Office of the Prime Minister's Chief Science Advisor
Kaitohutohu Mātanga Pūtaiao Matua ki te Pirimia

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13 June 2023

Dear Prime Minister,

At our May 11 meeting, we discussed my 2019 Briefing to PM Ardern (attachment 1) on the major evidence synthesis undertaken by Royal Society Te Apārangi on genetic editing (GE). I reiterated that I agree with the widely held view that our current legal and regulatory frameworks are not appropriate for the genetic tools available in 2023. The scientific and legal definitions are sometimes at odds and, importantly, definitions of key concepts are inconsistent across the relatively large number of acts. For example, at the intersection of the Medicines Act 1981 and the Hazardous Substances and New Organisms (HSNO) Act 1996 there is confusion about whether modifying human cells creates a legally defined 'new organism'. These anomalies need addressing. Beyond this, within the confines of the HSNO Act itself, the 'time stamp' on the list of genetic tools that do not attract regulation creates further anomalies. For example, mutagenesis by radiation or chemicals, which creates multiple uncontrolled changes to DNA, is much less regulated than a single controlled change by one of the modern GE technologies. It is analogous to saying that electric cars should attract a greater penalty than petrol cars, because electric cars were not in use in 1998.

As I have consistently observed since taking up this role, the way forward requires more nuanced thinking, as outlined in attachment 1, and I note that internationally the conversation is moving forward, strengthening the case for change. In particular:

- The Regulatory Horizons Council in the UK has proposed a processed-based trigger for regulations (all products of modern biotechnology will be regulated) with a product-based risk assessment to determine release conditions (Regulatory Horizons Council Report on Genetic Technologies, Sep 2021, updated in Jul 2022, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1089198/regulatory_horizons_council_report_on_genetic_technologies_july_2022.pdf).
- Food Standards Australia New Zealand are looking to refine definitions for gene technology and new breeding techniques. This is likely to result in food produced by gene editing techniques being more widely available in New Zealand despite the fact that it would not be practical to grow them here. (Food Standards Australia New Zealand Proposal P1055 - Definitions for gene technology and new breeding techniques, last updated Jan 2022,

https://www.foodstandards.gov.au/code/proposals/Pages/p1055-definitions-for-gene-technology-and-new-breeding-techniques.aspx). This was the subject of an excellent discussion hosted by Food HQ and including industry voices, who followed up with the attached letter (attachment 2) emphasising the advantages of moving beyond the over-simplified 'product vs process' debate.

- The European Commission is undertaking a review of the regulations around plants obtained by targeted mutagenesis (gene editing) and cisgenesis (genetic changes that do not introduce foreign genes). This is likely to increase production of plants using these technologies in one of New Zealand's key high value markets (European Commission Legal Framework for Plants Obtained by Targeted Mutagenesis and Cisgenesis and for Their Food and Feed Products, adoption scheduled for Q2 2023, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en).
- Japan is known for its strict regulation of genetic modification (GM), but a 2019 determination by an expert panel that gene-edited foods are safe (Science Insider Gene-edited Foods are Safe, Japanese Panel Concludes - Recommendation opens door to plants and animals produced using CRISPR and similar techniques, Mar 2019, https://www.science.org/content/article/gene-edited-foods-are-safe-japanese-panel-concludes) and a legal challenge to Japan's existing definition of genetic modification has led to three genetically edited foods being produced and sold in Japan (two kinds of fish modified to grow faster in aquaculture (https://www.seafoodsource.com/news/supply-trade/japan-s-government-taking-positive-stance-on-gene-editing-fish) and a tomato that could improve heart health (https://www.nature.com/articles/d41587-021-00026-2).

