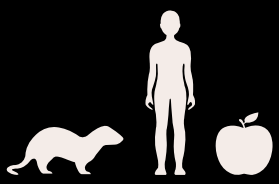
ROYAL SOCIETY TE APĀRANGI

GENE EDITING
LEGAL AND REGULATORY IMPLICATIONS

AUGUST 2019



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RATIONALE

Genetic technologies such as gene editing are developing quickly and their cost is rapidly falling. This is creating new approaches in health care, environmental management and food production, which have reached a point that challenges existing legal, regulatory and risk assessment systems, with some applications raising ethical concerns around the world.

Aotearoa New Zealand needs to ensure that its regulatory framework is able to accommodate these technological developments, while protecting our unique environment and indigenous and cultural heritage. The status of Māori as tangata whenua of Aotearoa, the principles of Te Tiriti o Waitangi/ the Treaty of Waitangi, and kaitiakitanga guardianship, also create a unique context in which New Zealand's regulatory framework needs to sit. Without regulatory reassessment, New Zealand risks being unprepared for both the new technologies' benefits, and the risks and challenges they bring.

As a global citizen, Aotearoa New Zealand also has an ethical obligation to share and contribute to global knowledge and understanding of the opportunities and risks that using these technologies present. New Zealand cannot leave this to other nations. Other countries and regions, such as USA, Europe, Australia and Japan, are currently reviewing their regulatory systems to ensure they keep pace with technological change and provide an appropriate level of oversight.

Alongside this, New Zealand industries, research communities, as well as local and central government, need to work together to raise awareness and assist New Zealand's diverse communities to understand the real risks and opportunities these new technologies bring, in order to inform any changes.

The Royal Society Te Apārangi Gene Editing Panel recognises that its competence does not extend to the whole of regulation design and writing. However, the Panel's mandate does include examining and deliberating on the research evidence, the implications of gene editing technologies, and identifying the issues which might need a policy response. With this in mind, the Panel has examined the current New Zealand legal and regulatory environment, informed by its analysis of, and stakeholder reaction to, a range of scenarios demonstrating possible future applications of gene editing techniques[1].

[1] royalsociety.org.nz/major-issues-and-projects/gene-editing-in-aotearoa/; Everett-Hincks J.M & Henaghan R.M (2019) Gene editing pests and primary industries – legal considerations. New Zealand Science Review, Vol 75 (2-3).

SUMMARY OF FINDINGS

1 Defining genetic modification

The Panel considers that New Zealand's statutory provisions and regulations around genetic modification need to account for an increasingly nuanced view, and reflect the modern reality that organisms cannot be simply categorised as 'genetically modified' or 'not-genetically modified'. This is also essential to support a constructive and meaningful conversation within New Zealand communities on their preferences for the use of these new gene technologies.

2 Regulatory complexity and consistency

The Panel considers that the development of a shared set of definitions across the regulatory system would be a useful first step to enabling a constructive debate and determining the degree of public support for use of genetic technologies for different applications. Clearer pathways for making decisions would also enable more efficient and effective navigation of the regulatory system across agencies and Acts. In future-proofing regulations, government should also seek to ensure that statutory provisions take into account Māori cultural views.

3 International regulation and enforcement

The Panel considers that the potential trade and regulatory enforcement impacts from different treatment of gene editing technologies in different countries need to be investigated to ensure that New Zealand's regulations continue to be fit-for-purpose, both domestically and internationally. New Zealand could also consider the recommendations from the Australian Office for the Genetic Technology Regulator and Food Standards Australia New Zealand reviews.

4 Making regulation proportionate to risk

The Panel considers that addressing issues such as definitions, complexity and inconsistency in the current legislation, and accommodating the advances in gene technologies, would be more effectively achieved with a risk-tiered approach where regulatory burden is commensurate with risk. This would support public confidence in decision-making and provide greater flexibility and adaptability to accommodate further scientific and technological changes in future.

