CURRENT AWARENESS OF GENETICALLY MODIFIED FOOD ISSUES

PROJECT F99

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SUMMARY

This report is one of a series intended to provide the New Zealand Ministry of Health with an independent source of current information on issues related to genetically modified foods. This report covers developments in the period April - June 2001.

1 INTRODUCTION

This project is intended to provide the Ministry of Health with an independent source of current information on genetically modified foods (GMFs). As defined in the project specification it is intended to include:

- scientific issues concerning safety, detection, and nutritional quality of genetically modified foods;
- the legislative situation overseas.

The aim is to condense this material into a useful form so that the Ministry can respond to issues and enquiries from other government agencies, industry and the general public. The project also aims to provide information to support the development of an appropriate enforcement strategy on standards for genetically modified foods.

This is the third of four reports for the 2000/2001 year and covers events from 14 March to 22 June 2001 (when the draft report was submitted to the Ministry of Health).

Wider issues concerned with environmental or social effects of genetic modification and genetically modified organisms (GMOs), biodiversity, gene transfer, insect resistance etc, are only covered peripherally in this report. This reflects the division of responsibility for genetically modified material, between the Ministry of Health and the Australia New Zealand Food Authority (ANZFA) for GMFs on one hand, and the Environmental Risk Management Authority (ERMA) for GMOs on the other.

For consistency, some alternative terms have been standardised in this report. "Corn" and "maize" are interchangeable; in this document "corn" is used throughout. Canola is a genetic variation of rapeseed (or oilseed rape) developed by traditional plant breeding to be low in both erucic acid and glucosinolates ("double low" variety). In this document "rapeseed/canola" is used throughout.

Abbreviations used throughout this document:

EU: European Union
FDA: Food and Drug Administration (US)
USDA: United States Department of Agriculture
MAFF: United Kingdom Ministry of Agriculture Fisheries and Food
ACNFP: Advisory Committee on Novel Foods and Processes (UK)
ACRE: Advisory Committee on Releases to the Environment (UK)
ERMA: Environmental Risk Management Authority
ANZFA: Australia New Zealand Food Authority

An important source for this project is the AgNet email newsletter produced by staff at the University of Guelph. Information and archives of the newsletter can be found at:

http://www.plant.uoguelph.ca/safefood/

2 DETECTION OF GENETICALLY MODIFIED FOODS: RECENT DEVELOPMENTS

2.1 Probability of GMO Copies in a DNA Sample

A letter to the journal Nature Biotechnology has discussed the factors influencing the limit of detection for GM foods (Kay and Van den Eede, 2001). One factor is that the weight of the genomic DNA from plants is large. For example, in a typical 100ng DNA sample used for PCR analysis, a single copy of the corn genome would represent 0.0027%. This indicates that there are practical lower limits for detection of GMOs.

A second problem is sampling error. It is generally acknowledged that sample sizes for GMO detection must be of a sufficient size to provide confidence that a low level of GM presence will be detected in the bulk material. This requires consideration of the likelihood that a GM unit (soybean, corn kernel) will be present in a sample of a defined size. This letter points out that the same issue applies to the subsampling of the homogenised sample i.e. the likelihood of a copy of the genome from a GM unit occurring in a subsample of a defined size will be a distribution around the actual level of GM material. Sampling errors become proportionally larger as the amount of target DNA in the sample becomes lower.

2.2 Criticism of Test Strips for Detecting GM Crops

A study of the performance of the SDI lateral flow test for Roundup Ready soybeans has been published (Fagan *et al*., 2001). Operators at grain handling facilities conducted analyses on a series of blinded samples containing defined proportions of conventional and transgenic soybeans. The rate of false negative results indicated that the kit was useful to screen soybeans that contain high levels of GM material, but would not be effective in detecting GM material at the level of 1% or lower. Limitations in operator performance rather than defects in kit materials were the primary contributors to the errors observed in the studies. The kits were reliable if carried out correctly. A similar kit to that used for this study has been approved by the USDA for the detection of the Cry9C protein in Starlink corn.

The study has been criticised by the American Crop Protection Association/Analytical Environmental Immunochemical Consortium, on the basis of poor study design. Their analysis of the paper is available at:

http://www.aeicbiotech.org/tech_notes/tech_comments.pdf

2.3 Future Testing Needs

A report by a US company, Strategic Consulting, predicts that the GM testing market will expand over the next 5 years. They predict that the current area of GM crops of 43 million hectares will expand to 85 million hectares by 2005. Testing is predicted to shift from determining the absence of GM contamination in GM free materials, to ensuring the presence of GM traits in future generations of crops. These future crops are predicted to have traits that confer advantages to food processors, and consumers (Source: Strategic Consulting press release 6 April 2001 via AgNet). The company has a website at:

http://www.strategic-consult.com/

3 GMF APPROVALS

The table of information on food use approvals of genetically modified crop plants from around the world has been updated to June 2001 and appears in Appendix 1. The focus is on food use approvals granted after assessment by the relevant national body (for example FDA in the US, ACNFP in the UK, or ANZFA in Australia and New Zealand). It does not cover approvals for environmental safety, cultivation or field trials. These are usually assessed by different national regulatory authorities (for example USDA in the US, ACRE in the UK, ERMA in New Zealand).

It is important to note that in the United States the FDA do not “approve” the use of GM foods. Their 1992 policy found that the safety of such foods would be covered by existing legislation and instead the industry could simply conduct a voluntary premarket consultation with the FDA. Currently the FDA is in the process of making such a pre-market consultation mandatory. The dates given in the table for the US refer to the date of the consultation.

