USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Required Report - public distribution

Date: 7/14/2014
GAIN Report Number: NZ1410

New Zealand

AGRICULTURAL BIOTECHNOLOGY ANNUAL 2014

New Zealand Biotechnology Environment

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Report Highlights:

There have been no official changes to the heavily regulated and cautious policy settings operated by the New Zealand Government in relation to products derived from biotechnology. A genetic engineered (GE) equine influenza vaccine is the only GE product approved for use in New Zealand, and there have only been 21 contained field trials approved to operate.

Even though a court case decision negatively impacted on the progress toward the use of new types of gene manipulation for advanced plant breeding it has prompted a review of the regulations in light of the rapidly evolving technologies in this area.

SECTION I. EXECUTIVE SUMMARY

In New Zealand, GE products are regulated under the 1996 Hazardous Substances and New Organisms Act (HSNO) and administered by the Environmental Protection Agency (EPA). (Prior to the formation of the EPA, the Environmental Risk Management Authority administered the HSNO Act.) The EPA operates in line with the New Zealand Government's (NZG's) cautious approach to biotechnology, only approving applications if the benefits outweigh the risks. In the regulation of products derived from biotechnology, EPA 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.

A GE equine influenza vaccine is the only GE product approved for a controlled release in New Zealand. Aside 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. Many in the research field attribute this to the costly, lengthy, and unproven nature of the regulatory approval process. However, there is on-going biotechnology research in New Zealand. To date, 21 contained field trials have been approved for a range of crops and animals.

There is a growing recognition among industry organizations, policy makers, farmers and others that there could be economic benefits to creating a more enabling environment for biotechnology. While products such as soy and cotton are not grown in New Zealand, there is an increasing recognition that genetic engineering could be used to develop products with agronomic benefits suitable to New Zealand with positive impacts for food security and environmental problem mitigation. Media articles over the last year are now evenly divided between pro and anti pieces. Some primary sector organizations and farmers remain cautious about the use of biotechnology out of concern that it will tarnish New Zealand's "clean and green" image and negatively impact on the ability to market products overseas.

Any review of the laws concerning biotechnology has not been high on the current Government of New Zealand's agenda because of the political sensibilities associated with the issue. However, it is reviewing the Resource Management Act (RMA) at present and has said it will act if necessary to amend the RMA to disallow it from being used to set district or regional rules on genetic engineering. In addition a court case decision in May 2014, which went against an earlier EPA determination, said any organisms resulting from two new within species gene manipulation techniques were to be considered new organisms for the purposes of the HSNO Act. This has prompted the Ministry for the Environment to review the Regulations to ensure they appropriately consider evolving technologies.

Genetically engineered food products sold in New Zealand must be approved by Food Standards Australia New Zealand (FSANZ). To date there are 65 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 HASNO 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 need to be labeled.

The New Zealand Government is a signatory to the Cartagena Bio-safety Protocol.

SECTION II.

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 State owned enterprises the Crown Research Institutes (CRIs): Plant and Food (crops), Scion (Forestry) and AgResearch (plants and animals) which receive both 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, lengthy, and risky process to get an approval for even a contained field trial.

Plant and Food has undertaken GE research on a range of plants including potatoes, onions, broccoli, cabbage, and 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, and growth and quality traits. Scion has linkages with several US companies and the US Department of Energy.

Ag Research 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, carbohydrate balance in the diet; reduce animal bloat; while at the same time reduce animal excretions of nitrogen; and possibly reduce methane emissions.

