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Report Highlights:

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). On October 14, 2023, New Zealand held a general election, which resulted in a change in Government. The new coalition government has agreed to introduce new biotechnology (gene technology) legislation by the end of 2024. This legislation intends to allow for greater use of gene technology while still ensuring strong protections for the health and safety of people and the environment. It will be based on Australia's Gene Technology Act 2000 and modified to a New Zealand context. Food Standards Australia New Zealand, the regulatory authority for approving the sale of GE food products in New Zealand, has approved 90 GE food and microbial-derived products to date.

Table of Contents

Contents

ACRONYM GLOSSARY

ACVM - Agricultural Compounds and Veterinary Medicines
ANZFSC - Australia New Zealand is the Australia New Zealand Food Standards Council
CRI - Crown Research Institute
CRISPR - Clustered regularly interspaced short palindromic repeats
DOC - Department of Conservation
EPA - Environmental Protection Authority
FoRST - Foundation for Research, Science and Technology
FSANZ - Food Standards Australia New Zealand
GE - Genetic Engineered
GEFNZ - GE Free New Zealand
GHG – Greenhouse Gas
GMO - Genetically Modified Organism
GONZ - Government of New Zealand
HSNO - Hazardous Substances and New Organisms Act
IBSC - Institutional Biosafety Committee
LMO - Living Modified Organisms
MAF - Ministry of Agriculture and Forestry (Current MPI)
MBIE - Ministry of Business, Innovation, & Employment
MFE - Ministry for the Environment
MoRST - Ministry of Research, Science and Technology
MPI - Ministry of Primary Industries
NBT - New Breeding Techniques
RMA Resource Management Act
RNAi - Ribonucleic Acid Interference
TALEN - Transcription Activator-Like Effectors Nucleases
ZFN-1 - Zinc Finger Nuclease type 1

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) historically 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, Māori culture and their relationship with the environment, and international obligations.

On October 14, 2023, New Zealand held a general election, which resulted in a change in Government. The new coalition government has agreed to introduce new biotechnology (gene technology) legislation by the end of 2024. This legislation intends to allow for greater use of gene technology while still ensuring strong protections for the health and safety of people and the environment. It will be based on Australia's Gene Technology Act 2000 and modified to a New Zealand context.

In the previous decade, there had been public debate and discussion around new GE techniques such, as "genome editing", and their applicability to New Zealand agriculture. More recently, it has been seen as a solution to for reducing greenhouse gas emissions and meeting the nation's carbon reduction targets in the future. At the same time, some primary sector organizations and farmers remain cautious about biotechnology out of concern that it may negatively impact their ability to market products overseas.

The Food Standards Australia New Zealand (FSANZ) must approve GE products sold in New Zealand. To date, FSANZ has approved 86 GE food products from plant origins, including four from microbial origins. All GE foods sold in New Zealand must be labeled. Animal feed falls outside the HSNO Act and may be imported into New Zealand as the governing legislation does not differentiate between GE and non-GE feed. Consequently, meat and other products from animals 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.

Chapter 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

The GE research environment in New Zealand hinges on a Royal Commission report dating back to 2001. The report's central conclusion was that it would be unwise for New Zealand to turn its back on the potential benefits of biotechnology but New Zealand should proceed cautiously, managing the risks associated with biotechnology while 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 complex and lengthy process to get approval, and even then, the approval can lead to uncertainty for a contained field trial.

CRI's Plant and Food division 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 leads forestry and biomaterials research. In 2010, Scion obtained approval to begin new field trials in June 2011. These trials focused on herbicide tolerance, reproductive traits, growth, and quality traits. Scion has links with several U.S. companies and the U.S. Department of Energy.

AgResearch enhances 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, consequently, increased animal productivity. AgResearch has received long-term funding to use novel biotechnologies for this plant breeding work. Currently, AgResearch is unwilling to apply for conditional release of any of these plants. AgResearch continues to import biotech plants to study containment trials.

Pastoral Genomics, a research consortium for forage enhancement through biotechnology, has researched a cis-genic (i.e., 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.
- Reduced animal methane emissions.

