New Zealand—GMO Rules and Regulations in New Zealand

Jack A. Heinemann, Dorien S. Coray, and Brigitta Kurenbach

Abstract The New Zealand legal and regulatory landscape for genetically modified organisms is split between food and environmental safety. Different regulators take primary responsibility. New Zealand and Australia jointly regulate GMOs used as food primarily through the Food Standards Australia New Zealand Act. Each country has its own environmental regulator. The apex law for research and release is the Hazardous Substances and New Organisms (HSNO) Act. The New Zealand courts have confirmed that products of synthetic biology and gene/genome editing techniques are GMOs for purposes of regulation under the HSNO Act. In some parts of the country, regulation also involves local government where districts or regions have opted to regulate under the Resource Management Act. There have been calls from some sectors to revise the definitions of GMOs and approach to regulation. However, the current government has indicated that this is not a priority and that doing so would harm the agricultural sector. The law as currently framed has contributed to there being no evidence of harm to human health or the environment, and no economic losses either. However, a recent determination by the Environmental Protection Agency to allow open air use of nucleic acids on eukaryotic organisms is too fresh to speculate on future effects.

Keywords Hazardous Substances and New Organisms Act · Biosecurity Act · Resource Management Act · Environmental Protection Authority · dsRNA · Genome editing · New organisms

J. A. Heinemann (✉) · D. S. Coray · B. Kurenbach
School of Biological Sciences, Centre for Integrated Research in Biosafety, and Centre for Integrative Ecology, University of Canterbury, Christchurch, New Zealand
e-mail: jack.heinemann@canterbury.ac.nz; brigitta.kurenbach@canterbury.ac.nz

© Springer Nature Switzerland AG 2020
A. Chaurasia et al. (eds.), GMOs, Topics in Biodiversity and Conservation 19, https://doi.org/10.1007/978-3-030-53183-6_37
Introduction

The legislative framework governing genetically modified organisms (GMOs) follows New Zealand’s international obligations to the agreements into which it has entered. For the purposes of this article, those agreements are relevant to GMOs used as food or in the environment. New Zealand does not formally regulate GMOs that have food safety approval, including those imported for animal feed, provided that any GMO ingredient is in a nonviable state. This article discusses the regulation of GMOs first as food and then provides more detail on the legislative framework for GMOs in the responsible development of safe biotechnologies, according to the country’s obligations as a Party to the Convention on Biological Diversity (CBD) and its family of treaties.

In New Zealand’s legal framework, GMOs are considered to be “new organisms.” Their status and regulation is consistent with the country’s strict biosecurity laws intended to reduce threats to its agriculture and unique biodiversity from invading organisms. The special feature of GMOs is that they are considered new even if they are created in New Zealand.

The use of genetic engineering technologies is widespread in biological research in the country, including at universities, polytechnical institutions, Crown Research Institutes, and hospitals. This use is contained. In addition, between 1988 and 1997, there were 53 approved outdoor field experiments involving GMOs, including those developed as potential vaccines, although not all proceeded (EPA). A further 20 field tests have been approved by the Environmental Protection Authority since it became the responsible agency. Tested GMOs have been food plants, flowers and trees, and bacteria and animals (EPA). With the exception of provision for emergency use of a vaccine for horses, there are no GMOs approved for outdoor use.

Food

GMOs for food fall under the 1991 Food Standards Australia New Zealand Act (Food Standards Australia New Zealand Act 1991). This legislation creates a bina
tional food regulator, Food Standards Australia New Zealand (FSANZ). Standard 1.5.2 of the FSANZ Act defines food produced using gene technology as “food which has been derived or developed from an organism which has been modified by gene technology” and gene technology as “recombinant DNA techniques that alter the heritable genetic material of living cells or organisms” (Food Standards Australia New Zealand Act 1991).

A treaty between the two countries, the Trans-Tasman Mutual Recognition Agreement (MPI), implemented through the Trans-Tasman Mutual Recognition Act of 1997, binds New Zealand to the decisions made by FSANZ.