Pastoral Genomics, a research consortium for forage enhancement through biotechnology, is researching a cis-genics (only using genes from within the ryegrass species for e.g.) approach to develop perennial ryegrass and/or clover plants that can contain 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 with the Noble Foundation in Oklahoma and the University of Florida. It has conducted controlled field trials in Florida and is looking now to commence field trials in Victoria, Australia.

b) COMMERCIAL PRODUCTION

There is no commercial production of GE plants in 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 unproven nature of the regulatory approval process. Apart from corn, the GE crops grown in the northern hemisphere and Latin America, 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, 57 GE events are 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 the year to end December 2012, New Zealand imported 165,967 tons of soybean meal (up 46% from the previous year), primarily for poultry and pig feed. At 99% of the volume, Argentina was by far the largest supplier, which suggests that virtually all of this imported feed would have been derived from GE soybeans.

e) FOOD AID RECIPIENT COUNTRIES

N/A

PART B: PLANT BIOTECH POLICY

a) REGULATORY FRAMEWORK

General Policy on Genetic Modification

While 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 the New Zealand Government's policy on GE.

The Environmental Protection Agency (EPA) is now the lead agency in minimizing and managing risks associated with genetic engineering. Under the 1996 Hazardous Substances and New Organisms (HSNO) Act, all GE products or materials 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. (See Appendix I for details of contained field trials and conditional releases that have been approved.)

There have been moves by some territorial authorities to set district or region wide by-laws on biotechnology which could ban GE products/materials altogether, or set rules which would be stricter and punitive if contravened. The territorial authorities contemplating this believe they are able to set rules under the auspices of the Resource Management Act (RMA). Policy for biotechnology has been a

central Government responsibility with all rules and regulations as set down by the Government applying to all territorial authorities and the administration of the rules by the central Government agencies. The GONZ (National Party led, right of center) has said it will act if necessary to amend the RMA to disallow it from being used to set district or regional rules on genetic engineering.

Developments during 2013/14

In March/April 2013 the EPA considered and ruled on an application by Scion (Crown Research Institute – forestry) to determine whether the use of custom Zinc Finger Nucleases (ZFNs) and custom Transcription Activator-Like Effectors (TALEs) results in organisms classed as genetically modified organisms, and therefore new organisms for the purposes of the HSNO Act.

The EPA decision making committee decided that organisms resulting from the use of Zinc Finger Nuclease type 1 (ZFN-1) and Transcription Activator-Like Effectors (TALEs) are not considered genetically modified, and therefore, are not new organisms for the purposes of the Act. This was in contradiction to EPA staff advice at the time which recommended the resulting organisms be treated as GMO's for the purposes of the HSNO Act. However the committee did say that this determination highlights the need for a review of the Regulations, as they are not keeping pace with a rapidly evolving field of science. They recommended that the Regulations be reviewed by staff at the Ministry for the Environment, to improve their clarity.

This seemed like a breakthrough for the scientific community involved with advanced plant breeding techniques but the new situation was short-lived. The Sustainability Council of New Zealand Trust, an anti GE activist/lobbying group appealed to the High Court against the decision by the EPA. In May 2013 the judge published her decision. She allowed the appeal. The EPA's determination was quashed. The judge also thought there were some problems with the drafting of the HSNO Act especially in light of current developments in the science.

In light of these developments it is the Ministry for the Environment's intention to review the Regulations to ensure they appropriately consider evolving technologies. They are currently working on the scope and process of the review. The High Court's decision will be considered as part of this review.

As a sidebar to this the GONZ is overhauling workplace safety legislation in a new Health & Safety at Work Bill due to become law by the end of 2014. Some of the functions the EPA formerly carried out concerning hazardous substances will be transferred to a new department "WorkSafe NZ". The EPA is saying that as part of this change it will re-write in plain English as much of the HZNO Act as is practical. How this will affect new organism's regulations is not known yet.

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, ERMA 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?
NZ 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 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; disease or be a 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. ERMA 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. However, as a result of ongoing research in the containment phase, many expect an application for a conditional release within the next few years.

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 Agriculture and Forestry (MAF)/Environmental Risk Management Authority (ERMA) Containment Standards; MAF Import Health Standards)
- Agricultural Compounds and Veterinary Medicines Act 1997
- Medicines Act 1981
- Food Standards Australia New Zealand Act 1991
- 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 ERMA, 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 ERMA.