The consortium has links with the Noble Foundation in Oklahoma and the University of Florida. Furthermore, the consortium has completed controlled field trials in Florida, 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, combined with conventional breeding for desirable traits. Then, once the desirable traits are 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). Meanwhile, no organization has applied for a conditional or full-scale release of a GE plant. Many in the research field attribute this to the costly, lengthy, and uncertain 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 with 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 imported GE food products approved by Food Standards Australia New Zealand (FSANZ). To date, 86 GE events have been approved by FSANZ, which may be contained in food products and can be imported into New Zealand. These food products may be for direct human consumption or animal feed. From January to August 2024, New Zealand imported 209,195 metric tons of soybean meal and hulls primarily for poultry and pig feed. At 68 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 can enter New Zealand if 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 be non-GE.

f) TRADE BARRIERS

No living GE products are approved for import into commercial growing enterprises. However, research entities have been able to import GE products/materials under strict containment conditions.

There is zero tolerance for any viable seed, GE or non-GE, inadvertently comingled with imported 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

REGULATORY FRAMEWORK

General Policy on Genetic Engineering

Even though the international environment regarding genetic engineering has changed significantly over the last decade, the report issued by the 2001 Royal Commission on Genetic Modification still guides GONZ policy on GE organisms. While no overt political factors 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) has been the lead agency in minimizing and managing risks associated with genetic engineering. Under the 1996 HSNO Act, the EPA prohibits all GE organisms' entry into New Zealand - unless the regulator formally approves them. The EPA can issue various levels of approval, including containment, conditional release, and full-scale release. To date, the GONZ has approved several contained field trials. 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 9 and 10.)

The New Zealand Productivity Commission in April 2021 submitted a report to the GONZ titled – New Zealand Firms: Reaching for the frontier. This report directly discusses Genetic Modification (GM) use in enhancing the NZ primary industries. In it, the Commission states that GM, more than ever offers

new opportunities for boosting productivity, solving biosecurity risks, and responding to climate change, and other environmental problems. The report states it is time to review HSNO, which regulates GM organisms and technologies. The last review of HSNO was conducted in 2001 by the Royal Commission on Genetic Modification. Since then, advances in science and technology have been substantial, particularly modern gene-editing technology techniques such as CRISPR, which the report states were never envisioned to be a reality at the time of the 2001 review.

The following recommendations were made within the Productivity Commission report:

	Recommendations
The Government should undertake a full review of the regulation of genetic modification (GM), to ensure it is fit for purpose and supports domestic innovation. The review should:	Consider the emerging regulatory approaches in other jurisdictions, particularly New Zealand's key product destination and competitor markets.
	Consider the trade and regulatory enforcement impacts from different treatment of GM technologies in different markets.
	Assess consumer attitudes in New Zealand and internationally.
	Consider the potential impacts on New Zealand firms that wish to retain GM-free status, and on New Zealand's reputation and brand more generally.
	Recognize Māori views on GM and the rights and interests of iwi in taonga species (indigenous flora and fauna).
	Coordinate with the whole-of-government work that is considering the recommendations of the Wai 262 report, particularly those relating to GM legislation.
	Look beyond the Hazardous Substances and New Organisms Act 1996, across all relevant acts and regulations, to ensure consistency of definitions and approach.
	Assess the fitness for purpose of the current regulatory oversight and enforcement arrangements.
	Consider the merits of separate legislation and/or a standalone regulator for genetic technologies.
	Undertake wide public engagement, including with Māori and industry, and backed by information resources to support public understanding of modern GM technologies.

In April 2022, the GONZ published its response to this report. In response to the recommendation that "The Government should undertake a full review of the regulation of genetic modification (GM), to ensure it is fit for purpose and supports domestic innovation," the GONZ responded:

> -the government has long considered that the New Zealand brand and value are best served by maintaining a 'proceed with caution' approach. However, we consider it timely to start informed conversations about New Zealand's use of GM technologies.