The treaty Agreement also provides a basis under exceptional circumstances for New Zealand to opt out of decisions made by FSANZ. These are described as
“exceptional health, safety, third country trade, environmental, or cultural grounds.” To our knowledge, New Zealand has only once exercised the opt out provisions of the Agreement (Terry 2007). In that case, it was on the basis of third-country trade implications.

Oversight of gene technology for use in food ends with a premarket assessment by FSANZ. After that, both countries rely on a non-codified “duty of care” from manufactures, suppliers, or others connected to the products of gene technology to adequately monitor any harm if it should later eventuate and to report and/or mitigate, as appropriate (Brent et al. 2003).

FSANZ recognizes guidance provided by Codex Alimentarius, a joint WHO and FAO body, and other high level international authorities (Brent et al. 2003). Because both Australia and New Zealand are members of the same organizations and subscribe to the same treaties on this matter, a joint regulator is harmonious for meeting both countries’ international obligations.

Domestic implications are not as clear cut. The FSANZ Act is entirely a product of Australian law, and the regulator is answerable only to the Australian minister in charge (Scott 2003). It is perceived to limit the normal powers of New Zealanders to hold public entities to account (Scott 2003). For example, Australians, but not New Zealanders, can request information under the Australian Freedom of Information Act (FOIA); FSANZ is not subject to the New Zealand equivalent 1982 Official Information Act (OIA). To our knowledge, FSANZ has never denied a request from a New Zealander for information. Nevertheless, it is unclear whether the information provided would have been gathered to the same standards used when a public agency was officially responding to a request made through the OIA.

National-Level Regulation of GMOs in the Environment (Nonfood Uses)

Australia and New Zealand diverge significantly in their international obligations for the use, exchange, and benefit sharing of GMOs. The remainder of this article will therefore be specific to New Zealand.

New Zealand is the home of both unique and rare species and is a country that is dependent on agriculture for much of its export income. Several laws recognize and protect both these attributes. The main legislative instruments of the national government for GMOs are the 1996 Hazardous Substances and New Organisms Act (HSNO Act, pronounced locally as “has no act”) and the 1993 Biosecurity Act that empowers authorities to act on illegal or potentially unsafe GMOs (Biosecurity Act 1993). In addition, the 1991 Resource Management Act (Resource Management Act 1991) provides for regulation of GMOs by local governments.
New Organisms

The HSNO Act encompasses all organisms whether or not they are a priori deemed to be biosecurity threats. Their status as new organisms places the burden of proof that the GMOs may be safely used in or released into New Zealand upon those who wish to use or release the organisms.

GMOs are a specific category of new organism in the HSNO Act. It states that “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” (Hazardous Substances and New Organisms Act 1996).

New Zealand’s definition is similar, but not identical, to that used by the Cartagena Protocol on Biosafety (CPB) to define living modified organisms (LMOs), which includes living genetically modified organisms. The Protocol definition of a living modified organism is “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.” Both the Protocol and the HSNO Act refer to in vitro techniques, but the Protocol emphasizes the use of nucleic acids, whereas the HSNO Act emphasizes modification of genes and other genetic material.

In many respects, the HSNO Act resembles European Union Directive 2001/18/EC. The similarity of language may be no accident because the frameworks have a common origin in those developed by the United Kingdom from the late 1970s onward (Heinemann 2015). Thus, it is also perhaps unsurprising that both New Zealand and the EU courts have arrived at similar interpretations of the scope of processes that create GMOs.

The EU and New Zealand adopted similar approaches in their legislative frameworks. Both regulate using what is called “process-based” legislation (Steinbrecher and Paul 2017), capture a broad category of processes used in making GMOs, and then use specific criteria in their regulations to determine what is and is not to be regulated (Heinemann 2015). For example, plants altered through the use of some chemical and radiation mutagenesis techniques are technically defined as GMOs but specifically excluded from GM assessment provisions (Atanassova and Keiper 2018).