5 Community engagement

The Panel considers that regulation needs to be informed by wide engagement with the public. Current information and culturally appropriate education resources about new genetic technologies and their application should be shared widely and feedback sought on public attitudes and ethical views.

6 Capacity and capability

The Panel considers that there should be ongoing development and support for the necessary capacity and capability within communities, the research sector and central and local government, to support effective engagement and decision-making around new biotechnologies. While some applications of gene technologies may be unacceptable or not feasible at this time, it is important that New Zealand has the means to assess developments and opportunities as they arise in future.

BACKGROUND

Since the dawn of life, the diversity of biology has been based upon genetic change. Random genetic mutations in nature have underpinned evolution and the diversity of plants, microbes, fungi and animals we now observe, and upon which humans depend for survival. Advances in science and technology have led to increasingly sophisticated plant and animal breeding programmes to select for favourable characteristics. Techniques such as irradiation and chemical mutagenesis have been used to induce mutation and thus increase opportunities to introduce favourable characteristics or remove unfavourable characteristics. These random mutagenesis techniques have led to many of the crops we eat today, which are not legally defined as genetically modified, but have a long history of safe use.

As the science and technology has advanced further, the potential for targeted and deliberate modifications in specific genes, or introducing genes from one species into another, has led to community concerns about the risks and the ethical implications of these advances. These techniques enable more efficient means to modify an organism in a targeted way, and accelerate the rate at which organisms can be modified. This is a cause for concern if the modifications overstep society's acceptance of the changes, as in the recent example of a scientist in China using genetic modification to modify human babies' heritable DNA. However, new techniques also enable a more precise means to achieve certain outcomes, because they reduce the risk of unwanted mutations that feature in random mutagenesis techniques.

In 2000, the New Zealand government responded to public concerns with its Royal Commission on Genetic Modification (GM) in the face of polarized views. The Royal Commission's main recommendation in 2001, that "*New Zealand should preserve its opportunities by allowing the development of genetic modification whilst minimising and managing the risks involved*", remains the basis for the Hazardous Substances and New Organisms Act 1996 (HSNO Act) and regulatory framework, following its subsequent amendments, nearly two decades on.

The science and its application to genetic manipulation has continually advanced since then, with powerful gene editing tools such as Zinc-finger nucleases, TALENs and now CRISPR-Cas being developed[2]. CRISPR-Cas, in particular, has brought much greater precision in altering genetic traits, and at a rapidly decreasing cost. These and other advances in the future will continue to open doors to a much wider range of potential applications, from addressing genetic diseases in humans to managing the environment, and accelerating conventional plant and animal breeding programmes.

These advances and potential new applications are challenging regulatory frameworks around the world. New Zealand needs to ensure that its legal and regulatory framework is future-proofed as technology continues to evolve, and is informed by constructive debate about whether these applications are acceptable to New Zealand communities.

Māori communities are taking a keen interest in these new technologies and how they might be applied within their cultural context. Attitudes to genetic modification and other genetic technologies have been partially surveyed or expressed in various fora, such as *Te Mata Ira: Guidelines for Genomic Research with Māori*. Various ethical and operational frameworks have been developed as a result to facilitate better engagement with Māori communities about such technologies[3].

[2] CRISPR-Cas (Clustered Regularly Interspaced Short Palindromic Repeats), TALENs (transcription activator-like effector nucleases).

[3] At the regulatory level in New Zealand, the HSNO Act sets out the statutory process for analysing and deciding on applications. The Environmental Protection Authority, (EPA) uses a risk/benefit assessment process that involves a dedicated Māori operational policy team (Kaupapa Kura Taiao). The EPA's statutory Māori Advisory Committee, Ngā Kaihautū Tikanga Taiao (Ngā Kaihautū), may provide advice from a Māori perspective to assist an EPA decision-making committee to understand Māori views. Advice from Ngā Kaihautū does not detract from, or seek to substitute in any form, the distinct perspectives of iwi, hapū and/or whānau, but aims to ensure those perspectives have been sought and considered by the EPA. In addition, some research institutions have developed internal processes and procedures for consultation on research (e.g. University of Otago, and Scion via the Te Aroturuki process). However, these processes have been ad hoc and voluntary, and therefore have not always been uniformly implemented. As background, see Hudson M. et. Al (2019) Indigenous Perspectives and Gene Editing in Aotearoa New Zealand. Front Bioeng. Biotechnol. 7:70.