In addition to this productivity report, the 2018 MfE advised that the regulatory setting was quickly becoming outdated. More recently, the NZ Climate Commission recommended the government review the GM regulatory framework, as the role of emerging technologies for reducing biogenic agricultural

methane through genetic engineering could ensure new emission-reducing technologies and practices in New Zealand.

On October 14, 2023, New Zealand held a general election for the next administration. The result of this election favored a change in government from the previous, who had been in power for the last six years. Prior to the election, the party that received the largest votes – the National Party- released a document called Harnessing Biotech outlining its intensions to update the HSNO Act. The party directly highlights that biotechnology has the potential to deliver enormous benefits for New Zealand, from combatting climate change and making advances in health science to lifting agricultural productivity and boosting exports.

The new coalition GONZ has agreed to introduce new gene technology legislation by the end of 2024. This legislation intends to allow for greater use of gene technology while still ensuring strong protections for the health and safety of people and the environment. It will be based on Australia's Gene Technology Act 2000 and modified to a New Zealand context.

If passed, this legislation will establish a new regulatory authority that will oversee the safe use of gene technology. The regulator is proposed to be an independent statutory officer housed at the EPA. A regulatory team would support the regulator to process applications and conduct the necessary risk assessments, as well as an expert Technical Advisory Committee and a Māori Advisory Committee.

The Ministry of Business, Innovation and Employment (MBIE) is leading the development of the new legislation. The timeline for the implementation plan will be confirmed when the Bill is introduced to Parliament later in 2024. The new regulator is expected to begin operating by the end of 2025.

What is containment?

Containment requires a GE organism and its heritable material to be contained and managed within a secured facility. Containment is 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 contained field test occurs when 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 unlikely 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 releasing a GE organism, such as regional restrictions where t GE organism might threaten an established industry. EPA believes this mechanism could be used for conducting research in the field, which 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 for full releases, as laid out in Section 36 of the Act. They must demonstrate that the positive effects outweigh the adverse effects.

To date, there have been no applications for conditional or unconditional releases in New Zealand. Considering the GONZ 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. Since no full or conditional releases have been approved, it is unknown how long the process would take. It would likely be no less than two years if not longer.

Legal Term	Laws and Regulations where term is used	Legal Definition
Genetically Modified Organism	• Royal Commission on Genetic Modification • Hazardous Substances and New Organisms (HSNO) Act 1996	Means 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 that has been modified by in vitro techniques.
Genetic Modification	• Royal Commission on Genetic Modification • Hazardous Substances and New Organisms (HSNO) Act 1996	Means the use of genetic engineering techniques in the laboratory involving: a) the deletion, multiplication, modification or moving of genes within a living organism; or b) the transfer of genes from one organism to another; or c) the modification of existing genes or the construction of novel (new) genes and their incorporation in any organisms; and/or d) the utilization of subsequent generations or offspring of genetically modified organisms.
New Organism	• Hazardous Substances and New Organisms (HSNO) Act 1996	a) an organism belonging to a species that was not present in New Zealand immediately before 29 July 1998: b) an organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation: c) an organism for which a containment approval has been given under this Act: d) an organism for which a conditional release approval has been given: e) a qualifying organism approved for release with controls: f) a genetically modified organism: g) an organism that belongs to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.

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 exist in New Zealand, including GE products/materials. The Act is administered by the Ministry for the Environment (MfE) but implemented by EPA, established as an independent body under the Act. It applies to anything that can potentially grow and reproduce, whether food or 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 approval from EPA.

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

Environmental Protection Authority:

The 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 directly 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 an 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 Māori advisory committee.

Food Standards Australia New Zealand (FSANZ):
FSANZ is responsible for developing food standards for Australia and New Zealand, emphasizing 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. FSANZ recently updated its resources on its website for Genetically modified foods.

The final approving body for standards developed by FSANZ is the Australia New Zealand Food Standards Council (ANZFSC). The council includes the Australian Commonwealth, state and territory Ministers of Health, and the New Zealand Minister of Health.

