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Report Highlights:

There have been no recent significant official changes to the genetically engineered (GE) policies established by the New Zealand government. Food Standards Australia New Zealand, the regulatory authority for approving the sale of GE food products in New Zealand, has approved 78 GE food products to date. These food products could be for direct human consumption or animal feed. All GE foods sold in New Zealand must be labeled. Meat and other products from animals that have been fed GE-derived feed do not require labeling. The products resulting from biotech microbial fermentation are imported into New Zealand, but there is no commercial activity of this nature happening outside of containment trials.

EXECUTIVE SUMMARY

In New Zealand, genetically engineered (GE) products are regulated under the 1996 Hazardous Substances and New Organisms Act (HSNO) and administered by the Environmental Protection Authority (EPA). Prior to the formation of the EPA, the Environmental Risk Management Authority administered the HSNO Act. The EPA operates in line with the Government of New Zealand's (GONZ) cautious approach to biotechnology, only approving applications if the benefits outweigh the perceived risks. In the regulation of products derived from biotechnology, EPA states that it considers the effects on the environment, health, and safety of people, the economy, the social and cultural well-being of people and communities, Maori culture and their relationship with the environment, and international obligations.

Many in the research field say the costly, lengthy, and unproven nature of the regulatory approval process is a barrier to commercial development of GE products. However, there is on-going biotechnology research in New Zealand. To date, twenty-one contained agricultural field trials have been approved for a range of crops and animals. However, only two are operational at present.

There is some public debate and discussion around new GE techniques such as “genome editing” and its applicability to New Zealand's aspirational goal of being “introduced-predator-species” free by 2050. At the same time some primary sector organizations and farmers remain cautious about the use of biotechnology out of concern that it may negatively impact on their ability to market products overseas at profitable prices. In April 2017, the Resource Management Act (RMA) was amended in the Resource Legislation Amendments Act 2017. One of the new regulations aims to limit territorial authorities' powers to set district or region wide by-laws on biotechnology, which could ban GE products/materials altogether or set rules that would be stricter and punitive if contravened than under the HSNO Act. However, there is a carve-out in the regulations, which may affect how the new regulations work when it comes to GE plants and animals. While there are no overt political factors that may influence regulatory decisions at an operations level, there has been no political will to modernize the laws pertaining to new organisms or GE.

GE food products sold in New Zealand must be approved by Food Standards Australia New Zealand (FSANZ). To date, there are 78 FSANZ approved GE food products that can be sold. All GE foods sold in New Zealand must be labeled. Animal feed falls outside of the HSNO Act and may be imported into New Zealand as the governing legislation does not differentiate between GE and non-GE feed. Meat and other products from animals that have been fed GE feed do not require labeling.

Food ingredients derived using microbial biotechnology are covered by the same laws and regulations as plants and animals bred using biotech processes.

The GONZ is a signatory to the Cartagena Bio-safety Protocol.

Table of Contents

Classification	Content Description	Page Number
CHAPTER 1	PLANT BIOTECHNOLOGY	4
PART A	Production and Trade	4
PART B	Policy	6
PART C	Marketing	17
CHAPTER 2	ANIMAL BIOTECHNOLOGY	18
PART D	Production and Trade	18
PART E	Policy	20
PART F	Marketing	21
CHAPTER 3	MICROBIAL BIOTECHNOLOGY	22
PART G	Production and Trade	22
PART H	Policy	22
PART I	Marketing	23
Appendix I	List of Contained Field Trials Approved in New Zealand	24

Chapter 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

The environment for GE research in New Zealand has largely been determined by a Royal Commission report dating back to 2001. The major conclusion of the report was that it would be unwise for New Zealand to turn its back on the potential benefits of biotechnology, but that New Zealand should proceed cautiously, managing the risks associated with biotechnology while simultaneously encouraging organic production and sustainable agriculture. Much of the research undertaken to date has been conducted by the Crown Research Institutes, (CRIs) such as the [Plant and Food](#) (crops), [Scion](#) (forestry), and [AgResearch](#) (plants and animals). These state-owned enterprises receive public and private sector funding. To date, only 13 contained field trials have been approved for a limited range of crop plants. It is a difficult and lengthy process to get an approval, and even then, the granting of an approval may be uncertain just for a contained field trial.

Plant and Food has undertaken GE research on a range of plants including potatoes, onions, broccoli, cabbage, cauliflower, and forage kale. However, their brassica trials were suspended after a breach of one of the field trial conditions when at least one GE plant was allowed to flower.

Scion has the lead on forestry and biomaterials research. Scion obtained approval in 2010 to begin a new set of field trials, which got underway in June 2011. These trials focus on herbicide tolerance, reproductive traits, growth, and quality traits. Scion has linkages with several U.S. companies and the U.S. Department of Energy.

AgResearch is charged with enhancing the productivity and profitability of the dairy, meat, and textile industries in New Zealand. AgResearch scientists and [Grasslanz Technology Ltd.](#), a subsidiary company, now have two gene constructs for white clover (*Trifolium repens*) to give grazing animals a better protein and carbohydrate balance in the diet, reduce animal bloat, and at the same time reduce animal excretions of nitrogen and possibly methane emissions. AgResearch also has a GE high lipid grass, which displays a step-change improvement in metabolizable energy and as a consequence increase in animal productivity. AgResearch has received long term funding to continue using novel biotechnologies for this plant breeding work. At present, AgResearch is still not willing to apply for conditional release of any of these plants. AgResearch continues to import biotech plants to study in containment trials.

Pastoral Genomics, a research consortium for forage enhancement through biotechnology, has researched a cis-genic (i.e., using engineered genes from within the ryegrass species) approach to develop perennial ryegrass and clover plants. The ryegrass contains genes that express traits for drought resistance, increased plant sugar levels, reduced use of nitrogen and phosphorus, and reduced animal

methane emissions. The consortium has links on this project with the Noble Foundation in Oklahoma and the University of Florida. It has conducted controlled field trials in Florida, which have now been completed. The trials verified the drought resilience trait in the ryegrass. This work has now been shelved in favor of large-scale non-regulated breeding techniques that utilize genomic selection.