In New Zealand, since the 2019 briefing, the conversation has also moved forward on several fronts:

- A report from Te Puna Whakaarouni, the MPI Food Sector think tank, outlined the technology of genetic editing and found that "*globally genetic technology has been applied across the food and fibre sector to improve yield, size, taste, and nutritional content of produce as well as develop resistance to factors such as disease, pests, drought, or salt tolerance*." The report also concluded that GM is not a significant factor in New Zealand's brand (Te Puna Whakaarouni Report on Modern Genetic Technology – What it is and how it is regulated, Feb 2023, https://fitforabetterworld.org.nz/assets/Te-Puna-Whakaaronui-publications/WELL-NZ-Modern-genetic-technology-2023.pdf).
- Science New Zealand has put out a position statement in which they say: "*Regulations that govern genetic modification research in New Zealand are 20 years old and in need of urgent review*." (Science New Zealand Position Paper on Gene Technologies, Feb 2023, https://sciencenewzealand.org/assets/Uploads/Files/SNZ-GE-Positioning-Paper-Feb-2023.pdf).
- The Productivity Commission has said that New Zealand will need to use modern gene editing technologies to meet the challenges facing the country: "*Modern genetic modification (GM) technologies such as gene-editing offer potential new opportunities for boosting productivity, improving health outcomes, reducing biosecurity risks, and responding to climate-change risks and other environmental problems effectively and efficiently. The regulatory framework for GM tools was last reviewed in 2001 and does not reflect technological advances since that time. The Government should review the GM regulatory framework, to ensure it is fit for purpose and supports domestic innovation. This review should include wide engagement with industry, Māori and the general public. It should assess consumer attitudes, and the potential impacts on New Zealand firms who wish to*

retain GM-free status, and on New Zealand's reputation and brand more generally." (The Productivity Commission Report on New Zealand Firms: Reaching for the frontier, April 2021, https://www.productivity.govt.nz/assets/Documents/Final-report-Frontier-firms.pdf).

- In addition, the Climate Change Commission suggest that NZ: "*Review current arrangements and develop a long-term plan for targeted research and development of technologies (including evaluating the role of emerging technologies such as genetic engineering) and practices to reduce biogenic emissions from agriculture.*" (Climate Change Commission - 2021 Draft Advice for Consultation, January 2021, https://haveyoursay.climatecommission.govt.nz/comms-and-engagement/future-climate-action-for-aotearoa/supporting_documents/CCCADVICETOGOVT31JAN2021pdf.pdf).

In response, there have been two workstreams undertaken by the Government. Firstly, under the guidance of Ministers Parker and Twyford, the Ministry for the Environment has produced an excellent consultation document to reduce unnecessary regulatory restrictions on biomedical research and development utilising genetically modified organisms. I am very supportive of this consultation going ahead as soon as possible, since it represents a considered first step in moving the conversation forward in an area of importance to the public.

This would hopefully be followed by a second consultation covering broader applications including those relevant to climate change, biodiversity, and the primary industries. This could include consideration of a regulator based on the Australian model, that could consider applications based on outcomes, not technological processes. The Australian Government has established an Office of the Gene Technology Regulator (https://www.ogtr.gov.au/) and my impression is that the regime has gained the confidence of the research sector.

Secondly, Minister Verrall is overseeing the passage of the Therapeutic Products Bill through Parliament. If passed, the Ministry of Health will develop risk proportionate regulations which will cover the use of human therapeutics produced by GM technologies as well as the use of GM cells and GM treatments as therapeutics. This is intended to remove the current barriers to authorising cell and gene-based treatments under the current Medicines Act 1981. These reforms will be consistent with previously announced reforms to the HSNO Act, and will address the cumbersome double regulation of gene edited therapeutic products under the HSNO and Medicines Acts. This was recently described by Minister Little in a speech to Medicines New Zealand on 24 August 2022 (Speech to Medicines New Zealand annual dinner | Beehive.govt.nz):

