

Gene editing pests and primary industries – legal considerations

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Keywords: genetic modification, gene editing, legislation, policy.

Introduction

To explore the implications of gene editing technology for New Zealand, the Royal Society Te Apārangi convened a multi-disciplinary panel of some of New Zealand's leading experts to consider the social, cultural, legal, ethical and economic implications of revolutionary gene-editing technologies for New Zealand. **This brief academic paper is the opinion of the authors, Everett-Hincks and Henaghan, and it informs and is informed by the work of the Royal Society Te Apārangi Gene Editing Panel.**¹

Gene-editing technologies use proteins, called enzymes, targeted to cut areas of DNA within an organism's genetic material. This process can modify genes, by enabling different repair information. In the past ten years researchers have developed these technologies to manipulate specific genes with growing precision, revolutionising biological science, accelerating research and offering an alternative tool in human healthcare, pest control and primary production. The bioeconomy is growing rapidly with the profusion of biotechnology products predicted to overwhelm regulatory systems.²

Advancement of gene editing technologies provides an opportunity to review current regulatory frameworks and devise

¹ Members of the Royal Society Te Apārangi Expert Gene Editing Panel <royalsociety.org.nz/major-issues-and-projects/gene-editing-in-aotearoa/gene-editing-panel/>.

² Preparing for Future Products of Biotechnology. 2017. National Academy of Sciences. The National Academies Press <www.nap.edu/24605>.

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a future-proof framework to keep abreast of rapidly advancing biotechnologies. The Hazardous Substances and New Organisms Act 1996 (HSNO Act) is the core legislation in a regulatory framework for gene editing technologies. Two decades have passed with minor amendments to HSNO Act. The HSNO Act never contemplated CRISPR-Cas gene editing technology, and might have, if a Commission on Biotechnology had been established to provide a horizon scanning function, as recommended by the Royal Commission on Genetic Modification in 2001. Open, honest and inclusive debate is required on whether *gene editing* is *genetic modification*.

The HSNO Act defines *genetic modification*³ and provides Regulations for when organisms are *not* genetically modified.⁴ Organisms are not genetically modified when they result solely from: selection;⁵ or from mutagenesis using chemical or radiation treatments that were in use prior to July 1998;⁶ or by the movement of nucleic acids using physiological processes;⁷ or spontaneous deletions, rearrangements and amplifications within a single genome.⁸ With the discovery of CRISPR-Cas gene

³ HSNO Act, section 2(1) *genetically modified organism* means, unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material—

- (a) have been modified by *in vitro* techniques; or
- (b) 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.

⁴ Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 (SR 1998/219). <www.legislation.govt.nz/regulation/public/1998/0219/latest/DLM255889.html>.

⁵ SR 1998/219, r 3(a).

⁶ SR 1998/219, r 3(ba).

⁷ SR 1998/219, r 3(d).

⁸ SR 1998/219, r 3(e).

editing technology and its ability to manipulate genetic material using *in-vivo* and *ex-vivo* techniques, the scientific definition of genetic modification is evolving and thus the legislative definition, relying on *in-vitro* manipulation along with exceptions in regulations, requires review. Currently in New Zealand the use of gene editing technologies, including CRISPR-Cas, is likely deemed *genetic modification* and the organisms for which CRISPR-Cas is used, are deemed *new organisms* according to the HSNO Act. It is an offence to: develop or field test; or knowingly import or release, a new organism without prior regulatory approval (HSNO Act, section 109).

The HSNO Act and its regulating authority, the Environmental Protection Authority (EPA), have undergone judicial analysis. Most notable was *The Sustainability Council of New Zealand Trust v The Environmental Protection Authority* (Scion case; wilding pine),⁹ which resulted in limiting the discretionary power of the EPA to assess editing techniques, emphasizing the *precautionary approach* and clarifying the classification of gene edited organisms as *new organisms* for the purposes of the Act. Additionally, the New Zealand Environment Court in *Federated Farmers of New Zealand v Northland Regional Council* (Northland Regional Council case; crops) enabled Regional Councils to control the use of genetic modification, under the Resource Management Act 1991, through regional policy statements and plans.¹⁰ These cases have wide-ranging implications for New Zealand and are not generally limited to genetically modified wilding pines and crops, and by analogy apply to other genetically modified plants and possibly animals.

