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Report Highlights:

New Zealand attitudes toward agricultural biotechnology are generally positive, but the issue of genetic modification continues to be a sensitive subject that evokes strong emotional responses. Genetically modified plants and animals are not commercially grown in New Zealand at present. However, a number of contained research trials involving genetically modified organisms are occurring and food products with GM content are legally offered for sale and consumption, following prior approval. New Zealand continues to play an important role internationally in securing international science-based trade rules for agricultural biotechnology products. This report required minimal updating from 2005.

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SECTION I. EXECUTIVE SUMMARY

The term 'biotechnology' tends to be used very broadly in New Zealand to mean technology based on applying biological processes. Genetic modification (GM) is one of these technologies. While attitudes in New Zealand toward agricultural biotechnology are generally positive, the issue of GM continues to be a sensitive subject that evokes strong emotional responses. At present, there is only a limited application of GM-related biotechnology in New Zealand's agricultural industry. When Prime Minister Helen Clark's Labour Government first took office in late 1999, there was concern that it would succumb to pressure from anti-GM groups such as the Greens and ban the possible development or use of biotechnology in New Zealand. This was reinforced by its initial actions, including the imposition of a voluntary moratorium on GMO releases. A year-long Royal Commission inquiry allowed a rational public debate on the issue and the Commission's report provided the general endorsement that the Government needed to move forward. The New Organisms and Other Matters Bill (2003) ended the GMO moratorium and established new regulations for their introduction. The Government has made it clear that the promotion of biotechnology is a key part of New Zealand's plan to move away from an economy still reliant on commodities toward one more based on high value-added, knowledge-intensive products. This is presently being achieved without commercial production of GM produce.

Genetically modified (GM) plants and animals are not commercially grown in New Zealand at present. However, a number of contained research trials involving genetically modified organisms are occurring and food products with GM content are legally offered for sale and consumption after regulatory approval. To date no application has been made for government approval for a commercial release of a GM crop or the sale of fresh/whole GM foods. This appears unlikely to change during the next couple of years and applicants wishing to apply will face regulatory hurdles. While many New Zealand farmers support the commercialization of appropriate GM crop varieties in New Zealand, the sector is approaching the issue cautiously. Embarking on such a path raises concerns as to its impact on New Zealand's 'clean and green' image in important overseas markets.

Although New Zealand does not produce or export agricultural biotech products, it continues to play an important role internationally in securing science-based trade rules for such products. For example, it joined, as a third party, the WTO dispute case taken by the U.S. and others against the EU's moratorium on approving agricultural biotech products. As a party to the Cartagena Biosafety Protocol it has worked to ensure that measures to protect the environment are not unfairly trade disruptive for biotech products.

U.S. agricultural products that are produced through modern biotechnology and exported to New Zealand focus on processed foods and planting seeds. U.S. exporters face regulatory challenges in selling GM foods in New Zealand, including product approval and compliance issues related to stringent labeling requirements. Although many New Zealand consumers appear cautious about purchasing GM foods, most place little effort in sourcing non-GM food products. However, if a GM food product receives negative media attention from anti-GM groups, it is likely to suffer a substantial, but temporary, drop in sales volume.

New Zealand routinely imports modest quantities of planting seeds for forage grass, grain crops, and vegetables. All seeds to be imported into New Zealand are required to be certified as GM free before they can be legally imported into New Zealand for commercial use. MAF accredited laboratories overseas test seed imports for sowing that claim to be free of GM seeds, before being allowed entry into New Zealand. Only seeds of crops that have commercially produced GM varieties are tested for unintentional GM presence. Imports of GM planting seed have to date been limited to research activity. Seeds imported for processing do not have to be tested for unintentional GM presence. The importation of GMOs

into New Zealand is not restricted by sanitary and phytosanitary measures established by Biosecurity New Zealand (BNZ) of the Ministry of Agriculture and Forestry (MAF), once they have been granted approval by the Environment Risk Management Authority (ERMA). GMOs can enter New Zealand under the appropriate import health standard (IHS) established for their species following approval, as they are no longer considered a new organism, and therefore, not restricted by the IHS. For example, Bt Corn would enter New Zealand under the general IHS for corn if ERMA were to grant it approval.