> *"The Medicines Act 1981 has not kept pace with changes in policy, clinical practice, or technological advances. As a result, there are longstanding gaps in the regulation of some therapeutic products. The response to COVID-19 has highlighted the lack of regulation of medical devices in particular, and gaps in the regulation of advanced cell and gene therapies. The Bill will address these challenges and regulatory gaps in order to enable timely development and adoption of emerging health technologies, such as genetic technologies and medicines…..*
>
> *…Turning now to genomic technology – which is rapidly expanding in testing, sequencing and genetic modification techniques (such as CRISPR), and may give rise to new treatments and interventions. Products involved in genomic medicine intended for a therapeutic purpose will be regulated under the Bill through their appropriate product categories. For example, gene therapies and advanced cell-based therapies (such as CAR T-cell personalised cancer treatments) are defined as 'biologics' (i.e., the class of therapeutic products that are or contain human cells or tissues) and will be regulated as medicines … Under the Bill, these products will be assessed by the regulator in a risk-proportionate manner to ensure safety, quality and efficacy for genomic medicines for*

market authorisation. New and bespoke pathways will be designed for novel genomic medicines and their clinical trials will be regulated as a controlled activity requiring a licence or permit.

The therapeutic product regime for biologics will run in parallel with other regulatory approval processes, including approval through the Environmental Protection Authority for all genetically modified organisms under the Hazardous Substances and New Organisms Act, and existing ethics approval processes.

Where appropriate, the product will be aligned with other regimes involving human cells and tissues and genetic information, including the Human Tissue Act and the Human Assisted Reproductive Technology Act."

The Ministry of Health has also recently released their Long-term Insights Briefing for consultation. This covers the broader topic of precision health and will be followed by policy work looking at the role of genomic medicine, including gene editing, in the delivery of health services in New Zealand. (The Ministry of Health Public Consultation on a draft Long-term Insights Briefing on Precision Health: Exploring opportunities and challenges to predict, prevent, diagnose, and treat disease more precisely in Aotearoa New Zealand, Public consultation opened May 2023, https://www.health.govt.nz/publication/precision-health-exploring-opportunities-and-challenges-predict-prevent-diagnose-and-treat-disease-0).

I look forward to working with officials on ensuring that these efforts to fix problems in New Zealand's genetically modified organism (GMO) regulations stay connected and also, in the longer term, taking a broader look at our GMO regulation in consultation with Māori, the public and industry. There is an opportunity to reframe the debate and address the issue of maintaining choice, while enabling industry, and the health and environmental sectors, to access the technologies they need to address their problems. We can also take the opportunity to align definitions with international treaties, particularly the Cartagena Protocol, and to leverage New Zealand's reputation for being trustworthy by being open and transparent about use of GE and its monitoring.

Given the high public interest in this area and the many public comments I have made on this topic, I propose to upload this letter onto our web page as an update to the publicly available 2019 Briefing at the end of June, for full transparency.

Yours sincerely

Juliet Gerrard

Cc Ministers Verrall, Parker, O'Connor, Henare & Brooking
Ruth Fairhall & John Scott, DPMC
Tabitha McMaster & Jordan Tinsley, PMO
Ian Town, CSA Ministry of Health

Attachment 1

Briefing on genetic editing 2019

Office of the Prime Minister's Chief Science Advisor
Kaitohutohu Mātanga Pūtaiao Matua ki te Pirimia

Briefing to the Prime Minister on the Report on Gene Editing from Royal Society Te Apārangi, 12/13 August 2019

***Context**: This briefing accompanies the Royal Society Te Apārangi report, and does not seek to repeat the material synthesised therein. It is not intended to be comprehensive, and focuses selectively on the issues that are relevant for policy.*

A. Commentary on the report and the substantive issues raised for policy makers

1. **Gene editing (GE) presents special challenges because it makes targeted modification of genes increasingly routine**. This new tool expands the repertoire of genetic engineering to allow more precise modifications to be made more routinely. This presents some urgency to create a clear framework to enable New Zealanders to make ethical decisions about its use, as is happening internationally.

