesday 19th December) two technical papers accompanied by two general discussion documents (factsheets) relating to developments in genetic technology. These papers cover the current and potential uses of gene editing in **pest control** and **healthcare**.
- The technical papers were produced by a Royal Society Te Aparangi Expert Panel, with support and advice from a Maori Reference Group.
- The aim of this series of papers is not to come to a view on the merits or otherwise of these technologies, but to usefully inform the inevitable and necessary societal debate on the use of these technologies.
- The Royal Society Te Aparangi has consulted the Ministry, and a number of other government agencies, in the development of the papers. The Ministry is supportive of the Royal Society's efforts in raising awareness and discussion of genetic technology.
- The Royal Society Te Aparangi is developing further papers on gene editing in agriculture, legislation and regulation, and Maori perspectives, for release in 2018.
- The Minister is referred to in today's NZ Herald article about the Royal Society papers: "Environment Minister David Parker yesterday said the Government had no plans to change the current law". [http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11961942]
- The Ministry is working with other agencies to actively monitor international

developments in genetic technology, including considering how well-placed New Zealand's current policy and regulatory framework, which dates from 1996, is to deal with new technology.

- The Ministry is providing a high level briefing on this topic to Minister Parker tomorrow (Wednesday 20 December), with the aim of discussing this further in 2018.

Please let me know if you have any questions.

Regards

Brian

Brian Hallinan – Manager, Environmental Risk and Innovation

Ministry for the Environment – Manatu Mo Te Taiao

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Released under the Official Information Act

From: Rachel Hyde [<mailto:Rachel.Hyde@mfe.govt.nz>]
Sent: Friday, 26 January 2018 11:57 AM
To: Joe Beaglehole <Joe.Beaglehole@parliament.govt.nz>
Cc: Debbie Teale <Debbie.Teale@mfe.govt.nz>
Subject: Productivity commission suggestions

Hi Joe,

Here are the four suggestions we have for Minister Parker on the Productivity Commission's next review.

Regards

Rachel

1. Reviewing New Zealand's approach to genetic biotechnology (also being proposed by MPI)

New biotechnology techniques offer increased precision for the genetic modification of plants and animals. This provides new opportunities in New Zealand to increase the productivity, value, resilience and sustainability of the primary sectors and wider economy. It also provides opportunities to meet the increasing challenges presented by drought and other changing climatic factors, as well as current and future pest and disease incursions. A new approach to biotechnology might also support further and more wide-ranging research, with benefits for further development of New Zealand's biotechnology industry. There are also potential advantages in understanding the interactions between the use of GMOs, the current restrictions on GMOs, and growth in NZ's economy (which could build on recent work by the Australian Productivity Commission).

The new biotechnologies, and the changes in international use of GMOs and their regulation, now mean that New Zealand's regulatory framework for genetic modification under the HSNO Act, which is over 20 years old, is increasingly difficult to enforce and may be limiting NZ's competitiveness. The Royal Commission on Genetic Modification reported in 2001. It envisaged New Zealand proceeding with caution with genetic modification, while protecting opportunities. This topic would consider how New Zealand is positioned to accommodate these new technologies and manage the risks, while realising the opportunities to increase the productivity, value and resilience of the New Zealand economy and society – especially the primary sectors, health, and the environment.

Recommendations 2-4 removed as out of scope

Rachel Hyde – Principal Advisor, Governance and Accountability
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Professor Kevin Esvelt 16.02.18

Professor Kevin Esvelt is an assistant professor at MIT. He is credited as the first to describe how CRISPR gene drives (a gene editing technique) could be used to alter the traits of wild populations and drive specific traits through the entire population.

Professor Esvelt is a vocal proponent for emphasising early transparency and universal safeguards in work that utilises gene drives. He focuses on working with communities and ensures community engagement precedes and guides the development of technology that will impact the environment. Professor Esvelt's team tries to avoid any private meetings with government officials unless a transcript will be made publically available.

His primary goal on this visit is to; *"learn how best to establish clear communications with the diverse peoples of Aotearoa, and particularly Maori, in order to most effectively solicit their concerns, suggestions and criticism"*

Last September, Professor Esvelt visited New Zealand to discuss whether his work on gene drive technology could be of benefit to Predator Free 2050 in terms of being both technically useful and socially acceptable. In November 2017, Professor Esvelt (with Neil Gemmell from Otago University) published an article in the scientific journal *Biology* expressing concern about the potential use of gene drive systems for conservation. This article was contrary to their earlier beliefs. They now believe that gene drive systems lack control mechanisms and therefore are highly invasive. Professor Esvelt continues to research gene drive systems, including local drive systems (e.g. daisy drive) that can only spread alterations through a local population of organisms.

Questions:

- In view of Professor Esvelt's revised position that gene drive systems should not be used for conservation management, what is his ongoing interest in NZ? Does he see value in New Zealand communities having conversations about the development of these systems to, for example, achieve the goals of Predator Free 2050?
- What process/protocols does Professor Esvelt use when engaging in public conversations around gene drive? While a government-led conversation is likely to have a different process and approach, are there any universal lessons he has learnt to ensure the conversation isn't polarising?
- What is his taking on how jurisdictions around the world are handling the regulatory issues?
- What does he perceive the next big hurdles/opportunities in biotechnology to be?
- What are his views on the wider genetic technology (not just gene drive) and how it is being developed and utilised?



To Hon David Parker, Minister for the Environment			Tracking #: 2018-B-04195
<u>Security Level</u>	IN CONFIDENCE	Number of Attachments	0
Date Submitted:	07.06.2018	Response needed by:	06.07.2018
MfE Priority:	Non-Urgent	Action Sought:	Decision

Genetic Technology – Overview and Next Steps

Key Messages

1. This briefing provides a high-level overview of recent developments in genetic technologies occurring globally, how other jurisdictions are responding and why this matters for New Zealand. It is a platform for further advice to you as the Minister responsible for the regulation of genetic technologies under the Hazardous Substances and New Organisms Act 1996 (HSNO).
2. Our monitoring of developments shows that the rapid pace of technological change is testing regulatory definitions and has led to other countries beginning to clarify and/or review their regulatory position. The developments raise questions as to whether New Zealand's regulatory framework is still appropriate as HSNO is becoming outdated in light of developments. We believe a broad public conversation is required to ascertain New Zealanders' views on these developments. This input could lead to future consultation on specific policy and/or regulatory changes to clarify New Zealand's position.

Development of new genetic technologies internationally

3. Recent and ongoing developments in genetic technologies are changing what is happening and what could be possible across a range of industries and sectors. The scale of change is already significant and technologies are still developing quickly. The technical advancements present new applications and methods for use in genetics that are accessible, easy to use, fast and have high success rates. It is becoming commonplace to use genetic technologies to make changes that are indistinguishable from natural genetic variation (changes that could occur naturally).
4. One key development is gene editing.¹ The distinguishing features of gene editing is the significantly increased precision of modification that can be made and the speed by which changes can occur, compared with earlier genetic modification (GM) tools. Gene editing can be used to make changes that:
 - are very small
 - leave no trace in an organisms genome
 - do not require the insertion of foreign DNA
 - could be indistinguishable from a naturally occurring organism
 - could be indistinguishable from changes made by a technique already exempt from regulation, or from naturally occurring mutations.

¹ Gene editing technologies use proteins, called enzymes, to cut a targeted area of DNA within the genome of a species. *Clustered Regularly Interspaced Short Palindromic Repeats* (CRISPR) is the most commonly mentioned gene editing approach.

5. These advances are challenging existing definitions of GM and what constitutes a genetically modified organism (GMO). Regulatory authorities globally are now considering questions about what is or should be regulated as a GMO. Currently, there is no clear international consensus on the best way to regulate the use of new genetic technologies, with countries taking a variety of different approaches.
6. There are jurisdictions choosing not to regulate some organisms made using new technologies (e.g. USA) and others that are reviewing how their regulatory frameworks apply in light of the developments (e.g. European Union). There are also countries doing both (e.g. Australia). Some countries have not made any changes and/or are unsure on what changes they will make. Despite the varying approaches, major players appear to be moving towards less regulation on some organisms created using 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 with organisms developed through conventional breeding.

New Zealand's regulation of GMOs

7. In New Zealand a GMO is defined as any organism containing or derived from genetic material that has been modified *in vitro*², this applies to plants, animals and microbes³. The HSNO (Organisms Not Genetically Modified) Regulations 1998 (Not-GM regulations) set out an exhaustive list of techniques that are captured by the GMO definition but are exempt from regulation. The list only contains techniques deemed safe and in use prior to 29 July 1998. Some of the technologies in this list have been used for more than 60 years and are generally considered to be conventional plant breeding techniques.
8. The Not-GM regulations were amended in 2016, in response to a 2014 court decision that adopted a strict interpretation of the regulations. This amendment clarified that no new mutagenesis technologies (such as gene editing) created after 1998 are captured by the Not-GM regulations. For new techniques to be added the Not-GM regulations would need to be reviewed and amended by Order in Council.
9. The strict interpretation of the regulations means organisms created using new technologies developed in recent years, e.g. gene editing, will be more highly regulated than organisms created using techniques listed in the Not-GM regulations or naturally occurring organisms, regardless of the level of risk they present.
10. Settings in the HSNO Act ensure New Zealand has a very robust assessment process and high threshold for the approval of GMOs (for research, field trials and commercial use). As a result there are no GMOs commercially available in New Zealand. We do allow food products with non-viable GMO ingredients into New Zealand (approximately 77 approvals currently) under the Food Standards Code, which is administered by Food Standards Australia New Zealand (FSANZ).
11. The HSNO Act has never had a full review and the legislation therefore has not evolved since 1998. The settings in the Act mean that transgenic technology⁴ receives a high level of scrutiny. Organisms developed using new and more precise technologies receive the same level of scrutiny as earlier GM techniques as they are not listed in the Not-GM regulations. This may be an unnecessarily high threshold, particularly when 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. This may

² *In vitro* means taking place in a test tube. This is in contrast to *in vivo* modification, which occurs inside an organism.

