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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developments raise questions as to whether New Zealand's regulatory framework is still appropriate as HSNO is becoming outdated in light of developments.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

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[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

7/6/18

Glenn Wigley
Director Marine, Environmental Risk and Science **Date**

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

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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

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[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.

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[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.