There is also laboratory work, at Plant and Food CRI, using accelerated breeding of apple trees where GE has been used to reduce the age of flowering which will be combined with conventional breeding for desirable traits. Then, once the desirable traits have been incorporated successfully, it is planned that the GE genes will be bred out to leave a non-GE plant. Bio-pesticides are another field being researched (see PART D (a), in the animal section of the report).

b) COMMERCIAL PRODUCTION

There is no commercial production of GE plants in New Zealand (NZ). No organization has submitted an application for a conditional or full-scale release of a GE plant. Many in the research field attribute this to the costly, lengthy, and uncertainty within the regulatory approval process. Conventional (or non-GE) corn is grown in New Zealand. The other major crops grown in the northern hemisphere and Latin America that have GE variants, such as soybeans and cotton, are not grown commercially in New Zealand.

c) EXPORTS

There are no exports of commercial GE plants from NZ.

d) IMPORTS

New Zealand permits the import of GE food products that have been approved by Food Standards Australia New Zealand (FSANZ). To date, 78 GE events have been approved by FSANZ, which may be contained within food products and can be imported into New Zealand. These food products may be for either direct human consumption or for animal feed. In 2019, New Zealand imported 374,293 metric tons of soybean meal and hulls primarily for poultry and pig feed. At over 99 percent of the volume, Argentina was by far the largest supplier, which suggests that imported feed could be derived from GE soybeans. Under the current laws, GE seeds for sowing cannot be imported unless they undergo the lengthy approval process under the 1996 HSNO Act. None have yet.

e) FOOD AID RECIPIENT COUNTRIES

New Zealand does not provide food aid on a regular basis. In the event of a natural disaster or humanitarian crisis, emergency shipments of food may be carried out, but since New Zealand does not cultivate GE crops any food aid would not be GE.

f) TRADE BARRIERS

No living GE products are approved to be imported for commercial growing enterprises. Research entities have been able to import GE products/materials under strict containment conditions.

There is a zero tolerance for any viable seed, GE or non-GE, inadvertently comingled with imports of processed feed from plant origin. In addition, there are strict regulations for the handling of whole grain feed imports to stop any viable seeds from getting into the natural environment and being able to grow, which would contravene the laws applying to new biotech organisms.

Food products (i.e. that cannot be planted and grown) containing GE events must be approved by FSANZ. Once approved, there are no further barriers.

PART B: POLICY

a) REGULATORY FRAMEWORK

General Policy on Genetic Engineering

Even though the international environment with respect to genetic engineering has changed significantly over the last decade, the report issued by the Royal Commission on Genetic Modification in 2001 still guides GONZ policy on GE organisms. While there are no overt political factors that may influence regulatory decisions at an operations level, there has been no political will to modernize the laws pertaining to new organisms or GE.

Since its formation in 2010, the New Zealand Environmental Protection Authority (EPA) is the lead agency in minimizing and managing risks associated with genetic engineering. Under the 1996 Hazardous Substances and New Organisms (HSNO) Act, all GE organisms are prohibited entry into New Zealand unless EPA has formally approved them. The EPA can issue various levels of approval including containment, conditional release, and full-scale release. To date, several approvals for contained field trials have been approved. However, no new trials have been approved since 2011. (See Appendix I for details of contained field trials and conditional releases that have been approved.)

There is no Biosafety Committee/Authority; however, the EPA essentially fills that role. (Its functions are outlined on pages 8/9.)

What is containment?

Containment requires that a GE organism and its heritable material be contained and managed within a containment facility. Containment is the place where basic research takes place to create or develop a GE organism and to gather information to apply for a field test or release application. In New Zealand, a field test is considered contained as the GE organism and any heritable material cannot leave the field test site and must be retrieved or destroyed at the end of the field test. To ensure the GE organism is contained, EPA implements comprehensive operational, physical, or biological controls. In the case of

a crop, it might be a control on flowering to prevent the release of pollen or seed. Activities considered “low risk GE research in containment” are subject to a rapid assessment process and may be approved by delegated bodies such as the Institutional Biosafety Committee (IBSC) at the research institution where the work will take place. These applications are not notified for public comment.

What is a release?

New Zealand GE regulations permit two types of releases: a release with controls (a conditional release) and a release without any controls or restrictions (an unconditional release). Release approvals can only be given if the GE material is determined to be not likely to cause: significant displacement of native species; significant deterioration of natural habitats; significant adverse effects on human health and safety; significant adverse effects to New Zealand’s genetic diversity; and be a disease or vector for disease.

The HSNO Act did not originally contain a provision for a conditional release. The Act was amended in 2003 in response to a recommendation from the Royal Commission. This change was intended to facilitate coexistence by providing a mechanism for imposing controls or conditions on a release of a GE organism, such as regional restrictions where the presence of the GE organism might pose a threat to an established industry. EPA believes this mechanism could be used for conducting research in the field that would be difficult to do under conditions that require full containment (e.g., where the GE organisms would be allowed to flower or set seed). However, under the HSNO Act, conditional releases must meet the same minimum standards as for full releases, as laid out in Section 36 of the Act, and must demonstrate that the positive effects outweigh adverse effects.

To date, there have been no applications for conditional or unconditional releases in New Zealand. In light of the Government approval process that weighs benefits against risk, as other plant biotechnologies begin to provide wider benefits to the general population (rather than just perceived agronomic benefits to farmers), it is more likely that an application for a conditional release could be approved. Because no full or conditional releases have been approved it is not known how long the process would take. It would likely be no less than two years if not longer.

The Main Laws Governing “Genetic Modification”:

- Hazardous Substances and New Organisms (HSNO) Act 1996;
- Hazardous Substances and New Organisms (Methodology) Order 1998;
- Hazardous Substances and New Organisms (Low-risk Genetic Modification) Regulations 2003;
- Imports and Exports Restrictions Act 1988;
- Import and Exports (Living Modified Organisms) Prohibition Regulations 2005;
- Customs and Excise Act 1996;
- Bio-security Act 1993 (including Ministry of Primary Industries (MPI)/Environmental Protection Agency (EPA) Containment Standards; MPI Import Health Standards);
- Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997;
- Medicines Act 1981;

- Food Standards Australia New Zealand Act 1991; and
- Official Information Act 1982.