SECTION II. BIOTECHNOLOGY TRADE AND PRODUCTION

Biotechnology is seen as a critical area to New Zealand's ongoing efforts to maintain its competitiveness in the international trade of its agricultural products. Investment from both the public and private sectors is creating a biotechnology industry in New Zealand that stresses benefits to areas critical to New Zealand's agricultural sectors. Despite the importance of biotechnology to New Zealand's agriculture, the issue of genetic modification does not enjoy widespread public acceptance. Although there are several ongoing contained trials, there are no commercial plantings of genetically modified (GM) crops in New Zealand. This is not expected to change in the next couple of years. It is legal, however, to offer for sale food with GM content in New Zealand. Approval for food with GM content is granted on a case-by-case basis.

The biotechnology survey, undertaken by the government agency Statistics New Zealand¹, estimated biotechnology expenditures by companies and research organizations in New Zealand for the 2005 financial year at NZ\$ 517 million, excluding the University sector. Biotechnology related income was valued at NZ\$ 676 million, excluding the University sector (these figures include all biotechnology, including agricultural)².

1 <http://www.stats.govt.nz>

2 <http://www.stats.govt.nz/products-and-services/hot-off-the-press/biotechnology-survey/biotechnology-survey-2005-hotp.htm>

SECTION III. BIOTECHNOLOGY POLICY

The New Zealand government is investing in research for the biotechnology sector as a means to stimulate economic growth and enhance its international competitiveness. The government's framework for its biotech investment is outlined in its Biotechnology Strategy³. Biotechnology, including genetic modification, is identified by the Government as one of three primary areas for direct government involvement. This supports the New Zealand government's Growth and Innovation Framework, which aims to return New Zealand to the top half of the OECD countries, as measured by per capita GDP rankings.

Despite the importance of biotechnology, there are currently no genetically modified crops grown in New Zealand on a commercial basis. Imports of genetically modified material (such as seeds) are for research purposes only. Many of the GM plant species imported for research are sourced from the United States. Although a significant amount of research related to genetic modification is ongoing in New Zealand, there have been no applications to grow genetically modified crops on a commercial scale to date. Current GM research in New Zealand is not conducted with the aim of growing GMOs commercially in New Zealand in the near future. Regardless of this, three main benefits result from this research: 1) New Zealand maintains its research capabilities in GM to ensure that it does not lag behind once GMOs do begin to be commercialized in New Zealand, 2) this research helps develop techniques that are useful in other areas of biotechnology, such as gene markers, and 3) some of this technology is sold to overseas interests, who often invest in New Zealand to perform this research, providing a short-term source of income.

New Zealand is investing heavily in non-GM areas of biotechnology. Research is performed by a combination of Crown Research Institutes (government research organizations), universities and the private sector. New Zealand's principal focus is in the areas of: 1) large animal biology (particularly sheep and dairy cows), 2) plant species important to New Zealand, such as forage grasses to improve the performance of grazing animals, and 3) the development of new products derived from New Zealand's agriculture, such as understanding the raw constituents of milk, its structure and functionality. The website for the Ministry of Research, Science, and Technology (MoRST) describes New Zealand's research strengths⁴.

MoRST is charged with developing New Zealand's research and innovation policies. Although it establishes research allocation guidelines and policies, it contracts other agencies to handle the allocation process. The main distributor of government funding in New Zealand is the Foundation for Research, Science and Technology⁵ (FRST). FRST is a Crown entity charged with investing in innovation and fostering the creating of new knowledge.

