Ministry for the Environment
Manatū Mō Te Taiao

PO Box 10362, Wellington 6143
Website: www.mfe.govt.nz
Freephone: 0800 499 700

19-D-01859

s 9(2)(a)

Dear s 9(2)(a)

Thank you for your email of 2 September 2019 requesting the following under the Official Information Act 1982 (the Act):

> "I note that in 2018 the Minister for the Environment was provided with a briefing note "Genetic Technology – Overview and Next Steps" (tracking #: 2018-B-04195, *copy attached for ease of reference*).
>
> In relation to the briefing note, I would be grateful if you would provide me with the following:
>
> 1. A copy of the Minister's response to the briefing note.
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> 2. Copies of any work undertaken in relation to:
>
> - Analysis of the opportunities and challenges for New Zealand presented by:
> - Developments in new genetic technologies and uses
> - International regulatory policy responses to these developments
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> - 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.
>
> (*page 5, paragraph # 26 of briefing note*)
>
> 3. Copies of updates provided to the Minister in relation to international developments (*page 5, paragraph # 26 of briefing note*).
>
> 4. Copies of any advice provided to the Minister in relation to options for models of public engagement on new genetic technologies (*page 5, paragraph # 27 of briefing note*).
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> I would also be grateful if you would provide me with:

A. Copies of any other work undertaken by the Ministry in relation to genetic technologies, genetic modification or genetic engineering;

B. Information on any work proposed to be undertaken by the Ministry relating to genetic technologies, genetic modification or genetic engineering; and

C. The names of any other agencies, departments or ministries that the Ministry has consulted or worked with in relation to its work on genetic technologies, genetic modification or genetic engineering."

The Ministry for the Environment has identified 11 documents 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(b) to prejudice the entrusting of information to the Government of New Zealand on a basis of confidence by—

(i) the Government of any other country or any agency of such a Government; or

(ii) any international organisation

9(2)(b)(ii) to protect information where the making available of the information would likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information

9(2)(g) maintain the effective conduct of public affairs through

(i) the free and frank expression of opinions by or between or to Ministers of the Crown or members of an organisation or officers and employees of any department or organisation in the course of their duty

(ii) the protection of such Ministers, members of organisations, officers, and employees from improper pressure or harassment

18(d) the information is or will soon be publicly available.

The scope has been interpreted to include all policy work done or planned on genetic technologies that the Ministry for the Environment has taken the lead on since May 2018 (when briefing note 2018-B-04195 was submitted). We clarified with you that this did not include information already released to you.

Some out of scope information has also been removed from the documents being released to you. This is set out in the table below.

No further work was undertaken in response to the briefing referred to in your request.

On 12 August 2019, the Minister for the Environment announced that he has tasked officials with providing advice "on where lower regulatory hurdles ought to be considered to enable medical uses that would result

in no inheritable traits, or laboratory tests where risk is mitigated by containment." You can find the press release at this link: https://www.beehive.govt.nz/release/government-responds-royal-society-te-apārangi-report-gene-editing. This advice is currently being developed.

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.

With regard to any other agencies, departments or ministries that the Ministry has consulted or worked with in relation to its work on genetic technologies, genetic modification or genetic engineering, these are:

- Environmental Protection Authority
- Ministry for Primary Industries
- Ministry of Business, Innovation and Employment
- Ministry of Foreign Affairs and Trade
- Department of Conservation
- Department of Prime Minister and Cabinet

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

Please note that due to the public interest in our work the Ministry for the Environment publishes responses to requests for official information on our website on our OIA responses page shortly after the response has been sent.

If you have any queries about this, please feel free to contact our Executive Relations team.

Yours sincerely

Glenn Wigley
Director, Natural and Built System

List of documents

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19-D-01859

Cathy Harlow
cathy.harlow@pg.canterbury.ac.nz

Dear Cathy

Thank you for your email of 2 September 2019 requesting the following under the Official Information Act 1982 (the Act):

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G. W. Wigley

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To Hon David Parker, Minister for the Environment			Tracking #: 2018-B-04195
Security Level	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 led 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 microbes[3]. 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 technology[4] 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

[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.

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 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 possible 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;

Yes/No

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

Signature

Glenn Wigley
Director Marine, Environmental Risk and Science

7/6/18
Date

Hon David Parker
Minister for the Environment

9/6/18
Date

Ministry for the Environment contacts

Position	Name	Cell phone	1st 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

[5] Transgenic 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.

challenges to agencies enforcing regulations when organisms defined as GM and conventionally bred organisms cannot be differentiated.

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

[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.

United States of America (USA)

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 acrylamide[10] 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 disappeared[11]. 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.

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[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/.

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 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.

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

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 (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

[13] SDN-1techniques 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.

areas that have been indicated as current Government priorities (e.g. climate change mitigation/adaptation and predator control/conservation).

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
• 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	• Improved growth and disease tolerance • Modified traits such as sterility to reduce risk of wilding pine spread • Improved wood density and quality	• 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**
• 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	• Higher-yielding crops • Grass with more efficient use of nitrogen and phosphorus, which will reduce fertiliser needs and result in less run-off	• 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)	Opportunities to: • 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)	Opportunities to: • Develop fruit trees resistant to pests and diseases • Possible solutions to control pests and diseases Responsible for: • 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)	Responsible for: • Oversight of New Zealand's involvement with Food Standards Australia New Zealand • FSANZ approving GM food products • Labelling of GM foods
Forestry (Minister Jones)	Opportunities to: • Use sterile plantation trees which do not cause wilding problems • Use trees with GM developed resistance to pests and diseases
Foreign Affairs (Minister Peters)	Responsible for: • 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)	Responsible for: • New Zealand's science and research investment
Local Government (Minister Mahuta)	Responsible for: • Local government GM decision making under the Resource Management Act
Climate Change (Minister Shaw)	Opportunities to: • Use GM technology for climate mitigation such as stock with reduced methane emissions and drought-tolerant pasture species
Conservation (Minister Sage)	Opportunities for:

	• Possible solutions for pest control
Associate Minister for the Environment (Minister Sage)	Responsible for: • Oversight of the EPA who is responsible for making decisions on new organism applications
Health (Minister Clark)	Responsible for: • GM medical medicines and therapies Opportunities for: • 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.