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

Environmental Protection Agency:
The Environmental Protection Agency (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 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 is a bi-national independent statutory authority operating under the Food Standards Australia New Zealand Act 1991. It 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 GE. The final approving body for standards developed by Food Standards Australia New Zealand is the Australia New Zealand Food Standards Council (ANZFSC) 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 of 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 GE.

Ministry for the Environment: Currently, MFE advises the NZG 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 new super ministry that

became an entity on July 1st, 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.

Within MBIE the former Ministry of Science and Innovation (MSI) which itself was established as recently as February 2011, through the merger of two agencies - the Foundation for Research, Science and Technology (FoRST) and the Ministry of Research, Science and Technology (MoRST) is 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 & Innovation (S & I) agency sees as having increasing importance in the future, especially as it relates to food security. In this context, S & I takes a holistic view incorporating food safety, environmental sustainability, value chain robustness, and traceability. S & I is reportedly agnostic on the technologies that could be developed to meet the challenges it foresees but, at this stage, it is not clear what role S & I envisages for GE technology in relation to food security and ecological sustainability.

b) APPROVALS

The Approval Process for GE materials

The EPA makes all decisions on the importation and domestic use of living modified organisms (LMOs) that are GE on the basis of a thorough assessment of the potential risks and benefits posed by the organisms, under the requirements of the 1996 HSNO Act. 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 taken into account 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);
- 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 and weighs these up against the 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. In the case of GE animals, conditions could include high security fencing and requirements for disposing of waste. 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 by 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's 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 Maori 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 Maori culture and traditions as they relate to their ancestral lands, water, sites, flora and fauna be taken into account. 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 Maori.

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. A copy of the paper can be found at:
http://www.royalsociety.org.nz/publications/policy/yr2012/consultation-on-the-hsno-act/

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 GE issues. 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, and also 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 Environmental Risk Management Authority on Māori issues) is given a statutory basis within the Act. Previously there was no requirement in law for ERMA to have a Māori advisory committee, but this has been changed to make it mandatory.

c) FIELD TESTING

Contained GE Field Trials

Since the HSNO Act was implemented in 1996, New Zealand has approved 13 applications for GE plant 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.

Some New Zealand companies have opted to take their GE trials offshore. The 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. With this in mind, three groups are conducting 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.

Practitioners feel that the level of scrutiny over a contained field trial application is the same as the high level afforded a commercial release application. This means it is practically impossible to ascertain, via field trials, whether a trait/product is safe or its real benefits and costs, which could then warrant a commercial release application.

d) STACKED EVENT APPROVALS

Stacked event approvals would follow the same approval process outlined above. However because stacked events are relatively more complex than a single event the approvals process is likely to be more lengthy and costly.

e) ADDITIONAL REQUIREMENTS

N/A

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

GE Food Regulations

GE foods and ingredients can only be sold in New Zealand if they have been assessed for safety by FSANZ and approved by the Australia New Zealand Food Standards Council (ANZFSC), a council of Australian and New Zealand health ministers. There are 65 FSANZ approved GE food products able to be sold in New Zealand. A total of 69 applications have been lodged with FSANZ but four have been withdrawn or are still under assessment. For more information see: http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx

As of 2001 under Standard A18/1.5.2 of the Australia New Zealand Food Standards Code, which 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 have this fact noted on the label. If a food or ingredient has altered characteristics, this must also be on the label. For example, if oil was made from a plant that had been GE so that its oil boils at a higher temperature, the oil would 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;
- 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 help consumers make an informed choice about the food they buy. 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 to ascertain 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.

The application process for approval of a GE Food will usually take nine months for a general procedure (1 round of public comment) and 12 months for a major procedure (2 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.