The HSNO Act

The HSNO Act regulates research into and release of all living things that do not already exist in New Zealand, including GE products/materials. The Act is administered by the Ministry for the Environment (MfE) but implemented by EPA, which was established as an independent body under the Act. It applies to anything that can potentially grow, reproduce, and be reproduced, whether or not it is also a food or a medicine. Before any new organism, including a GE product/material, can be imported, developed, field tested, or released into the environment, the applicant must get the approval from EPA.

The Key Government Agencies Responsible for Administering and Enforcing GE Policy are:

Environmental Protection Authority:

The Environmental Protection Authority (EPA), created in June 2010, became operational on July 1, 2011. HSNO Act technical and regulatory functions that fell under the Ministry for the Environment, Ministry of Economic Development, and the former Environmental Risk Management Authority have now been brought together and consolidated under the EPA. The EPA is now responsible for the following functions which stem from the HSNO Act:

- Advising the Minister of any matter relating to the purpose of the Act;
- Processing applications for approvals;
- Making decisions (by way of appointed decision-making board independent of the staff) on applications for approvals and setting related controls;
- Monitoring and coordinating HSNO compliance and enforcement activities;
- Preparing reports for the Minister for the Environment in relation to applications that have been called in by the Minister;
- Issuing, amending, and revoking group standards for hazardous substances;
- Maintaining a register relating to hazardous substances and new organisms;
- Participating in the work of international bodies dealing with hazardous substances and new organisms;
- Providing technical advice;
- Monitoring the implementation of regulations; and,
- Supporting the Maori advisory committee.

Food Standards Australia New Zealand (FSANZ):

FSANZ is responsible for developing food standards for both Australia and New Zealand, emphasizing the protection of public health and safety. The standards cover composition, labeling, and contaminants, including microbiological limits. They apply to all food produced or imported for sale in Australia and New Zealand, including food products that are or contain products derived from genetic engineering. The final approving body for standards developed by Food Standards Australia New

Zealand is the Australia New Zealand Food Standards Council (ANZFS). It is comprised of the Australian Commonwealth, state and territory Ministers of Health, and the New Zealand Minister of Health.

Ministry for Primary Industries (MPI):

MPI, officially an entity in March 2012, has assumed all the roles of the former Ministry of Agriculture and Forestry (MAF); the Ministry of Fisheries, New Zealand Food Safety Authority, and Bio-Security New Zealand. MPI is responsible for enforcing the conditions for genetic engineering imposed by the EPA on approved field tests and conditionally released organisms. This work also involves the inspection of containment facilities for research in containment and ensuring importers comply with the HSNO Act. MPI is also responsible for administering standards for safety, labeling, and composition of food sold in New Zealand, including imported food and foods produced using genetic engineering.

Ministry for the Environment (MfE):

Currently, MfE advises the GONZ on environmental laws and policies, including managing the risks of introducing new organisms. It is responsible for the management and maintenance of the HSNO Act.

Ministry of Business, Innovation, & Employment (MBIE):

MBIE is a super-ministry that became an entity on July 1, 2012. This ministry now contains four former government departments and ministries, which were the Ministry of Science and Innovation, the Ministry of Economic Development, the Department of Labour, and the Department of Building and Housing. MBIE encompasses two former science agencies that were merged in 2011: the Foundation for Research, Science and Technology (FoRST) and the Ministry of Research, Science and Technology (MoRST). MBIE is now the lead agency driving science and innovation in New Zealand. It is tasked with directing knowledge and technology transfer from the science and innovation sector to businesses and other research users.

One of the key themes running through the biological sciences in New Zealand is “ecological sustainability” – an area that the Science and Innovation agency sees as having increasing importance in the future, especially as it relates to food security. In this context, Science and Innovation takes a holistic view incorporating food safety, environmental sustainability, value chain robustness, and traceability. Science and Innovation is reportedly agnostic on the technologies that could be developed to meet future challenges. At this stage, it is not clear what role Science and Innovation envisages for GE technology in relation to food security and ecological sustainability.

GE Animal Feed Regulations

GE feed is covered by the Agricultural Compounds and Veterinary Medicines (ACVM) regulations 2001, which are issued under the ACVM Act (1997). The ACVM regulations state that materials fed to animals should be safe and not cause harm to the animal. A distinction between GE and non-GE feed is not made. When imported, animal feed gains entry to New Zealand under its general import health standards with no distinction made between GE and non-GE animal feed.

The current approach taken by FSANZ recognizes that many animal feeds are derived from the same GE commodities (e.g. corn, soy) that are used for human consumption, and, as a result, it is difficult to keep the food and feed chains completely separate. FSANZ’s policy is to avoid “split use” approvals, where a GE plant receives approval for use as animal feed, but not for human food. This approach, which is also practiced in the United States and Canada, arose following an incident in the United States where traces of a GE corn (known as StarLink™ corn), which had been approved for animal feed only, were found in human food products. The incident caused consumer concern and disruption to trade and highlighted that adventitious contamination can occur despite well-developed identity preservation and segregation systems being in place. It is now common practice for GE plants intended primarily for feed use to undergo food safety assessment and approval for human food use to prevent similar incidents occurring in the future. This policy is intended to minimize the risk of unapproved products entering the food supply because of inadvertent co-mingling of grain/seeds during transport and storage and ensures that their products are evaluated for food and feed uses. Examples of GE crops that have been developed primarily for animal feed but have also been granted approval as human foods in Australia and New Zealand include high lysine corn and herbicide-tolerant alfalfa.

b) APPROVALS

There are no GE crops or plants approved for general cultivation in New Zealand. There are now 78 FSANZ approved GE food products able to be sold in New Zealand for animal or human consumption. A total of 83 applications have been lodged with FSANZ. Three have been withdrawn and two are under assessment. For more information and a list of the approved foods/traits see: <http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx>.

The Approval Process for GE materials

The EPA makes all decisions on the importation and domestic use of all new living organisms that may or not have a GE origin. This is based on a thorough assessment of the potential risks and benefits posed by the organisms under the 1996 HSNO Act requirements. If approval is given for development in containment, further approval must be given before the organisms can be field tested, conditionally released, or fully released. Approval is only given if, in the opinion of the EPA, the benefits of the GE product outweigh the risks.