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)).

⁴ Transgenic organisms are those that have a gene or genetic material from a sexually incompatible species inserted to achieve a desirable trait. This was the common 1990s view of what GM entailed.

result 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 (such as medical treatments, crops, trees or forage with beneficial properties). Anecdotal evidence suggests the high level of regulation is discouraging potential applicants from submitting an application to the Environmental Protection Authority (EPA) for field trials in containment or a release of a GMO as the perception is they are unlikely to be successful or it will take too much time, effort and financial backing.

12. As genetic technologies continue to develop and international views and regulations evolve, the government may wish to consider how these could and/or should be used in New Zealand. Currently it is difficult to use the new technologies outside containment due to our stringent legislative regime. There will be a point when New Zealand should assess whether the policy settings in the HSNO Act are appropriate.
13. Maintaining our current position is becoming increasingly difficult for a variety of reasons:
 - Enforcement of the legislation has become difficult as products created using new technologies may arrive at our borders indistinguishable from products developed using unregulated techniques. There is not likely to be a mechanism to test how the product was created.
 - New Zealand developers test and sell products potentially beneficial to New Zealand overseas but their products cannot be used in New Zealand.
 - The definitional gap between what is considered GM under the Food Standards Code and the HSNO Act could widen, leading to different regulation of the same product.
 - New Zealand will not be able to receive the environmental benefits of some GMOs.
 - The high approval threshold could be a barrier to responding to major environmental concerns, such as kauri dieback, as New Zealand's research and reactive capacities may be suboptimal to develop/use tools to respond to threats and opportunities at a time when GM is becoming more widely used and the challenges it could help tackle are becoming more pressing.

New Zealand consideration of these issues

14. The broad application of the new technologies and the perception that New Zealand is 'GM-free' indicates that a national conversation will be helpful to find out New Zealanders views on new genetic technologies and their potential use. While such a conversation is likely to develop naturally in an ad hoc way, the complexity and wide reach of the new technologies suggests that it would be useful for government to take a lead on the most appropriate timing and scope of such a conversation. There are already some conversations occurring in New Zealand, e.g. the establishment of a gene editing panel by the Royal Society of New Zealand Te Apārangi to explore social, cultural, legal and economic implications of gene editing in New Zealand. There have also been some discussions on biotechnology and gene editing through iwi engagement, e.g. discussions on biotechnology occurring within the EPA's Te Herenga National Māori Network.
15. The current regulatory settings under HSNO are becoming quickly outdated, creating issues with the enforcement of the legislation. Regardless of whether New Zealand wishes to have a high threshold for the use of new genetic technologies or take a more permissive approach, we recommend updating the settings to clarify New Zealand's position. The Ministry for the Environment believes public input is required to decide on the approach New Zealand wishes to take before proposing any specific policy or regulatory changes. This approach (similar to that currently being undertaken in Australia) would allow for an open and transparent conversation without predetermining whether New Zealand should be using the technology or what regulation is appropriate for the technology. The outcome of such a conversation may then lead to specific policy and/or legislative changes with further public discussion.

16. We plan to investigate possible approaches to a future participatory public process to identify key issues and inform our policy analysis. There are several approaches to a public conversation; the specific method would be dependent on the purpose of such a conversation.
17. Some possible approaches are shown below and should not be considered an exhaustive list. The contentious nature of GM, complex issues involved, and the wide range of views on the topic mean that a public conversation will need to be carefully considered and the approach well planned to ensure it is effective and constructive. There is a risk that unless the conversation is done well the outcome could be worse than not having a conversation at all.
18. Possible options that government could explore include:
- A high level conversation to gauge overall public views and identify key issues about the developments in genetic technologies and New Zealand's regulatory environment, without putting forward options for change. This approach is currently being used by the Australian Department of Health. Such a conversation could be done through e.g. another Royal Commission, the Prime Minister's Chief Science Advisor, the Productivity Commission, or the Ministry (supported by other departments).
 - Consultation on the primary legislation, through a general discussion document seeking feedback on the performance of the system, followed by proposing specific amendments. This approach was used in the development of the HSNO Act.
 - Consultation on the scope and risk settings of the Not-GM regulations through a discussion document and workshops, followed by a consultation document setting out specific proposals for amendment. This approach is being used by the Australian Office of the Gene Technology Regulator.
 - Structuring a public conversation around specific opportunities or challenges where GM organisms may provide a significant benefit e.g. health, environmental (kauri dieback, myrtle rust) or sterile pine trees.
19. The methods available for consultation have varying levels of formality. For example, a Royal Commission would be a more formal process whereas a Ministry or Prime Minister's Chief Science Advisor-led conversation would be able to use more interactive and flexible participatory processes to achieve great reach.
20. Policy thinking on the approach to a public conversation is still in its infancy. We will provide you with a briefing before the end of 2018 with an assessment of the feasible options and our recommendations going forward. We will include further analysis of both the risks of not having a conversation (such as potentially missed economic and environmental opportunities) and those that will arise in having a conversation (such as polarised public views, misinformation/lack of understanding on what the conversation is about). We will also consider who should lead such a conversation, such as whether government is best placed to lead, what other groups could possibly come on board, and exploring options for an external group to lead the conversation.
21. Our engagement to date has principally been with government agencies, Crown Research Institutes, and the Royal Society.
22. We recognise that we need to adequately acknowledge and integrate Mātauranga Māori and Māori perspectives. The Ministry has not yet engaged with Māori perspectives in relation to GMOs (although others have been engaged in this space). The Ministry for the Environment will work with existing contacts to build understanding on how to effectively understand perspectives in this area. We will undertake external engagement as required with appropriate stakeholders after we provide you with further advice in December.
23. We will be able to complete the necessary background work with current resource levels by the end of 2018.

24. Leaving a public conversation for too long (e.g. 2-3 years away) could mean that New Zealand risks missing opportunities, playing catch-up on the international stage, and facing increasing compliance issues from GMOs indistinguishable from conventionally developed organisms. It could also run the risk of having to narrow the conversation to specific legislative changes as a response to international positioning without gauging high level attitudes within New Zealand first.
25. There is also a risk that conversations will be informed by overseas models and practices, which may not be relevant to New Zealand, or by interest groups that do not have a good understanding of the science involved, which could result in misinformation and misunderstanding about what the new technologies are and can do.

Ministry for the Environment background work in 2018

26. We, with other agencies, will continue to monitor and analyse the following areas in 2018 to assist Ministers in developing New Zealand's response to international developments:
- analysis of the opportunities and challenges for New Zealand presented by:
 - developments in new genetic technologies and uses
 - international regulatory and policy responses to these developments
 - regulating rapidly-changing technology under our current framework
 - monitoring of public views on the uses of genetic technologies in a range of applications (e.g. vaccines, pest control, plant breeding)
 - exploration of possible approaches to a participatory public process to identify key issues and explore policy solutions.
27. We will provide you with updates during the year on any international developments.
28. We will also provide you with advice by the end of 2018 on options for a models of public engagement on new genetic technologies; including the benefits/ risks, trade-offs and cultural consideration of each option.

Recommendations

29. We recommend that you:

- a. **Advise** if you would like to meet with Ministry for the Environment officials to discuss developments in genetic technologies and potential policy implications;
- b. **Note** that the Ministry for the Environment, with other agencies, plans to continue its work over the next 6 months to:
- better understand the opportunities and challenges for New Zealand presented by:
 - developments in new genetic technologies and uses
 - international regulatory and policy responses to these developments
 - regulating rapidly-changing technology under our current framework
 - monitor public views on the uses of genetic technologies in a range of applications (e.g. vaccines, pest control, plant breeding)
 - explore possible approaches to a participatory public process to identify key issues and explore policy solutions.
- c. **Note** that the Ministry for the Environment will provide updates on significant international developments in genetic technology during 2018.
- d. **Note** that the Ministry for the Environment will provide you with a briefing on models of public engagement for undertaking a government-led conversation on new genetic technologies by the end of 2018.
- e. **Refer** this briefing to other Ministers you consider appropriate. Refer to table two (page 16) for Ministers with a potential interest and/or responsibility in genetic technologies.