From: WAI-POI, Daniel (ENV)
To: s 9(2)(a)); Mariska Wouters
Subject: FW: E-copies of SBSTTA and SBI briefs
Date: Saturday, 30 June 2018 2:53:33 AM
Attachments: Out of Scope
CBD - SBSTTA22 - Delegation Brief - July 2018.docx

[UNCLASSIFIED]

Sorry guys, should have sent this to you at the same time.

From: WAI-POI, Daniel (ENV)
Sent: Monday, 25 June 2018 8:56 p.m.
To: Tim Strabala; s 9(2)(a) ; Christopher Wilson (Chris) s 9(2)(a)); Laura Wakelin; Fionna Cumming
Cc: PATERSON, Rosemary (ENV)
Subject: E-copies of SBSTTA and SBI briefs

[UNCLASSIFIED]

Hi all,

Please find attached copies of the briefs. They are with the printers now and the physical copies should be ready to be picked up later this afternoon.

Laura/Tim – can you drop by later this arvo or tomorrow to pick up your copies?

Cheers,

Daniel Wai-Poi

Policy Officer – Biodiversity, UNEP, UNCCD and Chemicals/Waste
New Zealand CBD, Cartagena Protocol & ABS National Focal Points
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[UNCLASSIFIED]

CONVENTION ON BIOLOGICAL DIVERSITY

22nd Meeting of the Subsidiary Body on Scientific, Technical, and Technological Advice (SBSTTA22)

Montréal, Canada
2-7 July 2018

New Zealand Delegation Brief

POLI-58-969

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5 Synthetic Biology

Agenda item 5: synthetic biology

Relevant documents

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CBD/SYNBIO/AHTEG/2017/1/3
CBD/SYNBIO/AHTEG/2017/1/2
CBD/COP/DEC/XIII/17
UNEP/CBD/COP/DEC/XII/24
UNEP/CBD/COP/DEC/IX/29

The Issue

COP13 (Decision XIII-17) extended the mandate of the AHTEG on Synthetic Biology and the open-ended online forum. The AHTEG's report contained only a light assessment of whether new developments in the field of synthetic biology could lead to impacts on biodiversity and the objectives of the Convention (beyond that of existing LMOs). The AHTEG noted that existing risk assessment and risk management guidance could apply to most of the products of synthetic biology. Following s 6(b) instruction from the Secretariat, the AHTEG did not complete an assessment of whether synthetic biology is a 'new and emerging issue'.

The draft recommendation suggests continuation of the AHTEG. Given the limited membership of the AHTEG and its work to date, a more useful way forward could be through the use of an online forum with the AHTEG convening solely to consider whether synthetic biology is a 'new and emerging issue'.

New Zealand objective

- To support reasonable and open initiatives to share information on this topic, with a preference for use of the online forum over the AHTEG.
- To only support a synthetic biology-specific instrument if a clear case is presented that there is a need for something beyond existing frameworks, including the Cartagena Protocol.
- 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.
- To support reasonable and science-based risk assessment and risk management provisions that are consistent with our existing domestic framework.

Talking Points

- New Zealand thanks its colleagues and other stakeholders who contributed to the online forum and the AHTEG. The online forum highlighted the large volume of information that already exists on this topic.

- We support the need for caution in managing adverse effects where there is scientific and technical uncertainty about the effects of a modified organism. Our domestic approach and legislation is informed by this approach.
- New Zealand can support further research and information sharing on the benefits or adverse effects of synthetic biology, provided that this is done in the context of the objectives of the Convention. We ask that Parties and others continue to provide evidence of the effects of living modified organisms that exist or could plausibly exist based on current scientific understanding of the technologies involved.
- New Zealand notes that the findings from the online forum and the AHTEG are that organisms from synthetic biology come under the definition of LMO. There are established practices and ample publicly available guidance for risk assessment of LMOs and we encourage Parties to use these.
- New Zealand notes that developments in synthetic biology encompass a range of applications. Gene drive is an example of one type of application. We should assess each application of a technology based on its own positive and adverse effects. The effects of one application should therefore not be confused with possible effects from other applications.
- New Zealand notes with concern that the AHTEG was advised not to complete the analysis required in its Terms of Reference as to whether synthetic biology meets the criteria for a 'new and emerging issue'.
- New Zealand is also concerned at the very late appearance of the Information Paper (INF17) as an apparent replacement for the AHTEG analysis on whether synthetic biology meets the criteria for a 'new and emerging issue'. The statements quoted in the paper reflect AHTEG discussions of other issues, not the 'new and emerging issue' criteria specifically, and they may lose meaning taken out of context or without analysis.
- New Zealand also has concerns about the ability of the AHTEG to make progress on the issue of synthetic biology, should its mandate be extended. It is New Zealand's view that the continuation of the synthetic biology online forum is the more effective means of information sharing. We consider that the main role of the AHTEG should be to complete its analysis on whether synthetic biology meets the criteria for a 'new and emerging issue'.
- Based on these points, we have a number of textual suggestions for the draft recommendation:
    - First, we suggest that paragraph 9 be deleted and replaced with:

      Decides to extend the mandate of the Ad Hoc Technical Expert Group on Synthetic Biology and that it should work online and in coordination with the process under the Cartagena Protocol, as appropriate, to: (a) complete analysis whether synthetic biology meets the criteria for 'new and emerging' issues requested in paragraph 1(e) of the Annex of Decision XIII/17; and (b) prepare a report on the outcomes of its work for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice;

- This would then require changes to several other paragraphs. Paragraph 12(b) could be reworded to say:

  To facilitate the work of the Ad Hoc Technical Expert Group on Synthetic Biology to complete analysis on whether synthetic biology meets the criteria for 'new and emerging' issues requested in paragraph 1(e) of the Annex of Decision XIII/17;

- Paragraph 10 could be changed to ensure the COP provides clear and useful instructions to the online forum:

  Also decides to extend the Open-ended Online Forum on Synthetic Biology and that it should work primarily online with a lead moderator and in coordination with the process under the Cartagena Protocol, as appropriate, to: (a) review new information about developments in synthetic biology, and actual examples of their positive and negative impacts on the objectives of the Convention; and (b) prepare a report summarising the online discussion for consideration by the Subsidiary Body on Scientific, Technical and Technological advice;

- Paragraph 11 could be changed to ensure the COP provides a clear request to Parties and others to contribute information to the online forum and the AHTEG:

  Invites Parties, other Governments, indigenous peoples and local communities, and relevant stakeholders, to provide the Executive Secretary with relevant information for inclusion in the work referred to in paragraphs 9 and 10 above, and to continue to nominate experts to take part in the online forum on synthetic biology;

- Paragraph 13 would need a small change too, with the addition of reference to the "open-ended online forum".