Ministry for Primary Industries (MPI):
MPI, officially established 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 safety standards, 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. The ministry is responsible for managing and maintaining 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 GONZ departments and ministries: the Ministry of Science and Innovation**,** the Ministry of Economic Development, the Department of Labour, and the Department of Building and Housing. In 2011, the GONZ merged two former science agencies into MBIE**.** In addition, the ministry also includes 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. The ministry also helps transfer knowledge and technology 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 regarding food security. In this context, science and innovation take a holistic view, incorporating food safety, environmental sustainability, value chain robustness, and traceability. The agency is reportedly agnostic on the technologies developed to meet future challenges. At this stage, the role Science and Innovation envisions for GE technology concerning food security and ecological sustainability is unclear.

GE Animal Feed Regulations

GE feed falls under the 2001 Agricultural Compounds and Veterinary Medicines (ACVM) regulations under the ACVM Act (1997). The ACVM regulations state that materials fed to animals should be safe and not cause harm to them. 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) used for human consumption, and, as a result, it is difficult to keep the food and feed chains 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, also practiced in the United States and Canada, arose following an incident in the United States where traces of 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 standard practice for GE plants intended primarily for feed use to undergo food safety assessment and approval for human food use to prevent similar incidents from occurring in the future. This policy is designed to minimize the risk of unapproved products entering the food supply because of inadvertent co-mingling of grain/seeds during transport and storage. Furthermore, the policy ensures that their products are evaluated for food and feed uses. Examples of GE crops developed primarily for animal feed but have also been approved as human foods in Australia and New Zealand include high lysine corn and herbicide-tolerant alfalfa.

a) APPROVALS

There are no GE crops or plants approved for general cultivation in New Zealand. However, there are now 86 FSANZ-approved GE food products for sale in New Zealand. A total of 90 applications have been lodged with FSANZ. Three have been withdrawn and one is under assessment.

FSANZ approved two applications in 2022. These are a variety of insect-protected corn (Bayer CropSciences) and a variety of drought and herbicide-tolerant wheat (Trigall Genetics). FSANZ has approved an application to permit food derived from wheat line IND-00412-7, also known as 'HB4 wheat'. This wheat is tolerant to drought and the herbicide glufosinate. Food from HB4 wheat may enter the Australian and New Zealand food supply via imported processed products, either wheat flour or finished products such as baked goods.

For more information and a list of the approved foods/traits, see:

https://www.foodstandards.govt.nz/consumer-information/consumer/current-status-genetically-modified-foods-applications

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 may not have a GE origin. This decision thoroughly assesses 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 decision-makers to consider the following matters:

- the sustainability of all native and valued introduced flora and fauna;
- the intrinsic value of ecosystems;
- public health;
- the relationship of Māori 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 likely 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 any organisms should be released. Under a conditional release, the 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. The EPA can grant a full release if no potential risks need to be managed by the imposition of conditions. The 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 integral to 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 to 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 have reported that New Zealand's requirement for absolute containment is challenging 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 provide further recognition of 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 releasing GE materials in New Zealand, the HSNO Act requires that the Māori culture and traditions related to their ancestral lands, water, sites, flora, and fauna be considered. This means that the 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.

Furthermore, 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, treat low-risk organisms, and change the regulation from technique-based to trait-based.

Treaty of Waitangi and Genetic Modification

New Zealand's Royal Commission on Genetic Modification investigated the Crown's responsibilities under the Treaty of Waitangi concerning agricultural biotechnology issues. They recommended that the HSNO Act be amended to give effect to the principles of the Treaty of Waitangi.

The GONZ 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 GONZ 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 how the application and decision-making processes work.

The HSNO Act has been amended to emphasize 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. *Nga Kaihautu Tikanga Taiao* (the body that advises the EPA on Māori issues) is also given a statutory basis within the Act. Previously, there was no requirement in law for EPA to have a Māori advisory committee, but this it is now mandatory.

b) 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 because of the combination of events), the approval process is likely to be more lengthy and costly.

c) 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. In June 2011, Scion was approved to conduct a long-term field trial utilizing two species of pine to test 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 in Australia and the United States, fees are charged in New Zealand for field trial applications. 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, more onerous, and riskier 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 has potential benefits for a full commercial release application.