Aotearoa is unique and the Treaty of Waitangi is part of our constitution.¹¹ The HSNO Act contains provisions designed to ensure Māori views are taken into account when decisions are made about genetically modified organisms (HSNO Act, sections 4, 6(d) and 8). However, the Waitangi Tribunal concluded in the 2011 WAI 262 Report 'that the law and policy in respect of genetically modified organisms does not sufficiently protect the interests of kaitiaki in mātauranga Māori [i.e. custodians or guardians of the body of knowledge originating from Māori

ancestors] or in the genetic and biological resources of taonga species'.¹² Better implementation of Treaty of Waitangi principles and protection of kaitiaki in mātauranga Māori interests are central to inclusive decision making about gene editing in Aotearoa. Valuing the Treaty of Waitangi in legislation ensures that Treaty of Waitangi principles will underpin and guide all policy and decision making.

Throughout the paper the authors conclusions are expressed as *considerations*, for review by government, regulators, policy makers, stakeholders and the public. New Zealand's regulatory framework warrants review in light of advanced genetic technologies and evolving societal, cultural and ethical views. This paper provides an analysis of New Zealand's regulatory framework, primarily focussing on the HSNO Act and other statutes as they apply to gene editing technologies (in particular CRISPR-Cas9) in pest control and primary industries.

While emphasis has been on the science and technical aspects of the law, Treaty of Waitangi principles should be the *overriding consideration* in a quest for policies that generate ora – intergenerational wellbeing for all of Aotearoa.

The Royal Commission of Genetic Modification recommended, in 2001 'New Zealand should preserve its opportunities by allowing the development of genetic modification whilst minimising and managing the risks involved'.¹³ This is the underlying principle of this paper.

Regulation of the use of gene editing and gene drives for pest control

Next generation and novel pest control tools are being considered for use in New Zealand.¹⁴ Gene drives using advanced gene editing technology have been investigated as a potential tool to assist the government in achieving New Zealand Predator Free status by 2050.¹⁵

Gene-editing tools have not been used to date in conservation of wildlife, but their use in the control of non-native invasive organisms is being explored with the use of gene drives.

In 2015, researchers demonstrated the use of CRISPR-Cas9 to develop 'gene drives', a genetic system named for the ability to 'drive' itself and nearby genes through populations of organisms over many generations. In normal sexual reproduction, offspring inherit two versions of every gene, one from each parent. Each parent carries two versions of the gene, having a 50% chance that a particular variant of the gene will be passed on. However, gene drives ensure that the genetic modification will almost always be passed on, allowing that variant to spread rapidly through a population. Dearden and co-authors offer a list of potential target species in New Zealand for genetic modification with technologies developed and required to implement a gene drive system.

⁹ *The Sustainability Council of New Zealand Trust v The Environmental Protection Authority* [2014] NZHC 1067, (2014) 18 ELRNZ 331. The EPA has the power, upon receipt of an application, to determine whether an organism is a new organism for the purposes of the HSNO Act. In October 2012, Scion, the Crown Research Institute for forest resources, applied to the EPA for a determination of whether forest plants created by using Zinc-Finger Nuclease Type 1 (ZFN-1) and Transcription Activator-Like Effectors (TALENs) techniques were new organisms. In its application, Scion argued that ZFN-1 and TALENs techniques were equivalent to genetic changes made in plants through chemical mutagenesis and therefore were within the EPA's exemptions. EPA staff concluded that plants created with ZFN-1 and TALENs would be considered genetically modified organisms. But the EPA Committee decided that these plants would be exempt under the Regulations because ZFN-1 and TALENs techniques are more similar to chemical mutagenesis than genetic modification. The High Court Judge ruled that the exemption list is a closed list. The conclusion was based on an interpretation of the language of the Regulation and that the regulations did not prescribe factors for the EPA to add other techniques to the list. The Judge interpreted the HSNO Act and the regulations as not implicitly giving the EPA discretionary power to add to the exemption list and ruled that the EPA could not expand the exemption list to include techniques similar to chemical mutagenesis and adding to the exemption list was a political decision, not an administrative decision.