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) 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. To prevent similar incidents occurring in the future it is now common practice for GE plants intended primarily for feed use to undergo food safety assessment and approval for human food use. This policy is intended to minimize the risk of un-assessed and unapproved products entering the food supply because of inadvertent co-mingling of grain/seeds during transport and storage, and ensures that their use as feed will not pose indirect risks to humans. Examples of GE crops that have been developed primarily for animal feed but which have also been granted approval as human foods in Australia and New Zealand include high lysine corn, and herbicide-tolerant Lucerne.

h) TRADE BARRIERS

Food products containing GE events must be approved by FSANZ. FSANZ approvals are concerned with food safety and are science based. Once approved there are no further barriers. No LMOs are approved to be imported for commercial growing enterprises. Research entities have been able to import GE products/materials under strict containment conditions.

i) INTELLECTUAL PROPERTY RIGHTS (IPR)

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

j) 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 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 be a 'good international citizen'. Several industries, however, such as the dairy sector, are concerned that the EU or other countries might use the "precautionary principle" to restrict trade.

New Zealand is one of the few major agricultural exporters that are a signatory to the Cartagena Protocol. The NZG 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 plays a useful role in helping to shape balanced decisions at Protocol meetings.

While many countries have signed up to the new protocol and supplementary agreements: "Liability and Redress" and "Access and Benefits" adopted by the Conference of the Parties to the Cartagena Protocol in Nagoya, October 2011, New Zealand isn't a signatory to either agreement yet.

k) INTERNATIONAL TREATIES/FOR A

NZ is a member of both CODEX and the International Plant Protection Convention.

l) RELATED ISSUES

N/A

m) 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 a number of items from retail shelves and working 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.

n) LOW LEVEL PRESENCE POLICY

There is zero tolerance for the presence of an unapproved GE food in the food supply, even if it is unintentional.

PART C: GE PLANT MARKETING

a) MARKETING ACCEPTANCE

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 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 GE whereby it insists on non-GE food ingredients to be used in its house or private branded products including non-GE feeds being fed to animal products which are sold under the house or private brand. It has no stance on third party or regular products sold through its stores as long as 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/community-social-responsibility/healthy-communities.

b) PUBLIC/PRIVATE OPINIONS

When asked, most New Zealand consumers express caution about GE foods. However, negative attitudes toward GE may be weakening. According to recent surveys and interviews, actual purchasing behavior does not always correlate with expressed negative attitudes toward GE. 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, apples in particular) in New Zealand oppose the adoption of GE crops or forages because of the concern that it will tarnish 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 which showed that the public were 67-75% in favor of the trials.

It would seem that below the surface of the public media there is a groundswell of thinking that GE is a technology that could have significant beneficial outcomes not only in terms of production efficiency but also in terms of environmental footprint.

Business adviser KPMG in its Agribusiness Agenda released June 2011 called for a national debate on agricultural questions such as genetic engineering. In the report, based on interviews with more than 80 agribusiness leaders, KPMG said the use of genetic engineering was moving into the international mainstream and there is a concern that if the country is not open to discussing the issue, New Zealand's agricultural sector could be left behind by its international competitors. This was the first time a large company involved with the primary sector has gone public with this sort of message.

Further to its 2011 release, KPMG said the following in its 2012 Agenda media release: "Previous Agendas have highlighted the need for a mature conversation around the use of genetic technologies in our farming systems. The reality is that there is little discussion taking place on this issue at the moment. Most in the industry have put it in the proverbial 'too hard' basket. Meanwhile, the rest of the world is talking in detail about these technologies. It is generally agreed cis-genic engineering is less of an issue, as natural selection would achieve the same outcomes over a longer timeframe. The potential economic and environmental benefits from the pasture cultivars being developed by New Zealand scientists could be significant. However we are no closer to proving whether the benefits can captured, the environment protected and our markets maintained, than we were this time last year. The growing global demand for food makes this a critical debate, and we have an obligation to at least consider it openly".

c) MARKETING STUDIES

Associate Professor John Knight of Otago University's Marketing Department released a report in March 2011 summarizing a series of marketing research studies which concluded that it is highly unlikely that introduction of GE drought-tolerant grasses into New Zealand would have any long-term deleterious effect on perceptions in overseas markets, particularly in Europe, of food products sourced

from New Zealand.