The New Zealand government also aids the commercial side of the biotechnology industry. The main organization responsible for this is New Zealand Trade and Enterprise⁶ (NZTE). NZTE performs three main functions in conjunction with the biotechnology sector: 1) work with individual businesses to build their commercial capacity, 2) improve the business environment to foster enterprise and growth, and 3) help build international linkages. The focus when building international linkages mainly relates to international research collaboration and sourcing finance. An example of improving the business environment is NZTE's involvement with the creation of NZBio⁷. NZBio is primarily tasked with accelerating growth of the biotechnology sector by creating opportunities and removing barriers in the sector. NZBio achieves this by working with both government and industry.

³ <http://www.morst.govt.nz/?CHANNEL=BIOTECHNOLOGY&PAGE=Biotechnology>

⁴ <http://www.morst.govt.nz/?CHANNEL=NZ%27S+STRENGTHS&PAGE=NZ%27s+strengths>

⁵ <http://www.frst.govt.nz/>

⁶ <http://www.nzte.govt.nz/>

⁷ <http://www.nzbio.org.nz>

NEW ZEALAND REGULATION OF GM

Two statutory regulatory bodies manage the use of GMOs and foods with GM content under New Zealand's regulatory framework. The Environmental Risk Management Authority⁸ (ERMA) regulates new organisms, while Food Standards Australia New Zealand⁹ (FSANZ) regulates food safety and labeling and undertakes safety assessments of GM foods. New GMOs and food with GM content are assessed on a case-by-case basis by either of these agencies before they can be used or sold in New Zealand. Two other government agencies are worth noting. The New Zealand Food Safety Authority¹⁰ (NZFSA) is responsible for food safety and the suitability of standards, as well as their implementation and enforcement. Biosecurity New Zealand¹¹ (BNZ), which resides within the Ministry of Agriculture and Forestry¹² (MAF), is responsible for allowing the entry of products into New Zealand. GMOs can enter New Zealand under Import Health Standards (IHSs) developed by BNZ for their appropriate species, once approved by ERMA or FSANZ. Prior to this, they are considered new organisms and will be denied entry by BNZ. For example, Bt Corn could enter New Zealand under the general IHS for corn while GM food for human consumption enters under the appropriate general IHS. MAF accredited overseas laboratories test/analyze seed imports for sowing that claim to be free of GM seeds before being allowed entry into New Zealand.

Detailed information on New Zealand regulations is outlined below for: 1) importing and growing genetically modified organisms, 2) GM food approval and 3) GM animal feed regulations.

REGULATORY FRAMEWORK FOR GROWING GMOS

Rules governing the introduction of GMOs into New Zealand are outlined in the Hazardous Substances and New Organisms (HSNO) Act¹³ (1996). The HSNO Act is administered by the Ministry for the Environment, but the Act's implementation is the responsibility of ERMA, an independent body established under the Act. ERMA's review of applications for the release of GMOs is undertaken on a case-by-case basis. The Minister for the Environment expressed the view in 2003, that New Zealand would benefit from allowing the "cautious, considered release" of GMOs, with a resulting small increase in New Zealand's GDP over the next decade.

The HSNO Act was most recently amended by the New Organisms and Other Matters (NOOM) Bill (2003) in October 2003. The NOOM Bill came into effect to coincide with the expiry of New Zealand's voluntary two year moratorium on the introduction of GMOs. The NOOM Bill set new regulations for the introduction of GMOs. New Zealand's commercial release moratorium had precluded applications for the commercial planting of biotechnology crops, the commercial importation of biotechnology seeds, the release into the environment of biotechnology animals and, to a lesser extent, human and veterinary medicines containing GMOs. It did not, however, affect the use and sale of processed biotechnology foods and ingredients. The moratorium gave the government time to assess environmental implications and the implementation of a legislative framework for biotechnology. Further information regarding the HSNO Act is available on the ERMA website.