d) INNOVATIVE BIOTECHNOLOGIES

Currently, innovative biotechnologies (such as using 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 those 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 questioned breeding techniques (chemical or radiation mutagenesis) that existed 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.

e) 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.

f) 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 ANZFSC, a council of Australian and New Zealand health ministers. As of 2001, all GE foods in New Zealand must be labeled under Standard A18/1.5.2 of the Australia New Zealand Food Standards Code, which outlines the legal requirements for selling and labeling GE food. This policy highlights 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 exact wording "genetically modified" must be on the label. 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 is usually 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 like 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 concerning food derived using new breeding techniques (NBTs) such as genome editing. This development comes from acknowledging that the wording of the original Code is now out of date. There are no changes to the Code yet, but the proposed changes are currently going out for public consultation (October 2021).

Labeling of GE Animal Feed

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

g) MONITORING AND TESTING

MPI does not inspect individual food import shipments to ensure 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 primarily 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 processing 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 in 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. It 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 and potential conflicts with other international obligations. New Zealand aims to help shape balanced decisions at Protocol meetings.

New Zealand is not 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 in October 2011.

m) INTERNATIONAL TREATIES/FORUMS

New Zealand is a member of CODEX and the International Plant Protection Convention. GONZ officials indicate they have not been heavily involved with 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 is best described as a "very interested observer."

n) RELATED ISSUES

None

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

When asked about this issue, 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 for New Zealand's 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 adopting GE crops or forages because of the concern that it will reduce New Zealand's "clean

and green" image and negatively impact 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 in 2012, a series of online public polls showed that the public was 67-75 percent in favor of the trials.

b) MARKETING ACCEPTANCE/STUDIES

Biotechnology remains a politically sensitive subject in New Zealand, evoking strong opposition from the Green Party and a small number of anti-biotech non-governmental organizations (NGOs), often with influence out of proportion to their numerical support. These groups seek to prevent commercial releases of products derived from biotechnology into the environment and impose restrictions against consuming 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 privately 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 importer's responsibility to label the product, not that of the supermarket.

Chapter 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

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

AgResearch, New Zealand's largest CRI, has received two approvals to research GE cows. One approval was to field test GE cattle with modified casein genes, and the other was 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 several 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 and 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 continues to do GE work on transgenic goats, cattle, and mice, as well as ongoing research on diabetes, cancer, human infertility, and blood clotting.

Bio-pesticide research and development are 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 targets 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 the African black beetle, Porina caterpillar, and plantain moth,
- Forage and vegetable pests, such as Diamondback moth and
- Pests and diseases of corn.

The bio-pesticide research usually involves insects or bacteria that either eat/destroy the pests of the crop plants mentioned or are vectors for a disease agent that 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 are being isolated, purified, and studied.

Products that can be sprayed and 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. Still, if it is a live biological control agent, it will be regulated by the New Organisms branch of the HSNO Act.

In 2022, the New Zealand government released its first Emissions Reduction Plan (ERP), focused on how the nation would reach its obligations outlined in the Paris Agreement, where New Zealand committed to reduce greenhouse gas emissions. An objective was announced following the ERP with the aspiration to be the first country in the world to price agricultural emissions. Agriculture is highlighted as the largest contributor to the national greenhouse gas emissions (48.1 percent). As a result, scientists view biotechnology in multiple scenarios to reduce greenhouse gas emissions. This will help minimize bio enteric methane, which is estimated to be ~35 percent of New Zealand's total Greenhouse gas emissions.

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 organization has applied for a conditional or full-scale release of a GE product.

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

b) EXPORTS

There are none for commercial use.

c) IMPORTS

There are none for commercial use.

d) **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 are governed by the same laws and regulations as plants and other organisms detailed in the plants Chapter 1 of this report. The same GONZ departments and agencies are involved. Cloned animals with no genetically engineered traits are not new organisms and uncovered 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 contain or destroy 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 GONZ regulations.

d) LABELING AND TRACEABILITY

The same regulations, laws, and administrative bodies apply to animals as outlined in PART B - g). Since 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 labeled 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 as much media attention on GE animals or cloning as 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 need to embrace the technology and would benefit from additional science-based information on its 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 in sufficient detail to differentiate microbial biotech-derived ingredients from conventional ingredients. New Zealand imports microbial biotech-derived food ingredients, such as, enzymes traditionally used in alcoholic beverages, dairy products, and processed food products. Likewise, New Zealand imports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients. Appendix II shows the imports of foods and food ingredients likely to contain microbial biotech-derived ingredients. The leading origin of these foods is Australia at US$208 million in 2023, followed by the United States at US$60 million.

