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

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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.