¹⁰ *Federated Farmers of New Zealand v Northland Regional Council* [2015] NZEnvC 89, [2015] NZRMA 217 at [47].

¹¹ Harris BV. 2005. *The Treaty of Waitangi and the Constitutional Future of New Zealand*. NZ Law Review 189.

¹² Waitangi Tribunal Ko Aotearoa Tenei: A Report into the Claims Concerning New Zealand Law and Policy Affecting Maori Culture and Identity (Wai 262, 2011).

¹³ Royal Commission on Genetic Modification. 2001. Ministry for the Environment. www.mfe.govt.nz/sites/default/files/media/Hazards/Royal%20Commission%20on%20GM%20in%20NZ-Final.pdf

¹⁴ Dearden PK *et al.* 2018. The potential for the use of gene drives for pest control in New Zealand: a perspective. *Journal of the Royal Society of New Zealand*. p 1–20.

¹⁵ Predator Free 2050. Department of Conservation <www.doc.govt.nz/predator-free-2050>

Potential target species include vespine wasps, pasture damaging weevils, Australian blowfly, possum, stoat, rats and mice.¹⁶

Gene editing a pest to include a gene drive would be regulated primarily by the HSNO Act. However, many statutes require referral, providing a complex regulatory framework for evaluating advanced genetic technologies as a method for controlling, managing and eradicating pests. It is seldom that one path would be taken. For example, administering a gene drive to rid New Zealand's conservation estate of possums will likely require at a minimum: animal ethics approval (Animal Welfare Act), a Pest Management Plan (RMA and Biosecurity Act), a conservation management plan (Conservation Act 1987), risk assessment for the agricultural industry and trade (Agricultural Compounds and Veterinary Medicines Act 1977), wild animal controls (Wild Animal Control Act 1977), along with approval from the Director General of Conservation (Conservation Act 1987), in addition to EPA approval for the new organism (HSNO Act 1996, section 27).

Gene drives are a disruptive technology, having the potential to lead transformational change in conservation, agriculture and in areas that we have not yet considered. It is recommended that regulation of gene drives in all contexts is required, as they risk reducing population genetic diversity along with potential development of resistant populations or strains.¹⁷ For production animals and plants, these effects render the affected population more susceptible to management, disease and environmental challenge in the future.

No one organism should be evaluated in isolation of its ecosystem. A risk assessment method incorporating a long-term time-scale view, over a number of breeding cycles, is required to: reduce resistance to gene drives in pests and unwanted organisms; assess the impact on an ecosystem over time; investigate unintended consequences; and for production animals and plants (non pests) retain genetic diversity, essential for adaptation to changing environmental and management conditions.

(1) **Consideration:** Risk assessment undertaken by the EPA balances beneficial effects against adverse effects (HSNO

¹⁶ Dearden PK *et al.* 2018. The potential for the use of gene drives for pest control in New Zealand: a perspective. *Journal of the Royal Society of New Zealand*. p 1–20.

¹⁷ *Ibid.*

Act, section 38). Adverse effects will still be realised. An environmental bottom-lines approach is more supportive of the precautionary approach and should be deployed for disruptive technologies.

(2) **Consideration:** Regulatory complexity limits our ability to provide a coordinated and timely response. Regulation of gene editing technologies and their products comprises multiple pieces of legislation with different regulatory authorities. Biotechnologies (including gene editing technologies) would benefit from a single statute and a single entry-point for applications.

