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Biotechnology Still at Crossroads in New Zealand

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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 biotechnology. A GM equine influenza vaccine is the only GMO approved for use in New Zealand, and there have only been 21 contained field trials approved to operate. However there is a growing recognition among industry organizations, policy makers, farmers and others that there could be both economic and environmental benefits to creating a more enabling regulatory playing field for GM technology.

GM food products sold in New Zealand must be approved by Food Standards Australia New Zealand (FSANZ). To date, FSANZ has approved 54 GM food products. All GM foods sold in New Zealand must be labeled. GM animal feed falls outside of the HSNO Act and may be imported as the governing legislation does not make a distinction between GM and non-GM feed.

Section I. Executive Summary:

In New Zealand, genetically modified organisms (GMOs) 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 HSNO Act was administered by the Environmental Risk Management Authority.) The EPA operates in line with the New Zealand Government's (NZG's) cautious approach to GM technology, only approving applications if the benefits outweigh the risks. In the regulation of GM organisms, 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 GM equine influenza vaccine is the only GMO approved for use 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 GMO. Many in the research field attribute this to the costly, lengthy and unproven nature of the regulatory approval process. However, there is on-going GM 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 GM technology. While products like corn and cotton are not grown in New Zealand, there is an increasing recognition that genetic modification could be used to develop products with agronomic benefits suitable to New Zealand and positive impacts for food security and environmental problems mitigation. Media articles over the last two years have suggested the need to rethink New Zealand's restrictive stance on GM technology or risk being left behind by competitor countries that have embraced the technology. Some primary sector organizations and farmers remain cautious about the use of GM technology out of concern that it will tarnish New Zealand's "clean and green" image and negatively impact on the ability to market products overseas.

It would seem that just below the radar of the public media there is a groundswell of thinking that genetic modification is a technology that could have significant beneficial outcomes not only in terms of production efficiency but also in terms of environmental footprint. There is an initiative by the scientific community to see the HSNO Act regulations moderated to make it more efficient and less costly.

GM food products sold in New Zealand must be approved by Food Standards Australia New Zealand (FSANZ). To date, FSANZ has approved 54 GM food products. All GM foods sold in New Zealand must be labeled. GM animal feed falls outside of the HSNO Act and may be imported into New Zealand as the governing legislation does not differentiate between GM and non-GM feed. Meat and other products from animals that have been fed GM feed do not need to be labeled.

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

SECTION II. PLANT BIOTECH TRADE AND PRODUCTION

Production and Trade Situation

New Zealand permits the import of genetically modified food products that have been approved by Food Standards Australia New Zealand (FSANZ). To date, FSANZ has approved 54 food products, with GM events contained within them, for import into New Zealand. New Zealand also permits the import of GM animal feed. In the year to end April 2012, New Zealand imported 134,822 tons of soybean meal, primarily for poultry and pig feed. At over 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 GM soybeans.

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Many of the GM crops grown in the northern hemisphere, such as soybeans and cotton, are not commercially grown in New Zealand.

GM Crops & Plant Research

The environment for GM 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 GM technology, but that New Zealand should proceed cautiously, managing the risks associated with GM technology while simultaneously encouraging organic production and sustainable agriculture. Much of the research undertaken to date has been conducted by crown research institutes (CRIs), such as Plant and Food, Scion and AgResearch, which receive both public and private sector funding.

Plant and Food has undertaken GM 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 genetically modified 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. In June 2010, AgResearch scientists and Granslanz Technology Ltd., a subsidiary company, announced that they believe they can improve white clover (*Trifolium repens*) to give grazing animals a higher intake of protein, while at the same time reducing methane emissions. Scientists also believe the genetic breakthrough could improve animal health and reduce nitrogen waste.

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 express genes for drought resistant; 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 is conducting controlled field trials in Florida.

SECTION III. PLANT BIOTECH POLICY

General Policy on Genetic Modification

While the international environment with respect to GMOs 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 genetic modification.