4 LEGISLATIVE POSITION OF OVERSEAS GOVERNMENTS REGARDING GENETICALLY MODIFIED FOODS

4.1 Food Use Approvals

4.1.1 European Union

On 14 February 2001 the European Parliament adopted a joint text concerning the deliberate release into the environment of genetically modified organisms. This text effectively replaces Council Directive 90/220/EEC. The member states now have 18 months after the approval date to incorporate the regulation into national law.

The full Directive is available at:

http://europa.eu.int/eur-lex/en/archive/2001/l_10620010417en.html

although it is required to be a registered subscriber to access the document. An alternative source is:

ftp://debate:friends@sgiserv.unibe.ch/home/debate/Directive2001-18-EC-Engl.pdf

The following background to the revisions proposed for the amended directive is taken from an ISB News Report (http://www.isb.vt.edu) via AgNet (written by Shane Morris Centre for Safe Food University of Guelph mailto:morris@uoguelph.ca)

"On February 23, 1998, the Commission adopted a Proposal for a Directive, which was intended to amend Directive 90/220/EEC on the deliberate release into the environment of GMOs. The Proposal sought to increase the transparency and efficiency of the decision-making process, promote harmonization of risk assessment, and introduce clear labelling requirements for all GMOs placed on the market. The Commission hoped to clarify the scope and definitions of the Directive and included all direct and indirect ecological aspects. In addition, it proposed to introduce mandatory monitoring for GM products and mandate a time limitation (renewable) of ten years, maximum, for first-time consent. The commission also hoped to introduce compulsory monitoring of GMOs after they have been placed on the market, provide for a common methodology to assess the risks associated with their release, and include a mechanism to allow the release of the GMOs to be modified, suspended, or terminated when new information on risks becomes available.

The agreement reached this month as a result of conciliation covers in particular the following issues:

- Marker genes. A deadline was introduced for the gradual elimination of antibiotic resistance markers in GMOs, specifically, the end of 2004 for commercial releases (part C) and end of 2008 for research purposes (part B).
- Environmental liability. The Commission undertook to bring forward a legislative proposal on environmental liability before the end of 2001, covering also damage resulting from GMOs.

- Interaction effects. Potential cumulative long-term effects associated with the interaction of GMOs with the environment and other GMOs are taken into account in the context of the risk assessment carried out prior to authorization.
- Pharmaceuticals. The compromise provides an exemption for pharmaceuticals used for human research purposes (part B of the directive), provided that the sectoral Community legislation governing their authorization fulfils certain criteria (e.g., an equivalent risk assessment, explicit consent).
- Public registers. It was finally agreed that GMOs released in the trial period (part B) should be registered and details of the trial release made available to the public. The locations of GMOs to be released for market (part C of the Directive) will require that notification is placed with the appropriate authorities and made known to the public in a manner deemed appropriate.
- Time-limited consent. The first-time consent for a release of GMOs is limited to a maximum of ten years. It was agreed that the renewal of an initial authorization would also be limited in time. As a general rule, the renewed consent will be valid for an additional ten-year period. This period may be limited or extended under special circumstances.
- Labelling and traceability of GMOs. The Directive contains general rules on traceability and labeling of GMOs. In addition, the Commission announced its intent to propose appropriate legislation on traceability and labeling for GMOs and products derived from them.

The new Directive also includes the following proposals:

- mandatory monitoring after GMOs are placed on the market;
- mandatory consultation of relevant Scientific Committee(s);
- mandatory consultation of the public concerning both experimental and commercial releases;
- the application of the precautionary principle when implementing the Directive;
- the opportunity for consulting Ethics Committee(s) on issues of general nature; and
- the institution of a new inter-institutional procedure (comitology) in accordance with Council Decision 1999/468/EC of June 28,1999, which includes consultation with the European Parliament and the possibility for Council to adopt or reject a Commission Proposal by qualified majority."

To complete the updating of the framework of legislation for GMOs in Europe, new proposals on labelling and traceability of GM foods are expected to be announced by the EU in late June 2001 (Source: Reuters 12 June 2001 via AgNet).

4.1.2 Sri Lanka

In April 2001 the Sri Lankan Minister of Health announced regulations prohibiting the import of any foods containing GM ingredients. Furthermore, importation of a range of foods, principally soy and corn derived, were prohibited unless they were accompanied by a certificate from an accredited laboratory or competent government authority certifying that they did not contain any material or ingredient that had been subjected to genetic modification (Source: Sri Lankan legislation). The ban had been intended to come into effect on 1 May 2001, but has now been postponed till September 2001, after protests by traders seeking more time to comply (Source: Agence France Presse 11 June 2001 via AgNet).

4.1.3 Thailand

In May 2001 Thailand approved Roundup Ready soybeans for human consumption, the first GM crop to be approved in that country. The approval was given by the Thailand Biosafety Centre (Source: AgWeb News 1 May 2001 via AgNet).

4.1.4 Japan

In May 2001 the Japanese Ministry of Agriculture approved several GM plant varieties (herbicide tolerant corn NK603, Bt corn MON863, and herbicide tolerant rice G2-59, G2-70 and G2-138). Full approval of the varieties is pending a mandatory safety assessment by the Ministry of Health, Labour and Welfare (Source: AgWeb News 18 May 2001 via AgNet).

4.2 Rule Making by International Organisations

4.2.1 Codex Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology

The Codex Ad Hoc Intergovernmental Task Force on Food Derived From Biotechnology was established in July 1999 with a 4 year time frame. The purpose of the Task Force is to develop international standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology.