Yes/No

Yes/No

Signature

Glenn Wigley
Director Marine, Environmental Risk and Science

Date

Hon David Parker
Minister for the Environment

Date

Ministry for the Environment contacts

Position	Name	Cell phone	1 st contact
Principal author	Olivia Chamberlain	0224930557	
Responsible Manager	Brian Hallinan	0220668420	✓
Director	Glenn Wigley	0274917806	

Genetic Technology – Overview and Next Steps

Technology has moved beyond New Zealand's regulatory framework

1. Recent developments have meant that what is regulated as genetic modification is not clear-cut. Previously, 'transgenic' organisms were the focus of discussion and regulation.⁵ The technology that is now available is capable of a range of processes and outcomes, which give increased precision and opportunities over what could previously be achieved and often do not result in a transgenic organism. These include:
 - speeding up a naturally-occurring process
 - producing organisms indistinguishable from those that occur naturally
 - mimicking what a technique exempt from regulations can do
 - turning genes 'on' or 'off' without adding any foreign DNA.
2. Technology that is now in use globally was not contemplated when the HSNO Act was passed in 1996 or during the Royal Commission on Genetic Modification in 2001. The current regime is inflexible and reflects a 1998 understanding of GM and the social priorities at the time. The Not-GM regulations exempt some techniques available in 1998 from being regulated as GM. The High Court has determined that this is an exhaustive list.⁶ This means organisms created using new technologies developed in recent years will have to go through a full approval process, even if:
 - they pose a lower risk than naturally occurring organisms or organisms developed using techniques listed in the Not-GM regulations.
 - they are indistinguishable from naturally-occurring organisms or organisms developed using techniques listed in the Not-GM regulations..
3. Agencies consider that the original framework of the HSNO Act, and how it has been applied since the High Court decision, may be limiting New Zealand's ability to consider uptake of appropriate new technology and therefore preventing the benefits and advancements that new technologies could provide. It is also providing increasing challenges to agencies enforcing regulations when organisms defined as GM and conventionally bred organisms cannot be differentiated.

⁵Transgenic organisms are those that have a gene or genetic material from a sexually incompatible species inserted to achieve a desirable trait.

⁶ *Sustainability Council v Environmental Protection Authority* [2014] NZHC 1067. This High Court case established that only techniques specifically listed in the HSNO (Organisms Not Genetically Modified) Regulations are, or can be made, exempt. Similar techniques or techniques that do the same thing are not exempt unless expressly stated in the regulations.

International Responses

4. The international context of genetic technology regulation is complex. There is no universal definition of GM or GMO.⁷ There is no consensus on the best way to regulate genetic technologies, with countries taking a variety of approaches. How jurisdictions regulate is dependent on the level of flexibility and interpretation within their domestic legislation, the existing use of GM in their jurisdictions, and willingness to review their current policies.
5. Different regulatory schemes use different methods for determining what falls inside and outside the scope of regulation. A common approach is to use triggers; that is, to specify which factors will trigger or make the regulations apply. New Zealand, like many other countries, operates a process trigger, which means that any organism that has been developed using a particular genetic technology is subject to the regulatory requirements of the HSNO Act, regardless of the actual level of risk presented by the final product. In other countries regulation is based on the risk presented by the final product (a 'product trigger'), regardless of technique used. The USA uses a product trigger. Others, such as the EU and Canada, use a combination of both approaches.
6. Jurisdictions around the world are at varying stages of determining how to deal with new technologies. The questions policy makers and regulators around the world are now asking include:
 - whether organisms with genetic changes indistinguishable from naturally occurring organisms should be regulated (e.g., a flower genetically edited to be white, which is exactly the same as a white flower created through unregulated cross-breeding)
 - whether organisms produced by a technique with results indistinguishable from those produced by an already exempt technique should be regulated (e.g. using gene editing to get the exact same result as radiation treatment listed in the not-GM regulations)
 - whether regulatory frameworks generally triggered by process used to create the product rather than the product itself, are commensurate with risk.
7. There is a range of approaches emerging internationally. Countries appear to be leaning towards not regulating organisms as GMOs when:
 - they could have occurred naturally or produced by conventional plant breeding techniques;
 - do not contain any foreign DNA;
 - are null segregants.⁸

We set out some country examples below

United States of America (USA)

⁷ Countries, including New Zealand, that are party to the Cartagena Protocol on Biosafety have agreed on a definition of a 'living modified organism'. However, countries such as Australia, Canada and the United States are not party to the Protocol and do not use this definition. Some countries have incorporated the definition verbatim while others have alternative, but similar, wording in domestic legislation. In New Zealand the HSNO Act predates the Cartagena Protocol but still has similar wording and gives effect to the Protocol.

⁸ Null segregants are organisms that used GM as an intermediate step in development but the final organism does not contain any foreign or intentionally altered DNA.

8. The USA is one of the leading countries in the uptake of genetic technologies. What happens in the USA has considerable influence on global responses.
9. The USA's Co-ordinated Framework for the Regulation of Biotechnology 1986 covers a range of legislation. At least one agency is involved in the approval process, depending on the classification given to an organism and its intended use.⁹
10. On 28 March 2018 the United States Department of Agriculture (USDA) clarified that there is no regulation for plants created using new technologies, provided that they:
- could otherwise have been developed through traditional breeding techniques
 - are not plant pests (such as viruses or bacteria)
 - have not been developed using plant pests.
11. There are some crops that require risk assessment as they could not have occurred naturally or through traditional breeding techniques. Several of these crops have been given regulatory approval and are commercially available, including potatoes with reduced acrylamide¹⁰ and apples that do not go brown.
12. It is likely that more products created using new technologies with altered traits will be commercialised, as there is a clear path to market for such products. The USDA announcement is likely to open the way for more products.
13. The USA uses new genetic technologies in other sectors, such as health and pest control. Several clinical trials that use CRISPR gene-editing technology are underway (e.g., for editing of human T cells to target tumours) as well as studies to target mosquitoes that carry malaria.
14. There has also been the development of disease-resistant American chestnut trees with the intention of reintroducing them to areas from which they have disappeared¹¹. This technology has been raised as having potential to help combat the presence of kauri dieback and myrtle rust in New Zealand.

European Union

15. The EU has a conservative approach to the environmental release of GMOs. Despite this there is a lot of research and design investment in Europe.
16. It is ambiguous how some applications of the new technologies (such as CRISPR) currently fall under the EU regulatory framework.
17. The European Court of Justice (ECJ) is actively considering how new genetic techniques should be regulated after an application from the French court requested a ruling. A decision is expected soon. In January 2018, an advisory legal opinion from the Advocate General to the ECJ concluded that new techniques should be considered GM, but should be exempt from regulation under EU law. This opinion is non-binding; however it carries considerable weight and will be looked at by the ECJ in its decision-making process.
18. If the Advocate General's opinion is adopted by the ECJ, the EU regulatory regime will have taken the opposite position to New Zealand. The EU regime would consider many

⁹ The agencies that could be involved are the US Environmental Protection Authority, US Food and Drug Agency and the US Department of Agriculture.

¹⁰ Acrylamide is a chemical that potatoes heated to high temperatures in the presence of certain sugars can express. One variety is already approved for food use in New Zealand and five more similar varieties will soon be allowed as FSANZ approved them on 7 December 2017. These are only available in processed potatoes such as frozen chips.

¹¹ <https://www.acf.org/our-community/news/new-genetically-engineered-american-chestnut-will-help-restore-decimated-iconic-tree/>.

new techniques exempt from regulation whereas in New Zealand the list of techniques exempt from regulation is limited to those listed in the Not-GM regulations.¹²

19. If the Advocate General's opinion is affirmed, EU foodstuffs and pharmaceuticals derived from organisms made with techniques that are exempt from regulation as GMOs in the EU could still be considered GM products in New Zealand (if they are also a viable organism e.g. it can reproduce) and subject to restrictions under the HSNO Act. They would also be subjected to approval processes (e.g. from FSANZ for food products or Medsafe for pharmaceuticals). Enforceability will be difficult as it may not be possible to detect what technique was used to make a product. It will also make labelling requirements under the Food Standards Code difficult. These difficulties will be common with any countries that do not regulate products from new technologies as GMOs. The Ministry will undertake further analysis of the impact on New Zealand when a final ECJ decision is released and we will provide you with a briefing. There are no immediate effects as a result of the Advocate General's opinion.

Australia

20. Australia is actively reviewing its policy and regulatory frameworks, with three reviews being undertaken by the Department of Health, the Office of the Gene Technology Regulator, and Food Standards Australia New Zealand.

The Department of Health (DoH)

21. The Australia Gene Technology Scheme was introduced in 2001 and has been reviewed twice since its commencement (2006, 2011). The current third review of the scheme is again focused on the ongoing achievement of the policy objectives, but it is doing this with a future-focused lens, taking into account the rapidly developing and innovative area of gene technology.
22. The current review includes a discussion on whether to change the process-based system to, for example, a product-based approach with tiered levels of risk.
23. After three rounds of consultation, the DoH has produced a preliminary for comment. The report has 33 findings that include a recognition that the scheme has not kept up to date with technological advances. The DoH expects to present recommendations to all state governments later this year. We will brief you on their findings at this point.