Regulatory framework

The Panel makes the following observations based on its analysis of the current legal and regulatory framework.

Defining genetic modification

Many countries and regions, including Canada, USA, Australia, UK and Europe, are grappling with how to define and regulate gene edited plants, microbes, fungi and animals in response to new gene editing technologies. As in other countries, gene editing technology now has the potential to leapfrog New Zealand's regulations and legislation and its ability to support the previous recommendations of the Royal Commission on Genetic Modification in terms of securing the opportunities while managing risks.[4]

The HSNO Act is the primary means of regulating genetically modified organisms in New Zealand.[5] In the two decades since its enactment, there have only been minor amendments to the Act. The HSNO Act defines *genetic modification*[6] and provides regulations for when organisms *are not* genetically modified.[7] A number of New Zealand's statutes and Local Government unitary plans now include the term *genetic modification* but do not define it.

The definitions of genetic modification in the HSNO Act, appear to no longer be fully 'fit for purpose.' For example:

- The use of gene editing technologies, including CRISPR-Cas, are deemed *genetic modification* under current legislation, and the resulting organisms are, therefore, classed as *new organisms*. By contrast those generated by random mutagenesis, which results in many more gene alterations in addition to the desired change, do not count as *new organisms*. It does not make scientific sense for organisms with genetic changes that are already found in their population to be considered *new organisms* under the HSNO Act.
- CRISPR-Cas can be applied using *in-vivo* (within the body of an organism) techniques, thereby no longer fitting the legislative definition relying on *in-vitro* (within a laboratory vessel) manipulation[8]. This possibility was not envisaged when the legislation was developed, yet it now opens the door to new treatments for cancer and other health conditions.
- Gene editing can involve deleting genes already present in the genetic code of organisms, guided by the cell's own normal repair processes[9].
- Genetic modification cannot be detected in some situations because it is not practically possible to distinguish some simple gene edits from naturally occurring mutations, or those induced by irradiation or chemical mutagenesis.
- Organisms can be modified in containment, but produce offspring through cross breeding that are free of the gene editing machinery and genetic modifications made whilst in containment (null segregants). (E.g. a fast flowering gene used to speed up reproduction rates and thereby reduce the time needed to create new plant varieties through conventional plant breeding methods)[9].

The Panel notes that the intentional deletion of even a single gene base-pair is considered a genetic alteration, and gene editing techniques provide a continuum of change that starts at the scale of natural mutations, and ends with the future possibility of creating synthetic organisms.

1

The Panel considers that New Zealand's statutory provisions and regulations around genetic modification need to account for an increasingly nuanced view, and reflect the modern reality that organisms cannot be simply categorised as 'genetically modified' or 'not-genetically modified'. This is also essential to support a constructive and meaningful conversation within New Zealand communities on their preferences for the use of these new gene technologies.

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

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

[6] 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.

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

[8] Royal Society Te Apārangi (2017) Gene editing in a healthcare context.

[9] Royal Society Te Apārangi (2018) Gene editing in the primary industries.