The first meeting of the Task Force was held in Chiba, Japan in March 2000. At that meeting a programme of work was decided that included the development of two major texts:

- A set of broad general principles for risk analysis of foods derived from biotechnology; and,
- Specific guidance on the risk assessment of foods derived from biotechnology, with priority given to foods of plant origin.

The second meeting of the Task Force was held from 25-29 March 2001, also in Chiba Japan. It continued work on development of the two texts.

1. Proposed draft principles for the risk analysis of foods derived from modern biotechnology.

   This document incorporates the overarching principles for risk analysis. A key part of the document is the definition of “modern biotechnology” and “conventional counterpart”. The “modern biotechnology” definition was formulated to be consistent with the Cartagena Protocol on Biosafety. The “conventional counterpart” is required as a comparator for application of the “substantial equivalence” concept. The proposed definition left open the possibility that in the future foods derived from modern biotechnology could be used as conventional counterparts. This was debated, and finally it was agreed to leave this possibility open, but noted that for the foreseeable future such foods would not be used as comparators.

The most contentious issue of the meeting was the inclusion of traceability as a risk management measure. This issue was linked with the need for post market monitoring, as traceability would be an important tool in conducting such monitoring. A paper on traceability, prepared by the delegation from France, provided the basis for discussion. Traceability was desired in order to allow product withdrawals, monitoring of unintended and long term effects, to assist labelling and to facilitate identity preservation systems. Opponents regarded the universal imposition of traceability as an unacceptable burden on producers (especially in developing countries), and unworkable in many instances. Further discussion failed to resolve this point and the matter was retained as an unresolved point (i.e. in "square brackets" in the document).

2. Proposed draft guideline for the conduct of safety assessment of foods derived from plants obtained through modern biotechnology (later changed to "recombinant DNA plants").

This paper focuses on the technical detail of applying the concept of "substantial equivalence" in order to identify similarities and differences between the new food and its conventional counterpart.

A Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived From Biotechnology was held in January 2001, and this provided a substantial revision of the assessment of this issue. Incorporation of the revised scheme into the safety assessment document was desired, but considered too great a task to be handled at the Task Force meeting. A Working Group, chaired by Canada, was set up to handle this issue, and will also consider reorganisation of the section on assessment of possible toxicity, for which several proposals were advanced at the Task Force meeting.

At the conclusion of the meeting both draft documents were advanced from Step 3 to Step 5 of the 8 Step Codex process.

The mandate of the Task Force also includes microorganisms and animals derived from modern biotechnology. Given the limited time available for the meetings of the Task Force it was recognised that addressing modified animals may not be feasible. However, a new Working Group, hosted by the US, was established to address the safety assessment of modified microorganisms. A Joint WHO/FAO Expert Consultation on this issue, to facilitate the work of the Task Force, was also offered and accepted, but needs to be formally approved by WHO/FAO.

The full report from the meeting is available from:

ftp://ftp.fao.org/codex/alinorm01/al0134ae.pdf

4.3 Labelling

4.3.1 Thailand

Thailand's Commerce Ministry plans to introduce compulsory labelling of edible goods with contents linked to GMOs. The Commerce Ministry plans to discuss the issue with the Ministry of Agriculture and Cooperatives before officially introducing the measure, which is expected by the end of 2001 (Source: Dow Jones Newswires 15 March 2001 via AgNet)

4.3.2 Japan

In April 2001 the Japanese rules for labelling of genetically modified organisms became mandatory. Under these rules, food products containing up to 5% of approved GM crops will be exempt from labelling. Animal feed and food products in which DNA or protein from GM materials cannot be detected using existing technologies will be exempt from labelling.

Japan imports 12 million tons of corn each year for animal feed and another four million tons for food. In 2000 95% of this corn came from the US. Japan also imports about 4.8 million tons of soybeans a year, also mostly from the US (Source: Agriculture Online 28 March 2001).

An unofficial English translation of the labelling standard is available at:

http://www.maff.go.jp/soshiki/syokuhin/hinshitu/organic/eng_yuki_gmo.pdf

4.3.3 China

China's State Council has passed the "Regulations Concerning the Biotech Safety Management of Agriculture Gene Alteration" (Draft Version). These regulations appear to require the labelling of GM food (Source: China Online 16 May 2001 via AgNet). Under the new rules Chinese-foreign joint ventures and foreign owned companies need government approval to research or test genetically altered products. Sellers of modified seeds, seedlings or animals need official permits, and labelling of genetically altered products will be required (Source: Associated Press 6 June 2001 via AgNet).

A Greenpeace press release applauding the move included the following details. Bt cotton is grown on one million hectares in China, which represent approximately one third of the total crop. This is for industrial (clothing) rather than food use. Delayed ripening tomatoes and virus resistant sweet pepper have also been approved for commercial growing but their permit for seed production has yet to be granted.

4.3.4 Codex Committee on Food Labelling

The Codex Committee on Food Labelling held its twenty ninth session in Ottawa in May 2001. Amongst the topics discussed was the labelling of foods derived from modern biotechnology. Most discussion centred around the definitions of the various terms employed with such foods. The report from the meeting is available at:
ftp://ftp.fao.org/codex/alinorm01/al0122ae.pdf

5 CURRENT DEVELOPMENTS

5.1 Resources

5.1.1 USDA Economic Research Service Briefing Room

A web-based "briefing room" has been established by the Economic Research Service of the USDA. Documents on the website discuss economic and trade data related to biotechnology and agriculture, both in the US and internationally.

The site is located at:

http://www.ers.usda.gov/Briefing/Biotechnology/

5.1.2 FAO biotechnology glossary

The FAO has developed a website offering a glossary of terms used in biotechnology, as a resource for researchers, students and technicians, especially those whose first language is not English.