The regulator created by the HSNO Act is the Environmental Protection Authority (EPA; previously the Environmental Risk Management Authority). New organisms not already covered by the Biosecurity Act are governed by this Authority. The Ministry for Primary Industries (MPI) is the enforcement agency for both.
When Is a New Organism a GMO?

In what is regarded as a world-first decision, New Zealand’s High Court ruled that organisms made using the techniques of gene/genome editing, including CRISPR/Cas9, ZFN, and Talens, are omitted from the list of exclusions to the HSNO Act (Kershen 2015). Thus, most if not all living applications of synthetic biology (Secretariat 2015) probably would be subject to regulation. This decision was followed later by a similar one of the European Court of Justice (Callaway 2018).

The High Court ruling was prompted by an EPA determination under Section 26 of the HSNO Act that some applications of these techniques were sufficiently similar to excluded techniques that they were not to be subject to its GMO provisions. This determination conflicted with internal staff advice and interpretation of the legislation (Kershen 2015).

The Sustainability Council of New Zealand initiated a High Court appeal of the EPA determination. The Court quashed the EPA’s determination because “the Authority erred in its interpretation of the regulation because it considered that the regulations did not set out an exhaustive list and that techniques that are comparable and sufficiently similar to those listed in the Regulations should also be excluded” (Mallon 2014).

More recently, the EPA issued another Section 26 determination that eukaryotic organisms “treated with externally applied double-stranded RNA molecules to induce a small interfering RNA (siRNA) response do not fulfil the definition of genetically modified organisms detailed in the Act and therefore are not new organisms for the purposes of the HSNO Act” (EPA 2018a). This determination applies only to organisms exposed to RNA molecules, not organisms created by alteration of DNA to produce new RNA molecules (Heinemann 2019).

In this case, the determination by the New Zealand EPA’s Section 26 Committee was similar to the advice received from EPA staff, who also anticipated that these techniques would soon be relevant to open air applications of double-stranded RNA-based pesticides (EPA 2018b). This determination is being challenged because it relied upon knowledge about only a few kinds of eukaryotes, contradicted existing knowledge of them and other eukaryotes, and failed in other respects such as properly considering the risk of harmful viruses being released (Heinemann 2019).¹

Here again, New Zealand was at the forefront of setting regulations on new biotechnological applications. Few if any other parties to the CPB have regulations on this open air (externally applied) use of nucleic acids (Heinemann 2019; Heinemann and Walker 2019). Internationally, at least one other CPB member country, Mauritania, has requested the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management for advice on conducting risk assessments and management of this kind of technology, referred to as “environmental application of in vitro nucleic acid techniques” (AbdelKawy 2016; CBD 2016). Presently, the New

¹For example, as a vector for SARS-CoV-2 should batches become contaminated during manufacturing or post-sale.
New Zealand EPA has called in the decision to deregulate the use of externally applied double-stranded RNAs but has yet to make a final determination.

**Local-Level Regulation**

New Zealanders have been exercising their rights to participate in the regulation and safe use of GMOs for many decades. Among other manifestations of this engagement are numerous districts and regions that have adopted their own regulations through local planning processes. This mirrors similar trends in Europe (USDA 2017). Presently, the Hastings, Auckland, Whangarei, and Far North Districts have implemented provisions for local decision-making on the release of GMOs. The Northland Regional Council is considering the same after being prompted by the Whangarei and Far North District Councils to include provisions for the region’s coastal and marine areas. These districts comprise a significant proportion of the area of the North Island of New Zealand and cover the areas in which a majority of New Zealanders reside.

A large number of public and private research organizations and some universities, as well as private citizens and experts, have participated in one or more local planning processes. For example, submissions for the Auckland District planning process included among others the University of Otago, the government Centre of Research Excellence the Maurice Wilkins Centre, the Crown Research Institute Scion, experts from the consortium Pastoral Genomics, the industry groups NZBIO and Federated Farmers, and indirectly the Royal Society of New Zealand through a report commissioned from them by Federated Farmers.