The Office of the Gene Technology Regulator (OGTR)

24. The OGTR performs technical reviews (separate to reviews of the overall Gene Technology Scheme). It is currently undertaking a technical review of the Gene Technology Regulations to provide clarity about whether organisms developed using a range of new technologies are subject to regulation as GMOs, and to ensure that new technologies are regulated commensurate with the risk they pose. The technical review is intended to provide an interim solution while broader policy considerations associated with new technologies are being progressed through the overall policy review of the scheme.
25. An exposure draft with proposed amendments was made publically available for comment from November 2017 to February 2018. The OGTR is now considering the issues raised in submissions and finalising the draft amendments. The Regulator will then propose the amendments to the Commonwealth, State and Territory governments for agreement.
26. The OGTR's current proposal, if accepted, will mean that null segregants and some forms of gene editing techniques, generally referred to as Site Directed Nucleases-1

¹² As established in *Sustainability Council v Environmental Protection Authority* [2014] NZHC 1067.

(SDN-1)¹³ are not regulated as GM (both of these types of organisms are regulated as GM in New Zealand). SDN-1 techniques do not introduce DNA from another species and make changes that are within the bounds of normal genetic variation. They can speed up the process and produce fewer unintended effects. The decision on null segregants will put into regulation what is already occurring in practice.

Food Standards Australia New Zealand (FSANZ)

27. FSANZ is consulting with the Australian and New Zealand public to consider whether, and how, food derived from new technologies should be captured for pre-market approval, and whether the definitions for 'food produced using gene technology' and 'gene technology' should be changed to improve clarity about which foods require pre-market approval.
28. FSANZ's discussion document considers a range of options from treating new techniques like conventional breeding techniques ('given a green light once a technique has been proved safe') or like current GMOs (which would mean that each application requires a rigorous safety assessment).
29. The review will not directly result in changes to the Food Standards Code (which governs food safety in both Australia and New Zealand). After completing the review FSANZ will decide whether to prepare a proposal to amend the Code, which would involve further public consultation. There is no timeframe for preparing a proposal, although it is unlikely to be this year.
30. If FSANZ decides that amendments to the Code are necessary, this might result in a situation where the HSNO Act and the Food Code are not consistent. For example, a food import could potentially be given market approval for New Zealand through FSANZ, but under the HSNO Act it would still be considered a GMO and could not be imported or produced in New Zealand without going through a rigorous assessment process.
31. The Ministry for Primary Industries (MPI) has made a submission to this review, with input from the Ministry for the Environment. MPI considers foods that are identical to those developed through conventional breeding or could occur naturally should be exempt from requiring a pre-market assessment and approval as a GM food. The submission also acknowledges the potential definitional inconsistencies between the Food Standards Code and the HSNO Act, and implications of such gaps.

Interest for New Zealand

Opportunities

32. New Zealand has an opportunity to position itself on current GM technologies before new products start reaching our shores. This includes consideration of the workability of the regulatory system, such as enforcement, and whether the high thresholds in the Act create a disincentive for New Zealand-specific solutions. For example, AgResearch is currently under taking field trials on a drought-tolerant ryegrass in the USA – it chose not to apply for approval to test this in New Zealand.
33. There are possible opportunities for new technologies in a number of sectors, as set out in an illustrative list in Table 1 below. These opportunities have the potential to assist in areas that have been indicated as current Government priorities (e.g. climate change mitigation/adaptation and predator control/conservation).

¹³ SDN-1 techniques involve the use of gene editing that does not use a template to repair the cut that has been made in DNA. The cut is repaired by natural repair mechanisms that join the two 'cut' ends back together without using a template (guide DNA sequence). No foreign or additional DNA is added to the organism.

34. While there are indications of the potential new technologies may have for predator control (such as the use of gene drives), these uses are still a long way off. They would require significant development before their possible use should be considered. There is still uncertainty as to whether such methods would be successful or should be used and significant background research that would be required before testing could even occur. For that reason we do not believe the use of genetic technologies for predator control should be the instigator for a public conversation on genetic technologies.

Table 1: Examples of potential uses of new genetic technologies beneficial for New Zealand

Environment	Forestry	Industrial
<ul style="list-style-type: none"> • Climate mitigation such as stock with reduced methane emissions and drought-tolerant pasture species • Animal and plant pest control • Use of genetic tools to breed kauri and pohutukawas resistant to diseases (e.g. such as kauri dieback and myrtle rust) • Potential treatment of diseases for horticultural crops 	<ul style="list-style-type: none"> • Improved growth and disease tolerance • Modified traits such as sterility to reduce risk of wilding pine spread • Improved wood density and quality 	<ul style="list-style-type: none"> • Microbes and other organisms used in the production of biofuels and other products • Microbes used for environmental mitigation (e.g. to degrade harmful/wasteful plastic) • Enhanced ability of plants and/or bacteria to bind heavy metals
Food	Farming Forage	Health
<ul style="list-style-type: none"> • Improved traits such as non-browning apples, milk free from allergenic protein, 'tearless' onions • Improved nutritional benefits such as low-acrylamide potatoes • Entirely new food production platforms such as synthetic or plant based alternatives to meat and dairy 	<ul style="list-style-type: none"> • Higher-yielding crops • Grass with more efficient use of nitrogen and phosphorus, which will reduce fertiliser needs and result in less run-off 	<ul style="list-style-type: none"> • Medical treatments that target disease-causing genes • Medical treatments that modify and reintroduce a patient's cells • Vaccines using modified viruses • Pharmaceuticals – producing drugs using GM microbes or animals

Challenges

35. It will become increasingly difficult to enforce current regulations as some organisms developed using new technologies are indistinguishable, both visually and by DNA testing, from non-GM organisms or organisms produced using an exempt technique. Attempting to regulate one but not the other will be virtually impossible in practice and will result in disproportionate regulation where the risks from an organism produced in either way are the same.

36. New Zealand-based companies may decide to go offshore to avoid New Zealand's rigorous controls. This could result in New Zealand missing out on the benefits from products designed for the New Zealand environment.

New Zealand's regulatory framework

37. The Ministry for the Environment's current focus is to keep abreast of developments in genetic technologies internationally and monitor how other jurisdictions respond. This will aid us to understand the broader environment in which New Zealand's regulatory framework operates. Our policy work this year will consider the impact of regulation in other countries on New Zealand's system, and the benefits and risks of our system.

New Zealand's GM legislation is over 20 years old

38. GM is regulated under the HSNO Act, which has been in place for 22 years. The HSNO Act emphasises precaution in the regulation of organisms that meet the definition of a GMO as specified in the Act and do not have an exemption under the Not-GM regulations. Over this time genetic science has also advanced substantially and has challenged existing regulatory frameworks.

39. The Act has never been fully reviewed, though some amendments to the Act were made following the Royal Commission in 2001.

Definitions under HSNO do not align controls to risk

40. Legislation can be based on technique (process) or product (outcome). The HSNO Act sets regulatory requirements and provides a risk-assessment framework based on the 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. For example, gene editing can be used to more swiftly produce an organism that could have occurred naturally or produced through traditional plant breeding – yet the gene edited organism would be highly regulated whilst the naturally-occurring one or the one from traditional plant breeding would have no regulation at all. As the use of new technology becomes more widespread this issue will become more prevalent.

Approval process

41. The use of any new organism requires approval under the HSNO Act from the EPA. If an application for the contained use, development or release of a new organism is submitted, the EPA undertakes a risk/benefit assessment of the new organism under the provisions of the HSNO Act on a case-by-case basis.

42. The HSNO Act sets out a specific methodology for the assessment and decision-making process, including considering effects on native species, biodiversity, and natural habitats. If any of the Act's minimum standards cannot be met, or cannot be *shown* to be met, then the EPA must decline the application.

43. This risk assessment framework sets a very high threshold for the release of a new organism, including GMOs. People can apply for a GMO field trial (in containment) or a full release; however the high threshold for either of these approval options appears to discourage would-be applicants. Anecdotal feedback from stakeholders and EPA is that the high thresholds make it essentially impossible to obtain a release approval for virtually any GMO in pastoral and horticultural species, and that there is no clear path to market, which discourages commercial development.

44. The system has ensured that 1998-era transgenic technology has been given a high level of scrutiny, while other techniques that mimic natural processes and techniques that were well understood at the time were exempted in the Not-GM Regulations. As the legislation has not evolved, new technologies receive the same level of scrutiny as older transgenic techniques when this may be an unnecessarily high threshold.

How we got to where we are

45. In 2001–2002 a Royal Commission investigated a way forward for GM in New Zealand. The Royal Commission's recommendation was to "proceed with caution". It did not advocate for a complete ban on GM technology, however the interpretation of the Commission's recommendation has contributed to the current cautious approach. This coupled with the perception that something will not get approved, has led to a very conservative operation of the Act's settings.
46. To date only three GMOs have been approved for conditional release in New Zealand:
- *Proteqflu*, an equine influenza vaccine
 - *Pexa-Vec*, used in a clinical trial for patients with liver cancer
 - *Telomelysin*, used in a clinical trial for patients with advanced and inoperable melanoma.
47. No GM organisms are commercially available and no application for a full environmental release has ever been received by the EPA. Some GMOs are approved for research in containment. New Zealand maintains a certain level of capability with genetic technologies. The majority of MBIE-funded research is in genomics or uses GM technologies as part of a research project that is not primarily about GMOs. There is currently relatively little research into developing GM products or GMOs for eventual commercial application. Research in this space appears to be exploratory rather than close-to-market.