Under the HSNO Act, the EPA must evaluate the potential risks of new organisms according to strict minimum standards. The HSNO Act requires that the following matters be considered by decision makers:

- the sustainability of all native and valued introduced flora and fauna;
- the intrinsic value of ecosystems;
- public health;
- the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu (sacred places), valued flora and fauna, and other taonga (sacred or treasured things); and

- the economic and related benefits and costs of using a particular new organism; and
- New Zealand's international obligations.

When considering a new GE organism for conditional or full release, EPA must first decide whether the organism would be likely to have any significant effect on the environment or human health and safety. EPA then looks at any potential economic and other benefits compared to perceived risks. The cost/benefit analysis provides a basis for the final decision on whether or not any organisms should be released. Under a conditional release, EPA stipulates certain conditions such as restrictions on where GE crops can be grown, compulsory buffer zones between the GE crop and conventional crops, regulations on planting time, or controls on how the crop is harvested and processed. Under a conditional release scenario, MPI is responsible for enforcing compliance. EPA can grant a full release if there are no potential risks that need to be managed by the imposition of conditions. EPA's decision to approve or decline an application can be appealed to the High Court. If the application goes ahead, conditions are monitored and enforced by MPI.

Consultation with the public is an integral component in the case-by-case decision making process. The HSNO Act requires EPA to notify the public of applications it considers likely to be of significant public interest. The public notice provides a means by which any person may make a written submission in the application. A public hearing of an application may also be held if one is requested by the applicant, by a person who has made a submission, or if EPA considers that a hearing is necessary to ensure due consideration of all the relevant matters.

It is worth noting that New Zealand is unique in its requirement that the benefits must be considered alongside the risks. For field trials, many report that New Zealand's requirement for absolute containment is difficult to meet and that the need for public consultation for contained field trials is costly.

In line with recommendations from the Royal Commission, the HSNO Act was amended to give greater recognition to the knowledge and experience of Māori values by those involved in the decision-making process on new organisms, including GE organisms. When EPA considers applications for the release of GE materials in New Zealand, the HSNO Act requires that the Māori culture and traditions as they relate to their ancestral lands, water, sites, flora, and fauna be considered. This means that EPA must assess the potential impact of the organisms on indigenous plants and animals – as well as introduced ones – that are valued by the Māori.

Further to this, in May 2012 the Royal Society published a consultation paper that called for a fresh look at the HSNO Act to reduce administrative overheads, revise the existing organisms register, the treatment of low risk organisms, and a change of regulation from technique based to trait based (Note: a copy of this paper can be obtained from FAS/Wellington.)

Treaty of Waitangi and Genetic Modification

New Zealand's [Royal Commission on Genetic Modification](#) investigated the Crown's responsibilities under the Treaty of Waitangi in relation to issues pertaining to agricultural biotechnology. They recommended that the HSNO Act be amended to give effect to the principles of the Treaty of Waitangi.

The government agreed to amend the HSNO Act to more appropriately reflect the Treaty of Waitangi relationship and in 2002 set up a Māori Reference Group to assist with this. The government considered the Māori Reference Group's report, along with the advice of officials, and decided to make legislative changes to the Act to introduce practical changes to the way the application and decision making processes work.

The HSNO Act has been amended to give greater emphasis to the knowledge and experience of Māori values by those involved in the decision-making process on new organisms, including GE products/materials. It does this by adding knowledge of the Treaty of Waitangi and tikanga Māori to the range of expertise and experience the Minister considers when appointing members of the Authority. As well, Nga Kaihautu Tikanga Taiao (the body that advises the EPA on Māori issues) is given a statutory basis within the Act. Previously, there was no requirement in law for EPA to have a Māori advisory committee, but this has been changed to make it mandatory.

Regulatory Creep 2016 to 2020

Even though the legislation controlling GE organisms has been determined by the central Government anti-GE activists have been working in the regions to use the planning processes under the Resource Management Act (RMA) to have territorial authorities introduce new regionally based rules, which would ban GE organisms or severely limit the practicality of any introductions.

The previous government led by the right of center National Party tried to limit territorial authorities' powers to set district or region wide by-laws on biotechnology through the Resource Legislation Amendments Act 2017 (passed into law April 2017). The new regulations give powers to the central Government Minister to regulate jurisdiction where the RMA duplicates another act. In theory, the HSNO Act would supersede any attempts by territorial authorities to use the RMA to ban GE plants or animals. However, the Maori Party, a coalition partner with the National Party in the previous government, managed to get a carve-out in the regulations, which may affect how the new regulations work when it comes to GE plants and animals.

Other third parties may challenge the territorial authorities' rights to be able to regulate GE organisms through the Environment Court. Territorial authorities would treat new organisms derived from genome editing as genetically engineered as a result of the 2014 High Court ruling (see PART B paragraph e) for more information on this ruling).

There have been no publicly announced official reassessments of the standing of innovative technologies. There is no new policy development work going on involving the regulation of GE

products or similar innovative technologies. In terms of regional restrictions, currently any introduction of new GE organisms is prohibited in the Hawkes Bay and the Auckland territorial regions (except for medical purposes).

Following pressure from members of the public and interested groups, the Northland region initially did not adopt rules that would discriminate against GE organisms being introduced to the region. However, this decision was appealed in the courts by an anti-GE group. In defense against this appeal, a small coalition of free-choice groups joined the Northland Regional Council.

Now the Northland Regional Council has reversed its previous decision to leave out any anti-GE bylaws before the Environment Court appeal case has even been heard. Four councilors have been tasked with drawing up precautionary non-GMO provisions to be included in the Regional Plan. The Waikato region is now looking at introducing anti-GE rules; however, it is unlikely there will be any decision before 2021.

c) STACKED or PYRAMIDED EVENT APPROVALS

Stacked event approvals would follow the same approval process outlined above. However, because stacked events are seen as relatively more complex than a single event (with effects that could occur as a result of the combination of events), the approval process is likely to be more lengthy and costly.

d) FIELD TESTING

Contained GE Field Trials

Since the HSNO Act was implemented in 1996, New Zealand has approved 13 applications for GE plants for contained outdoor field trials. The most recent was in June 2011 when Scion was approved for a long-term field trial utilizing two species of pine to trial many traits concerned with herbicide tolerance, reproduction, wood growth, and quality. A complete listing of the field trials being conducted in New Zealand can be found in Appendix I. Unlike Australia and the United States, fees are charged in New Zealand for applications for field trials. There is only one plant breeding field trial currently operating.