PART D: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES

None

b) STRATEGIES AND NEEDS

There are opportunities for on-going capacity building and outreach in New Zealand, particularly in working better with the media to provide a balanced view of the risks and benefits of GE technology. In addition to speaking tours and seminars for journalists, opportunities include increasing the use of social media to provide a clear and consistent message about the risks and benefits of GE technology.

Chapter 2. ANIMAL BIOTECHNOLOGY

PART E: PRODUCTION AND TRADE ANIMAL BIOTECH

a) BIOTECHNOLOGY PRODUCT DEVELOPMENT

There are no field trials being carried out at present that would likely to 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, and one application for a conditional release of a GE organism.

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.

On June 5, 2009, GE Free New Zealand won their case against AgResearch and ERMA (the predecessor to EPA). The Court found that the applications were too generic to 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. GE Free then sought to take the case to the Supreme Court. The Supreme Court rejected the case without hearing it which has ended this legal challenge. AgResearch is now operating its field trials utilizing goats, sheep, and cattle with a new approval. (See Appendix I.)

GE Free 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 trial. He concluded there are significant risks. GE Free applied to ERMA (former HSNO Act administrator) to reassess their approval of this trial. ERMA did not progress this application because GE Free did not pay the application fee, nor did it 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.

b) COMMERCIAL PRODUCTION ANIMAL BIOTECH

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 are no commercially grown GE or cloned animals in New Zealand.

c) BIOTECHNOLOGY EXPORTS

None for commercial use.

d) BIOTECHNOLOGY IMPORTS

None for commercial use.

PART F: ANIMAL BIOTECH POLICY

a) REGULATION

Animal GE research and commercialization is governed by the same laws and regulations as plants and other organisms as detailed in the plants chapter 1 of this report. The same Government departments and agencies are involved.

With respect to contained field trials, conditions of approval are likely to include: very high levels of animal husbandry, a sturdy vermin proof fence, control of any effluent, and a method to dispose of dead animals that contains or destroys the novel genes.

b) LABELING AND TRACEABILITY

The same regulations and laws and administrative bodies apply to animals as outlined in PART B (g) above. With respect traceability because there are no commercial releases there are not policies developed. However all deer and cattle are individually traced with Electronic Identification ear tags under the National Animal Identification and Traceability Scheme so this scheme could track GE cattle or deer.

c) TRADE BARRIERS

The trade barriers are the same as outlined in PART B (h) above.

d) INTELLECTUAL PROPERTY RIGHTS (IPR)

At this stage because there are no commercial releases, this area of IPR has not been tested.

e) INTERNATIONAL TREATIES/FOR A

NZ 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.

PART G: GE ANIMAL MARKETING

a) MARKETING ACCEPTANCE

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 GE sections of this report on marketing apply also to animal GE though the level of acceptance would be less for GE animal.

b) PUBLIC/PRIVATE OPINIONS

The discussion in the Plant GE PART C (b) of this report on public/private opinions would also apply to animal GE however there isn't the level of media output on animal GE to draw much in the way of general conclusions on opinions. Generally it is felt there is a lower level of positive opinion on animal biotechnology

c) MARKETING STUDIES

None available.

PART H: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES

None

b) STRATEGIES AND NEEDS

There are opportunities for on-going capacity building and outreach in New Zealand, particularly in working better with the media to provide a balanced view of the risks and benefits of GE technology. In addition to speaking tours and seminars for journalists, opportunities include increasing the use of social media to provide a clear and consistent message about the risks and benefits of GE technology.

Appendix I: Contained Field Trials Approved in New Zealand

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