- We would also like to suggest a number of minor changes, including:

  - Removing the words "recognizes the need to thoroughly consider the" from paragraph 2 and replacing it with "notes that there may be". Applications should be assessed case-by-case, according to their potential benefits and adverse effects.

  - Removing the reference to "guidance" from paragraph 6, changing "urges" to "calls upon" and replacing "in order to avoid potentially significant and irreversible adverse effects to biodiversity" with "vis-à-vis the three objectives of the Convention". As we have already noted, there is already sufficient guidance on this issue and what is required is more research. We support the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

  - Deleting the words "and how it may contribute to progress towards the 2030 Agenda for Sustainable Development" from paragraph 12(c). The CBD should remain focused on the post-2020 framework.

  - Replacing "is needed" in paragraph 3 with "may be useful" in order to better reflect what horizon scanning exercises are capable of.

- Deleting "develop and" and "well-designed strategies in order" and replacing them with "appropriate measures" in paragraph 7. There are already well-established practices for LMOs in containment.
- Deleting the word "rapid" from paragraph 4. The potential issue is not the rapidity of the changes, but the changes themselves.

- We are happy to provide the Secretariat with a written summary of these changes.

Draft recommendation

The Subsidiary Body on Scientific, Technical and Technological Advice may wish to consider a recommendation along the following lines: The Conference of the Parties, Recalling decisions XII/24 and XIII/17,	s 6(b)
1. *Takes note* of the outcomes of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology held in Montreal, Canada, from 5 to 8 December 2017;4	s 6(b)
2. *Notes* that synthetic biology is a cross-cutting issue that may concern all three objectives of the Convention on Biological Diversity, and s 6(b) potential benefits and potential adverse effects of synthetic biology applications vis-à-vis the three objectives of the Convention;	s 6(b)
3. *Also notes* that regular horizon scanning, monitoring and assessing of developments in the field of synthetic biology s 6(b) for reviewing new information regarding the positive and negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and those of its Protocols;	s 6(b) .
4. *Recognizes* that ~~rapid~~ advances arising from research and development in the field of synthetic biology may pose challenges to the ability of some countries, in particular those with limited experience or resources, to assess the full range of potential impacts of synthetic biology applications;	s 6(b) .

4 CBD/SBSTTA/22/4, annex.

5. *Also recognizes* the need for a coordinated and non-duplicative approach on issues related to synthetic biology under the Convention and its Protocols, as well as among other conventions and relevant organizations and initiatives;	s 6(b)
6. *Further recognizes* that, while there could be potential benefits to the development of organisms containing engineered gene drives, additional research s 6(b) is needed before any organism containing engineered gene drives is considered for release into the environment, including the lands and territories of indigenous peoples and local communities, and, given the current uncertainties regarding engineered gene drives, s 6(b) Parties and other Governments to take a precautionary approach in the development and release of organisms containing engineered gene drives, including experimental releases, s 6(b) ;	s 6(b)
7. *Calls upon* Parties, other Governments and relevant organizations to s 6(b) to prevent or minimize the exposure of the environment to organisms, components and products of synthetic biology under contained use;	s 6(b)
8. *Also calls upon* Parties, other Governments and relevant organizations to disseminate information and share their experiences on scientific assessments of the potential benefits and adverse impacts of synthetic biology, including that of organisms containing engineered gene drives, taking into account but not limiting themselves to information based on modelling and scenarios, data from experiments performed under contained use, and experience gained through the management of pests and invasive alien species and from the use of living modified organisms that have been released into the environment;	s 6(b)
s 6(b)	s 6(b)

s 6(b) [redacted]	[redacted]
10. *Also decides* to extend the Open-ended Online Forum on Synthetic Biology s 6(b) [redacted]	s 6(b) [redacted]
11. *Invites* Parties, other Governments, s 6(b) [redacted] indigenous peoples and local communities, and s 6(b) [redacted] relevant stakeholders to provide the Executive Secretary with relevant information for inclusion in the s 6(b) [redacted] referred to in s 6(b) [redacted]	s 6(b) [redacted]

s 6(b)	
12. *Requests* the Executive Secretary:	
(a) To convene moderated online discussions under the Open-ended Online Forum on Synthetic Biology;	s 6(b)
(b) To facilitate the work of the Ad Hoc Technical Expert Group on Synthetic Biology s 6(b)	s 6(b)
(c) To further pursue cooperation with other organizations, conventions and initiatives, including academic and research institutions, from all regions, on issues related to synthetic biology s 6(b)	s 6(b)
(d) To explore ways to facilitate, promote and support capacity-building and knowledge sharing regarding synthetic biology, taking into account the needs of Parties and of indigenous peoples and local communities, including through necessary funding, and the co-design of training materials in the official languages of the United Nations and, where possible, in local languages.	s 6(b)
13. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the work of the Ad Hoc Technical Expert Group s 6(b) Synthetic Biology and submit a recommendation to the Conference of the Parties at its fifteenth meeting.	s 6(b)

5 General Assembly resolution 70/1, annex.

Background

1 COP13 (decision XIII-17) extended the mandate of the AHTEG on Synthetic Biology (with a new terms of reference) and the open-ended online forum to support the work of the AHTEG. s 6(b) [redacted]

Online forum

2 New Zealand submitted information to the Secretariat and contributed to three of the four online forum topics. Our view is that:

- Current biotechnology approaches and techniques, including synthetic biology and gene drive, are already covered by the Cartagena Protocol definition of living modified organism (LMO).
- Existing risk management measures and best practises used for existing LMOs are sufficient for risk management.
- There are many existing RARM guides already available to Parties that provide ample direction on the evaluation of scientific uncertainty in the assessment of risk and its management, as well as subsequent decision-making processes.
- Assessment of proposed GMOs/LMOs/organisms from synthetic biology should be done on a case-by-case basis, taking into account the risks and risk management controls relevant to the specific organism and its intended use.