The newly created Environmental Protection Agency (EPA) is now the lead agency in minimizing and managing risks associated with GMOs. Under the 1996 Hazardous Substances and New Organisms (HSNO) Act, all GMOs are prohibited entry into New Zealand unless they have been formally approved by EPA. (This function was recently handled by the Environmental Risk Management Authority (ERMA).) 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.)

What is containment?

Containment requires that an organism and its heritable material be contained and managed within a containment facility. Containment is where basic research takes place to create or develop a GMO and to gather information to apply for a field test or release application. In New Zealand, a field test is considered contained as the 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 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 GMO 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 GM 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 GMO 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 GMO, such as regional restrictions, where the presence of the GMO 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 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 GMOs. 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 GMO, 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 GM Policy

Environmental Protection Agency: On June 3, 2010, the New Zealand Government officially announced the creation of the new Environmental Protection Agency (EPA), which became operational on July 1, 2011. Technical and regulatory functions that fell under the Ministry for the Environment, Ministry of Economic Development, and the Environmental Risk Management Authority have now been brought together and consolidated under the EPA. Among other things, the EPA will be responsible for undertaking all of the functions currently performed by ERMA under the HSNO Act. The functions currently performed by ERMA that will be transferred to the EPA include the following:

- 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 GMOs. The final approving body for standards developed by Food Standards Australia New Zealand is the Australia New Zealand Food Standards Council (ANZSC), which is made up of the Australian Commonwealth, state and territory

Ministers of Health and the New Zealand Minister of Health.

Ministry for Primary Industries (MPI): MPI officially came into being in March 2012 and has assumed all of the roles of the former Ministry of Agriculture and Forestry (MAF), and is the result of the Ministry of Fisheries, New Zealand Food Safety Authority, and Bio-Security New Zealand all being merged to form one super ministry. MPI is responsible for enforcing the conditions for genetically modified organisms imposed by the EPA on approved field tests and conditionally released organisms. This work also involves the inspection of containment facilities for research in containment and ensuring importers comply with the HSNO Act. MPI is also responsible for administering standards for safety, labeling and composition of food sold in New Zealand, including imported food and foods produced using genetic modification.

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 Science and Innovation (MSI): MSI, established in February 2011, was formed through the merger of two agencies - the Foundation for Research, Science and Technology (FoRST) and the Ministry of Research, Science and Technology (MoRST). MSI is now the lead agency driving science and innovation in New Zealand. It is tasked with directing knowledge and technology transfer from the science and innovation sector to businesses and other research users. It is hoped the merger will streamline the science policy and funding functions and create a stronger link between policy and funding allocation.

One of the key themes running through the biological sciences in New Zealand is “ecological sustainability” – an area that MSI sees as having increasing importance in the future, especially as it relates to food security. In this context, MSI takes a holistic view incorporating food safety, environmental sustainability, value chain robustness, and traceability. MSI 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, if any, GM technology will play as it relates to food security and ecological sustainability.

Ministry of Business, Innovation, & Employment (MBIE): MBIE is a new super ministry due to commence operations on July 1st, 2012. This new ministry is important because one of the four existing Government Departments and Ministries due to be merged to form it is the MSI described above. The other Government entities in the merger are: the Ministry of Economic Development; the Department of Labour; and the Department of Building and Housing.

The Approval Process for GMOs

All decisions on the importation and domestic use of living modified organisms that are genetically modified are made by EPA 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 GMO 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 organism for conditional or full release, EPA must first decide whether or not 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 GM crops can be grown, compulsory buffer zones between the GM crop and conventional crops, regulations on planting time, or controls on how the crop is harvested and processed. In the case of GM animals, conditions could include high security fencing and requirements for disposing of waste. Under a conditional release scenario, MAF 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 MAF.

Consultation with the public is an integral component in the case-by-case decision-making process. The HSNO Act requires EPA to publicly notify applications where it considers there is likely to be significant public interest in the application. 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 GMOs. When applications for the release of GMOs in New Zealand are considered by EPA, 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 genetic modification 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 genetically modified organisms. 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.

Contained GM Field Trials

Since the HSNO Act was implemented in 1996, New Zealand has approved 13 applications for GM plant 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 GM trials offshore. A number of groups feel that the New Zealand regulations are too expensive or onerous and they are better able to conduct their trials overseas, particularly in Australia and the United States.