The site is located at:

http://www.fao.org/biotech/gloss.htm

5.2 Human Health

5.2.1 Starlink corn – assessment of Cry9C allergic reaction claims

Starlink corn is a variety that was genetically engineered to contain the Cry9C variety of insect toxin derived from the bacteria *Bacillus thuringiensis*. The US Environmental Protection Agency licensed the corn for use as animal feed, industrial non-food uses and seed production, but not for human food use. The reason was that there were concerns that the Cry9C protein had some characteristics in common with proteins that are known allergens for humans. Testing conducted in accordance with standard allergenicity assessment procedures showed that the protein did not originate from an allergenic source and did not share amino acid sequence similarity with known allergens or toxins. However, unlike the other Cry proteins, the Cry9C protein was not readily digestible in simulated gastric fluids and had been shown to be heat stable at 90°C. In September 2000 this variety of corn was discovered at low levels in some corn products intended for human food use, and a widespread sequence of recalls was initiated.

The US Food and Drug Administration had received 51 "adverse event reports" (AERs) from individuals who reported adverse reactions which may have been caused by exposure to the Cry9C protein. The US Centres for Disease Control (CDC) was asked to help investigate these cases. A case definition was developed, and 23 cases were eliminated for a variety of reasons (symptoms did not occur within the established time frame following product consumption, symptoms attributed to a previously existing illness etc.). From the 28 individuals who met the case definition interviews were able to be conducted with 24, and 17 provided blood samples for testing.

Allergic reactions are mediated by a class of antibodies called immunoglobulin E (IgE) which bind to the allergen. The 17 blood samples were analysed by the FDA and an independent laboratory for IgE antibodies which bound to the Cry9C protein. None of the blood samples tested were found to contain Cry9C-specific-IgE.

The press release from CDC stated: "Although the study participants may have experienced allergic reactions, based on the results of this study alone, we cannot conclude that a reported illness was a Cry9C allergic reaction".

The entire study report is available at:

http://www.cdc.gov/nceh/ehhe/Cry9cReport/

Further information supplied by Aventis to the EPA indicates that potential exposure to Cry9C in food is much lower than previously estimated. The Aventis data concerns the levels of Cry9C in finished food products, and appears to confirm the EPA's own results that wet milling eliminates the protein, while dry milling denatures but does not completely eliminate the protein. The new information is available at:

http://www.epa.gov/pesticides/biopesticides/

5.2.2 New GM crops with properties relevant to human health

(Note that this information is taken from material in the scientific literature. It will not be comprehensive and will not cover all the crops being developed by biotechnology companies)

5.2.2.1 Increased flavonol levels in tomatoes (Muir et al., 2001)

Along with carotenoids such as lycopene, tomatoes are also a source of flavonoids. These chemicals are thought to provide health benefits through their antioxidant properties. The evidence is strongest for one group of flavonoids, the flavonols, such as quercetin and kaempferol. One of the enzymes in the biosynthetic pathway to flavonols is chalcone isomerase. Scientists in the UK and the Netherlands have successfully introduced a gene for this enzyme from Petunia into tomatoes. This caused in increase in flavonol levels by up to 78 fold.

5.2.2.2 Healthier cottonseed oils

The Australian CSIRO Plant Industry Division has announced the successful development of cotton plants which produce oil with a higher oleic acid content. This was achieved by switching off the gene that converts mono-unsaturated fatty acids into polyunsaturates. Such oils could be used to make margarine without the need for hydrogenation, which produces trans fatty acids, which have adverse effects on blood cholesterol levels.

Another cotton plant was engineered to alter the proportions of different saturated fatty acids in cottonseed oil. Normally the oil contains mostly palmitate, with small amounts of stearate. In the engineered plants, the saturated fatty acid content is altered to be mostly stearate. Palmitate in the diet raises blood cholesterol levels while stearate is considered neutral (Source: CSIRO media release at http://www.csiro.au/).

5.2.3 UK Royal Society to update 1998 statement on GM plants

In 1998 the Royal Society issued a report on the use of GM plants for human food use. Since then there has been considerable research into the issues, so the Society has convened a working party to update the statement. The revised report is expected later in 2001. The original report, and news about the update are available from:

http://www.royalsoc.ac.uk/policy/index.html

5.2.4 Assessment of human health effects of Bt toxins

The US Environmental Protection Agency (EPA) is responsible for assessing the safety of pesticides, including the Bt toxins produced by many GM crops. As part of the EPA reassessment process for Bt toxins in corn, cotton and potatoes, a Scientific Advisory Panel (SAP) was assembled and this group held a public meeting in October 2000. The report from this meeting was made available in March 2001. The scientific issues considered were:

- Insect resistance management;
- Gene Flow/Outcrossing, Environmental Fate in the Soil and Non-target Organism Effects; and,
- Benefit and Economic Analysis, Product Characterization and Human Health Effects.

On the topic of human health effects the Panel considered that there were two concerns related to exposure/consumption of proteins – acute toxicity and allergenicity. The Panel supported evaluation of Bt-pesticidal proteins by acute dose-range animal studies and, if required in exceptional cases, by semi-chronic repeated exposure. A discussion of allergenicity concluded that it was not possible at present to set a threshold below which there would be no concern. Some additional data to characterise the protein were suggested. Where no effects were seen in acute oral exposure animal studies, even at high doses, other forms of toxicological study were considered unnecessary.