AHTEG report

3 The AHTEG report (CBD/SYNBIO/AHTEG/2017/1/3) listed a range of recent technological developments and that these recent developments and their pace could have a number of negative impacts. The AHTEG noted that containment strategies might be needed to minimise the environmental exposure from organisms, components and products of synthetic biology. It noted that existing risk assessment and risk management (RARM) approaches for LMOs could provide a good basis for the risk assessment of organisms developed through synthetic biology. The AHTEG echoed concern by a number of online forum submitters that there was a need to grow capacity, and to continue sharing the available guidance from a range of sources.

4 The AHTEG report (paras 27-31) concluded that most organisms already developed through synthetic biology, or currently under research and development, come under the definition of LMO. This includes organisms containing engineered gene drives. The report noted that techniques involving cell-free systems did not result in the development of living organisms. Protocells that were capable of transferring or replicating genetic material might be developed in the future and those might be regarded as LMOs.

5 The AHTEG report (paras 32-38) noted that most tools currently in use to detect, identify and monitor LMOs could also be used for organisms developed through synthetic biology and that challenges might arise when the resulting organism was indistinguishable from a naturally occurring or conventionally-bred counterpart. s 6(b) [redacted]

/...

s 6(b) However, setting aside the difficulties in compliance enforcement that such a situation would create, New Zealand's regulatory framework relies on knowing which technique (process) was used to make an organism to decide whether or not it is a GMO for the purposes of the HSNO Act.

6 The AHTEG report (para 15e) noted that biotechnology tools have become increasingly available in some countries to the 'do-it-yourself' community and the public at large outside of formal laboratory facilities. In New Zealand, approval is needed from the EPA to import or make GMOs.

7 The AHTEG report (para 19) referred to biosecurity concerns about the 'dual use' nature of some advances in synthetic biology. This is about organisms from synthetic biology being used for legal and illegal purposes. This is not unique to synthetic biology and applies to any technology. Illegal use is addressed under the Biological Weapons Convention.

8 The AHTEG report (para 30) noted that there were different interpretations whether organisms modified through epigenetic engineering contained novel combinations of genetic material and whether such organisms would be LMOs.

9 Discussion in the online forum and in the AHTEG report at times conflated specific concern about the potential (global) impacts of organisms from engineered gene drives with developments in genetic technologies more generally. The AHTEG noted that additional research and guidance were needed before any organism containing engineered drives could be considered for release into the environment, and that a precautionary approach might be warranted in the development and release of organisms containing engineered gene drives, including experimental releases. The AHTEG also noted that internationally agreed standards for containment of organisms containing engineered gene drives might be useful to avoid accidental releases from laboratory facilities

10 This follows COP13 which saw the African Group introduce a new agenda item on a possible moratorium on gene drives. s 6(b) The moratorium proposed was not accepted but Parties agreed to a reference in the text that the precautionary approach that is used with respect to living modified organisms could also apply to LMOs containing gene drives.

New and emerging issue

11 s 6(b)

/...

12 The Secretariat then undertook an analysis of the AHTEG's reports against the seven criteria for the selection of new and emerging issues as per paragraph 12 of Decision IX/29. This Information Paper (CBD/SBSSTA/22/INF/17) was submitted very late. s 6(b)

[redacted]

Other fora

13 In 2016 IUCN Members adopted Resolution 6.086 (Development of IUCN policy on biodiversity, conservation and synthetic biology) to examine the impacts of the production and use of the products resulting from synthetic biology on the conservation and sustainable use of biodiversity, to recommend how IUCN could engage in ongoing discussions with the synthetic biology community and to develop guidance on the topic. In early 2018, an IUCN Synthetic Biology and Biodiversity Conservation Task Force was created to oversee the implementation of Resolution 6.086. It is expected to develop policy recommendations for the consideration of the IUCN Council before the 2020 World Conservation Congress. Refer https://www.iucn.org/theme/science-and-knowledge/our-work/culture-science-and-knowledge/synthetic-biology-and-biodiversity-conservation.

Definition of synthetic biology

14 COP13, after many hours of negotiating at this COP and the previous SBSTTA meeting, reached a compromise on an operational definition of synthetic biology, which it considered useful as a starting point to facilitate scientific and technical deliberations. The language adopted does not actually require that the definition be used (decision XIII-17 paragraph 2). The operational definition is copied here for convenience:

> The COP acknowledges that the outcome of the AHTEG on Synthetic Biology on an operational definition was "synthetic biology is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems" and considered it useful as a starting point for the purpose of facilitating scientific and technical deliberations under the Convention and its Protocols.

Digital Sequence information

15 s 6(b)

[redacted]

General information

/...

16 The New Zealand delegation declined an invitation to co-host a discussion on gene drive at SBSTTA with the Imperial College London.

MfE, EPA and ENV and MPI
June 2018

European Court of Justice Decision on Gene Editing Techniques

Date Submitted: 09.08.2018		Tracking #: 2018-B-04808	
Security Level	In Confidence	MfE Priority:	Non-Urgent

	Action sought:	Response by:
To Hon David Parker, Minister for the Environment	Noting	21 August 2018

Actions for Minister's Office Staff	**Return** the signed report to MfE.
Number of Attachments 0	Titles of attachments: Nil
Note any feedback on the quality of the report	

Ministry for the Environment contacts

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

European Court of Justice Decision on Gene Editing Techniques

1. This briefing provides you with an overview of the recent European Court of Justice ruling on the regulation of new genetic technologies under European Union law, and how this compares with New Zealand and other jurisdictions. It will also briefly address a German study on the detectability of gene edited products that your office referred to the Ministry for the Environment.

European Court of Justice Ruling

2. The European Court of Justice (ECJ) ruled on 25 July 2018 that organisms obtained by mutagenesis are considered genetically modified organisms (GMOs) under EU Directive 2001/18/EC (the GMO Directive)[1]. While this has always been the case in the European Union (EU), the ruling has clarified that new technologies such as gene editing are also captured.

3. The ECJ ruled that new techniques/methods that have emerged since the adoption of the Directive in 2001 are **not** subject to the exemption set out in Annex 1 B of the Directive for mutagenesis techniques. This means that organisms created using new genetic technologies (including gene editing that does not use DNA from other species) are subject to regulation as GMOs and must comply with the same strict regulations that transgenic organisms do.