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 GONZ departments and agencies are involved.

b) APPROVALS

Currently, the approval process is the same as in Chapter 1, Part B b) Approvals. 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 result from microbial biotech in the origin country, they would be assessed and approved by FSANZ. At present,

FSANZ has approved four biotech microbial-derived food ingredients: Soy leghemoglobin derived from *Pichia Pastoris* strain MXY0051 in analogues of meat, and three lactose-type compounds derived from E-coli K-12 and BL21 derived strain for infant formula. Currently, FSANZ is assessing several applications to import a range of ingredients derived from biotech microbes.

See: Food produced using gene technology - microbial origin

c) LABELING and TRACEABILITY

The same regulations in Chapter 1, Part B g) Labeling and Traceability (page 15) apply to any microbial biotech-derived food ingredients. Note that FSANZ has several 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 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 Pinus radiata 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 lacto globulin 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, Pinus radiata 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, Pinus radiata and Picea abies 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 Bacillus thuringiensis), 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 gene function and genetic performance.	All research under GMD02028 was carried over to ERMA200223 13 April 2010
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 (Beta vulgaris vulgaris).	Completed
GMF98011	Carter Holt Harvey	GM Trees	To field test, in Waikato, pre-reproductive Pinus radiata, 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 Bacillus thuringiensis to confer resistance to lepidopteran insects, for breeding purposes, in Waikato.	Unused due to Company Closure

Source: EPA

Appendix II: New Zealand Food Imports with Ingredients Likely Derived from Biotechnology

New Zealand Imports of Foods and Food Ingredients Likely to Contain Ingredients derived from Biotech Microbial Processes						
HS Code	Description	Calendar Year (Value: USD)			January-August	
		2020	2021	2022	2022	2023
2106	food preparations nesoi	401,737,600	443,664,347	423,360,336	282,538,600	262,370,718
1905	bread, pastry, cakes, biscuits, and other bakers' wares; communion wafers, empty capsules for medicine etc., sealing wafers, rice paper etc.	186,516,821	207,815,309	195,570,150	121,257,170	137,015,605
2204	wine of fresh grapes, including fortified wines; grape must (having an alcoholic strength by volume exceeding 0.5% vol.) nesoi	140,776,743	175,709,765	152,269,496	89,145,377	93,224,324
2103	sauces and preparations therefor; mixed condiments and mixed seasonings; mustard flour and meal and prepared mustard	94,381,492	113,783,756	112,963,141	71,773,697	81,230,946
0406	cheese and curd	60,112,834	70,075,360	65,641,142	40,515,551	55,600,895
1904	prepared foods from swelling or roasting cereals or products; cereals (exc corn), in grain form flakes or worked grain prepared n.e.s.o.i	56,788,094	59,223,232	53,486,105	35,643,024	41,862,949
2203	beer made from malt	59,470,093	59,176,798	66,493,138	37,366,862	40,831,495
2009	fruit juices nt fortified w vit or minls (incl grape must) & vegetable juices, unfermented & nt containg add spirit, whet or not containing added sweeting	30,396,473	36,940,140	40,013,307	25,052,738	33,431,941
3507	enzymes; prepared enzymes nesoi	11,452,348	14,150,446	13,984,238	9,144,864	9,566,059
190110	food preparations for infant use, put up for retail sale, nesoi	9,875,989	7,493,046	10,025,611	6,866,150	7,466,221
All	Total Imports	1,051,508,487	1,188,032,199	1,133,806,664	719,304,033	762,601,153

Source: TDM LLC

Attachments:

No Attachments