The full report is available from:

http://www.epa.gov/scipoly/sap/whatsnew.htm

5.2.5 UK Medical Research Council and Potential Health Effects of GM Foods

In 1999 the UK Medical Research Council (MRC) established an Expert Group to consider the range and mechanisms of the potential health effects of GM foods on humans, as well as the feasibility of undertaking research in this area (research proposals can be submitted to the MRC). The Groups report, recommendations and conclusions have now been endorsed by the MRC Boards and Council and these were released in March 2001.
The press release stated:

“The report concluded that most of the theoretical health risks presented by GM foods are already addressed in current regulatory assessments and, at present, there is no evidence to suggest that GM foods are harmful to human health. However, where unresolved issues remain this was considered to be due to a lack of evidence either supporting or refuting either proposed or specific health effects. The report identified areas where further research or study might be of benefit. These included randomised controlled trials to assess potential short-term health effects of GM foods and the development of biomarkers of GM food exposure. A major recommendation of the report was the need for further research into the mechanisms of food allergenicity. Greater understanding in this area would be equally relevant to GM and non-GM foods. “

The press release and the full report can be obtained from:

http://www.biotech-info.net/GM_research_med.html

5.2.6 Potential for transfer of DNA from soybean fed to mice (Hohlweg and Doefler, 2001)

DNA from bacteriophage M13 and the cloned gene for the green fluorescent protein (GFP) have previously been used as test genes for food ingested DNA in mice and shown to persist in various tissues. New research has used soybean leaves fed to mice with analysis for the plant specific nucleus encoded ribulose-1,5-bisphosphate carboxylase (Rubisco) gene. The gene, or fragments of it, could be recovered from the intestine after up to 49 hours, and from the cecum after up to 121 hours after ingestion. It appears that plant associated DNA is more stable to digestion than naked DNA. Rubisco gene-specific PCR products were amplified from spleen and liver DNA but this is likely to have been from foreign DNA in the process of being eliminated. There was no evidence for the expression of orally administered genes. Mice were also fed GFP DNA for 8 generations but no DNA could be detected in analyses of tail tips and internal organs. The organism appears to eliminate foreign DNA via the liver-bile-intestinal route.

5.2.7 Golden rice

Argument continues over the likely value of the vitamin A enriched rice being developed, principally at the International Rice Research Institute (IRRI) in the Philippines. In a letter to the Journal of the American Dietetic Association (Nestle, 2001) it is argued that no single nutrient added to food can be as effective as a remedy for dietary deficiencies. Many children exhibiting symptoms of vitamin A deficiency suffer from generalised protein-energy malnutrition and intestinal infections that interfere with the absorption of beta-carotene and its conversion to vitamin A.

IRRI has indicated that it is likely to take at least three years of breeding before field trials of the rice could be commenced. This period will be required to transfer the pro-vitamin A trait into indica-type rice. It will be another two years before it is available to farmers (Source: Open letter from IRRI 23 March 2001 via AgNet).

5.3 Consumer Issues

5.3.1 Genetically modified animals

The UK Royal Society has released a report considering the use of genetically modified animals. The reports considers all uses of genetically modified animals, including:

- Medical research: genes that cause disease
- Medical research: creating GM animals to understand gene function
- Toxicity testing
- Therapeutic proteins
- Xenotransplantation
- GM animals for agricultural uses (including development of disease resistance)
- Current uses of GM animals
- GM insects

GM animals for food use are considered briefly. Transgenically derived animal food products are considered to be “a long way off” due to a number of difficulties, including:

- poor efficiency of modification processes
- long breeding cycles
- incomplete knowledge of farm animal genomes
- desirable traits are polygenic (i.e. require alteration of several genes)
- lack of venture capital
- concerns about animal welfare and food safety.

The full report is available from:

http://www.royalsoc.ac.uk/policy/index.html

5.3.2 Consumer GM Call Centre in Canada

The Food Biotechnology Centre is a national not-for-profit association in Canada which established a call centre in 1999 to answer questions about the use of biotechnology in Canada’s agricultural system. They receive approximately 30,000 calls per month. A spokesperson for the centre said that most of the concern over the use of biotechnology resulted from the “knowledge gap” and many consumers felt they were uninformed about the technology (Source: Central Alberta Adviser 18 March 2001 via AgNet).

5.3.3 Canadian honey banned in Europe

New European regulations have banned Canadian honey because it cannot be certified as GMO free. Trace amounts of GMO canola pollen have reportedly been found in shipments, although after filtration only 0.1% of the honey is pollen (Source: Ontario Farmer 3 April 2001 via AgNet).

5.3.4 Survey of GM ingredients in Ireland

The Food Safety Authority of Ireland (FSAI) has released the results of a survey of tortilla chips and taco shells for genetically modified ingredients. The survey was undertaken to determine the level of GM contents in various foods and to ensure that industry is adhering to food labelling regulations. This is the first in a series of planned surveys by the FSAI and forms part of its new responsibilities as the competent authority for novel food, including genetically modified food, in Ireland. Results show that GM maize ingredients were present in 19 of the 26 samples tested, with the majority having levels below 0.1% - considerably less than the 1% threshold level that triggers the labelling requirement. Of the 19 positive samples, 8 contained trace levels of GM DNA that were too low to be quantified. The remaining 11 contained slightly higher levels - one contained 0.5% GM maize, another contained 0.4%, and all other samples contained less than 0.1%. Although 19 GM positive samples were detected, no unlicensed GM maize was positively identified in this survey. EU labelling regulations relating to GM foods require that foods containing genetically modified ingredients at or above the 1% threshold, must have clear labelling to indicate that it contains GM ingredients. As none of the samples in this study were found to contain GM maize at, or above the threshold limit of 1%, specific GM labelling was not required on these food products. All brands tested therefore were fully compliant with the relevant legislation. The regulations do stipulate however, that for food products below the 1% threshold level, industry must be able to prove that the food product came from a non-GM source and that if any GM is found, it is as a result of incidental contamination.