4. The decision clarified that only methods of mutagenesis that have conventionally been used in a number of applications with a long safety record are exempt from regulation. However, what constitutes a long safety record is not defined.

5. s 9(2)(g)(i)

6.

Comparison with New Zealand

7. The EU's approach to GMOs aligns with New Zealand's current position, which also requires gene editing technologies to go through the same stringent approval process as transgenic organisms and does not allow new mutagenesis techniques (such as gene editing) to be exempt.

8. Techniques exempt from regulation as GM in New Zealand are set out in the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 (Not-GM Regulations). The Not-GM Regulations were amended in 2016 to clarify that no new mutagenesis technologies (such as gene editing) created after 1998 are captured by the Regulations.

9. The Ministry for the Environment has previously advised that the advances occurring in genetic technologies may result in New Zealand's legislation no longer being fit for purpose (Briefing 18-B-04195: Genetic Technology- Overview and Next Steps).

[1] The relevant articles of Directive 2001/18/EC are set out in appendix one.

Decision's impact on New Zealand

10. s 9(2)(g)(i) [redacted]

Comparison with USA

11. The ECJ and New Zealand's approach is based on regulating the technique used to create an organism. This approach differs from the 'product' based approach the USA takes, where regulation is based on the risk posed by a particular product/organism rather than the technique that was used to created it.

12. The USA's approach was clarified by the United States Department of Agriculture (USDA) on 28 March 2018 when the department stated that there would be 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 and bacteria)
    - have not been developed using plant pests

13. USA Secretary of Agriculture Sonny Perdue put out the following statement in response to the ECJ decision on 27 July 2018:

    "Government policies should encourage scientific innovation without creating unnecessary barriers or unjustifiably stigmatizing new technologies. Unfortunately, this week's ECJ ruling is a setback in this regard in that it narrowly considers newer genome editing methods to be within the scope of the EU's regressive and outdated regulations governing genetically modified organisms… we encourage the EU to seek input from the scientific and agricultural communities, as well as its trading partners, in determining the appropriate implementation of this ruling... in light of the ECJ ruling, USDA will re-double its efforts to work with partners globally towards science and risk based regulatory approaches"

14. s 9(2)(g)(i) [redacted]

Comparison with Australia

15. The Department of Health is currently reviewing the Australian Gene Technology Scheme. This review includes a discussion on whether the Australian scheme should change its process-based system (which is currently similar to New Zealand and the ECJ ruling) to a product-based approach (similar to the USA).

16. The Office of the Gene Technology Regulator (OGTR) has proposed that techniques that do not introduce DNA from another species and make changes that could occur within the bounds of normal genetic variation would not be regulated as GM. The OGTR intends to propose these amendments to the Commonwealth and State and Territory governments for their agreement in 2018.

17. The ECJ decision means some organisms the OGTR has proposed should not be regulated as GMOs will be considered GMOs in the EU.

Detectability Study

18. Your office has referred a German study to us addressing the detectability of gene editing in some products.

19. In July 2018, this study, jointly prepared by the German regulatory authority (BVL) and US Corporation DowDuPont, confirmed that most products of genome editing under the right circumstances could be detected and monitored in the same way traditional GMOs are, so long as the signature left in the DNA is revealed by the developer.

20. s 9(2)(g)(i)

21. [redacted]

Recommendations

22. We recommend that you:

a. **Note** that the European Court of Justice ruling is in alignment with New Zealand's domestic genetic modification legislation

b. **Note** that the position of the European Court of Justice differs from Australia's proposed changes and the United States of America's approach

c. **Note** that concerns around detectability of gene editing are still prevalent from an enforcement perspective

Signature

Brian Hallinan
Manager: Environmental Risk and Innovation

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

Appendix 1: Key Provisions - European Union GMO Directive 2001/18/EC

European Directive on the deliberate release into the environment of genetically modified organisms

Article 1

Objective

In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when:

- carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community,

- placing on the market genetically modified organisms as or in products within the Community.

Article 2

Definitions

For the purposes of this Directive:

(1) "organism" means any biological entity capable of replication or of transferring genetic material;

(2) "genetically modified organism (GMO)" means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;

Within the terms of this definition:

(a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;

(b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;

(3) "deliberate release" means any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment;

Article 3

Exemptions

1. This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

From: Brian Hallinan
To: Mariska Wouters; Olivia Chamberlain
Subject: FW: Minister Parker and Sage meetings - download
Date: Wednesday, 1 August 2018 5:26:38 PM

Fyi – I found a message with Joe's summary of the GE discussion, including a reference to there not being a clear time for the ECJ work (although that may have come up later)

From: Glenn Wigley
Sent: Monday, 30 July 2018 1:17 PM
To: Brian Hallinan <Brian.Hallinan@mfe.govt.nz>; Phillipa Guthrey <Phillipa.Guthrey@mfe.govt.nz>; Meredith Davis <Meredith.Davis@mfe.govt.nz>; Olivia Chamberlain <Olivia.Chamberlain@mfe.govt.nz>
Cc: Amanda Moran <amanda.moran@mfe.govt.nz>
Subject: Minister Parker and Sage meetings - download

Hi all Out of Scope
Out of Scope

Thanks for all the info to assist myself for this morning's meetings

Minister Parker

1 – Out of Scope .

2 – Genetic engineering – Minister reaffirmed his view from the paper. Below is how the discussion has bene recorded by Joe B. We had a brief discussion where Min Parker reaffirmed the views he made in the briefing note. s 9(2)(g)(i)

Brief discussion on EU decision, including alignment with NZ settings . Minister wanted a note on this decision We didn't discuss timeframes, so let's discuss this afternoon.