A fundamental disagreement over the proper jurisdiction for the regulation of GMOs arose early in the process. Local governments relied upon the Resource Management Act (RMA) 1991 to justify adopting local regulations. Objections to this were heard by the Environment Court followed by an appeal to the High Court. Both courts ruled unambiguously that the RMA gave local bodies the power to regulate the use and release of GMOs in their jurisdictions.

A further argument against the use of the RMA was that it was duplicating work already performed by the national regulator, the EPA. However, the approach taken at the local level was found to not only be legally valid under the RMA; any actual duplication was ruled irrelevant to the RMA (Mathias 2018).

During each of the quasi-judicial proceedings used by local governments in the adoption of their 10-year plans as required by the RMA, the proposed forms of regulation were opposed by some sectors and private experts. In general, the nature of the opposition was that there existed a scientific consensus on the safety of GMOs and that there was a significant economic risk should additional regulations inhibit their use.

---

2 One of us (Heinemann) was a formal expert witness in all these processes.
The hearing judges found in all four cases so far (with one still pending) that the basis for asserting a scientific consensus on safety was unconvincing. In particular, the case for safety was largely based on use as food, which was irrelevant to environmental regulation. Moreover, the evidence provided was specific to crop plants and the regulations applied to all kinds of organisms including viruses, bacteria, fungi, other plants, and animals. Finally, there was no counter evidence to an expert economist who found that adoption of the additional local regulations would have no adverse economic effects.

**Summary and Future Directions**

GMOs fall under the scope of several laws in New Zealand. Reflecting New Zealand’s international obligations, it has laws for both food safety standards and the environmental and contained research use of GMOs. The category of regulated organisms includes the products of new techniques such as gene editing and other forms of mutagenesis, with some older techniques specifically excluded by the regulations. These laws determine the activities of a variety of regulators at or above the national level, including FSANZ, EPA, and the MPI, and local government bodies.

New Zealand law appears aligned with at least the EU for the foreseeable future. New Zealand also appears most closely aligned to the EU in its approach to regulation, especially for the management of environmentally released GMOs. It has a “process trigger” for its legislation and requires specific categories of processes to be excluded from provisions.

Beginning with the High Court ruling confirming that new techniques of mutagenesis are within the coverage of the HSNO Act, there have been calls from some to revise the law. Advocacy for revision reappeared following the similar European Court of Justice ruling. Interestingly, the language used both in and outside of New Zealand is very similar, possibly homologous, with frequent calls in various countries to amend legislation to that which is “fit for purpose” (Devuyst 2018; Jones 2018; Manhire 2018). In the recent past, the RMA has been amended, but those changes did not affect local government from asserting rights to regulate GMOs not intended for use as medicine (Davison 2017).

Taking into consideration both environmental and economic safety, the current government is signaling that changes to GMO regulation are not coming in the foreseeable future (Dreaver 2018). The topic of GMOs and other kinds of biotechnology is as polarized and fraught in New Zealand as elsewhere. However, to date, the combination of approaches taken by the country to regulate GMOs has prevented any known irreversible harm to the environment or human health.
References

AbdelKawy O (2016) Submission by Mauritania for suggestions on Risk assessment guidance on additional topics. Le Ministère de l’Environnement et du Développement Durable, La Mauritanie. https://bch.cbd.int/database/attachment/?id=16832

Atanassova A, Keiper F (2018) Plant breeding innovation: a global regulatory perspective. Cereal Chem 95:8–16

Biosecurity Act (1993). http://www.legislation.govt.nz/act/public/1993/0095/latest/DLM314623.html

Brent P, Bittisnich D, Brooke-Taylor S, Galway N, Graf L, Healy M, Kelly L (2003) Regulation of genetically modified foods in Australia and New Zealand. Food Control 14:409–416

Callaway E (2018) CRISPR plants now subject to tough GM laws in European Union. Nature 560:16

CBD (2016) UNEP/CBD/BS/cop-mop/8/8. Convention on Biological Diversity. https://www.cbd.int/doc/meetings/bs/cop-mop-08/official/bs-mop-08-08-en.pdf

Davison I (2017) RMA reforms pass into law with support from Maori Party. New Zealand Herald. https://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11833888