The survey is available from the FSAI website at:

http://www.fsai.ie/news_index.htm

5.3.5 Unapproved GM potatoes found in snacks in Japan

In May 2001 the Japanese Ministry of Health, Labour and Welfare has reported the presence of New Leaf Plus potatoes in snack foods ("Ozakku" potato chips and "Jagariko" snacks) in Japan. New Leaf potatoes are approved in Japan but not New Leaf Plus. Monsanto was puzzled by the finding, as the New Leaf Plus variety was grown on only a few thousand acres among the 2 million acres of potatoes planted in the US (Source: St Louis Despatch 28 May 2001 via AgNet). Japan imports more than 50% of all US potato exports worth US$260 million (Source: National Potato Promotion Board 8 June 2001 via AgNet).

As a result of this event, the Japanese Ministry of Agriculture, Forestry and Fisheries plans to add mashed potato, potato chips and other potato products to the foods requiring labelling under the regime that took effect in April 2001 (Source: Associated Press 20 June 2001 via AgNet).

5.4 Agricultural and Environmental Issues

5.4.1 New GM crops with properties relevant to agriculture

(Note that this information is taken from material in the scientific literature. It will not be comprehensive and will not cover all the crops being developed by biotechnology companies).

5.4.1.1 Potato sprouting

The control of potato sprouting behaviour by genetic mechanisms would offer advantages for two reasons. Firstly the ability to suppress sprouting during potato storage and transport would offer an alternative to the current chemical means of control. Secondly the stimulation of sprouting would offer the ability to grow more than one crop per year by reducing the dormancy period.

Acceleration of sprouting has been reported for potato tubers which have been engineered to contain an inorganic pyrophosphatase gene from the bacterium *Escherichia coli* (Farré et al., 2001). Inorganic pyrophosphate plays a role in an number of cell biochemical reactions which are linked to sprouting, so it was assumed that the increase in its production by expression of the pyrophosphatase enzyme was responsible for the acceleration of sprouting. However the exact mechanism has yet to be clearly identified.

5.4.1.2 New Bt toxin varieties

In March 2001 Monsanto requested that the US EPA review applications to register new varieties of cotton and corn. The Monsanto MON863 (or MaxGuard) corn contains the Cry3Bb variety of Bt toxin which confers resistance to the corn rootworm complex. The cotton variety contains two "stacked" Bt toxin encoding genes to broaden the insect resistance. The Bt genes encode for the Cry3Bb1 and Cry2Ab2 toxins. Exemption from the requirement for a tolerance was granted by the EPA in May 2001 for the period to May 2004.

Mycogen (Dow/Pioneer) are also developing a similar rootworm resistant Bt corn variety (149B1) which contains the Cry1F toxin (Source: Nature Biotechnology 2001; 9: 399). This toxin has reduced toxicity to non-target organisms. The exemption from the requirement for a tolerance was granted by the EPA in June 2001.

5.4.1.3 Improving rice yields by influencing iron metabolism (Guerinot, 2001; Takahashi et al., 2001)

Iron, along with nitrogen and phosphorus, is one of the of the limiting nutrients for plant growth. However, iron deficiency cannot be addressed by applying fertiliser, as the problem is one of solubility, rather than the amount in the soil. Iron has limited bioavailability in alkaline soils, which have been estimated to account for 30% of the world's arable soils.

Plants have strategies for tackling this problem, one of which is used by grasses, including rice. This involves releasing low molecular weight compounds called siderophores into the soil to bind iron. The complex is then taken up by the plant using a specific receptor. This mechanism has been used by scientists in Japan to improve the yield of rice from alkaline soils. They introduced genes from barley that encode an enzyme that catalyses a step in the production of the rice siderophore, deoxymugineic acid. The resulting plants showed a fourfold increase in yield from alkaline soils in laboratory trials.

5.4.2 Bt resistance management strategy (Dove, 2001)

The US Environmental Protection Agency has developed a Bt resistance management strategy, designed to prevent the selection of Bt resistant insects caused by the widespread planting of insect resistant crops. The strategy involves the planting of 20% (for corn) or 50% (for cotton) of farm acreage in non-Bt crops, thus providing a breeding ground for insects so that genetic susceptibility to the toxin is maintained in the insect population.

The most recent annual survey of compliance with the resistance management strategy suggested that approximately 30% of farmers may not be implementing the strategy correctly, as they were unable to recall the size of the refuges on their farms. The EPA does not enforce compliance with the strategy but so far there does not appear to be any evidence that Bt resistant insects are predominating.

5.4.3 Canadian farmer Percy Schmeiser and Monsanto patent infringement

On 29 March 2001 a Canadian judge ruled in favour of Monsanto and Monsanto Canada in its case against Canadian farmer Percy Schmeiser for patent infringement. Monsanto claimed that Schmieser had grown Roundup Ready canola without having signed the standard "technology use agreement" and therefore infringing the patent. The defense argument was that the Roundup resistant canola crop arose from the farmer's own development of herbicide resistant plants found on his land. However, analysis of plant material from the farm showed the presence of gene constructs developed by Monsanto (Fox, 2001).