International obligations

48. The Cartagena Protocol on Biosafety (the Protocol) to the Convention on Biological Diversity (CBD) aims to ensure the safe handling, transport and use of living modified organisms (LMOs) between countries. The Protocol has been in force since 2003.
49. New Zealand is one of 171 parties to the Protocol and has implemented its obligations under the HSNO Act and other legislation and regulations. New Zealand actively contributes to Parties' discussions about improving risk assessment and risk management practices.
50. For several years, the CBD has been considering developments in genetic technologies and impacts on biodiversity. Its November Conference of the Parties (COP) will again discuss this topic. The Ministry of Foreign Affairs and Trade will lead advice to Ministers to prepare for the November COP.

Public conversations occurring now

51. The Royal Society Te Apārangi has convened a multidisciplinary panel on gene editing to discuss the potential use of gene editing in different sectors. The Royal Society has said that the aim of the Panel is not to come to a view on the merits or otherwise of these technologies, but to inform the inevitable and necessary societal debate.
52. In December 2017 the Panel released two technical papers and two general discussion documents on the current and potential uses of gene editing in pest control and healthcare. It is developing further papers on gene editing in agriculture, legislation and regulation, and Māori perspectives, for release in 2018. These papers follow on from resources produced last year to explain gene editing technology.¹⁴ The Society is holding a number of stakeholder forums this year to discuss their findings. Last year the Society also hosted a series of panel discussions hosted by Kim Hill.

¹⁴ royalsociety.org.nz/gene-editing-technologies

53. We are supportive of the Royal Society's efforts in raising awareness and encouraging discussion of genetic technology.

The Ministry for the Environment is preparing to respond to international developments

54. We want to be prepared for New Zealand to respond to international developments. We are continuing to do background analysis on the policy settings of the HSNO Act to be in a good position to advise you about the policy and regulatory issues arising from international developments in genetic technologies.

55. We are monitoring:

- a. developments in new genetic technologies
- b. international regulatory and policy responses to these developments
- c. potential impacts on New Zealand of these international developments.

56. This information will help us to assess:

- a. the enforceability of our regulatory regime when products developing using a new technology arrive at our border
- b. opportunities and impacts for New Zealand if we were to choose to use (or not) new technologies
- c. whether the HSNO Act is fit for purpose to regulate the developments.

57. This work is a desk-based exercise. At this stage we are seeking input from other agencies, including the Departmental Science Advisors (DSA) network. We are also tapping into existing conversations and analysis, including the Royal Society's panels.

58. The contentious nature of GM and the wide range of views on the topic mean that any decisions about the policy settings and regulatory framework should include public input. However, a public conversation needs to be carefully considered and planned to ensure it is effective and constructive. The Ministry for the Environment believes this should involve an open and transparent process, entered into without preconceived ideas about whether New Zealand should be using the technology or any potential policy and/or legislative changes. We will provide you with advice by the end of 2018 on possible approaches to seeking input from stakeholders and the public in future policy work.

Consultation and Collaboration

59. The Ministry for the Environment has consulted with the Ministries of Business, Innovation and Employment, Foreign Affairs and Trade and Health, the Ministry for Primary Industries, the Department of Conservation, the Environmental Protection Authority and the Treasury in the drafting of this briefing.

60. The Ministry for the Environment has convened a cross agency group of the above agencies that meets every few months to keep in contact about the latest developments, and to contribute to the Ministry's work programme.

61. We have provided the table (Table 2) below as a guide to the broad range of portfolios with either an interest and/or responsibility in addressing GM issues in New Zealand.

Table 2: An overview of portfolios (and relevant Minister) with an interest or responsibility relating to genetic modification in New Zealand

Portfolio (and relevant Minister)	Interest/Responsibility
Agriculture (Minister O'Connor)	<p>Opportunities to:</p> <ul style="list-style-type: none"> • Use GM forage with improved food value, decreased nutrient requirements, and resistance to drought • Speed up the breeding of new fruit tree varieties
Biosecurity (Minister O'Connor)	<p>Opportunities to:</p> <ul style="list-style-type: none"> • Develop fruit trees resistant to pests and diseases • Possible solutions to control pests and diseases <p>Responsible for:</p> <ul style="list-style-type: none"> • Enforcing compliance of use of GM organisms approved by the EPA • Enforcing requirements relating to imports of GMOs • Enforcing containment requirements of laboratories holding new organisms, including GMOs
Food Safety (Minister O'Connor)	<p>Responsible for:</p> <ul style="list-style-type: none"> • Oversight of New Zealand's involvement with Food Standards Australia New Zealand • FSANZ approving GM food products • Labelling of GM foods
Forestry (Minister Jones)	<p>Opportunities to:</p> <ul style="list-style-type: none"> • Use sterile plantation trees which do not cause wilding problems • Use trees with GM developed resistance to pests and diseases
Foreign Affairs (Minister Peters)	<p>Responsible for:</p> <ul style="list-style-type: none"> • New Zealand's obligations under the Convention for Biological Diversity and its Cartagena Protocol on Biosafety (governs the movement of living modified organisms between countries)
Research, Science and Innovation (Minister Woods)	<p>Responsible for:</p> <ul style="list-style-type: none"> • New Zealand's science and research investment
Local Government (Minister Mahuta)	<p>Responsible for:</p> <ul style="list-style-type: none"> • Local government GM decision making under the Resource Management Act
Climate Change (Minister Shaw)	<p>Opportunities to:</p> <ul style="list-style-type: none"> • Use GM technology for climate mitigation such as stock with reduced methane emissions and drought-tolerant pasture species
Conservation (Minister Sage)	<p>Opportunities for:</p>

	<ul style="list-style-type: none"> • Possible solutions for pest control
Associate Minister for the Environment (Minister Sage)	Responsible for: <ul style="list-style-type: none"> • Oversight of the EPA who is responsible for making decisions on new organism applications
Health (Minister Clark)	Responsible for: <ul style="list-style-type: none"> • GM medical medicines and therapies Opportunities for: <ul style="list-style-type: none"> • GM medical treatments that target disease-causing genes • Medical treatments that modify and reintroduce a patient's cells • Vaccines using modified viruses • Pharmaceutical drugs using GM microbes or animals

Next Steps

62. We recommend that you meet with Ministry for the Environment officials to discuss the developments in genetic technology and its potential risk and benefits for New Zealand.
63. We will brief you on developments as they arise. We will provide you with a briefing on international developments as they occur and a briefing in November about further steps towards a participatory process for a possible public conversation.



NEW ZEALAND
FOREIGN AFFAIRS & TRADE



11 June 2018

► Minister of Foreign Affairs For action by 18 June 2018

CONVENTION ON BIOLOGICAL DIVERSITY NEGOTIATING POSITION

BRIEFING General Purpose

PURPOSE To seek your approval of New Zealand's negotiating position for technical and implementation meetings of the Convention on Biological Diversity, 2 to 13 July 2018.

Recommended referrals

Minister for the Environment	For information by	18 June 2018
Minister of Conservation	For information by	18 June 2018
Minister for Crown/Maori Relations	For information by	18 June 2018
Minister for Maori Development	For information by	18 June 2018
Minister of Agriculture	For information by	18 June 2018
Minister of Forestry	For information by	18 June 2018
Minister for Climate Change	For information by	18 June 2018

Contact details

NAME	ROLE	DIVISION	WORK PHONE	MOBILE PHONE
Rosemary Paterson	Divisional Manager	Environment	s9(2)(a)	
Daniel Wai-Poi	Policy Officer	Environment		

Minister's Office comments

CONVENTION ON BIOLOGICAL DIVERSITY NEGOTIATING POSITION

Key points

- From 2 to 13 July, meetings of the implementation and scientific bodies of the Convention on Biological Diversity (“Convention” or “CBD”) will be held. The New Zealand delegation will be led by the Ministry of Foreign Affairs and Trade.
 - The New Zealand negotiating position will be guided by principles of:
 - alignment with domestic policy;
 - flexibility, practicality and workability; and
 - cost effectiveness of programmes and of the Secretariat itself.
 - The meetings will discuss a number items of interest to New Zealand, including:
 - the process to determine the future framework for international biodiversity, including what replaces the current set of biodiversity goals when they expire in 2020;
 - funding for international biodiversity work in developing countries;
 - mechanisms to make implementation of the Convention more effective;
 - the mainstreaming of biodiversity into the sectors of energy and mining, infrastructure, manufacturing and processing, and health, in the form of best practice guidelines;
 - whether digital records of genetic information counts as ‘genetic material’ under the Convention, and are hence subject to access and benefit sharing requirements. Officials believe that they do not;
 - the effects of new genetic technologies on biodiversity. The Secretariat has recommended further research and information sharing on the possible effects of these technologies, an approach officials support;
 - the effectiveness and implementation of the Nagoya Protocol, a protocol under the Convention which addresses the need for fair and equitable access conditions for genetic resources, as well as benefit sharing arrangements for the utilisation of those resources. New Zealand’s ability to shape these discussions will be limited by the fact that we are not a party to the Protocol; and,
 - options for the future incorporation of indigenous peoples’ traditional knowledge in the work of the Convention with decisions to be made in 2020.
- The meetings will result in a set of recommendations on these issues, amongst others, to the decision-making Conference of Parties, which will next meet in November. We will seek a detailed negotiating mandate ahead of this Conference and following outreach to the public and stakeholders.