Regulatory complexity and consistency

The Panel's analysis of various scenarios against current legislation and regulation highlighted the legislative complexity around the use of gene editing in New Zealand. For example:

- The purpose of the HSNO Act is to protect the environment and health and safety of people and communities, and it was never intended for new organisms to include human beings. Human cells, outside of the human body, are deemed *human tissue* and are regulated by the Human Tissue Act 2008. The HSNO Amendment Act 2003 added the term human cell in a transitional provision. As a result, *organism* is defined in the HSNO Act as including a *human cell* (grown or maintained outside the human body). If gene editing were to be used in New Zealand to treat a patient's bone marrow to create blood cells that target the patient's cancer cells, the resulting blood cells, if genetically modified outside the body, would be classified as a new organism according to the HSNO Act.
- If gene editing were to be used to develop and administer a gene drive[10] to rid New Zealand's conservation estate of possums, it would require the navigation of multiple pieces of legislation with different regulatory authorities (see Appendix A). For example, animal ethics approval (Animal Welfare Act 1999) during development, EPA approval for the new organism (HSNO Act 1996, section 27), the Biosecurity Act 1993 if the organism is imported (to minimize inadvertent importation of pests or diseases) or is, in itself, likely to be a pest and, in some territorial authorities a plan change and/or a resource consent under the Resource Management Act 1991 (RMA). A gene drive organism could be incorporated into, or controlled by, pest management plans (RMA and Biosecurity Act) or conservation management plans (Conservation Act 1987, Wild Animal Control Act 1977, Marine Reserves Act 1971, Reserves Act 1977, Marine Mammals Protection Act 1978).
- The joint food regulatory system with Australia includes a Standard for the regulation of food produced using gene technology, which is now under review. This means the food products of genetically modified organisms are regulated separately to the organisms themselves.

Currently, the legal and scientific definitions are not harmonised across Acts and regulatory frameworks, meaning that there is no shared common language with which to engage with communities. Debates are likely to be confused by this lack of harmony. For example, the use of *human* versus *human cell* (or embryo); *animal* excluding and including invertebrates (such as the honeybee); *pest* versus *unwanted organism*; and *biological product* versus *biological compound*.

Such complexity may also limit the ability to provide coordinated and timely responses to the big environmental and societal challenges such as biosecurity threats; new and invasive diseases (to plants, animals and humans); medical trials; and regional and national climate change challenges to valued flora, fauna and primary produce.

In some cases, necessary definitions are missing. For example, *genetic modification* is not defined in the Human Assisted Reproductive Technology 2004 (HART) and Animal Welfare Acts, nor do they refer to the HSNO Act for definition.

The provisions that acknowledge the importance and protection of taonga Māori and consideration of the Treaty of Waitangi, or recommendations of the WAI 262 Report[11], are also inconsistent, may not go far enough (i.e. *take into account* rather than *recognise and provide for*), and in some cases are completely absent from these Acts.[12]

2

The Panel considers that the development of a shared set of definitions across the regulatory system would be a useful first step to enabling a constructive debate and determining the degree of public support for use of genetic technologies for different applications. Clearer pathways for making decisions would also enable more efficient and effective navigation of the regulatory system across agencies and Acts. In future-proofing regulations, government should also seek to ensure that statutory provisions take into account Māori cultural views.

International regulation and enforcement

Internationally, New Zealand is part of a global trading and standards environment. Other countries and regions such as USA, Europe, Australia and Japan are already considering what changes may be needed to their systems to effectively regulate new genetic technologies like gene editing. International agreements to which New Zealand is a party, such as the Cartagena Protocol[13] that regulates the movement of genetically modified organisms (GMOs) between countries, also contain different definitions of genetic modification to those found in the HSNO Act.

In Australia, a scientific and technical review of the Australian Gene Technology Regulations 2001 was initiated in October 2016, by the Office for the Genetic Technology Regulator (OGTR)[14], which defines what constitutes gene technology and genetically modified organisms for the purposes of the Gene Technology Act 2000. The review resulted in the exemption of gene editing using site directed nucleases without introduced templates to guide genome repair (SDN-1) from regulatory oversight, from October 2019. As the repairs would be guided by the cell's normal repair processes, organisms modified using SDN-1 cannot be distinguished from conventionally-bred animals or plants, and there is no evidence that they pose safety risks that warrant regulation.