Some New Zealand companies have opted to take their GE trials offshore. The science groups involved with GE products feel that the New Zealand regulations are too expensive, too onerous, with too much risk as to the outcome of a field trial application even for a very beneficial organism. Three groups have conducted field trials overseas, particularly in Australia and the United States. Essentially, the results of these trials will give the groups the data needed to base a comprehensive application for an NZ field trial sometime in the future.

Science groups and commercialization developers feel that the level of scrutiny over a contained field trial application is the same as the high level afforded to a commercial release application. The onerous trial conditions make it practically impossible to ascertain whether a trait/product is safe or potential benefits that would be considered for a full commercial release application.

e) INNOVATIVE BIOTECHNOLOGIES

Currently, innovative biotechnologies (such as the use of CRISPr-CAS9 and other gene editing techniques) are considered GE organisms and are subject to the HSNO Act.

Regulatory Developments

A 2014 High Court ruling effectively established that organisms resulting from breeding techniques like genome editing, such as Zinc Finger Nuclease type 1 (ZFN-1) and Transcription Activator-Like Effectors Nucleases (TALENs) systems, would be considered new organisms under the HSNO Act and subject to the HSNO regulations. The Court's ruling also brought into question breeding techniques (chemical or radiation mutagenesis) in existence prior to HSNO's enactment.

As a result, the Ministry for Environment reviewed the regulations that were valid under the New Organisms sections of the HSNO Act in mid-2014. The changes to the regulations, which took effect in September 2016, corrected a grammatical error, and allowed chemical or radiation mutagenesis techniques already in use prior to 1998 to be used in New Zealand without violating the HSNO Acts provisions for new organisms.

f) CO-EXISTENCE

As there is no commercial production of GE crops, New Zealand has not established a threshold to manage co-existence of GE and non-GE crops.

g) LABELING and TRACEABILITY

Labeling of GE Foods

GE foods and ingredients can only be sold in New Zealand if they have been assessed for safety by FSANZ and approved by the ANZSC, a council of Australian, and New Zealand health ministers. As of 2001, under Standard A18/1.5.2 of the Australia New Zealand Food Standards Code that outlines the legal requirements for the sale and labeling of GE food, all GE foods sold in New Zealand must be labeled. This means that any food, food ingredient, food additive, food processing aid, or flavoring that contains genetically engineered DNA or protein must be noted on the label with at least the specific wording "genetically modified." If a food or ingredient has altered characteristics, the same wording "genetically modified" must be on the label. For example, if oil derived from a GE plant was boiled at a higher temperature, the oil would still have to be labeled even though no GE material would be present. A GE ingredient does not have to be listed on the label when:

- It is a flavoring in the food and makes up less than 0.1% of that food; or
- An ingredient unintentionally contains GE material at levels of less than 1% of that ingredient; or
- It is a highly refined food, other than that with altered characteristics, where the effect of the refining process is to remove novel DNA and/or novel protein; and

- It is a processing aid or food additive, except where novel DNA and/or novel protein from the processing aid or food additive remains present in the food to which it has been added.

Genetically engineered foods are labeled to provide information to consumers. They are not labeled for safety reasons, as only those GE foods assessed by FSANZ as safe are approved for sale. Negative content labeling such as “GE-free” is not addressed as part of the labeling standard. Meat and other products from animals that have been fed GE feeds do not need to be labeled as GE. Also, there are no labeling requirements for foods prepared in restaurants, either as takeaways or eaten on site (this includes takeaway meals prepared in supermarkets).

Meeting the requirements of New Zealand's GE food labeling regulations places a burden on manufacturers, packers, importers, and retailers to take reasonable steps to determine if the food is GE or has a GE ingredient and if the GE food is approved. The importer usually has the primary responsibility for ensuring the accuracy of the label and compliance with New Zealand's GE food labeling requirements. Wholesalers and retailers usually demand GE-free declarations from their supplier/importer, which passes liability in the event of GE labeling non-compliance back to the importer. New Zealand food legislation requires businesses to exercise due diligence in complying with food standards. Meeting those obligations is usually interpreted to require a paper or audit trail similar to a quality assurance system. There are no additional traceability requirements.

GE Food Labeling Regulations

The application process for approval of a GE food will usually take nine months for a general procedure (one round of public comment) and 12 months for a major procedure (two rounds of public comment). Usually, a GE food with a single trait would be a general procedure. However, where the application is more complex (e.g. including a nutritional trait), the major procedure may be used.

FSANZ has embarked on a project to amend the Food Standards Code with respect to food derived using new breeding techniques (NBTs) such as genome editing. This comes from an acknowledgement that the wording of the original Code is now out of date. There are no changes to the Code yet.

Labeling of GE Animal Feed

There is no requirement to label as such any animal feeds which contain GE ingredients.

h) MONITORING AND TESTING

MPI does not inspect individual food import shipments for compliance with GE food labeling requirements. Periodic compliance audits conducted by MPI usually start by selecting several items from retail shelves and working the paperwork back to the local manufacturer or the importer of record. For imported food, this largely consists of a review of importer compliance with their responsibility to adequately document the GE content of their food imports based upon information obtained from overseas exporters/manufacturers and that food product labels indicate GE content if necessary.

There is no testing of imported feed for GE DNA. MPI relies on the documentation required in the Import Health Standard and on the processing of the imported feed once it is in New Zealand to render any DNA non-viable.

i) LOW LEVEL PRESENCE POLICY

There is zero tolerance for the presence of unapproved GE feeds or GE food in the food supply even if it is unintentional. (However, please see the FSANZ labelling rules above in sub part g)

j) ADDITIONAL REGULATORY REQUIREMENTS

There are no additional requirements.