The NOOM Bill 2003 created a "conditional release" category of approval for new organisms, including biotechnology products. This permits ERMA to accept for review and its approval

⁸ <http://www.ermanz.govt.nz/>

⁹ <http://www.foodstandards.govt.nz/>

¹⁰ <http://www.nzfsa.govt.nz/>

¹¹ <http://www.biosecurity.govt.nz/>

¹² <http://www.maf.govt.nz>

¹³ <http://www.legislation.govt.nz>

applications for release of biotechnology products with controls applied on a case-by-case basis. These control measures allow ERMA to impose conditions to prevent, minimize or manage any risks identified during the risk assessment. They are set based on the type of GM application, from laboratory to contained field trials. MAF monitors implementation of these controls. Under the provisions of the NOOM Bill, ERMA can approve a conditional release for biotechnology products that will allow field trial activity to expand from the limited scope of a fully contained trial to larger farm-scale. It also allows for applications to sow commercial crops. To date there have been no applications for a conditional release. Further information can be found at the ERMA website¹⁴. This includes the application process for the seven categories of approval for the importation and/or development of GMOs and a schedule of fees. Additional resources are available elsewhere on the site, including reports and media releases regarding some of the contained trials that have been approved¹⁵.

Of the approval categories, there are two of relevance to those wishing to grow GMOs on a commercial basis in New Zealand. The first is 'Release of a New Organism.' If approval is granted under this category a new organism will be allowed uncontrolled use in the environment. Such approval for a GMO is extremely unlikely under New Zealand's current regulatory environment. The other category is the 'Conditional Release of a New Organism.' This category includes a broad range of circumstances, from a contained scientific trial through to a full commercial release. Under a conditional release ERMA is able to specify restrictions on the GMO. Examples include where the crop or animal is located, conditions under which it could be grown and used, and what type of monitoring needs to be implemented. Section 38D of the HSNO Act outlines some of the controls that may be placed on an application. To date ERMA has not received an indication that applications to commercially grow GMOs in New Zealand in the near future are likely.

Currently only contained trials are being undertaken with GMOs in New Zealand. The categories of interest for researchers are 'Import a New Organism into Containment,' 'Develop a Genetically Modified Organism in Containment,' and 'Field Test a New Organism in Containment.' Both importing a new organism into containment (both GM and non-GM) and developing a GMO in containment are applicable for a variety of purposes, such as research and production of biopharmaceuticals. Unless otherwise stated in the approval, such an approval is not restricted to the applicant and may be used by anyone, provided that all controls are adhered to.

The category of 'Field test a new organism in containment' is suitable for researchers wishing to grow a GM crop for research purposes. If approved, containment requirements are outlined in the approval in order to manage any risks to the environment or human health and safety. These controls can include factors such as the length of time the approval is valid for, the size of the trial, requirements for removal of any heritable material at the end of a GMO trial and reporting requirements during the trial.

The New Zealand government has not set regulatory guidelines governing co-existence of GM and non-GM crops. Instead, ERMA will set control measures related to coexistence for each individual approval of a conditional release of a GM crop. Controls would include, but not be limited to, specifying planting distances and buffer zones. The New Zealand Government has publicly expressed the belief that New Zealand can allow organic crops, conventional crops, and GM plants and animals to co-exist without curtailing anyone's rights. The Minister for the Environment suggested in 2003, however, that it "might be years before

¹⁴ <http://www.ermanz.govt.nz/no/index.asp>

¹⁵ <http://www.ermanz.govt.nz/resources/no-pubs.asp>

any significant release of GMOs occurs in New Zealand and that GM fresh food is not likely to be on sale in New Zealand for at least five years."

Following the introduction of the NOOM Bill, some industry participants have maintained that the cost associated with gaining new organism approval and the regulations that had to be met were prohibitive. This reduced the number of applications. Indeed, between the introduction of the HSNO act in 1996 and ERMA's review in 2004, there were no importations of new plant species, either GM or non-GM, on a commercial basis. ERMA addressed industry cost concerns in 2004, standardizing and significantly reducing application costs. ERMA has since received positive feedback regarding the current regulations and their associated costs.