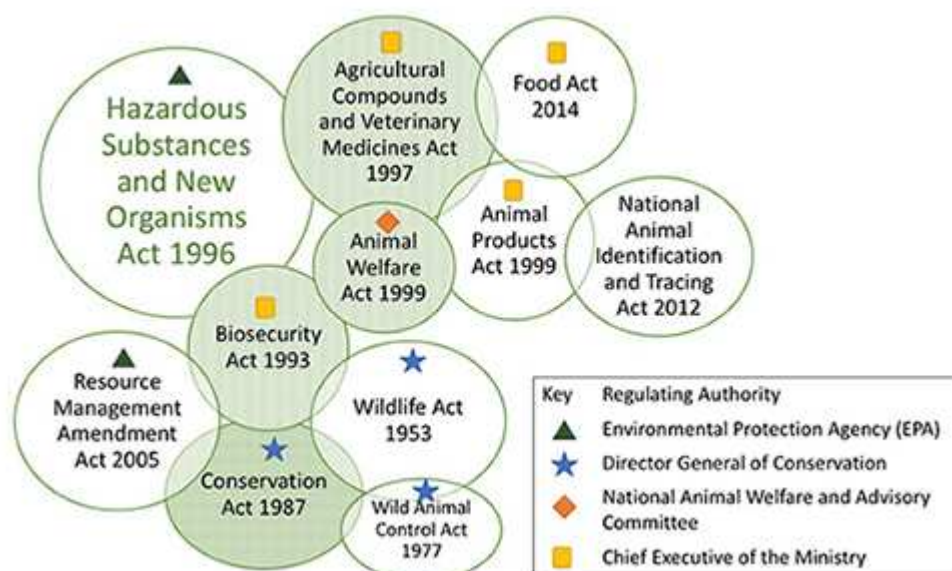
Proposed use of CRISPR-Cas

The purpose for which CRISPR-Cas and other advanced genetic technologies are proposed to be used will direct the regulation pathway. Pest management is legislated under the Biosecurity Act 1993, where pest and unwanted organism are defined. Pest is also defined in the Agricultural Compounds and Veterinary Medicines Act 1997 in relation to agricultural security, where agricultural security is defined as the exclusion, eradication and effective management of pests or unwanted organisms under the Biosecurity Act (section 2(1)).

(3) **Consideration:** Regulatory definition of 'pests' and 'unwanted organism' differs between multiple statutes. Legislative overlap for pests and unwanted organisms leads to regulatory complexity causing confusion for policy makers. Differing definitions in legislation and science will cause confusion for everyone. The following terms need to be defined consistently across legislation: animal, pest, unwanted organism, management of animals, biological product/compound and genetic modification.¹⁸

¹⁸ *Animal* is defined differently in both the Animal Welfare and ACVM Acts. *Pest* is defined differently in the Animal Welfare, Biosecurity and ACVM Acts. *Organism* and *unwanted organism* have the same meaning in both the Biosecurity and HSNO Acts. Animal Welfare Act refers to *biological product*. Does this have the same meaning as *biological compound* in the Agricultural Chemicals and Veterinary Medicines Act? Animal Welfare Act includes *genetic modification* of breeding animals, but does not define *genetic modification* and does not refer to the HSNO Act for definition. *Management* of animals is not defined in legislation and therefore could be interpreted to mean the control and eradication of agricultural pests.

Figure 1. New Zealand legislation influencing genome editing technologies in animals and other organisms. The Hazardous Substances and New Organisms Act 1996 is the primary statute. Overlapping statutes have interacting provisions. Please note that the Animal Welfare Act and the HSNO Act are not joining, as the Animal Welfare Act's **genetic modification** term does not refer to the HSNO Act for meaning. Regulating authorities for each of the statutes, are presented in the key provided.