2. **The Royal Society Te Apārangi (RSNZ) convened an expert panel[1] who have done useful work unpacking some possible impacts of gene editing across applications in healthcare,[2] pest control[3] and the primary industries.**[4] These case studies illuminate some of the hazards and benefits of using genetic editing in different contexts and includes a helpful indication of the timeframes on which they could be deployed, which are generally longer than one would assume from current public debates. We can speculate that most New Zealanders would accept the use of gene editing to cure cancer;[5] and that most would probably reject the use of gene editing to modify children and mokopuna, a scenario that has already played out in China with modification of twin human babies.[6] There will be a

[1] https://www.royalsociety.org.nz/major-issues-and-projects/gene-editing-in-aotearoa/. Although the Māori working group report has not reported as part of this work, effort has been made to incorporate considerations from te ao Māori in the main RSNZ document.
[2] Healthcare scenarios include the possibility of treating human tissues within individuals to cure disease; the possibility of altering genes passed on to subsequent generations (*e.g.* to reduce the risk of breast cancer); the possibility of modifying children to improve their athletic performance. Each has different time horizons, hazards and benefits, and highlights the complicated intersection of the HSNO Act and the Medicines Act.
[3] Pest control scenarios include using genetic technologies to eliminate invasive wasps, possums, stoats and rats. Each has different time horizons, hazards and benefits, and highlights the complicated intersection of the HSNO Act, the Agricultural Compounds and Veterinary Medicines Act (ACVM) as well as the need for evaluation of how the technologies apply to the Animal Welfare Act, the Biosecurity Act, the Conservation Act and the Resource Management Act, which in some instances contain different definitions of key terms.
[4] Primary industries scenarios include reducing weediness in introduced trees; modifying ryegrass endophytes for greater stress and pest resistance of the host ryegrass; speeding up development of new apple cultivars for premium export; improving disease resistance in mānuka, a taonga species; modifying cows to produce less allergenic milk. Each has different time horizons, hazards and benefits, and highlights the complicated intersection of the HSNO Act and the National Parks Act, the Reserves Act, the Resource Management Act, the ACVM and the Cartagena Protocol.
[5] In its report in 2001, the Royal Commission on Genetic Engineering found that most of the public "were comfortable with genetic modification for medical purposes." Available at: https://www.mfe.govt.nz/publications/hazards/report-royal-commission-genetic-modification
[6] See *e.g. Cyranoski 2019*: The CRISPR baby scandal: What's next for human gene editing? Nature 566: 440-442. Available at: https://www.nature.com/articles/d41586-019-00673-1

range of views on the many possible applications of genetic editing in between these two scenarios. The report emphasises the lack of a clear regulatory and legal framework to enable New Zealanders to make these important choices. I endorse this view. We need a future-proof framework that is internally consistent across Acts and regulatory agencies, and that enables a clear debate to be held around the hazards and benefits of new genetic tools, in the context of each specific application proposed. I fully endorse the panel's observation that this debate needs wide public engagement.

3. **The RSNZ panel was criticised by some for taking advocacy views** as discussed in the opening comments from the Chairs, but aimed to present the different gene editing scenarios without bias, to illuminate the ethical, cultural and legal issues they present. Some public consultation was included in their process, but more substantive input is required, especially from Māori, and I note that no specific perspective of the Māori reference group has been included.[1] In the meantime, a recent paper led by Māori researchers Hudson and Mead has reviewed contemporary te ao Māori views from a range of authors on genetic technologies, and how key Māori values (*e.g. whakapapa, mauri, mana, kaitiakitanga)* speak to the use of these tools.[7] The discussion generally supports the observations made by the Chairs of the RSNZ report. A conclusion from Hudson, Mead *et al.*, that *"... a widespread social license for the use of gene-based technology is unlikely in the short term. Generally, Māori do not oppose new and emerging gene technologies* a priori*, but instead raise concerns about how the technologies should be used and the rationale, objectives and consequences of choosing them."* provides a helpful framing, which resonates with my own views, and has informed this response to the RSNZ report. It also aligns with the analysis of Everett-Hincks and Henaghan, authors of the legal analysis which forms part of the panel's work, who frame their scientific and technical considerations within the over-riding consideration of a quest for policies that create *ora* and intergenerational wellbeing for all New Zealanders,[8] in the overarching context of the Treaty of Waitangi.[9]