New Zealand's GMO-related regulations can appear daunting to foreign investors. Most industry participants argue, however, that although complex, New Zealand has a very robust and consistent regulatory system in place, which is not burdensome to work through once understood. Although contained field trials of GMOs are undertaken in New Zealand, ERMA has to date received no indication of applications potentially being made in the next couple of years for the commercial release of GMOs. Regulations surrounding a commercial release would be far more stringent and burdensome than those of a field trial. In a separate issue, New Zealand's Green Party attempted to reinstate the moratorium on GMOs. A Member's Bill was introduced in March 2005, but was voted out of Parliament at its first reading.

Criteria Considered by ERMA for GMO Releases

Applications to ERMA seeking Government approval for the release of a GMO into the environment must describe in detail all scientific evidence available regarding the nature of the organism. If conditional release were requested at a farm-scale, data in the submission regarding fully contained field trials would be included in the approval request packet. Included in the application should be evidence of: 1) the anticipated economic costs and benefits if approval is granted, 2) the anticipated impact of the organism on the environment, and 3) data related to human health and potential impact on food safety if it is a food crop. Also included in the application should be information related to Maori interests and the results of consultations with the Maori. The NOOM Bill adds cultural, spiritual, and ethical considerations to the list of criteria against which the Minister for the Environment may initiate a "ministerial call-in" which allows the Minister rather than ERMA to make the final decision on approval of an application to release a GMO into the environment.

Although ERMA's application costs for a commercial release are now considered by many to be low, the cost and time involved in public consultations, outlined above, is extremely high. Many industry participants view this as the main reason for the lack of GMO applications for commercial release in the foreseeable future. The cost of public consultations far outweighs the likely benefits of commercially growing a GM crop and the first to attempt the process will face substantial hurdles.

Approvals for field tests of a GMO are restricted to the applying organization only, requiring other organizations to apply separately if they wish to run trials containing the same GMO. However, organisms may be approved for use by people/organizations other than the original applicant if the use of an approved organism will be under exactly the same circumstances as the original approval. In the case of a conditional release (for example, to commercially grow a GMO crop) the approval could either be restricted to one user or left open, allowing anyone the opportunity to grow the crop in future. Unless specified, there is no time limit on applications. As a result, many applications approved by ERMA in 1998 and 1999 remain valid and are still in use by some applicants. Conditional release approvals expire either on the close of the date on which the last control that the approval relates to,

or five years after the date on which the approval is granted. In the case of a full release, the approval will lapse in five years if not used.

The HSNO Act, as amended by the NOOM Bill, includes penalties for those who fail to maintain compliance with the introduction of new organisms. Breaches of the Act and its regulations are subject to a schedule of fines. Penalties can be imposed up to NZ\$ 500,000 per individual or NZ\$ 10 million per company. If it is determined that a contravention of the regulations, i.e. the terms set for the conditional release of the GMO by ERMA, has occurred in the course of producing a commercial gain, the non-compliant company can be subjected to a fine equivalent to three times the estimated gain or 10 percent of the company's annual revenue.

Certification of Imports of non-GM Planting Seeds

New Zealand requires that all imports of non-GM planting seeds, which have commercially grown GM varieties available, be tested and certified as free of any GM seeds. On August 1, 2002, MAF implemented a final protocol that required testing certification for the unintentional presence of GM corn in conventional sweet corn (maize) seed imports. In October 2002, MAF expanded its GMO-free planting seed certification requirements by implementing an IHS for testing rapeseed, followed by one for soybeans in January 2003. New Zealand has a zero tolerance policy in regard to the presence of GM varieties -- if any GM seed is detected, regardless of the level of contamination, that shipment will be rejected.

In 2004, traces of Bt11 corn were detected in sweet corn samples taken from several fields in the North Island. MAF was unable to determine with certainty the source of the Bt11 corn. The possibility was discussed that the original seed lines imported from the United States may have contained GM seeds even though they were documented as GM-free before entering New Zealand. At the time of the detection, Bt11 -- and all other GM corn varieties - - could not legally be grown in New Zealand on a commercial basis. Bt11 corn, however, does appear on the list of genetically modified foods approved by FSANZ for human consumption in New Zealand.