Food Standards Australia New Zealand (FSANZ) is also undertaking a review of the Food Standards Code to assess its application to food products derived from new genetic technologies, and to consider the definitions of "food produced using gene technology" and "gene technology". Half of New Zealand's domestic food supply is imported[15] and therefore any amendments to the Food Standards Code may have implications for trade.

Because it is not practically possible to distinguish some simple gene edits from naturally occurring mutations, or those induced by irradiation or chemical mutagenesis, the enforcement of GMO regulations at the New Zealand border may become impractical and compliance very difficult under the current regulatory environment.

3

The Panel considers that the potential trade and regulatory enforcement impacts from different treatment of gene editing technologies in different countries need to be investigated to ensure that New Zealand's regulations continue to be fit-for-purpose, both domestically and internationally. New Zealand could also consider the recommendations from the Australian OGTR and FSANZ reviews.

[10] Gene drives are a genetic system that ensure the genetic modification will almost always be passed on, allowing that variant to spread rapidly through a population. In this way it would be possible, for example, to spread a gene that suppresses fertility in females in a pest species population.

[11] The Waitangi Tribunal concluded in the 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 or in the genetic and biological resources of taonga species*" (Ko Aotearoa Tenei, Chapter 2; The Genetic and Biological Resources of Taonga Species, page 86).

[12] All persons exercising powers and functions under the HSNO Act are to *take into account* the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga (section 6(d)) and the Treaty of Waitangi (section 8).

[13] 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).

[14] Australian Government Department of Health, Office of the Gene Technology Regulator ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewregulations-1

[15] FAOSTAT, Commodity Balances -Livestock and Fish Primary Equivalent & Commodity Balances – Crops Primary Equivalent. Food and Agriculture Organization of the United Nations, Rome, Italy. fao.org/faostat/en/#data

Making regulation proportionate to risk

The current regulatory framework for GMOs is *process*- rather than *outcome*-based, i.e. focusing on the process used to introduce the genetic traits rather than what the trait is and what its impacts might be. This may result in inconsistent regulatory outcomes, where like products (in terms of their characteristics and potential risk) are not treated equally under regulations. For example, CRISPR can be used to generate a wide range of traits that can also be generated by less precise, yet unregulated technologies and practices (i.e. conventional breeding, or chemical and radiation mutagenesis).

The question of whether GMO regulation should be based on the process or the outcome, or a hybrid of both, is currently being debated in other countries, with different jurisdictions adopting different approaches. New Zealand has a largely process-based approach, along with the European Union, whereas Canada has adopted a 'novel product'-based approach and the United States has implemented a hybrid system.

The Panel's view is that process-based regulatory systems, which are premised on a binary system of 'modification', will become increasingly obsolete and unsustainable, as the potential for genetic changes becomes more sophisticated with new technologies, in comparison with existing conventional mutagenesis approaches.

For example, there are genetic technologies exempt from regulation listed in HSNO's 'Organisms Not Genetically Modified' Regulations that were in use before July 1998, such as chemical and irradiation mutagenesis. However, they do not include CRISPR-Cas technology because it was developed after July 1998, even though the outcome sought may be the same. Furthermore, a High Court decision in 2014[16] stated that the exemption list was an exclusive list, not a list of examples for guidance, and it could not be interpreted to include other techniques that were similar to chemical mutagenesis.

A risk-tiered regulatory approach, for example one similar to that supported by the Australian Legislative and Governance Forum on Gene Technology in its recent review of the National Gene Technology Scheme[17], would give more flexibility to make regulation proportionate to risk in response to changing technologies. It would allow risk assessment to be consistently applied across industries and products where the outcomes are the same and support public confidence in decision-making about which research and applications are appropriate in New Zealand. It would also attract investment to implement and commercialise the results of successful research. A risk-tiered approach could also reflect the history of safe use, with the regulatory burden reducing or increasing as more is known, uncertainty is reduced, and the level of risk with different approaches is better understood.