Given resourcing issues, the Minister is not inclined to pursue more work in this area

Out of Scope

Glenn

Sustainability Council Letter on EPA Decision on dsRNA

Date Submitted: 31 .08.18		Tracking #: 2018-B-04866	
Security Level	In confidence	MfE Priority:	Non-Urgent

	Action sought:	Response by:
To Hon David Parker, Minister for the Environment	Noting	11 Sept 2018
CC Hon Eugenie Sage, Associate Minister for the Environment		

Actions for Minister's Office Staff	**Return** the signed report to MfE.
Number of Attachments	Nil
Note any feedback on the quality of the report	

Ministry for the Environment contacts

Position	Name	Cell phone	1st contact
Principal Author	Mariska Wouters		
Responsible Manager	Brian Hallinan	022 066 8420	✓
Director	Glenn Wigley	027 491 7806	

Sustainability Council Letter on EPA Decision on dsRNA

Key Messages

1. This briefing provides you with background information regarding a recent letter to you from the Sustainability Council about a recent determination by the Environmental Protection Authority (EPA) under the Hazardous Substances and New Organisms Act 1996 (HSNO Act). We will draft a reply to this Ministerial, which is due 12 September 2018.
2. In May this year, the EPA exercised its power to decide an application on a section 26 determination that a specific double-stranded RNA (dsRNA) application does not produce a genetically modified organism (GMO) for the purposes of the HSNO Act.
3. The Sustainability Council has recently written to you to say that this decision creates a loophole that allows GMOs into New Zealand, is a flawed decision and represents EPA "recidivism". An EPA section 26 determination five years ago was appealed by the Sustainability Council. This led to amendments to the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 (the Regulations), which effectively locked the definition of genetic modification relating to mutagenesis into the 1998 understanding of the term.
4. The EPA makes decisions independently of Ministers and the Ministry for the Environment (MfE). Neither the Minister nor MfE have power to overturn an EPA decision. The EPA may provide further advice to Ministers regarding its decision next week.
5. The Sustainability Council's letter suggests that it may seek a judicial review of the decision, and sets out actions that the Minister could take in relation to the EPA decision.
6. There is a risk that the outcome of a potential judicial review and/or debate on this issue could lead to further pressure to make minor changes to the Regulations, rather than a broad analysis of the HSNO Act's settings relating to genetic modification.

EPA determination

7. Any applicant can request a section 26 determination from the EPA to determine whether or not an organism is a new organism for the purposes of the HSNO Act (section 26(1)). If the EPA determines an organism is not a new organism, then it will fall outside the scope of the HSNO Act and the Act's provisions will not apply to it. This means any individual will be able to import, possess or use that organism in New Zealand. If the outcome of an application is that an organism is considered a new organism, then the HSNO Act will apply and an application must be made to the EPA to import, possess or use that new organism in New Zealand.
8. In this case, *Manaaki Whenua Landcare Research* (Landcare) asked for a determination on whether eukaryotic[1] cell lines that had been treated with externally applied double-stranded RNA molecules for the purpose of inducing a transient small interfering RNA (siRNA) response are new organisms for the purposes of the HSNO Act.
9. When considering the application, the EPA Decision-making Committee (the Committee) decided that a eukaryotic cell that has been treated with dsRNA molecules is an organism. The Committee then considered the technique against the definition of a GMO assessing

[1] Eukaryotes are organisms whose cells have a nucleus enclosed within membranes, as opposed to prokaryotes (includes bacteria) which do not have an enclosed nucleus. Eukaryotes include all plants, fungi, and animals (mammals, birds, insects, reptiles etc).

whether any genes or genetic material would be modified by the treatment with externally applied dsRNA molecules. The Committee also assessed the ability of the siRNA molecules to replicate and their ability to be inherited. The Committee made several key decisions against these considerations:

- Because the treatment does not modify genes or genetic material it is not considered GMO.
- Whilst siRNA molecules can replicate within treated cells, they remain solely as RNA molecules in the cell cytoplasm outside the nucleus. They do not integrate into the genome, because the molecules are not reverse-transcribed into DNA, therefore they are not inheritable by the organism
- Because no genes are altered it's not necessary to consider if the technique was used *in vitro*.

10. Based on these points, on 1 May 2018 the EPA Committee made a section 26 determination stating that eukaryotic cell lines treated with externally applied dsRNA molecules for the purpose of inducing a transient siRNA response are not genetically modified and therefore not new organisms under the HSNO Act.
11. While the application for the section 26 determination was made by Landcare, the determination applies to anyone who would wish to use this technique.
12. This decision only applies to eukaryotic cells treated in such a way. The use of another technique (not already regulated under the HSNO Act or that has been subject to a section 26 determination) would require a section 26 determination or a HSNO approval. This decision cannot be extrapolated to apply to similar techniques.
13. The EPA may provide you with further information about the decision.
14. We have provided some further information about the science involved in Appendix One, based on the EPA's public decision documents.

Sustainability Council Letter

15. On 21 August 2018 the Sustainability Council wrote to the Hon David Parker, Minister for the Environment, disagreeing with the EPA's determination. The letter states that:
    - this determination allows for a "loophole" in New Zealand law,
    - the technology does produce GMOs,
    - this loophole now allows for GMOs to be produced without regulation, and
    - the determination means the technique can now be used on any organism without any risk assessment or public consultation and this puts people, the environment, and New Zealand's exports, at risk.
16. The Sustainability Council has referred to the recent European Court of Justice (ECJ) decision that ruled new gene editing technologies should be regulated as genetic modification (see 2018-B-04195). This is only one international perspective. There are several other countries, such as the United States, that do not require some gene editing products to be regulated. The EPA Committee can only base its decision on a section 26 determination on the HSNO Act itself.
17. The Sustainability Council considers that the EPA continues to make decisions that are not in line with the HSNO Act, and compared this decision to one made by the EPA in 2013 (see below). The Sustainability Council also notes that the EPA is making these determinations without public consultation. There are no requirements to publically notify or

consult on a section 26 determination for *new organisms* (which differs from the section 26(3) requirement to publicly notify some *hazardous substances* determinations).

18. The Sustainability Council has requested that you take urgent action on this determination. The Council has proposed three actions for you to consider:

    i. Request the EPA to review its determination. Section 26(6)[2] provides for the EPA to revoke or reissue a decision based on 'further information'.

    ii. Issue a regulation by Order in Council that deems use of dsRNA as described in the EPA determination to produce a GMO, using section 140(1).

    iii. Ask the High Court to judicially review the EPA determination.

19. The Sustainability Council argues that it could utilise option 1 and 3 themselves but it "has no intention of becoming a routine 'pooperscooper' for EPA mess".