Co-existence

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

GM Food Regulations

GM 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 (ANZFS), a council of Australian and New Zealand health ministers. FSANZ has approved 54 GM food products for sale in New Zealand and there are another 4 applications in progress. See: <http://www.foodstandards.govt.nz/consumerinformation/gmfoods/>

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 GM food, all genetically modified 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 modified 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 genetically modified so that its oil boils at a higher temperature, the oil would have to be labeled, even though no genetically modified material would be present. A genetically modified 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 genetically modified 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;

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

GM 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 GM foods assessed by FSANZ as safe are approved for sale. Negative content labeling such as “GM Free” is not addressed as part of the labeling standard.

Meat and other products from animals that have been fed GM feeds do not need to be labeled as genetically modified. Also, there are no labeling requirements for foods prepared in restaurants, either as takeaways or eaten in situ (this includes takeaway meals prepared in supermarkets).

Meeting the requirements of New Zealand's GM food labeling regulations places a burden on manufacturers, packers, importers, and retailers to take reasonable steps to determine if the food is genetically modified or has a GM ingredient and to ascertain if the GM food is approved. The importer usually has the primary responsibility for ensuring the accuracy of the label and compliance with New Zealand's GM food labeling requirements. Wholesalers and retailers usually demand GM-free declarations from their supplier/importer, which passes liability in the event of GM 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.

MPI does not inspect individual food import shipments for compliance with GM 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 GM content of their food imports based upon information obtained from overseas exporters/manufacturers, and that food product labels indicate GM content if necessary.

The application process for approval of a GM 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 GM 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.

GM Animal Feed Regulations

GM 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 GM and non-GM feed is not made. When imported, animal feed gains entry to New Zealand under its general import health standards, with no distinction made between GM and non-GM animal feed.

The current approach taken by FSANZ recognizes that many animal feeds are derived from the same GM 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 GM 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 GM 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 GM plants intended primarily for feed use to also 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 as a result of inadvertent co-mingling of grain/seeds during transport and storage, and also ensures that their use as feed will not pose indirect risks to humans. Examples of GM 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.

Cartagena (Biosafety) Protocol

The Cartagena Protocol on Biosafety entered into force for New Zealand on May 2005, following New Zealand's ratification of the agreement in February 2005. The protocol regulates the trade of living modified organisms. New Zealand was already assessing genetically modified organisms before 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 living modified organisms (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.

SECTION IV. GM PLANT MARKETING ISSUES

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 NGO organizations often with influence out of proportion with numerical support. These groups seek to prevent commercial releases of genetically modified organisms into the environment as well as to impose restrictions against consumption of foods with GM content.

In New Zealand, there are two major nationwide supermarket chains. One of the chains, "Foodstuffs", a cooperative, has taken a stance on GM whereby it insists on non-GM food ingredients to be used in its house or private branded products including non-GM 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>.

When asked, most New Zealand consumers express caution about GM foods. However, negative attitudes toward GM may be weakening. According to recent surveys and interviews, actual purchasing behavior does not always correlate with expressed negative attitudes toward GM. Likewise, many New Zealand farmers support the commercialization of GM plants appropriate to New Zealand pastoral style agriculture and growing conditions, and have expressed concern that, by not embracing GM technology, 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 GM 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.

However, Associate Professor John Knight of Otago University's Marketing Department would dispute this. He released a report in March 2011 which concludes that it is highly unlikely that introduction of GM 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.

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 cisgenic modification 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 be 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".

Following a break-in and vandalism of Scions GM pinetree contained field trial earlier in 2012, there were a series of online public polls conducted which showed that the general public were 67-75% in favor of the trials.

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

SECTION V. CAPACITY BUILDING AND OUTREACH

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 GM 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 GM technology.

SECTION VI. ANIMAL BIOTECH

Development and Use

There are no commercially grown GM animals in New Zealand. In addition, there are no field trials being carried out at present that would likely to lead to a commercial release of animals containing GM event(s) within the next five years. There have been six applications for contained field trials of GM animals approved, and one application for a conditional release of a GM organism (GM vaccine for Equine Influenza) approved. This approval has not been exercised yet.