Bernadette Cavanagh
for Secretary of Foreign Affairs and Trade

CONVENTION ON BIOLOGICAL DIVERSITY NEGOTIATING
POSITION

Recommendations

It is recommended that you:

- 1 **Note** the upcoming meetings of the subsidiary bodies of the Convention on Biological Diversity and the agenda items of interest to New Zealand; Yes / No
- 2 **Agree** to the negotiating principles and positions outlined in this paper. Yes / No

Rt Hon Winston Peters
Minister of Foreign Affairs

CONVENTION ON BIOLOGICAL DIVERSITY NEGOTIATING POSITION

Report

1. Two meetings of subsidiary bodies of the Convention on Biological Diversity (CBD) will be held in Montreal in July. From 2 to 7 July, the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) will meet, and from 9 to 13 July, the Subsidiary Body on Implementation will meet. Both subsidiary bodies provide advice to the Conference of Parties (COP), which is the ultimate decision making body of the CBD. The next COP will be in November 2018 in Egypt, and New Zealand ministers will be invited. Advice on attendance is being prepared.

New Zealand's negotiating position

2. We propose that the New Zealand delegation be guided by the following principles when negotiating recommendations:
 - a) consistency with relevant domestic policy settings;
 - b) flexibility, practicality and workability;
 - c) whether issues discussed are within the CBD's mandate; and
 - d) cost effectiveness of programmes and of the Secretariat itself.
3. The meetings will consider the following items of interest to New Zealand.

The post-2020 framework

4. The current set of international biodiversity goals (known as the Aichi targets) expire in 2020. The upcoming meetings will discuss the process to determine the framework that replaces them. It is important to New Zealand that the process is led by Parties ^{s6(a)} that it does not preclude our developing a national biodiversity strategy now (as decided by the Minister of Conservation); and, that it is participatory, inclusive, comprehensive, knowledge-based, and iterative. The substance of the new framework will be discussed in the two year period after the COP this year, leading to adoption in 2020.

Progress on funding levels for international biodiversity efforts

5. The level of funding required to prevent further biodiversity loss is a long-standing point of contention. The July meetings will likely focus on the accuracy of reporting. New Zealand believes the current goal for doubling support from developed to developing countries, which Parties agreed as a collective goal in 2014, is feasible and reflective of current fiscal constraints. Our last stocktake, in 2016, showed an increase in aid for biodiversity, but below the doubling target.

Mechanisms to review implementation of the Convention

6. The upcoming meetings will continue discussions on possible mechanisms to improve implementation of the Convention. Officials propose to advocate for mechanisms that are flexible, voluntary, inexpensive and efficient.

CONVENTION ON BIOLOGICAL DIVERSITY NEGOTIATING POSITION

Mainstreaming biodiversity into other sectors

7. The upcoming meetings, and the ministerial event at the COP at the end of the year, will include discussions of mainstreaming biodiversity into energy and mining, infrastructure, manufacturing and processing, and health. The CBD's goal is to create conditions whereby the importance of biodiversity is fully integrated into policy, regulation and legislation in these areas.

Whether digital information is genetic material

8. A number of countries have argued that digital information detailing, for instance, the genetic code of an organism, should be considered a "genetic material" as defined by the CBD and Nagoya Protocol and, hence, subject to access arrangements to ensure benefits (such as royalties) are paid to the resource owners. The CBD definition of "genetic material" is of material "containing functional units of heredity". As such, officials do not believe that digital information is captured within the definition and therefore recommend that New Zealand does not support this argument.

The effects on biodiversity of genetically modified organisms

9. There is a lively debate around if and how new genetic technologies affect biodiversity and whether the topic should even be discussed within the CBD. The meeting paper on the topic recommends states have strategies to prevent potential environmental harm by genetically modified organisms, a precautionary approach to gene drives, and the sharing of relevant information. New Zealand supports these suggestions.

The Nagoya Protocol – access and benefit sharing for genetic resources

10. The Nagoya Protocol sits under the CBD and promotes fair and equitable access to, and benefit sharing from the utilisation of, genetic resources. New Zealand is not a party to Nagoya, ^{s9(2)(f)(iv)}. We would need to establish a bioprospecting regime before we could become a party. A number of aspects of the Nagoya Protocol will be discussed at the meetings, including its effectiveness and the need for a multilateral benefit-sharing mechanism. Officials will report further on the Protocol following these meetings.

Integrating indigenous peoples' traditional knowledge into the CBD (Art 8j)

11. There is a Working Group on integrating indigenous peoples' traditional knowledge into the wider work of the CBD. The Secretariat has suggested ways to improve this integration. New Zealand will need to complete consultation of iwi/hapu/whanau before a recommendation is made on which option we wish to support. As such, the delegation will support the compromise reached in earlier meetings to delay a decision on this matter until the 2020 COP.

Remaining agenda items

12. The delegation will also closely follow a range of other issues of interest to New Zealand such as invasive alien species, pollinators, marine issues, the effectiveness of the CBD, and the connections between biodiversity and climate change adaptation.

From: Mariska Wouters
Sent: Wednesday, 7 November 2018 1:39 PM
To: Hayden Johnston (Parliament)
Cc: Brian Hallinan; Glenn Wigley
Subject: FW: Min Sage ask for advice on gene drives in CBD - for comment by COP 7 November
Attachments: Brief for Min Sage - Gene drive technology and the Convention on Biological Diversity - November 2018.docx

Hi Hayden,

Further to your question about NZ's position on gene drive technology at the upcoming Conference of the Parties of the Convention on Biological Diversity, in relation to a recent letter from the Sustainability Council to Minister Parker. Please find attached advice being provided by MFAT (supported by MfE and EPA) to Minister Sage who is attending the High-level Segment event ahead of the COP.

Cheers
Mariska

From: Kayla Kingdon-Bebb [<mailto:Kayla.Kingdon-Bebb@parliament.govt.nz>]
Sent: Tuesday, 6 November 2018 10:49 a.m.
To: fcumming@doc.govt.nz; WAI-POI, Daniel (ENV)
Cc: Penny Race
Subject: Advice for CBD HLS

Hi Both,

Minister Sage recently was provided the enclosed letter from the Sustainability Council of NZ on Gene Drive, which relates to a recent article in the New Scientist (also enclosed).

As this correspondence relates specifically to discussions at the COP CBD, she has requested that some advice on this matter is included in the briefing being prepared for her.

If officials haven't already covered this topic in the briefing, I suggest you may wish to reach out to colleagues at MfE for some assistance, as I understand the high level policy on gene drive sits within Hon Parker's portfolio responsibilities.

Cheers,
Kayla



Dr Kayla Kingdon-Bebb | Principal Advisor (Conservation)
Office of Hon Eugenie Sage
Minister of Conservation | Minister for Land Information | Associate Minister for the Environment
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Gene drive technology and the Convention on Biological Diversity

Gene drive technologies are covered under both the Convention on Biological Diversity, under discussions of synthetic biology (new genetic technologies), and the Cartagena Protocol on Biosafety, under the item on risk assessment and risk management.

In their letter, the Sustainability Council of New Zealand has drawn attention to language in paragraph ten of the draft Convention on Biological Diversity decision on synthetic biology. The draft paragraph states that:

10. Calls upon Parties and other Governments, taking into account the current uncertainties regarding engineered gene drives, to apply a precautionary approach, in accordance with the objectives of the Convention, [with regard to][and refrain from] the release, including experimental release, of organisms containing engineered gene drives;

The text in square brackets are two options that are still to be decided by the countries that are Parties to the Convention on Biological Diversity. The Sustainability Council of New Zealand has called for the deletion of "with regard to" and the retention of "and refrain from".

In addition to the paragraph mentioned by the Sustainability Council of New Zealand, there is text in the decision:

- recognising that more research and analysis is required before any organisms containing gene drives are released into the environment;
- recognising that the free, prior and informed consent of indigenous peoples may be required before any possible release that might impact on their livelihoods, traditional knowledge or use of land and water;
- encouraging Parties and stakeholders to share information and data on the potential impacts of gene drives; and,
- deciding to establish an expert group that looks at, amongst other things, the potential impacts of organisms containing engineered gene drives.

Under the draft decision on risk assessment and risk management, there is text:

- establishing another expert group that will also look at gene drive and whether existing guidance is adequate to address these technologies;
- recognising that more research and analysis is required before any organisms containing gene drives are released into the environment; and,
- deciding to continue discussion over whether additional risk assessment and risk management guidance is required following a Secretariat-facilitated study into gene drives.

The above decisions were only agreed after long discussions at the Convention's scientific and technical body in July. The language (like the language in paragraph ten), represents a delicate compromise.

A number of countries wish to continue research into gene drives. s6(a)

A smaller number of countries are seeking the "refrain from" language that the Sustainability Council of New Zealand supports.