Previous Sustainability Council appeal of EPA section 26 determination

20. The HSNO Act contains the definition of what is a GMO in New Zealand. The Regulations expressly provide for certain organisms that meet the GMO definition to *not* be regarded as genetically modified for the purposes of the HSNO Act. Therefore these organisms do not require HSNO Act approval as GMOs. A section 26 determination, in relation to GMOs, means that the EPA can determine whether or not an organism is covered by the Regulations. If it is covered, then a HSNO approval is not required.

21. In 2013 the Sustainability Council appealed a section 26 determination by the EPA to the High Court. The Sustainability Council had been consulted on the application and was therefore able to appeal the determination (section 126). An EPA Committee had determined that two 'genome editing' treatments (ZFN1 and TALENs) were sufficiently similar in their effect to chemical treatments already listed in the Regulations. The Committee determined that organisms resulting from these two treatments were not GMOs on the grounds that clause 3(1)(b) in the Regulations was a list of examples and that it was not exhaustive.

22. In 2014, the interpretation of the Regulations adopted by the EPA Committee was challenged in the High Court. The High Court did not consider whether organisms resulting from those two treatments ought to be regulated, but rather considered how the drafting and interpretation of the Regulations for those treatments could be applied.

23. The 2014 High Court decision:

    - Identified drafting errors in the Regulations (clause 3(1)(b)), and
    - Adopted a strict interpretation of the Regulations, resulting in uncertainty about the status of some traditional chemical and radiation treatments that were assumed to be unregulated.

24. Following public consultation, in 2016 Cabinet approved amendments to the Regulations that:

    - Corrected minor errors in clause 3(1)(b) of the principal Regulations as identified by the High Court; and
    - Ensured that all organisms that result from mutagenesis that uses chemical and radiation treatments that were in use before 29 July 1998 are not to be regarded as GMOs. This was in line with previous industry and regulatory practice before the

[2] Note that the letter refers to section 26(3).

High Court decision. Organisms resulting from mutagenesis treatments developed after this date would continue to be regulated as GMOs.

25. These amendments addressed the immediate issues arising from the High Court decision. At the time, the Ministry noted that new plant and animal biotechnologies are challenging regulatory regimes for GMOs internationally.

Section 26 appeal provisions

26. Under section 26 of the HSNO Act, any party to an application under section 26, or any person who made submissions to the Authority on the application, may appeal against the decision of the EPA to the High Court on a question of law.

27. The EPA, when analysing the application, provided the Department of Conservation (DOC) and the Ministry for Primary Industries (MPI) opportunity to comment on the application. Neither DOC, MPI, nor the applicant, chose to appeal the decision.

28. The Act has no requirement to publically notify or to consult on a section 26 determination for new organisms. In those situations it means there is also no appeals provisions under the HSNO Act.

29. The Sustainability Council was not a party to the application, nor did it make a submission on the decision, and therefore is not able to lodge an appeal, however it can ask for a judicial review on the basis that it is affected by the decision.

30. The EPA may revoke or reissue a determination issued by it under section 26 if it receives further information.

31. Section 26 determinations are an important pathway to provide clarity on whether something is considered a hazardous substance or a new organism (including GMOs). This is a mechanism by which the limits of the definition can be tested and is not considered a loophole to the legislation. While there may be ambiguity in definitions at times, section 26 allows the EPA to make statutory determinations on whether organisms are new organisms and make decisions to clarify such ambiguities.

Role of Ministers

32. The Minister for the Environment cannot overrule a decision by the EPA. The Minister is not an appeal authority for EPA decisions and may not direct the EPA in relation to an application. However, if an application is made in the future, it is possible the Minister could call it in under section 68, provided the section 68 tests are met. Call in provisions do not apply to section 26 determinations.

33. The Minister does not have the power to make the EPA review its decision as the Sustainability Council suggests. While a Minister may ask the EPA to reconsider a decision, the EPA itself will decide whether to review a decision based on any further information it receives.

34. We do not recommend that Ministers get involved in any EPA decision making as this could be perceived as crossing the line with the EPA's independence.

Role of the Ministry

35. MfE does not play a role in the EPA decision making process. MfE has an interest in how the Act is applied to new genetic technologies and any policy implications there may be as a result. Based on the committee's findings on this specific case, the decision appears consistent with the definition of GMO under HSNO.

Risks

36. Based on the legal action taken by the Sustainability Council in the past it is likely it will consider asking the High Court to judicially review the EPA's determination.
37. There is a risk that the emergence of new technologies will make further ambiguities become apparent, leading to further differing opinions on what should and should not be regulated under the HSNO Act.
38. MfE does not consider ad hoc 'patching' the legislation through amendments to the Regulations or the broader HSNO Act to be an adequate long term solution to dealing with developments in technology.
39. If similar issues arise in areas that are considered ambiguous under the legislation it may be useful to seek legal clarification from the Crown Law Office to assist in clarifying the situation.

Signature

Brian Hallinan
Manager, Environmental Risk and Innovation

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

Appendix One - What is siRNA and why use it?

1. siRNA is a double-stranded molecule that can interfere with the expression of specific genes. Production of siRNA is a form of innate immunity/defence against viruses, which often have double-stranded RNA (dsRNA) intermediate forms as part of their replicative life cycle in the host cell.
2. This response can be used by researchers through externally applied dsRNA to prompt a siRNA response by the cell. Depending on the dsRNA that is introduced the resulting siRNA response will bind to specific messenger RNA (mRNA)[3] molecules blocking the translation of the mRNA into protein, and directs it to degradation by other cellular proteins. This suppresses (but does not modify the gene) the expression of a specific gene (or genes, depending on the dsRNAs that are introduced into the cell).
3. Using externally applied double-stranded RNA molecules to induce a transient small interfering RNA (siRNA) response could be used as a therapeutic agent and for agricultural purposes which are transient and do not alter the organism's genome.
4. The examples below of how siRNA could be used are from the EPA staff assessment document and other references. The section 26 determination did not provide an indication of what Landcare may be proposing to use siRNA for:

    a. Medical

        - siRNAs could make it possible to target virtually any gene for therapeutic intervention.
        - siRNAs maybe able to inhibit the replication of Hepatitis B.
        - siRNA could target a prion-prone protein which inhibits prion formation in cells.
        - Cancer treatment applications.

    b. Agricultural

        - Use of siRNA as pesticides. This includes the use of oral dsRNA (converts to siRNA internally) uptake by insects.
        - siRNA as a means of inducing plant viral resistance.
        - Commercial RNAi-based products, such as this siRNA application, could be in market by the early 2020s (unclear if in NZ).