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 states that it ratified the Protocol to be a 'good international citizen'. The New Zealand government, with its strong environmental policy focus, favors the Cartagena Protocol. 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 has made interventions during past Protocol meetings that have been helpful to the United States' position. Both countries are concerned about documentation requirements, liability and compliance arrangements, and potential conflicts with other international obligations. New Zealand helped to shape more balanced decisions at the meeting in May 2005. New Zealand's Green political party was very critical of New Zealand's role in the talks in Brazil during March, 2006, stating that New Zealand was preventing agreement on documentation requirements under the Protocol.

GM FOOD APPROVAL

Foods with GMO content can be offered for sale and consumption in New Zealand after being assessed and approved by FSANZ. This is the result of a mandatory standard for foods produced using modern biotechnology, which came into effect in 1999. GM food (including assessment, approvals and labeling) is regulated under the joint Australia and New Zealand

Food Standards Code. The Code was established under a bilateral Treaty, 'Agreement between the Government of New Zealand and the Government of Australia Establishing a System for the Development of Joint Food Standards' (1995, amended 2002). This is provided for in legislation under the Food Act 1981, which prohibits the sale of food produced using gene technology, unless the food has been assessed by FSANZ and listed in the food code standard. Approval for food with GM content is granted on a case-by-case basis. The approval process is very transparent and open for public comment. The technical assessment undertaken is consistent with the Codex Alimentarius Commission's Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and subordinate safety assessment guidelines.

Information for those wishing to apply to FSANZ to introduce a new food produced using gene technology, as provided for in the Australia New Zealand Food Standards Code, is available on the FSANZ website¹⁶. FSANZ had received 34 applications for safety assessments of bioengineered foods as of February 2006¹⁷. Of these, 29 had been approved, three applications were being processed, and two applications were withdrawn. A summary of FSANZ review results for applications of GM foods for human consumption, as well as its general policies for GM food, are available on the FSANZ website¹⁸.

Labeling of Food with GMO Content

Mandatory New Zealand labeling requirements for foods produced using gene technology became effective in December 2001. They are among the world's most stringent. Biotechnology labeling is required if a food in its final form contains detectable DNA or protein resulting from the application of gene technology, with a few exceptions. The New Zealand government believes that its labeling requirements provide consumers the information necessary to decide whether or not to consume foods with GMO content and are not based on food safety concerns.

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.

The labeling of ingredients required of all food products for sale in New Zealand is covered by Standard 1.2.4¹⁹ of the Australia New Zealand Food Standards Code. Unless specifically exempted, all packaged food must include a statement or list of ingredients and compound ingredients used in the manufacture of that food on the label. The labeling of food produced using gene technology is explained in Standard 1.5.2²⁰.

Foods produced using gene technology are required to be labeled as such. NZFSA defines this as food that is, or contains as an ingredient, including a processing aid, a food in its final form produced using gene technology that contains novel DNA and/or novel protein, or has altered characteristics. This definition does not extend to the following

¹⁶ <http://www.foodstandards.gov.au/standardsdevelopment/informationforapplic559.cfm>

¹⁷ <http://www.foodstandards.gov.au/whatsinfood/gmfoods/gmcurrentapplication1030.cfm>

¹⁸ <http://www.foodstandards.gov.au/whatsinfood/gmfoods/index.cfm>

¹⁹ http://www.foodstandards.gov.au/srcfiles/Standard_1_2_4_Labelling_of_Ingred_v74.pdf

²⁰ http://www.foodstandards.gov.au/srcfiles/FSC_1_5_2_GM_v77.pdf

- 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
- 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
- Flavors present in the food in a concentration no more than 1g/kg
- A food, ingredient or processing aid in which genetically modified food is unintentionally present in a quantity of no more than 10g/kg per ingredient

There is a one percent threshold for the unintentional presence of a GMO in non-GM food. Additionally, animals fed GM feed are not regarded as GM food.