AgResearch, New Zealand's largest CRI, has received two approvals to conduct research on GM cows. One approval was to field test GM 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 didn't 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 GM work on transgenic goats, cattle and mice. The human diseases they are working on are diabetes, cancer, human infertility and blood clotting.

Regulation

Animal GM research and commercialization is governed by the same laws and regulations as plants and other organisms as detailed in the plants section 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 which contains or destroys the novel genes.

Public Opinion

While attitudes toward GM 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 GM technology. The items in the Plant GM sections of this report on marketing and public opinion apply equally to animal GM

International Organizations

New Zealand is signatory to parts of the Cartagena Protocol.

Appendix I: Contained Field Trials Approved in New Zealand

| Code | Approval holder | Description | Purpose | Status |
|------------|--------------------------|-----------------------------------|---|--|
| ERMA200479 | Scion | GM Pine Trees | To field test in containment <i>Pinus radiata</i> with genetic modifications to alter plant growth/biomass acquisition, reproductive development, herbicide tolerance, biomass utilisation, wood density and wood dimensional stability | Commenced 1 June 2011 |
| ERMA200223 | AgResearch | GM Goats, sheep and cattle | To develop in containment genetically modified 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 |
| GMF98009 | AgResearch | GM Cattle | To field test, in Waikato, cattle genetically modified 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, <i>Pinus radiata</i> plants with genetic modifications to the genes controlling reproductive development. The total duration of this project including a post-trial monitoring phase is 22 years. | This field test has been completed (including post-harvest monitoring) |
| GMF99005 | Scion | GM Pine Trees | To field test, in the Bay of Plenty (Rotorua), over a period of 9 years, <i>Pinus radiata</i> and <i>Picea abies</i> plants genetically engineered for herbicide resistance. The total duration of this project is 11 years. | This field test has been completed (including post-harvest monitoring) |
| GMF03001 | Crop and Food Research | GM Onions | To field test onions modified for tolerance to the herbicide glyphosate, and to evaluate their environmental impact; herbicide tolerance; agronomic performance; development as cultivars and equivalency to non-genetically modified 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, modified for resistance (modified to contain genes derived from <i>Bacillus thuringiensis</i>), to caterpillar pests like cabbage white butterfly and diamondback moth. | This field test was suspended because of breach of controls and post harvest monitoring has been completed |
| GMR07001 | New Zealand Racing Board | GM Equine influenza vaccine | To gain approval to import for release genetically modified 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 genetically modified 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 |
| 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 - <i>Petunia</i> genetically modified for altered plant form or pigmentation. | Completed |
| GMF98004 | Betaseed Inc. | GM Sugar Beet | To evaluate agronomically important characteristics of herbicide tolerant (phosphinothricin resistant) sugar beet (<i>Beta vulgaris vulgaris</i>). | Completed |
| GMF98011 | Carter Holt Harvey | GM Trees | To field test, in Waikato, pre-reproductive <i>Pinus radiata</i> , in order to study factors influencing gene expression and to assess the influence of genetic modifications, involving the insertion of marker genes, on the growth and morphology of trees. | Completed |
| 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 trials went ahead but likely to have ceased now. |
| GMF98007 | Crop and Food Research | GM Potatoes | To field test, in Canterbury over 5 years, potato cultivars genetically modified for increased resistance to bacterial soft | Completed |

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|----------|---------------------------|-------------|---|-------------------------------|
| | | | rots, to evaluate resistance and yield performance of individual lines. | |
| GMF98008 | Crop and Food Research | GM Potatoes | To field test, in Canterbury over 5 years, potato cultivars genetically modified 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). | Ceased Operation |
| 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. | Ceased Operation |
| GMF98005 | Pioneer NZ Ltd | GM Maize | Import and field test GM maize modified 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 modified to contain Cry1A(b) protein from Bacillus thuringiensis to confer resistance to lepidopteran insects, for breeding purposes, in Waikato. | Unused due to Company Closure |