New Zealand's position on the text in paragraph ten is informed by the following objectives:

- To support a reasonable and science-based approach to synthetic biology that is consistent with our existing domestic framework. To only support mechanisms, such as horizon scanning and reporting, that are non-duplicative and add value.
- To support a precautionary approach to organisms containing engineered gene drives and to resist calls for a moratorium on this technology, in line with our domestic legislation that requires assessment on a case-by-case basis.

We do not support including the words "refrain from" as this s9(2)(f)(iv) and is incongruent with our domestic framework (the Hazardous Substances and New Organisms Act) which is based on a precautionary approach and scientific assessments on a case-by-case basis.

The Environmental Protection Authority has neither granted nor received any applications to develop gene drive organisms in containment.

In addition to the letter and emails from the Sustainability Council of New Zealand, officials have also been approached by the group Island Conservation that wants to see further research into gene drives as a potential method of pest control.

MFAT, MfE, EPA
November 2018

From: [Hayden Johnston](#)
To: [Mariska Wouters](#); [Ministerials](#)
Cc: [Brian Hallinan](#); [Glenn Wigley](#)
Subject: RE: Letter for Hon David Parker: Sustainability Council on GE and CBD Meeting - COR6623
Date: Wednesday, 28 November 2018 5:49:57 PM

Thanks Mariska, that's a really helpful summary.
Hayden

From: Mariska Wouters [mailto:Mariska.Wouters@mfe.govt.nz]
Sent: Wednesday, 28 November 2018 5:44 PM
To: Hayden Johnston <Hayden.Johnston@parliament.govt.nz>; Ministerials <ministerials@mfe.govt.nz>
Cc: Brian Hallinan <Brian.Hallinan@mfe.govt.nz>; Glenn Wigley <glenn.wigley@mfe.govt.nz>
Subject: RE: Letter for Hon David Parker: Sustainability Council on GE and CBD Meeting COR6623

Hi Hayden

The delegation hasn't had a chance to reply yet as they are a very small team and have multiple negotiations going on simultaneously.

New Zealand's position:

Based on our tracking of the negotiations, we don't think there are issues that need to be immediately addressed. NZ's officials are taking positions consistent with NZ's regulatory framework, and the direction of the negotiation is also consistent with our domestic approach.

Here's where the Parties are at:

The CBD COP concludes on Thursday. The contact group on Risk Assessment and Risk Management under the Cartagena Protocol reached consensus. The contact group on Synthetic Biology made significant progress. s6(a)

. Delegates will likely be considering the draft decisions in plenary today (Wed).

Draft decisions:

The draft consensus decisions are consistent with NZ's domestic regulatory framework. This includes taking a precautionary approach, appropriate risk assessment and risk management, and decision-making on a case-by-case basis.

A compromise position is underway regarding whether 'genome editing' should be specifically mentioned in the draft decisions for synthetic biology. Removing genome editing as a category for consideration under synthetic biology is supported by many parties (gene editing is a wide-ranging technology).

The draft decisions include agreement on the need for further research and broad international cooperation relating to gene drive organisms.

The discussion has moved away from a moratorium on gene drives, which enjoyed very little

support s6(a)), towards what might be required before a release of organisms containing gene drive technologies could occur. Para 9 of the draft synbio decision (see below) states that a gene drive organism should only be considered for release once the following is done:

Scientifically sound case-by-case risk assessments have been carried out

Risk management measures are in place to avoid or minimize potential adverse effects, as appropriate

Where appropriate, the “prior and informed consent”, the “free, prior and informed consent” or “approval and involvement” of potentially affected indigenous peoples and local communities is sought or obtained, where applicable in accordance with national circumstances and legislation.

Also, para 10 of the draft decision calls for more research on gene drives before consideration for release.

Both of these paragraphs are entirely consistent with New Zealand’s domestic legislation.

For your reference we’ve put the relevant draft decisions verbatim at the bottom of this email.

In the reply we will draft for the Minister we will clarify New Zealand's approach in detail.

Cheers

Mariska



Further information for your reference

Risk Assessment and Risk Management relevant draft decisions:

3. Also recognizes that, as there could be potential adverse effects arising from organisms containing engineered gene drives, before these organisms are considered for release into the environment, research and analysis are needed, and specific guidance may be useful, to support case-by-case risk assessment;

5. Calls for broad international cooperation, knowledge sharing and capacity-building to support, inter alia, Parties in assessing the potential adverse effects on the conservation and sustainable use of biodiversity from living modified fish and other living modified organisms produced through new developments of modern biotechnology, including LMOs developed through genome editing and LMOs containing engineered gene drives, taking into account risks to human health, the value of biodiversity to indigenous peoples and local communities, and relevant experiences of individual countries in performing risk assessment of such organisms in accordance with annex III of the Cartagena Protocol;

Synthetic Biology relevant draft decisions:

3. Agrees that broad and regular horizon scanning, monitoring and assessing of the most recent technological developments is needed[,taking into account that this may include genome editing,]for reviewing new information regarding the potential positive and potential negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and those of the Cartagena Protocol and Nagoya Protocol;

9. Calls upon Parties and other Governments, taking into account the current uncertainties regarding engineered gene drives, to apply a precautionary approach, in accordance with the objectives of the Convention, and also calls upon Parties and other Governments to only

consider introducing organisms containing engineered gene drives into the environment, including for experimental releases and research and development purposes, when:

- (a) Scientifically sound case-by-case risk assessments have been carried out;
- (b) Risk management measures are in place to avoid or minimize potential adverse effects, as appropriate;
- (c) Where appropriate, the “prior and informed consent”, the “free, prior and informed consent” or “approval and involvement”² of potentially affected indigenous peoples and local communities is sought or obtained, where applicable in accordance with national circumstances and legislation;

10. Recognizes that, as there could be potential adverse effects arising from organisms containing engineered gene drives, before these organisms are considered for release into the environment, research and analysis are needed, and specific guidance may be useful, to support case-by-case risk assessment;

-----Original Message-----

From: Hayden Johnston <Hayden.Johnston@parliament.govt.nz>
Sent: Wednesday, 28 November 2018 1:34 PM
To: Mariska Wouters <Mariska.Wouters@mfe.govt.nz>; Ministerials <ministerials@mfe.govt.nz>
Cc: Brian Hallinan <Brian.Hallinan@mfe.govt.nz>
Subject: RE: Letter for Hon David Parker: Sustainability Council on GE and CBD Meeting - COR6623

Hi Mariska - any sense from the negotiators about whether we need an urgent reply to this? Minister's Office want to know if so.

Thanks
Hayden

-----Original Message-----

From: Mariska Wouters [<mailto:Mariska.Wouters@mfe.govt.nz>]
Sent: Tuesday, 27 November 2018 2:49 PM
To: Hayden Johnston <Hayden.Johnston@parliament.govt.nz>; Ministerials <ministerials@mfe.govt.nz>
Cc: Brian Hallinan <Brian.Hallinan@mfe.govt.nz>
Subject: RE: Letter for Hon David Parker: Sustainability Council on GE and CBD Meeting - COR6623

Thanks Hayden.

We submitted the draft response to the first letter from the Sustainability Council to Ministerials on 16 Nov.

I'll check with the delegation to gauge their negotiation approach.

Cheers
Mariska

-----Original Message-----

From: Hayden Johnston <Hayden.Johnston@parliament.govt.nz>

Sent: Tuesday, 27 November 2018 2:25 PM

To: Ministerials <ministerials@mfe.govt.nz>

Cc: Brian Hallinan <Brian.Hallinan@mfe.govt.nz>; Mariska Wouters <Mariska.Wouters@mfe.govt.nz>

Subject: FW: Letter for Hon David Parker: Sustainability Council on GE and CBD Meeting - COR6623

Importance: High

For response please.

Note for Brian and Mariska - please confirm whether there are any issues that need to be addressed immediately.

Otherwise a response in due course.

Can you also please acknowledge the previous letter from the Sustainability Council (also attached).

Thanks

Hayden

-----Original Message-----

From: Claire Gibb

Sent: Tuesday, 27 November 2018 2:15 PM

To: Hayden Johnston <Hayden.Johnston@parliament.govt.nz>

Subject: FW: Letter for Hon David Parke : Sustainability Council on GE and CBD Meeting - COR6623

Importance: High

Claire Gibb | Private Secretary (Environment) Office of Hon David Parker Parliament Buildings | Wellington | New Zealand

s9(2)(a)

----- Original Message-----

From: John Blincoe

Sent: Tuesday, 27 November 2018 2:00 PM

To: Claire Gibb <Claire.Gibb@parliament.govt.nz>

Cc: Tracey Gallagher <Tracey.Gallagher@parliament.govt.nz>

Subject: Letter for Hon David Parker: Sustainability Council on GE and CBD Meeting - COR6623

Importance: High

Kia ora Claire and Tracey

This is the subsequent (identical) letter of 23 November 2018, addressed to Minister Parker

rather than Minister Sage.

It should also be designated COR6623.

The letter should be answered by Minister Parker, with the reply noting that the letter had originally been addressed to Minister Sage.