The label on a package of genetically modified food must include the statement 'genetically modified' in conjunction with the name of that food, food ingredient, food additive or processing aid. Unpackaged foods for retail sale (such as unpackaged fruit and vegetables, or unpackaged processed or semi-processed foods) must carry a display with the statement 'genetically modified' in association with the food or with the particular ingredient within that food. GM food prepared for immediate consumption, such as restaurant and take-away food, and catered meals do not need to be GM labeled, although consumers can request this information from businesses.

GM-Free Labeling

New Zealand's Commerce Commission has developed guidelines informing suppliers of how 'GM-free' labeling of products may be used, interpreted and enforced. It is intended that these guidelines will provide suppliers with an opportunity to minimize the adverse outcomes of an accidental Fair Trading Act breach (with regard to truth-in-labeling requirements), as well as strengthening consumer confidence that GM-free claims are well founded. GM-free means the complete absence of any genetically modified material, or use of a genetic modification process, in a food or food product. As it is a voluntary initiative, responsibility for developing a successful GM-free labeling system ultimately rests with stakeholders.

These guidelines were developed as a result of the New Zealand government's policy, which supports the position that consumers should have the choice whether to eat GM foods or not. This is made possible to a certain extent by New Zealand's food labeling requirements. The Royal Commission on Genetic Modification noted, however, that some people are concerned that food not labeled as containing GM content may contain some GM material, or may have been manufactured using a process involving genetic modification. This is the result of an information gap under Standard 1.5.2 due to several exemptions from the mandatory labeling of GM material or processes.

The New Zealand government directed an interdepartmental working group, consisting of the Ministry of Consumer Affairs and the New Zealand Food Safety Authority, to facilitate the development of this voluntary "GM-free" labeling system. This follows the findings of the Royal Commission on Genetic Modification. The Commission identified consumer demand for more information than the Joint Australia New Zealand Food Code requires about whether a food results from a genetic modification process or contains any GM material. Within this context, a key issue the Commission identified for consideration was "can people choose whether or not to eat genetically modified food?" Two exemptions in the code that contribute to this information gap are for flavorings and the unintentional presence of GM material, as long as the amounts involved do not exceed certain percentage thresholds. If they exceed these thresholds, then the flavoring or ingredient would have to be declared on the label. The other exemption is for food intended for immediate consumption, such as that available at restaurants, cafes, and take-away, self-vending and self-catering outlets. These shortcomings motivated the implementation of the voluntary GM-free labeling system, giving

companies the opportunity to assure their consumers that food products are completely free of GM or GM derived product.

Compliance

The NZFSA does not inspect individual food import shipments for compliance with GM-food labeling requirements. Periodic compliance audits conducted by NZFSA 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 NZFSA is currently reviewing its domestic food regulatory program, including penalties and sanctions to ensure they represent an adequate economic deterrent. It is intended that New Zealand food law will be consistent across sectors, and will be proportionate to the severity of other offence. There are no proposals for specific penalties relating to GM food.

A retail food audit conducted by NZFSA in September 2004 reportedly found 17 of the 117 processed products evaluated to have genetically modified (GM) content that exceeded a one percent threshold. These included two products that had been labeled as GM-free, which were referred to the New Zealand Commerce Commission for action under the Fair Trading Act 1986. Additional NZFSA measures were taken to ensure that companies involved with those products whose labels failed to provide information on their GM content, but did not have false GM-free declarations, meet future labeling compliance standards.

GM ANIMAL FEED REGULATIONS

Regulatory approval is not required to feed GM feed to animals. This 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 defined. When imported, animal feed gains entry to New Zealand under its general IHS, with no distinction made between GM and non-GM animal feed.

SECTION IV. MARKETING ISSUES

Biotechnology continues to be a politically sensitive subject in New Zealand that evokes strong opposition from the Green Party as well as other influential organizations. 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.