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

This has not been an issue because no GE plants have been released for cultivation yet, but NZ has a system of plant breeder's rights and respects the interests of offshore plant breeders.

l) CARTEGENA PROTOCOL RATIFICATION

The Cartagena Protocol on Biosafety entered into force for New Zealand on May 2005, following New Zealand's ratification of the agreement in February 2005. The protocol regulates the trade of "living modified organisms or LMOs". New Zealand was already assessing products derived from biotechnology for importation into New Zealand on a case-by-case basis. and ratified the protocol to reportedly be a 'good international citizen' to help achieve global consensus in this area.

New Zealand is one of the few major agricultural exporters that are a signatory to the Cartagena Protocol. The GONZ tends to have a similar stance on issues in the Protocol as the United States. Both countries are concerned about liability and redress, handling, transport, packaging, and identification issues relative to LMOs, as well as potential conflicts with other international obligations. New Zealand aims to help shape balanced decisions at Protocol meetings.

New Zealand isn't a signatory to the "Liability and Redress" or "Access and Benefits" agreements adopted by the Conference of the Parties to the Cartagena Protocol in Nagoya, October 2011.

m) INTERNATIONAL TREATIES/FORUMS

New Zealand is a member of CODEX and the International Plant Protection Convention. GONZ officials indicate that they have not been heavily involved with the genetic engineering issues apart from Codex labeling-related matters. While New Zealand supports a country's right to choose its best agricultural practices, its involvement in advocating for new technologies are best described as a "very interested observer."

n) RELATED ISSUES

None

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

When asked, most New Zealand consumers express caution about GE foods. However, negative attitudes toward genetic engineering may be weakening. According to some surveys and interviews, actual purchasing behavior does not always correlate with expressed negative attitudes toward genetic engineering. Likewise, many New Zealand farmers support the commercialization of GE plants appropriate to New Zealand pastoral style agriculture and growing conditions. They have expressed concern that by not embracing biotechnology they are falling behind their competitors. They are, however, cautious in their approach. Before making planting decisions most would want assurances that the marketing opportunities for their products (milk, meat, and wool) would not be impaired. Some agricultural/horticultural industry associations (kiwifruit and apples in particular) in New Zealand oppose the adoption of GE crops or forages because of the concern that it will reduce New Zealand's "clean and green" image and negatively impact on their ability to maintain price premiums for their products in some offshore markets.

Following a break-in and vandalism of Scions GE pine tree contained field trial earlier in 2012, there were a series of online public polls conducted that showed that the public were 67-75 percent in favor of the trials.

b) MARKETING ACCEPTANCE/STUDIES

Biotechnology continues to be a politically sensitive subject in New Zealand that evokes strong opposition from the Green Party, as well as a small number of anti-biotech non-governmental organizations (NGOs) often with influence out of proportion with numerical support. These groups seek to prevent commercial releases of products derived from biotechnology into the environment, as well as to impose restrictions against consumption of foods with GE content.

In New Zealand, there are two major nationwide supermarket chains. One of the chains, "Foodstuffs," a cooperative, has taken a stance on genetic engineering, insisting non-GE food ingredients be used in its house or private branded products, including non-GE feed for animal products sold under the house or private brand. It has no stance on third party or regular products sold through its stores if they are approved and labeled as regulated by FSANZ. It is the supplier or importers' responsibility to label the product not that of the supermarket. The Foodstuffs website is: <http://www.foodstuffs.co.nz/corporate-responsibility/environment/genetically-modified-foods/>.

Chapter 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

There are no developers or government entities conducting field trials that would likely lead to a commercial release of animals containing GE event(s) within the next five years. There have been six applications for contained field trials of GE animals approved.

AgResearch, New Zealand's largest CRI, has received two approvals to conduct research on GE cows. One approval was to field test GE cattle with modified casein genes and the other to develop transgenic cattle that can express functional therapeutic proteins in their milk. The first phase of field trial approvals expired in 2008. AgResearch applied for new approvals to continue the transgenic program for a number of species and a range of activities, including the production of biopharmaceutical proteins. These new applications were held up by legal action. These trials do not include cloned animals.

In June 2009, GE Free New Zealand (GEFNZ) won a court case against AgResearch and ERMA (the predecessor to EPA) regarding the specific field trials AgResearch was proposing with animals. The Court found that the applications were too generic and would not enable a risk assessment of the type required by the HSNO Act. On June 29, 2009, AgResearch filed a case in Appeals Court. Hearings were held in January 2010 and the Court of Appeal overturned the ruling of the High Court. GEFNZ then sought to take the case to the Supreme Court. The Supreme Court rejected the case without hearing it, which ended the legal challenge. AgResearch is now operating its field trials utilizing goats, sheep, and cattle with a new approval. (See Appendix I)

GEFNZ and the Soil and Health Association commissioned a report from a researcher at Canterbury University around the prospect for horizontal gene flow associated with the AgResearch animal trial. This report concluded there are significant risks. GEFNZ applied to ERMA (the former HSNO Act administrator, predecessor to EPA) to reassess the approval of this trial. ERMA did not proceed with the reassessment application because GEFNZ did not pay the application fee nor did GEFNZ provide new evidence to provide grounds for reassessment. AgResearch believes it has complied with the conditions of its approval correctly and, despite testing, has found no evidence of horizontal gene flow. AgResearch is continuing to do GE work on transgenic goats, cattle, and mice. The human diseases they are working on are diabetes, cancer, human infertility, and blood clotting.

Research and development of bio-pesticides is carried out at the Bio-Protection Research Centre near Christchurch. The work also involves the major CRI's and Lincoln and Massey Universities. The Bio-Protection Research Centre is targeting some of the most financially damaging pests and diseases

affecting New Zealand farming and horticulture. The initial research targets that have been determined in consultation with the Centre's industry partners include:

- Kiwifruit disease caused by *Pseudomonas syringae* PV. *actinidiae* (Psa),
- Pasture pests, such as: African black beetle, Porina caterpillar, and plantain moth,
- Forage and vegetable pests, such as Diamondback moth, and
- Pests and diseases of corn.