4. **A complex legal analysis across multiple Acts is included in the report, which is particularly useful for policy makers.** This is embedded throughout the RSNZ report and summarised in a stand-alone chapter. It points out multiple inconsistencies and loopholes between Acts and regulatory agencies that need to be remedied to cope with modern technology. The increasing interconnectedness of possible applications of genetic tools, demands consistency in legal definition (*e.g.* of 'an organism', 'a new organism', 'a pest', 'an unwanted organism'*)* across Acts.[3] A more extended analysis than is present in the RSNZ report is being published elsewhere[8] and lays the groundwork for a significant step forward in modernising our regulatory framework. To fully understand the detail behind these recommendations, I have met with Everett-Hincks and Henaghan and also heard reaction to their analysis from experts with views not represented in the RSNZ panel.[10] This conversation, coupled with extensive discussions over the last few years with the science community, suggests a large consensus for a reduction in regulatory reporting

[7] Hudson, Mead, *et al.* 2019: Indigenous Perspectives and Gene Editing in Aotearoa New Zealand. Frontiers in Bioengineering and Biotechnology 7: 1-9. https://www.frontiersin.org/articles/10.3389/fbioe.2019.00070/full

[8] Everett-Hincks and Henaghan, 2019: Gene editing in Aotearoa New Zealand – legal considerations for policy makers. Victoria University of Wellington Law Review, *in press*; Everett-Hincks and Henaghan, 2019: Gene editing pests and primary industries – legal considerations. New Zealand Science Review 75: 31-36, will be available at: https://scientists.org.nz/NZSR

[9] Of specific relevance here is that the Waitangi tribunal noted in the 2011 WAI262 report that '*the law and policy in respect of genetically modified organisms does not sufficiently protect the interests of kaitiaki in mātauranga Māori or in the genetic and biological resources of taonga species.* Waitangi Tribunal Ko Aotearoa Tenei: A report into the claims concerning New Zealand Law and Policy Affecting Māori Culture and Identity (Wai 262, 2011).

[10] Most recently at a meeting with Prof Mark Henaghan (Lawyer on RSNZ panel) and Prof Jack Heinemann (Professor of Genetics and Molecular Biology, University of Canterbury) at the University of Auckland, June 21st 2019.

requirements for GE technology used in the laboratory, where any risk is mitigated by containment; I am surprised this does not feature more prominently in the RSNZ report as a recommendation.

5. **As I have previously expressed publicly, I agree with the view that our current legal and regulatory frameworks are not fit for purpose.** The scientific and legal definitions are sometimes at odds and, importantly, definitions of key concepts are inconsistent across Acts. For example, at the intersection of the 'Medicines Act' and the 'Hazardous Substances and New Organisms (HSNO) Act' there is confusion about whether modifying human cells creates a legally defined 'new organism'. Hypothetically, if CRISPR-Cas were used to cure your grandmother's cancer, a case could be made that she was a new organism and therefore if she lived, she could not leave containment. These anomalies need addressing. Beyond this, within the confines of the HSNO Act itself, the 'time stamp' on the list of genetic tools that do not attract regulation creates anomalies. For example, mutagenesis by radiation or chemicals, which creates multiple uncontrolled changes to DNA, is much less regulated than a single controlled change at a specific point. It is analogous to saying that electric cars should attract a greater penalty than petrol cars, because electric cars were not invented in 1998.