New Zealand consumers are usually cautious when purchasing GM foods and have tended to avoid such foods when the GM debate was visible in recent years. Such attitudes may be weakening. Most New Zealanders place little effort in sourcing non-GM products and are unlikely to check the ingredients list of processed food products for the presence of GMOs. However, any GM food that receives negative media attention from anti-GM groups is likely to suffer a substantial, but temporary, drop in sales.

Most New Zealand farmers support the commercialization of appropriate GM varieties of crops in New Zealand. They are, however, cautious in their approach to potential application. Before making planting decisions, most will want assurances that there will be marketing opportunities for GM crops and that existing and potential markets for their non-GM products will not be disadvantaged by growing GM crops.

SECTION V. CAPACITY BUILDING AND OUTREACH

Outreach programs organized by FAS in New Zealand have mainly involved the use of recognized U.S. speakers promoting the benefits of biotechnology to New Zealand. The most recent was the Embassy supported visit of James Maryanski of the FDA in March 2005. He was a guest speaker at the first annual biotechnology conference organized by NZBIO. He shared FDA's experiences in addressing safety and regulatory issues related to GM foods in the United States. Dr. Maryanski met appropriate government officials and presented to the public in Wellington.

A year earlier, FAS and the Embassy's public affairs office organized the visit of Gregory Conko and Richard Fawcett to New Zealand. Their main aim in New Zealand was to promote the uptake of biotechnology in New Zealand by outlining its benefits and pointing out the flaws in the statements of detractors. They discussed issues such as biotechnology's impact on farming, the environment and consumer safety. They spoke at several venues, ranging from presentations to the public and press to meetings with government officials and industry groups.

In February 2003, FAS and the Embassy's public affairs section organized the visit of Patrick Byrne and Martina Newell-McGloughlin to New Zealand. They addressed the question of coexistence and the promise of the technology. They spoke to a variety of audiences, from the public to government officials and other scientists.

SECTION VI. REFERENCE MATERIAL

The Environmental Risk Management Authority – regulator under the HSNO Act
www.ermanz.govt.nz

The Ministry for the Environment – administers the HSNO Act
www.mfe.govt.nz

Food Standards Australia New Zealand – developed the safety and labeling standards, and undertakes any safety assessments, for GM foods
www.foodstandards.govt.nz

New Zealand Food Safety Authority – responsible for food safety and suitability standards/implementation/compliance/enforcement in New Zealand
www.nzfsa.govt.nz

Biosecurity New Zealand – part of the Ministry of Agriculture and Forestry responsible for imports into New Zealand
www.biosecurity.govt.nz

Ministry of Research, Science and Technology – implements the government’s research strategy and regulations
www.morst.govt.nz

Foundation of Research, Science and Technology – contracted by MoRST to allocate the majority of government funding for research
www.frst.govt.nz

Searchable database listing research projects that FRST has contributed funding to
<http://www.frst.govt.nz/database/abstracts/index.cfm>

NZbio – an incorporated society tasked with assisting the growth of New Zealand’s biotech sector
www.nzbio.org.nz

New Zealand Trade and Enterprise – assists and promotes New Zealand businesses
www.nzte.govt.nz

Biotechnology learning hub
<http://www.biotechlearn.org.nz/>

New Zealand’s Bioethics Council
<http://www.bioethics.org.nz/>

A list of New Zealand’s Crown Research Institutes
<http://www.morst.govt.nz/?CHANNEL=CROWN+RESEARCH+INSTITUTES&PAGE=Crown+research+institutes>

New Zealand’s Biotechnology Strategy
<http://www.morst.govt.nz/?CHANNEL=Biotechnology&PAGE=Biotechnology>

Full Text of the Hazardous Substances and New Organisms Act (1996)
http://www.legislation.govt.nz/libraries/contents/om_isapi.dll?clientID=642503312&hitsperheading=on&infobase=pal_statutes.nfo&record={6156CE5F}&softpage=DOC