4

The Panel considers that addressing issues such as definitions, complexity and inconsistency in the current legislation, and accommodating advances in gene technologies, would be more effectively achieved with a risk-tiered approach where regulatory burden is commensurate with risk. This would support public confidence in decision-making and provide greater flexibility and adaptability to accommodate further scientific and technological changes in future.

[16] Reference case: The Sustainability Council of New Zealand Trust v The Environmental Protection Authority [2014] NZHC 1067, (2014) 18 ELRNZ 331.

[17] Legislative and Governance Forum on Gene Technology Forum. 2018. health.gov.au/internet/main/publishing.nsf/Content/ohp-gene-tech-oct18-comm.htm

Community engagement principles and education

Informed discussion and engagement within New Zealand's diverse communities is a vital part of determining preferences and public acceptance for the use of any new gene technologies. When engaging with communities about regulatory change, the Panel proposes that consideration be given to adopting the following principles:

- **The uniqueness of Aotearoa/New Zealand** valuing our uniqueness, and making decisions tailored to our environment, and indigenous and cultural heritage.
- **The Treaty of Waitangi/Te Tiriti o Waitangi** adopting the principles of partnership, reciprocity, participation, autonomy, active protection, and mutual benefit enshrined in the Treaty of Waitangi as the basis for engagement and regulatory co-design between tangata whenua and the Crown, on Māori rights and interests, and their special relationship with their taonga.
- **Sustainability** sustaining and regenerating our unique but fragile environment for generations to come.
- **Being part of a global family** safeguarding those things that are uniquely ours, while sharing in and contributing to global developments.
- **The well-being of all** meeting the needs of all New Zealanders to ensure positive educational, health and social outcomes whilst reducing and avoiding inequalities.
- **Freedom of choice** recognising our diverse cultures and beliefs.
- **Participation and māramatanga/understanding** ensuring effective systems of consultation and engagement between the Crown and Māori communities, with understanding and informed consent.
- **Transparency and openness** committing to openness and sharing of information in ways that are accessible and understandable to all citizens and enable informed decision-making based on māramatanga.

The Panel's view is that there is wide disparity in community understanding of new genetic technologies and applications and, for many, the potential applications of the technologies is moving ahead of their understanding. There is a need to close this gap through wide and deep engagement with communities, and acknowledge that this needs to be done in a way that recognises the partnership between the Crown and Māori.

5

The Panel considers that regulation needs to be informed by wide engagement with the public. Current information and culturally appropriate education resources about new genetic technologies and their application should be shared widely and feedback sought on public attitudes and ethical views.

Capacity and capability

Effective decision-making around new biotechnologies will rely on best-practice skills and knowledge within communities, the research system and regulatory bodies. The range of considerations needed to make decisions has widened considerably since the original development of the HSNO Act and the EPA. Examples include mātauranga Māori, types of regulation and risk assessment, molecular biology, genetics, bioinformatics, environmental management, ecological and production systems modelling, and financial and economic assessment. Educating our younger generations now is critical for our future sustainability within a globally connected economy.

Decision-making on the impact of these technologies will increasingly need to assess and manage outcome risk. While some outputs of gene editing technologies will be similar to those that already exist using traditional technologies, other outputs may be unlike anything that exists today. Organisms will need to be evaluated in their environmental and social contexts and horizon scanning will be required to keep abreast of regulatory and biosecurity challenges.

6

The Panel considers that there should be ongoing development and support for the necessary capacity and capability within communities, the research sector and central and local government, to support effective engagement and decision-making around new biotechnologies. While some applications of gene technologies may be unacceptable or not feasible at this time, it is important that New Zealand has the means to assess developments and opportunities as they arise in future.

For further information

For more information and resources about gene editing, visit the Society's web pages: **royalsociety.org.nz/gene-editing/**, or contact **info@royalsociety.org.nz**.