B. The way forward requires more nuanced thinking than has served us in the past, in particular:

1. **Whether NZ is 'GM-free'[11] or not, is a debate about New Zealand's identity and international branding; this is a trade argument, which has little to do with the science.** It may be that there is a GM/GE-free branding advantage for some exporters. It may also be that this advantage is short lived as the conversation moves forward internationally. There is a lack of evidence either way. These, however, are not science arguments and need to take place in the context of mixed and shifting international regulations and consumer demands. Currently our regulatory view of genetic editing is consistent with that in Europe, but not with that in the US. The recent decision by Australia not to regulate genetic editing (unless new DNA is included) presents interesting local context.

2. **Arguing that 'GE is not GM' is not helpful.** There is a spectrum of genetic modification – at one end of this spectrum, the specific change can be minor and create an organism biologically identical to one that has arisen naturally (but still 'born' in the lab). At the other end of the spectrum we can create whole new synthetic organisms. The legal and regulatory frameworks need to recognise the range of current and future technologies and be future proof. A future framework could constructively remove the often somewhat arbitrary definition of whether a particular gene edit creates a 'new organism' or not, and focus instead on the hazards and benefits of the use of genetic editing in this particular instance, balanced against the alternatives. It also needs to cope with the fact that a genetically edited organism that was identical to one found in nature would create critical challenges to regulators (*e.g.* for import of fresh produce[12,13]).

3. **Arguing that 'GE is safe or GE is not safe' is not helpful**. GE is a tool and like most tools can be used for good and ill. We do not regulate all uses of 3D printing in case someone

[11] Confusingly, GE-free and GM-free are used synonymously – here the GE standing for genetic engineering, rather than genetic editing. For clarity – genetic editing is a type of genetic modification/genetic engineering. Many applications of GE are so subtle that it is argued by some that minor gene edits should be classed as non-GM.

[12] Ledford 2019: CRISPR conundrum: Strict European court ruling leaves food-testing labs without a plan. Nature July 23 2019. Available at: https://www.nature.com/articles/d41586-019-02162-x

[13] The RSNZ report points out that many genetically modified foods are already allowed in Aotearoa New Zealand.

prints a gun. But we do need to minimise use of tools, including CRISPR-Cas, by rogue actors (perhaps in the same way that we regulate access to hazardous substances such as TNT).

4. **The legal and regulatory framework must facilitate, not hinder, asking and answering the key ethical questions,** returning to our speculation that most New Zealanders would agree that the Chinese twins should not have had their genes edited, but that most would probably accept an edited gene if it cured cancer. We need an honest discussion of the hazards and benefits of the myriad possible applications of genetic tools, within the context of society's acceptance or otherwise of the use of these tools in each case. We need a legal and regulatory framework that enables this important discussion rather than have us focus on complex, sometimes contradictory, legal and scientific definitions of whether we have created a 'new organism.'

5. **We need to move beyond the over-simplified 'product vs process' debate.** The GE issue is often characterised as a debate between regulating products and regulating process. Again, this is too simple a view and a more holistic conversation about 'what triggers regulation' would be more useful. For example, GE could be controlled as a process outside registered institutions, but be allowed without regulation within registered institutions, in containment. There would then need to be a trigger for regulation of new 'products' emerging from such institutions, for example if the 'product' had sufficient novelty to enable intellectual property to be protected.

C. Although beyond the remit of my role as Chief Science Advisor I note that:

1. The Royal Commission recommended the establishment of a Parliamentary Commissioner for Biotechnology (which was never supported) and a Bioethics Council, which provided a forum for some of these tricky conversations until its disestablishment in 2009. Although there are bioethics committees run from the Ministry of Health, there is no overarching forum to address the breadth of applications within the current and future reach of gene editing. We need conversations that include strong Māori representation, and those who understand the social science that underpins our understanding of the extent of social and cultural license in Aotearoa New Zealand.

2. Gene editing technologies would benefit from a single point of entry for application.[8] The Australians have a specific 'Office of the Gene Technology Regulator' (OGTR). Moving the conversation from 'have we made a new organism?' to 'is the use of this new genetic tool in this context a good idea?' could be enabled by an analogous function to the OGTR in the EPA (perhaps reflected by a change from HSNO to HSNOG, allowing distinct conversations about GE, in addition to those about hazardous substances and those about new organisms?)