Devuyst P (2018) GMO directive is no longer fit for purpose, say EU scientific advisors. Informa. https://iegpolicy.agribusinessintelligence.informa.com/PL218317/GMO-Directive-is-no-longer-fit-for-purpose-say-EU-scientific-advisors

Dreaver C (2018) ‘The core technology of the future’: time to rethink NZ’s GMO-free status?. The Spinoff. https://thespinoff.co.nz/science/20-11-2018/the-core-technology-of-the-future-time-to-rethink-nzs-gmo-free-status/

EPA (2018a) Decision. Environmental Protection Authority. https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP203395/APP203395-Decision-FINAL-.pdf

EPA (2018b) EPA staff report. Determining whether eukaryotic cell lines treated with double-stranded RNA are genetically modified organisms: Environmental Protection Authority. https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP203395/APP203395-EPA-Advice-Document-FINAL.pdf

EPA. GM field tests. https://www.epa.govt.nz/industry-areas/new-organisms/rules-for-new-organisms/gm-field-tests/

Food Standards Australia New Zealand Act. 118 of 1991 (1991). https://www.legislation.gov.au/Details/C2016C01118

Hazardous Substances and New Organisms Act (1996). http://www.legislation.govt.nz/act/public/1996/0030/93.0/DLM381222.html

Heinemann JA (2015) Expert scientific opinion on the status of certain new techniques of genetic modification under Directive 2001/18/EC. University of Canterbury, Christchurch. https://www.canterbury.ac.nz/media/documents/science-research/inbi/new-techniques-of-genetic-modification.pdf

Heinemann JA (2019) Should dsRNA treatments applied in outdoor environments be regulated? Environ Int 132:104856

Heinemann JA, Walker S (2019) Environmentally applied nucleic acids and proteins for purposes of engineering changes to genes and other genetic material. Biosaf Health 1:113–123

Jones M (2018) Making the Gene Technology Act fit-for-purpose. Murdoch University. https://www.murdoch.edu.au/news/articles/opinion-making-the-gene-technology-act-2000-fit-for-purpose

Kershen DL (2015) Sustainability Council of New Zealand Trust v The Environmental Protection Authority: gene editing technologies and the law. GM Crops Food 6:216–222

Mallon J (2014) Sustainability Council of New Zealand Trust v The Environmental Protection Authority. High Court of New Zealand

Manhire T (2018) ‘I literally covered my wall in post-it notes’: meet NZ’s new chief scientist. The Spinoff. https://thespinoff.co.nz/science/13-11-2018/i-literally-covered-my-wall-in-post-it-notes-meet-nzs-new-chief-scientist/
Mathias GJ (2018) WDC and FNDC – GE Supplementary Opening Submissions. https://northlandregionalcouncil-my.sharepoint.com/:x:/r/personal/evaniaa_nrc_govt_nz/_layouts/15/Doc.aspx?src=7B3fb622a1-b3a9-45dc-8124-e66876c5d994%7D&action=default

MPI. Australia-New Zealand co-operation. https://www.mpi.govt.nz/law-and-policy/legal-overviews/food-safety/australia-new-zealand-co-operation/

Resource Management Act (1991). http://www.legislation.govt.nz/act/public/1991/0069/211.0/DLM230265.html

Scott C (2003) The creation of trans-Tasman authorities – Food Standards Australia New Zealand: public sector reform implications. N Z Pub Sec 26:14–19

Secretariat (2015) Meeting of the Ad Hoc Technical Expert Group on Synthetic Biology. https://www.cbd.int/meetings/SYNBIOAHTEG-2015-01

Steinbrecher RA, Paul H (2017) New genetic engineering techniques: precaution, risk, and the need to develop prior societal technology assessment. Environ Sci Policy Sus Dev 59:38–47

Terry S (2007) Food safety credibility. Sustainability Council, Wellington. http://www.sustainabilitynz.org/docs/FoodSafetyCredibility_GMLysineCorn.pdf

USDA (2017) EU-28. GAIN report: USDA Foreign Agricultural Service