The court ruling is available from:

http://www.fct-cf.gc.ca/bulletins/whatsnew/T1593-98.pdf

5.4.4 Benefits of transgenic canola to farmers

The Canola Council of Canada has released a report on the agronomic and economic impact of transgenic canola varieties, which are used by approximately 80% of growers to plant approximately 55% of the total canola acres in Canada. The survey involved 650 growers, with detailed cases studies of 13 growers. On average transgenic canola resulted in a 10% yield increase, and allowed savings (fuel for tillage, reduced herbicide use etc.) amounting to $464 million over the period 1997 to 2000. The full report is available at:

http://www.canola-council.org/

(see under "The Growers Manual" for "Agronomic and Economic Assessment of Canola")

5.4.5 Bt cotton in India

The Indian branch of Monsanto has announced that it expects to receive approval to commercially plant Bt cotton in India by the end of 2001. Large scale field trials and seed production were undertaken during 2000 (Source: The Economic Times 13 March 2001 via AgNet).

5.4.6 Starlink

Approximately 430 million bushels of corn have been placed in storage in the United States due to the presence of Starlink corn. The affected corn represents approximately 4% of the US production in 1999. Much smaller amounts of corn are expected to require storage from the 2000 crop; approximately 50 million bushels grown by farmers licensed to use it, and 20 million bushels from neighbouring fields. The corn will be rerouted for animal feed and ethanol production (Source: Washington Post, March 18 2001 via AgNet).

5.4.7 Bt corn and the Monarch butterfly

Considerable research is underway in the US to assess the risk to Monarch butterflies from the Bt toxins expressed in pollen from GM corn. A preliminary report from research being conducted at the University of Guelph was released in March 2000. The research examined the toxicity of Bt corn pollen to monarch larvae as well as the exposure of the larvae to pollen. The lethal dose required to kill 50% of the larvae was 389 BT 176 grains/cm^2 at 96 hours, following a 48 hour exposure period. The vast majority of pollen fell within a few metres of the corn field (approximately 90% within 5 metres). Pollen density (at peak pollen shed) from corn onto milkweed leaves was:

- -1 to 0 metres from border of corn field: mean 78, range 1-381 grains per cm^2
- 0 to +1 metres from border of corn field: mean 28, range 0-356 grains per cm^2
- 5 metres from border of corn field: mean 1.4, range 0-6 grains per cm^2.

The full report can be found at the University of Guelph Food Safety network site under Gen. Eng. Food/Crops:

http://www.plant.uoguelph.ca/safefood/

5.4.8 Commercial growing of GM crops

Bollgard cotton seed has been imported to Sulawesi in Indonesia from South Africa. The Indonesian Ministry of Agriculture allowed limited sales of genetically modified seed in Sulawesi from February 6 2001 (Source: Jakarta Post 17 March 2001 via AgNet).

In May 2001 approval for commercial growing of Roundup Ready cotton was given in Argentina by the Agriculture, Livestock, Fish and Food Secretary (Source: Press release at http://www.monsanto.com/monsanto/media/01/01may03_rr_cotton_argentina.htm). This means that Argentina has approved six GM crops for commercial planting (the others are Bt cotton, 3 corn varieties and Roundup Ready soy).

Monsanto has confirmed that it will cease selling its New Leaf variety of insect resistant potato (known as Naturemark potatoes in Canada). New Leaf never captured more that 5% of the commercial potato seed market, partly due to its increased cost in a market where there is a glut of potatoes, and partly due to food companies avoiding GM products. In 1999 about 55,000 acres were planted with New Leaf potatoes but this area halved in 2000. The introduction of New Leaf Plus, which is also resistant to the leaf roll virus, did not improve the situation. The company will concentrate on crops where the market is larger: oilseeds, cotton, corn and wheat (Source: Wall Street Journal 21 March 2001 via AgNet).

According to a farmer survey conducted by the USDA regarding planting intentions the amounts of GM crops planted in the United States will generally increase in 2001. The results were:

- Soybeans: increase from 54% in 2000 to 63% of the total crop in 2001
- Corn: decrease from 25% in 2000 to 24% of the total crop in 2001
- Cotton: increase from 61% in 2000 to 64% of the total crop in 2001

(Source: AP/Reuters 30 March 2001, via AgNet)

Thailand has apparently banned the release of genetically modified crops into the environment. The government has ordered the Agriculture Ministry to halt all genetically modified crop trials, which may include the current Bollgard cotton trials. The ban does not affect imports of raw material and goods linked to GMOs (Source: Science Now 12 April 2001 via AgNet).

5.4.9 Roundup Ready wheat

Extensive field trials of Roundup Ready wheat at more than 50 sites are planned for Canada during 2001. The Canadian Wheat Board is one of many organisations expressing concern about the development of GM wheat. The concern arises from the fact that overseas countries have not approved the crop for food use, and there will be difficulties in identifying and segregating the variety (Source: National Post 3 April 2001 via AgNet). Apparently the concern is greater for Canada as farmers export 40-60% of their hard red spring wheat, whereas the US only exports 20% of their crop (Source: Knight Ridder Tribune 5 April 2001 via AgNet). Japanese wheat importers told visiting US wheat industry representatives in April that they will obtain wheat from elsewhere if the US cannot guarantee the GM free status of their crop (Source: Reuters 24 April 2001 via AgNet).

A discussion of the trade implications of GM wheat is in the current ISB News Bulletin at:

http://www.isb.vt.edu/news/2001/news01.Jun.html

5.5 GM Animal Feed

5.5.1 Advisory Committee on Animal Feedingstuffs

In June 1999 the UK Advisory Committee on Animal Feedingstuffs (ACAF) was set up to provide advice on issues including the use of GM plants in animal feed. The ACAF annual report for 2000 is now available.

There is no EC or national legislation in the UK concerning the assessment or approval of novel animal feeds, including those containing or derived from GMOs, although the European Commission is currently working on proposals in this area. Until such rules come into effect, animal feeding aspects of new GM plants are considered under Council Directive 90/220 (now superseded by Directive 2001/18/EC). ACAF has set up a subgroup to advise on the impact, both on animals and the ultimate consumer, of GM crops used in animal feed.