- (4) **Consideration:** Once genetically modified, and deemed a new organism, is the new organism still deemed a pest or unwanted organism? For example, wilding pine species, lodgepole pine (*Pinus contorta*) are deemed unwanted organisms according to the MPI unwanted organism database (UOR).¹⁹ Would a genetically modified wilding pine species rendering it sterile and thus a new organism still be deemed a pest or unwanted organism? Reclassification of new organisms will be required, as they may no longer be deemed unwanted organisms or pests.
- (5) **Consideration:** Should EPA's assessment of risk differ for applications to genetically modify and release unwanted organisms and/or pests from that for non-pests? These organisms are already causing harm to the environment in their natural, non-genetically modified and wild type state. Review risk assessment provisions in the HSNO Act for genetically modifying pest and unwanted organisms.

- (6) **Consideration:** Regulatory complexity. Primary industries regulation of gene editing technologies and their products comprises multiple pieces of legislation with different regulatory authorities. Biotechnologies (including gene editing technologies) would benefit from a single statute and a single entry-point for application. (Refer to Figure 1, Consideration 2).

Gene edited plants and animals pose significant new challenges for regulation. Under current legislation (HSNO Act) and a judicial ruling in *The Sustainability Council of New Zealand Trust v The Environmental Protection Authority* [2014] NZHC 1067 (Scion case)²¹ on interpretation of that legislation, gene-edited crops and animals are deemed genetically modified. However, in many cases gene edited crops and animals will have genetic modifications that in theory could be induced by non-regulated methods, such as radiation or chemical-induced mutagenesis prior to 1998, or simply occurring naturally from spontaneous mutation (HSNO Act 1996; SR 1998/219, r 3(ba)). This calls into question the robustness of a risk management approach that focuses on how the modification is produced rather than the risks posed by the organism/product developed.

For importers, in the absence of a declaration process, it will be difficult to distinguish gene-edited organisms and products from non-modified contemporaries. The export of living modified organisms is prohibited, except as provided by the Imports and Exports (Living Modified Organisms) Prohibition Order 2005. Exporters require authorisation from the Minister for the Environment to export living modified organisms (LMO's) intended for: contained use (clause 6); food or feed or for pro-

Regulation of gene editing in primary production

Gene editing for primary production such as reducing environmental impact of wilding pines, responding to insect pests, speeding up apple breeding, protecting taonga species such as mānuka and providing new human health benefits from cow milk requires evaluation of a vast network of regulatory instruments alongside the HSNO Act.²⁰ Primarily, the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act); Animal Welfare Act 1999; Biosecurity Act 1993; Resource Management Act 1991; and the Cartagena Protocol to the Convention on Biological Diversity, require referral.

¹⁹ MPI Unwanted Organisms Database < www.mpi.govt.nz/protection-and-response/long-term-pest-management/handling-unwanted-organisms/>

²⁰ Gene editing in the primary industries. 2018. Royal Society Te Aparangi Gene Editing Panel <www.royalsociety.org.nz/major-issues-and-projects/gene-editing-in-aotearoa/>

²¹ *The Sustainability Council of New Zealand Trust v The Environmental Protection Authority* [2014] NZHC 1067, (2014) 18 ELRNZ 331.