The bio-pesticides research usually involves insects or bacteria that either eat/destroy the pests of the crop plants mentioned or are vectors for a disease agent, which will act against a specific pest of the crop plant. The crop plants are not being modified, but rather it is the insects, bacteria, or viruses that are being isolated, purified, and studied.

Products that can be sprayed and that utilize Ribonucleic Acid Interference (RNAi) are being developed. At the field testing and release stage, these products pose potential issues for the regulators because the regulatory system for bio-pesticides depends on the nature of the product. If it is a compound derived from a biological process, the product will be regulated by the Harmful Substances branch of the HSNO Act, but if it is a live biological control agent, it will be regulated by the New Organisms branch of the HSNO Act.

The Predator Free 2050 Initiative is led by the Government Ministry the Department of Conservation (DOC). There are no indigenous mammalian predators in New Zealand and introduced rats, stoats/ferrets, and cats are hunting some of the indigenous bird species to endangered numbers while possums are the major mammalian pest responsible for widespread plant damage and carry bovine TB. The scientific community and some supporters of "Predator Free 2050" have suggested that an alternative to the controversial toxin "1080" may be to use genome editing to create a gene drive or another genetic solution that would render possums and/or stoats infertile. However, the Department of Conservation (DOC) had been instructed to not embark on any work in relation to introduced predator/pest control that would take advantage of innovative genome editing technologies.

b) N/A

c) COMMERCIAL PRODUCTION

A GE equine influenza vaccine is the only GE product approved for conditional use in New Zealand. This approval has not been exercised yet. Apart from the New Zealand Racing Board and the Equine Health Association, no other organization has submitted an application for a conditional or full-scale release of a GE product.

There is no commercially grown GE or cloned animals in New Zealand.

d) EXPORTS

There are none for commercial use.

e) IMPORTS

There are none for commercial use.

f) TRADE BARRIERS

The trade barriers are the same as outlined in PART A (f); PART B (g) and (h) above.

PART E: POLICY

a) REGULATORY FRAMEWORK

Animal GE research and commercialization is governed by the same laws and regulations as plants and other organisms detailed in the plants Chapter 1 of this report. The same government departments and agencies are involved. Cloned animals that do not have any genetically engineered traits are not new organisms and not covered by the HSNO Act. The pieces of legislation that pertain to any animals would govern the use and management of cloned animals, i.e. the laws relating to animal welfare for example.

b) APPROVALS

With respect to contained field trials, conditions of approval are likely to include: very high levels of animal husbandry; sturdy high security fencing that is also vermin proof; control of any waste; and a method to dispose of dead animals that contains or destroys the novel genes. Only one contained animal field trial is currently operating (see Appendix - ERMA200223).

c) INNOVATIVE BIOTECHNOLOGIES:

At this stage New Zealand courts have determined that the use of gene editing that would change the phenotype of any animal or plant will result in it being classified as a new organism for the purposes of the HSNO act and would have to be approved as per government regulations.

d) LABELING AND TRACEABILITY

The same regulations, laws, and administrative bodies apply to animals as outlined in PART B g). Because there have been no commercial releases or applications for release, no traceability policies have been developed for GE animals. However, all deer and cattle are individually traced with electronic identification ear tags under the National Animal Identification and Traceability Scheme thereby allowing the scheme to track GE cattle or deer. In addition, there are no statutory requirements for products from cloned animals to be labelled as such.

e) INTELLECTUAL PROPERTY RIGHTS (IPR)

The country has not considered legislation to address the IPR for GE animals or for cloned animals.

f) INTERNATIONAL TREATIES/FORUMS

New Zealand is a member of both CODEX and the World Organization for Animal Health (OIE). New Zealand is also a signatory to parts of the Cartagena Protocol. Refer to the comments made in PART B m).

g) RELATED ISSUES None

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS

The discussion in Chapter 1, PART C a) of this report on public/private opinions would also apply to GE animals and cloning. However, there isn't the level of media attention on GE animals or cloning as there is on plant products. Generally, it is felt there is a lower level of positive opinion on animal biotechnology.

b) MARKETING ACCEPTANCE/STUDIES

While attitudes toward GE technology in New Zealand have moderated, consumers still do not readily embrace the technology and would benefit from additional science-based information on the risks and benefits of GE technology. The items in the plant marketing sections of this report (Chapter 1, PART C b) also apply to GE animals, though the level of acceptance would be less for GE animals. There are no marketing studies publicly available on either GE animals or cloning.

Chapter 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION

Although there is commercial microbial fermentation in New Zealand, there is no use of food ingredients derived from biotech microbes at present that are created in New Zealand.

b) EXPORTS

There are neither official statistics nor estimates on exports of microbial biotechnology products. However, New Zealand exports alcoholic beverages, dairy products, and processed products that may contain imported microbial biotech-derived food ingredients.

c) IMPORTS

There are neither official statistics nor estimates on imports of microbial biotechnology products. New Zealand imports microbial biotech-derived food ingredients, such as enzymes that are traditionally used in alcoholic beverages, dairy products, and processed products. Likewise, New Zealand imports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

d) TRADE BARRIERS

The trade barriers are the same as outlined in PART A f); PART B g) and h) above.

PART H: POLICY

a) REGULATORY FRAMEWORK

Research and commercialization are governed by the same laws and regulations as plants and other organisms detailed in the plants Chapter 1 of this report. The same government departments and agencies are involved.

b) APPROVALS

At present the approval process is the same as outlined in Chapter 1, Part B b) Approvals (page 11). Note that the EPA approved earlier in 2020 for the Crown Research Agency, AgResearch, to conduct contained trials using biotech microbes. Note that in the case of imported novel foods or food ingredients that may be the result of microbial biotech in the origin country they would be assessed and approved by FSANZ.

c) LABELING and TRACEABILITY

The same regulations outlined in Chapter 1, Part B g) Labeling and Traceability (page 15) apply to any microbial biotech-derived food ingredients. Note that FSANZ has two applications for food produced using gene technology with a microbial origin under assessment at present.

d) MONITORING AND TESTING

The same procedures outlined in Chapter 1, Part B, h) Monitoring and Testing (page 17) apply.

e) ADDITIONAL REGULATORY REQUIREMENTS

There are no additional requirements.