3. Progress requires bringing a combination of expert voices from all sides of the issue to the table, to create a legal and regulatory framework that is future proof. This will facilitate meaningful engagement with the public with a genuine focus on the hazard and benefit for each application, rather than invest time and taxpayers money arguing about arbitrary definitions ('*is granny a new organism now?*') in the current regulatory quagmire. A fresh, open-minded look at the legal, regulatory and policy framework is needed. My Office and the Chief Science Advisor Forum are happy to assist in any such process, which could, for example, be led from the Law Commission.

Attachment 2

FoodHQ letter to PMCSA re genetic technologies

Professor Dame Juliet Gerrard

Prime Minister's Chief Science Advisor

13th September 2021

Tēna koe Juliet

On behalf of FoodHQ, I would like to thank you for joining our recent workshop exploring the opportunities, barriers and considerations related to the potential use of genetic technologies in New Zealand.

FoodHQ believes New Zealand urgently needs a more nuanced discussion about our legal, regulatory and policy framework for the use of genetic technologies.

Regulations are changing internationally as other countries work through this general area, genetically modified products are found internationally and already imported into New Zealand, and potential New Zealand based technologies and products arising from the use of a range of genetic technologies are on the horizon.

New Zealand has a complex regulatory system with multiple inconsistencies between Acts and Regulatory Agencies. This system doesn't cope well with modern technologies and scenarios that were not envisaged when the Acts were written. We are aware of the Proposed New Breeding Technologies consultation that Food Standards Australia and New Zealand has been working on and look forward to being able to work constructively with them as it progresses.

As part of this wider topic, we appreciate the opportunity to share our thoughts on your "Briefing to the Prime Minister on the Report on Gene Editing from Royal Society Te Apārangi, August 2019".

- FoodHQ is supportive of your recommendations that New Zealand needs to move "the conversation from 'have we made a new organism?' to 'is the use of this new genetic tool in this context a good idea?". As you suggest, it would be useful to use a range of expert voices from all sides of the issue, along with meaningful engagement with Māori and the public, to help create a legal and regulatory framework that is future proof and enables a genuine focus on the risks and benefit for each application.

- FoodHQ also supports your recommendation of a single regulatory point for new applications similar to the Australian's 'Office of the Gene Technology Regulator' (OGTR) - potentially as an analogous function in the EPA. This would allow a distinct conversation about use of genetic technologies, separate from new organisms and hazardous substances.

- We support evaluating how to move food standards from a regulatory framework predominantly based on the processes used in production to instead have a more holistic framework that also considers the risks associated with the final products. We appreciate that there will be complexities in such a change, and it would require careful thought and

consultation to ensure consumers and producers were comfortable regarding the information they require to make an informed decision on purchase and consumption.

- There may be value in some discussion about the reversibility/irreversibility and segregation post implementation. Some modified organisms and associated phenotypic changes will be easier to segregate and some easier to remove or reverse than others.

- We envisage that there may be some potential sectors or uses of genetic technologies that are more well established or where the benefits of the application may be so clear cut that our society finds them more easy to accept. These may include those related to medical applications within clinical settings. However, we hope that it will also be possible to start to seed conversations across the broader spectrum – from laboratory based to field trials to commercial products; and from pest-control to climate mitigation to broader potential food-related uses that could deliver significant benefits of various types.

We are appreciative of you leading this sensitive conversation in a manner that is based on scientific evidence and clear communication. It is a discussion that has been avoided for some time because of its complexities, but it is important to start it now so we can begin to work through its nuances to enable New Zealanders to collectively shape the future of our country.

We look forward to seeing how the discussion progresses. Please let us know if we can provide any assistance to you as the discussion progresses.

Ngā mihi nui,

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