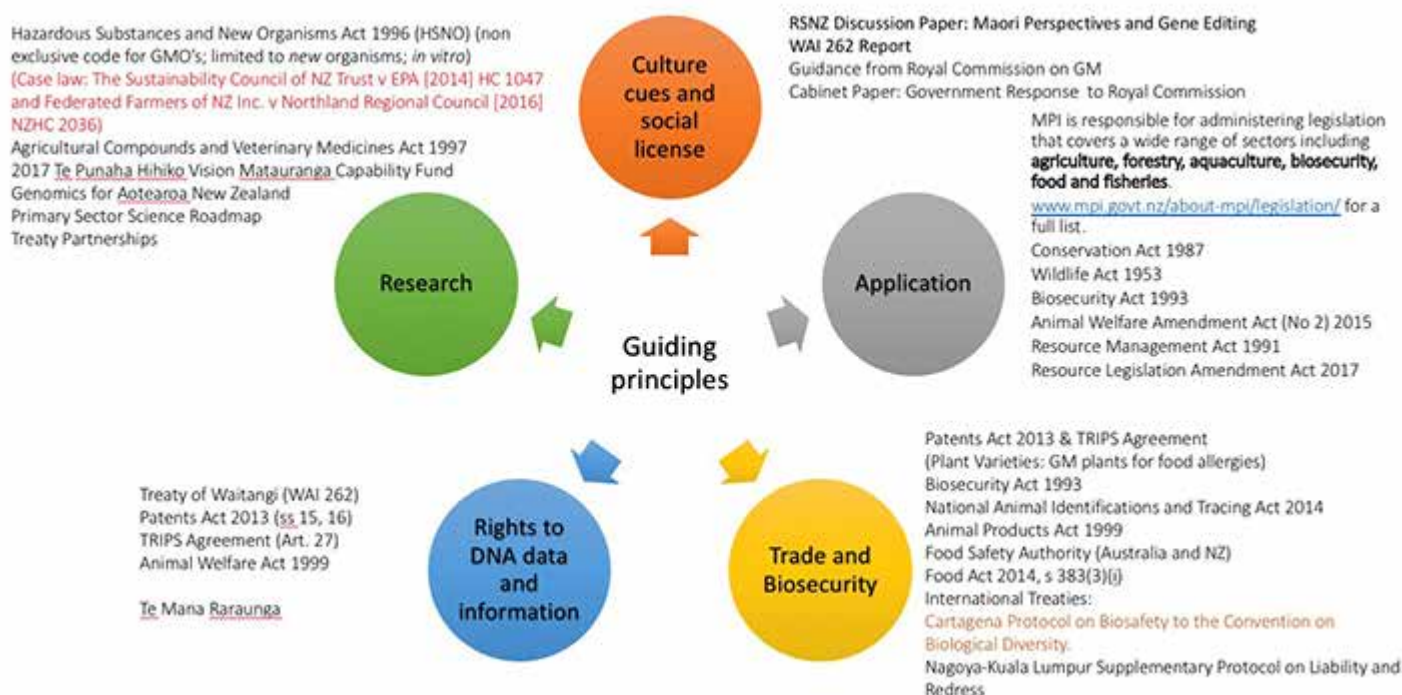


Figure 2. Gene editing regulation in New Zealand's primary industries.

cessing (clause 7); intentional introduction into the environment (clause 8), according to the Cartagena Protocol.²²

- (7) **Consideration:** *Regulatory oversight - challenge of recognising imported gene edited products, with international agreements on what is being regulated varying between countries. The definition of genetic modification differs between countries and jurisdictions. Gene editing cannot be detected in some situations. A review of international regulation is required along with an assessment of the implications for New Zealand's international trade agreements.*

Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act)

In addition to the HSNO and Biosecurity Acts, the ACVM Act has possibly the greatest effect on this technology. The purpose of the ACVM Act is to prevent or manage the risks associated with *agricultural compounds* (ACVM Act, section 2(1)),²³ ensure the use of *agricultural compounds* does not breach domestic food residue standards and consumers receive sufficient information about agricultural compounds (ACVM Act, section 4). The ACVM Act aims to achieve its purpose by providing that no *agricultural compound* may be used, including imported, manufactured or sold in New Zealand unless its use is authorised under the Act (ACVM Act, section 4A(1)).

Gene editing use in New Zealand's primary industries can meet the definition of a *biological compound* and subsequently an *agricultural compound* for managing plants and animals (ACVM Act, section 2(1)). The purpose of the Act is to prevent and manage risks associated with agricultural compounds to: public health; trade in primary produce; animal welfare and agricultural security (ACVM Act, section 4).

²² The Cartagena Protocol to the Convention on Biological Diversity, in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, is an international agreement that aims to ensure an adequate level of protection in the field of safe transfer handling and use of *living modified organisms* (LMOs). Particular attention is given to LMO resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, considering risks to human health and specifically focusing on transboundary movements (Article 1).