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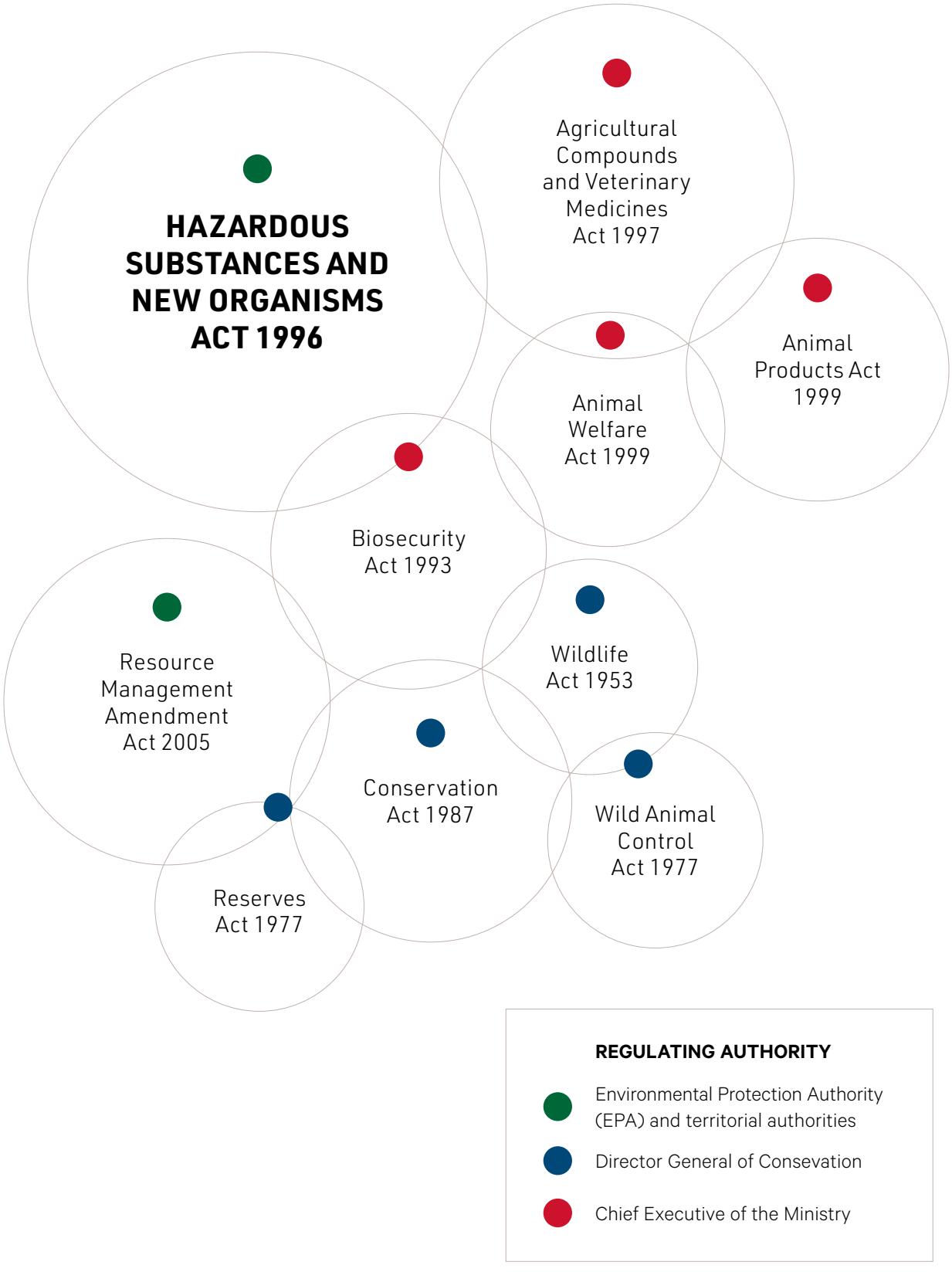
APPENDIX A

Legislation and regulatory authorities involved in administering a gene drive to rid New Zealand's conservation estate of possums



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