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

This not an issue at present because there is no commercialization yet.

g) RELATED ISSUES

N/A

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Food ingredient production methods, whether biotech or conventional, are not really in the general public consciousness; there is no real guide to the general acceptance of these products.

b) MARKET ACCEPTANCE/STUDIES

N/A

Appendix I: Contained Field Trials Approved in New Zealand

Only ERMA200479 and ERMA200223 are currently operating. No new trials have been approved

Code	Approval holder	Description	Purpose	Status
ERMA200479	Scion	“Genetically modified (GM)” Pine Trees	To field test in containment <i>Pinus radiata</i> with genetic engineering to alter plant growth/biomass acquisition, reproductive development, herbicide tolerance, biomass utilization, wood density and wood dimensional stability	Commenced 1 June 2011, approved to 2035. April 2012 the site was broken into and trees pulled out. Trial is still operating
ERMA200223	AgResearch	GM Goats, sheep and cattle	To develop in containment GE goats, sheep and cows to produce human therapeutic proteins, or with altered levels of endogenous proteins for the study of gene function, milk composition and disease resistance	Commenced 13 April 2010 and approved to 2030. This trial is currently operating.
GMF98009	AgResearch	GM Cattle	To field test, in Waikato, cattle GE with cattle casein genes or the human myelin basic protein gene, or deletion of the cattle lactoglobulin gene. Milk may have enhanced nutritive value or be valuable as a drug for multiple sclerosis.	All research under GMF98009 was carried over to ERMA200223 13 April 2010.
GMF99001	Scion	GM Pine Trees	To field test, in the Bay of Plenty (Rotorua), over a period of 20 years, <i>Pinus radiata</i> plants with genetic engineering to the genes controlling reproductive development. The total duration of this project including a post-trial monitoring phase is 22 years.	This field test has been completed (including post-harvest monitoring)
GMF99005	Scion	GM Pine Trees	To field test, in the Bay of Plenty (Rotorua), over a period of 9 years, <i>Pinus radiata</i> and <i>Picea abies</i> plants genetically engineered for herbicide resistance. The total duration of this project is 11 years.	This field test has been completed (including post-harvest monitoring)
GMF03001	Crop and Food Research	GM Onions	To field test onions engineered for tolerance to the herbicide glyphosate, and to evaluate their environmental impact; herbicide tolerance; agronomic performance; development as cultivars and equivalency to non-GE onions.	This field test has been completed
GMF06001	Crop and Food Research	GM Vegetable and Forage Brassicas	To assess the agronomic performance, in the Lincoln region, over 10 years of vegetable and forage Brassicas, specifically cabbage, broccoli, cauliflower and kale, engineered for resistance (engineered to contain genes derived from <i>Bacillus thuringiensis</i>), to caterpillar pests like cabbage white butterfly and diamondback moth.	This field test was suspended in 2008 because of breach of controls and post-harvest monitoring has been completed. Site continues to be monitored. The approval expired in Feb 2013.
GMR07001	New Zealand Racing Board	GM Equine influenza vaccine	To gain approval to import for release GE vaccines (Proteqflu and Proteqflu Te) to protect horses against Equine Influenza	Approved for conditional release – emergency use
GMF06002	Crop and Food Research	GM Alliums	To field test over 10 consecutive years, the vegetable alliums species onion, garlic and leek with GE agronomic and quality traits in order to assess their performance in the field and investigate the environmental impacts of these plants	Approved but it has not been activated. Approval granted to 2018.
GMD02028	Ag Research	GM Cattle	To develop transgenic cattle that can express functional therapeutic foreign proteins in their milk and to develop transgenic cattle to study	All research under GMD02028 was carried over to ERMA200223 13 April 2010

			gene function and genetic performance.	
GMD99003	NZ King Salmon	GM Chinook Salmon	To trial and develop GM Chinook Salmon	The trial was shelved in 2002 and a supply GM milt retained in frozen storage for future re-use
GMF98002	Crop and Food Research	GM Petunia	To assess the field performance of vegetative plants - Petunia GE for altered plant form or pigmentation.	Completed
GMF98004	Betaseed Inc.	GM Sugar Beet	To evaluate agronomically important characteristics of herbicide tolerant (Phosphinothricin resistant) sugar beet (<i>Beta vulgaris vulgaris</i>).	Completed
GMF98011	Carter Holt Harvey	GM Trees	To field test, in Waikato, pre-reproductive <i>Pinus radiata</i> , in order to study factors influencing gene expression and to assess the influence of genetic engineering, involving the insertion of marker genes, on the growth and morphology of trees.	Did not commence
GMF98010	Ag Research	Fermentation of GM E-coli	To field test large scale fermentation of E-coli bacteria to produce proteins capable of producing a hydatids vaccine	Approval date 1999 but trials did not commence.
GMF98007	Crop and Food Research	GM Potatoes	To field test, in Canterbury over 5 years, potato cultivars GE for increased resistance to bacterial soft rots, to evaluate resistance and yield performance of individual lines.	Completed
GMF98008	Crop and Food Research	GM Potatoes	To field test, in Canterbury over 5 years, potato cultivars GE for increased resistance to potato tuber moth, to evaluate resistance and yield performance of individual lines.	Completed
GMF98001	PPL Therapeutics (NZ) Ltd	GM Sheep	GM sheep for purpose of producing a biopharmaceutical (human alpha-1-antitrypsin, hAAT).	Completed
GMF99004	Ag Research	GM Sheep	GM sheep, with an inactivated myostatin gene, to increase the understanding of myostatin function in order to identify the effects on sheep muscularity.	Trials did not commence
GMF98005	Pioneer NZ Ltd	GM Maize	Import and field test GM maize engineered for tolerance to glufosinate-ammonium herbicide, for breeding purposes, in Waikato.	Unused due to Company Closure
GMF98006	Pioneer NZ Ltd	GM Maize	Import and field test GM maize engineered to contain Cry1A (b) protein from <i>Bacillus thuringiensis</i> to confer resistance to lepidopteran insects, for breeding purposes, in Waikato.	Unused due to Company Closure

Source: EPA

Attachments:

No Attachments