²³ The ACVM Act section 2(1) defines agricultural compound as—

(a) any substance, mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land, place, or water on or in which the plants and animals are managed, for the purposes of—

- (i) managing or eradicating pests, including vertebrate pests; or
- (ii) maintaining, promoting, or regulating plant or animal productivity and performance or reproduction; or
- (iii) fulfilling nutritional requirements; or
- (iv) the manipulation, capture, or immobilisation of animals; or
- (v) diagnosing the condition of animals; or
- (vi) preventing or treating conditions of animals; or
- (vii) enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals; or
- (viii) marking animals; and

(b) includes—

- (i) any veterinary medicine, substance, mixture of substances, or biological compound used for post-harvest treatment of raw primary produce; and
- (ii) anything used or intended to be used as feed for animals; and
- (iii) any substance, mixture of substances, or biological compound declared to be an agricultural compound for the purposes of this Act by Order in Council made under subsection (2).

Gene edited products used to *manage* animals will undergo risk assessment according to the ACVM Act. A *veterinary medicine*, according to the ACVM Act (section 2(1)), means any substance, mixture of substances, or *biological compound* used or intended for use in the *direct management* of an animal. A *qualifying veterinary medicine* is defined in the HSNO Act (section 2(1)) as a *veterinary medicine* that is or contains a *new organism*; and meets the criteria set out in section 38I(3) of the HSNO Act.

- (8) **Consideration:** *There is potential for imported gene-edited animals and plants (and other organisms) to bypass containment provisions in the HSNO Act and to be released without controls (HSNO Act, s 38I(1)). This is legally possible when advanced genetic technology is deemed a 'qualifying organism' in a 'veterinary medicine' used in the 'direct management of the animal'. This consideration would also apply to the management of pests. An assessment of potential implications is required should containment be bypassed, for a qualifying organism in a veterinary medicine. Should legislation be amended to ensure imported veterinary medicines are imported into containment?*

Animal Welfare Act 1999

The Animal Welfare Act determines whether animals can be manipulated (Animal Welfare Act 1999, section 3). The CRISPR-Cas genetic technique and the reproductive technique used to genetically modify animals is deemed a *manipulation* (Animal Welfare Act 1999, section 3(1)(a)(i) and section 3(1B)). Manipulation includes the breeding or production of an animal using any breeding technique (including *genetic modification*) that may result in the birth or production of an animal that is more susceptible to, or at greater risk of pain or distress during its life as a result of breeding or production (section 3(1B)). This provision considers the effect of *genetic modification* on the animal's production performance and on its progeny.

- (9) **Consideration:** *The associated effect of an edited gene on other genes in the animal may not be known and is required to determine the risk of adverse effects on resulting progeny under the Animal Welfare Act 1999 (section 3(1B)). Ensure animal genetic association analyses and findings are incorporated in risk assessment methods.*
- (10) **Consideration:** *Regulatory definition - genetic modification is not defined in the Animal Welfare Act and this Act does not refer to the HSNO Act for interpretation. Amend the Animal Welfare Act to refer to the HSNO Act for definition of genetic modification.*

Manipulation of an animal means to deliberately interfere with the normal physiological, behavioural, or anatomical integrity of the animal by deliberately subjecting it to a procedure which is unusual or abnormal when compared with that to which animals of that type would be subjected under *normal management or practice* (section 3(1)(a)). The procedure involves exposing the animal to any *microorganism* or *biological product* (section 3(1)(a)(ii)).

- (11) **Consideration:** *Lack of regulatory definitions and inconsistent regulatory definitions leads to stakeholder uncertainty for proposed use of advanced genetic technol-*

ogies. The following terms are not defined by the Animal Welfare Act 1999 and do not refer to other legislation for definition: normal management or practice, biological product and microorganism. Amend the Animal Welfare Act to include definition for these terms.