[3] Messenger RNA (mRNA) is a type of Ribonucleic acid (RNA) that conveys genetic information from DNA to the ribosome. Ribosomes are the sites of protein synthesis (translation) in the cell.

Genetic modification and gene editing – what is the difference?

The terms gene editing 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".

In New Zealand the terms genetic engineering and genetic modification have often been used interchangeably, with genetic modification used during the Royal Commission on GM which reported in 2001.

CRISPR-Cas9

One of the newer technologies which is often associated with gene editing is the use of "CRISPR-Cas9" to make the changes to the DNA of an organism. The most important feature of the use of this technique is that it enables very precise changes to be made to DNA. These precise changes 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.

But CRISPR-Cas9 technology can also move whole genes within a species or between species. Again, it does so 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. Gene editing and GM are not two different things. They are different parts of a continuum, together with mutagenesis techniques that are exempted in regulation from consideration as genetic modification, with no clearly defined cut off points.

Different ways of incorporating similar traits into a plant

When it comes to the development of organisms with specific environmental, health, food or other traits, there are often several ways these can be developed. For example a non-active gene might be able to be reactivated by very small changes to the promoter sequence which switches on a plant gene. Alternatively, an active form of the same gene could be taken from another species of plant, or a microorganism, and transferred to the plant.

Both plants then would have the same characteristic, e.g. a new flower colour, though one was developed using gene editing and the other by transgenic genetic modification. (The term transgenic is often used when the gene transferred comes from a different species of organism.)

Can the modifications be detected?

An important difference between the two plants, is that the one developed by precise editing of the DNA would very likely be genetically indistinguishable from the parent

plant. The changes in the DNA would be so small that the changes could have occurred through natural mutation. That is, while the change is certainly detectable, it would be essentially impossible to say definitively how it was generated without prior knowledge.

The transgenic plant would likely be much easier to detect. The promoter and terminator DNA sequences which are commonly used, are easy to detect using a simple screening process. This is the procedure used by MPI to screen for approved varieties (in other jurisdictions) of GMOs in imports of seeds, for example.

Regulation of gene edited organisms in New Zealand

New organisms including GMOs are regulated in NZ by the HSNO Act. This Act and its regulations do not currently differentiate 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). All are currently regulated as GMOs.

The fact that the gene edited group may not be able to differentiated from conventional organisms will be a progressively increasing regulatory problem as gene editing technologies become more widely used.

8

From: s 9(2)(a)
To: Brian Hallinan
Cc: Hayden Johnston (Parliament); Glenn Wigley; Mariska Wouters; Olivia Chamberlain
Subject: RE: Questions on Gene Tech paper
Date: Thursday, 6 September 2018 5:45:51 PM
Attachments: image005.png
image006.png
image007.jpg
image008.jpg
image009.jpg

[IN-CONFIDENCE]

Thanks Bryan

Very useful

Regards

s 9(2)(a)
Policy Advisor
Policy Advisory Group
Department of the Prime Minister and Cabinet

P s 9(2)(a)
M
E

cid:image002.png@01D43609.296F69C0

From: Brian Hallinan [mailto:Brian.Hallinan@mfe.govt.nz]
Sent: Thursday, 6 September 2018 5:06 p.m.
To: s 9(2)(a) [DPMC] s 9(2)(a) @dpmc.govt.nz>
Cc: Hayden Johnston (Parliament) <Hayden.Johnston@parliament.govt.nz>; Glenn Wigley <glenn.wigley@mfe.govt.nz>; Mariska Wouters <Mariska.Wouters@mfe.govt.nz>; Olivia Chamberlain <Olivia.Chamberlain@mfe.govt.nz>
Subject: Questions on Gene Tech paper

Hi s 9(2)

Thanks for our chat yesterday and your questions on the gene technology briefing to Minister Parker.

You were specifically interested in whether we could say *which* of the possible uses in Table One were linked to gene editing rather than the more traditional genetic modification. After thinking about the best way to answer, the best advice we can provide is that's not a distinction that is

easy to make, or supports decision-making under HSNO or when thinking about how the regime could look in the future.

I've attached a handful of bullets that set this out below, plus a short note that brings together some more detailed thinking (which combines material from MPI and EPA):

- The potential uses listed in table one are not an indication of work that is currently occurring or likely to occur in the future in New Zealand; they are simply areas identified to have potential uses.
- The new technologies provide a spectrum of 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. The potential uses listed above 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. Gene editing and GM are not two different things. They are different parts of a continuum, with no clearly defined cut off points.
- New Zealand's legislation does not make a distinction between gene editing and genetic modification. All techniques (except the small list set out in the HSNO (Organisms Not Genetically Modified) Amendment Regulations 2016) use the same risks and benefits assessment process under the HSNO Act.
- 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'.
- Under the HSNO Act any organism created using a new genetic technology will require approval.

For context when thinking about the briefing note, Minister Parker did not ask MFE to progress the thinking on preparing for a public conversation, nor did he forward the report to other Ministers, so our current workplan only has us keeping a watching brief on developments in gene technology.

Regards

Brian

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http://intranet.mfe.govt.nz/sites/all/files/Lockup-8pt.png

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Key messages GM:

Genetically Modified Organisms (GMOs) are regulated under the Hazardous Substances and New Organisms Act 1996. There are currently no plans to review the HSNO legislation and GM is not currently a priority for the Minister or 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. Officials at MfE 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 Environmental Protection Authority (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.

Background info – s 9(2)(g)(i) [redacted]:

- Earlier this year we provided a briefing to the Minister outlining developments in genetic technologies and suggesting it may be time to consider a public conversation on GM. ("2018-B-04195 - Genetic Technology - Overview and Next Steps" can be accessed via the following link: Out of Scope [redacted]) This briefing will soon be released on the MfE website as we have been getting a few OIA requests for it.

- Based on the level of interest expressed by the Minister and reprioritising of resource in MfE we are no longer undertaking the work proposed in the paper. We continue to monitor international developments but will not be putting resource into analysis of opportunities or challenges for New Zealand, monitoring public views and exploring approaches to a participatory public process.

- s 9(2)(g)(i) [redacted]