The letter to Hon Sage arrived at COP Friday 23 November 2018. Because Minister Sage had represented New Zealand at ministerial level earlier on in high level CBD discussions, the matter was initially brought to her attention.

Minister Sage having returned from the meeting, responsibility for the matter has now reverted to Minister Parker as the lead Minister on this matter.

In any event, New Zealand's position in the discussions was outlined in the attached extract from the CBD brief.

There was some urgency to this when the matter was initially raised by the Sustainability Council, because the CBD meeting was then apparently ongoing at officials level.

IF SENIOR OFFICIALS FEEL THERE IS ANYTHING THAT MINISTER PARKER NEEDS TO ACT ON IMMEDIATELY, PLEASE ASK THEM TO PROVIDE URGENT ADVICE.

Otherwise, a draft reply in due course please.

Best, John

John Blincoe | Senior Ministerial Advisor DDI s9(2)(a) | Email
john.blincoe@parliament.govt.nz

Office of Hon David Parker MP | Attorney-General | Minister for Economic Development |
Minister for the Environment | Minister for Trade and Export Growth | Associate Minister of
Finance

-----Original Message-----

From: Simon Terry [<mailto:simon.terry@sustainabilitynz.org>]

Sent: Saturday, 24 November 2018 11:45 AM

To: John Blincoe <John.Blincoe@parliament.govt.nz>

Subject: Re: FW: Letter for Hon Eugenie Sage

Hello John

The letter attached to the email below was addressed to Minister Sage on the understanding she was still at the COP and would be the person on the ground best placed to respond. I have since been informed she is back in New Zealand, and as the letter addresses a policy area I understand is the responsibility of Minister Parker, I have readdressed the letter to him - as attached.

Best regards

Simon

On 23/11/2018 5:30 p.m., John Blincoe wrote:

> Kia ora Simon

>

> I have sent your below email and attached letter to Minister Sage's office, and spoken to her Advisor about it.

>

> Best, John

>

> John Blincoe | Senior Ministerial Advisor DDI s9(2)(a) | Email

> john.blincoe@parliament.govt.nz

>

> Office of Hon David Parker MP | Attorney-General | Minister for

> Economic Development | Minister for the Environment | Minister for

> Trade and Export Growth | Associate Minister of Finance

>

>

> -----Original Message-----

> From: Simon Terry [<mailto:simon.terry@sustainabilitynz.org>]

> Sent: Friday, 23 November 2018 4:58 PM

> To: John Blincoe <John.Blincoe@parliament.govt.nz>

> Cc: stephanie.howard@sustainabilitynz.org

> Subject: Letter for Hon Eugenie Sage

>

> Dear John

>

> I would be grateful if you could forward this evening the attached letter to the Hon Eugenie Sage, as it concerns CBD negotiations that are live tomorrow.

>

> Yours sincerely

>

> Simon Terry

>

>

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> Simon Terry

> Executive Director

> Sustainability Council

> s9(2)(a)

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Simon Terry
Executive Director
Sustainability Council
s9(2)(a)

[Redacted]

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Advice to Minister Parker
In support of a media interview on genetic modification
28 February 2019

Government position in short

- The Government welcomes public interest in the topic and open debate on the issues
- There are no plans to review the current regulatory regime (Hazardous Substances and New Organisms (HSNO) Act 1996)
- Officials are keeping a watching brief on international developments

Current regulatory approach overview

- GMOs are regulated under the HSNO Act 1996. There are currently no plans to review the HSNO legislation and GM is not currently a focus for Ministers or the Ministry for the Environment (MfE).
- Internationally there is a lot of development occurring in the genetic technologies space. These developments are changing what is possible across a range of industries and sectors, particularly health and agriculture. Officials at MfE and other agencies are monitoring these developments and their potential impacts for New Zealand.
- There are already pathways under the HSNO Act to assess new organisms (including GMOs) for a range of applications. Anyone who wishes to field trial or release a GMO in New Zealand must apply to the EPA under the HSNO Act. The EPA will make an assessment of the application based on the risks and benefits on a case by case basis. There are no plans to review this process.

Royal Society recent papers

- Royal Society Te Apārangi has produced a series of papers, resources and discussions on gene editing in New Zealand.
- We are supportive of the Royal Society's efforts in raising awareness and encouraging discussion of developments in genetic technology
- If the Royal Society were to express views on the regulatory implications of their findings on gene editing in the NZ context, the government would welcome any further insight they can provide

Genetic modification and gene editing – what is the difference?

- The terms gene editing (GE) and genetic modification (GM) are becoming more commonly used to define different parts of the spectrum of different modifications made to the genome of plants, animals and microorganisms. Gene editing is also sometimes referred to as “GE”, a term that has previously been used as an acronym for “genetic engineering”.
- The HSNO Act refers to genetic modification and genetically modified organisms. In New Zealand the terms gene editing, genetic engineering and genetic modification have often been used interchangeably.

Regulatory framework – more information

- Under the HSNO Act, any organism created using a new genetic technology requires approval from the EPA, including GMOs containing “gene drive” (a tool to spread the impact of genetic changes rapidly through generations, which has been suggested as a pest control tool)
- The definition of a GMO under the Act is very broad and does not make a distinction between gene editing and genetic modification, nor between organisms with very minor changes made to their DNA (gene editing), and those where larger chunks of DNA (genes) are moved into the DNA (from within or beyond the particular species)
- Each application for the use of a GMO is considered by the EPA on a case-by-case basis

- As gene editing technologies become more widely used, it may become harder to differentiate gene edited organisms from naturally occurring organisms, which could be a progressively increasing regulatory problem
- Successive NZ governments have applied a precautionary approach to organisms containing gene drives. This approach is provided for under the HSNO Act and would be applied to such organisms, on a case-by-case basis and in an objective and responsible manner
- *[if needed]* New Zealand supports the decision at the meeting of the Conference of the Parties of the Convention on Biological Diversity (CBD, a UN body) in late 2018 that countries apply a precautionary approach to gene drive systems. This includes that:
 - countries only consider introducing organisms containing engineered gene drives into the environment, including for experimental releases and research and development purposes, when scientifically sound case-by-case risk assessments have been carried out;
 - risk management measures are in place to avoid or minimize potential adverse effects, as appropriate; and where appropriate, the 'prior and informed consent' or 'approval and involvement' of potentially affected indigenous peoples and local communities is sought or obtained, based on national circumstances and legislation.

Use of GMOs in NZ

- Scientists use GMOs for research purposes in the laboratory
- To date only 4 GMOs have been approved for conditional release in New Zealand
 - *Proteqflu*, an equine influenza vaccine
 - *Pexa-Vec*, used in 2 clinical trials
 - *Telomelysin*, used in a clinical trial for patients with advanced and inoperable melanoma
- There are currently no GM commercial crops in NZ. There are two approvals for field tests in containment (Scion's radiata pine and AgResearch's milk therapeutic proteins)
- AgResearch is undertaking field trials of GM rye grass in the USA

Developments in genetic technologies

- It is a rapidly developing field and the new technologies provide a spectrum of actual and potential uses
- This can be anything from gene editing to turn a single gene 'on' or 'off' in an organism through to transgenic changes on a wide scale. A number of potential uses therefore cannot be categorised as being the result of either gene editing or genetic modification as the same result could be created using a wide range of tools.
- Some new technologies can produce organisms that could also occur naturally and/or do not contain any foreign DNA, however the same technology could also be used to create a transgenic organism. Therefore, it is more appropriate to consider the risks and benefits of an individual organism rather than attempt to distinguish between 'gene editing' and 'genetic modification'.
- The science underpinning genetic controls for pest control is at a relatively early stage, and any genetic technologies are a long way from application internationally. The application of gene drive systems in mammals is still quite theoretical, i.e. it could be decades before a gene drive solution is developed for pests such as possums or rats.

CRISPR-Cas9 [background]

- One of the newer technologies that is often associated with gene editing is the use of “CRISPR-Cas9” to make the changes to the DNA of an organism. This enables very precise changes to DNA, which can be as small as editing (substituting) a single base pair in the organism’s DNA. The technology is moving very rapidly, and there are now CRISPR-Cas derivatives that can do single-base editing without actually cutting the DNA.
- CRISPR-Cas9 technology can also move whole genes within a species or between species, with much greater precision than earlier genetic modification techniques. It can also avoid the need to introduce antibiotic marker genes and other genetic material such as promoters and terminators (gene on and off switches).
- CRISPR-Cas9 and other new techniques therefore cover a broad spectrum of changes to the DNA of an organism.

Previous advice [background]

- In May 2018, MfE, working with other officials, provided advice to Minister Parker that gave an update on developments in genetic technology, and recommended the government initiate a public discussion. This advice has been released under the OIA, and proactively, and has been referred to in some recent media articles.
- Sir Peter Gluckman, in media interviews near the end of his term as the PM’s Chief Science Advisor, advocated for further public conversations in this area
- Professor Juliet Gerrard, the current PMCSA, stated earlier this month that GM is something very high in the list of issues that scientists would like to address. She advocates a calm look at the legal and regulatory framework because the Act was written before the new techniques were invented so it is not fit-for-purpose
- Minister Parker is scheduled to meet Julie Gerrard, on 1 May and this conversation will include GM as a topic.