Summary

At the International Summit of Gene Editing in 2015, Alta Charo reported that ‘the regulatory framework is going to determine the speed at which biotechnology moves from laboratory to research to marketed product’.²⁴

Existing regulation for a platform technology, such as advanced gene editing, with broad use is complex. Immediately, consistent interpretation of terms between statutes and international agreements is required as *statutory borrowing* of terms is rarely used.²⁵ The Scion Case has emphasized the importance of correctly interpreting *new organism* and *genetic modification*, concluding that the relevant Regulation (SR 1998/219, r 3) provides an exhaustive list that can only be modified by Parliament.²⁶ This decision has implications for CRISPR-Cas technologies, potentially classifying all organisms for which CRISPR-Cas is used as genetically modified when the nucleotide alteration may be no different than mutagenesis or a modification to wild type.

In summary, regulation of gene editing technologies has come to a crossroads and provides an opportunity to review current regulatory frameworks and devise a future-proof framework to keep abreast of rapidly advancing biotechnologies.²⁷

²⁴ Charo A. 2015. International Summit on Human Gene Editing: A Global Discussion. In: Olson S. (ed.) 2015. *International Summit on Human Gene Editing: A Global Discussion*. Washington (DC).

²⁵ Burrows and Carter Statute Law in New Zealand, 5th Edition. 2015. Statutory borrowing of definitions: Except in cases where one statute expressly adopts the definition of another, statutory borrowing seldom occurs as each statute is a separate entity and the meaning of the words in that statute do not depend on other statutes. There have been occasional instances of judicial borrowing of definitions in New Zealand. This practice may be adopted where two statutes are in *pari materia* (on the same subject), but this cannot be relied upon. Relevant case law suggests a number of factors when definitions may be borrowed and include: the statutes having a similar purpose, administered by the same officers and passed into law about the same time. A comparison of the purpose and context of the Acts is critical. Borrowing of definitions is only to take place with great caution.

²⁶ *The Sustainability Council of New Zealand Trust v The Environmental Protection Authority* [2014] NZHC 1067, (2014) 18 ELRNZ 331.

²⁷ Marchant GE, Stevens YA. 2015. A new window of opportunity to reject process based biotechnology regulation. *GM Crops and Food*. 6: 233–242.

In brief, this paper’s authors purport New Zealand would benefit from an integrated regulatory system for biotechnologies:

- a. Led by Treaty of Waitangi principles;²⁸
- b. Governed by shared values for Aotearoa New Zealand, such as: uniqueness of Aotearoa; our indigenous and cultural heritage; sustainability; being part of a global family; well-being of all; freedom of choice and participation (as recommended by the Royal Commission on Genetic Modification);
- c. Having a single entry-point for applications, to promote efficiency and minimise costs for researchers and stakeholders;
- d. Regulated by one Authority (for conservation, biosecurity, primary industries and human health), with capability to horizon scan;
- e. Incorporating WAI 262 recommendations, to enhance the statutory power of Maori;
- f. Incorporating sub-tiers of multidisciplinary expertise in conservation, biosecurity, primary industries and human health; containing scientific, advisory and ethics committees which strive to keep abreast of global biotechnology developments and aim to preserve opportunities for Aotearoa;
- g. Regularly reviewed and consistent interpretation of key statutory terms;
- h. That uses systems-based risk analysis processes, incorporating an environmental bottom-lines approach for disruptive technologies such as gene drives;
- i. That compares the new biotechnology against alternative tools and technologies; and
- j. That utilises modelling to assist the prediction of future genetic diversity and resistance in populations.

This paper has identified some of the complexities of the legislation inherent in regulating a rapidly developing technology where such advances may be well ahead of current frameworks and public acceptance. A resilient legislative and regulatory approach is required whereby new legislation for biotechnologies is developed and a single entry-point for biotechnology applications is implemented.

²⁸ The principles of the Treaty of Waitangi were discussed in *New Zealand Maori Council v Attorney General* [1987] 1 NZLR 641 (CA). The Court found that the agreement between Maori and the Crown gave rise to a *partnership*, to act in *good faith, fairly and reasonably*. The Crown’s duty extended to active protection of Maori in the use of their lands and other interests to the fullest extent practicable.