So far, the ACAF has considered the following issues in relation to GM crops:

- adventitious presence of RT73 GM oilseed rape in conventional seed stocks (the conclusion was that no threat to human or animal health via use in animal feed);
- review of research on the effects of processing on DNA in plant material, and plans for a study of the fate of transgenic material fed to chickens;
- review of animal feed labelling, and development of a report from a consultation exercise on labelling animal feed.

The report, and other information on ACAF is available from their website:

http://www.foodstandards.gov.uk/committees/acaf/summary.htm

5.5.2 GM material found in animal feed used for animals sold as "organic"

In March the Swiss Agriculture Ministry announced that GM materials had been found in organic animal feed. The soy used in the animal feed was found to be 17% GM. In Switzerland the legal limit for animal feed to be certified as organic is 3% or less of GM material. The result was that the meat could not be sold as organic, resulting in a loss of 1 million Swiss francs for farmers (Source: Organic Trade Services website http://www.organicts.com/newsnow/ via AgNet 12 March 2001).

5.5.3 Tests on animals fed GM crops

Japan has been conducting tests on the effect of feeding Starlink corn to 260 chickens and 8 cows. No notable differences were seen between test and control groups, and no trace of the Cry9C protein could be found in milk or eggs derived from the animals. The results of tests on pigs are expected in July (Sources: Jiji Press Tokyo 6 April 2001 and Reuters 12 April 2001via AgNet).

A review of 23 studies conducted over the last four years at universities in the United States, France and Germany on the feeding of GM crops as animal feeds has been published by Professor J Clark at the University of Illinois at Urbana Champaign. The conclusion was that there was no difference in weight gain, efficiency, milk composition or overall health when compared with animals fed traditional feed. The majority of genetically modified soybean and corn produced around the world is used as animal feed.

To obtain a copy of the study, contact Professor Clark via email at j-clark@uiuc.edu

5.5.4 Mandatory checks of animal feed in Japan

Japan's Agriculture Ministry will introduce mandatory safety checks on animal feed to guard against imports of unapproved GM crops (Source: Reuters 19 April 2001 via AgNet).

5.6 Miscellaneous

5.6.1 Seed standards in Europe

Following the release of draft proposals for seed purity dealing with the adventitious presence of genetically modified seed in conventional seed (see March 2001 report from this project) the EC Scientific Committee on Plants was asked for its opinion on various aspects of the proposal. The opinion of the committee was released on 13 March 2001. With regard to the proposed limits of 0.3% for cross-pollinated crops and 0.5% for self-pollinated crops, the Committee considered that these levels could only be achieved under ideal seed production conditions, and may need to be revised as GM crop production increases in Europe. The zero tolerance for unapproved crops was regarded as unobtainable in practice. When establishing levels of tolerance, the major constraint was the limit of analytical sensitivity of available detection methods (currently about 0.1%).

The full report is available from:

http://europa.eu.int/comm/food/fs/sc/scp/out93_gmo_en.pdf

5.6.2 Research into safety assessment in the UK

The UK Food Standards Agency has launched a new programme of research into the safety assessment of novel foods. This programme (G02) will have funding of 6 million pounds over three years. The projects will cover techniques relevant to genomics, proteomics and metabolic profiling and their application to the safety assessment of the next generation of GM foods. The announcement is available at:

http://www.foodstandards.gov.uk/pdf_files/require3.pdf

5.6.3 Canola seed recall in Canada

Seeds of Monsanto's glyphosate tolerant Quest Canola have been recalled by Agricore Cooperative Ltd and the Saskatchewan Wheat Pool after it was discovered that the GT73 variety was contaminated with the GT200 variety. GT73 has been approved for food use by a number of countries, while GT200 has not (Source: Knight-Ridder Tribune 10 May 2001 via AgNet).

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APPENDIX 1: Products of biotechnology and food use approvals (Updated June 2001)

Products that are the subject of applications or have been approved by ANZFA are in bold.

The primary sources for this information were:

USA: Food and Drug Administration website: http://vm.cfsan.fda.gov/~lrd/biocon.html

UK: Advisory Committee on Novel Foods and Processes (ACNFP) Annual Reports

European Union: Facts on GMOs in the EU (July 2000):

http://europa.eu.int/comm/food/fs/biotech/biotech_index_en.html

Canada: Health Canada website:

http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods

Japan:

Agriculture, Forestry and Fisheries Research Council Secretariat:

http://ss.s.affrc.go.jp/docs/sentan/eguide/commerc.htm

Innovative Technology Division MAFF:

http://ss.s.affrc.go.jp/docs/sentan/eguide/edevelpnew.htm

Australia/New Zealand: ANZFA website: http://www.anzfa.gov.au

Database with additional details: AgBios: http://www.agbios.com

The majority of this information has also been checked with the individual companies directly (Monsanto, Aventis (was AgrEvo), Novartis).

Note that this table does not include enzymes or vitamins derived from genetically modified organisms; these would be classed as food additives or processing aids and covered by ANZFA Standards A3 and A16 respectively.

Brand and variety (or line) names should not be regarded as exhaustive; many will exist for each transformation event.

Some background information is useful in interpreting the information about these crops.

Several companies in the genetically modified foods area have changed or merged in recent years. The five major agricultural biotechnology companies are:

Monsanto (the agricultural unit of Monsanto is to be merged with Pharmacia and Upjohn company, to form a new biotechnology company called Pharmacia. Monsanto will then concentrate on pharmaceuticals. The planned merger between Monsanto and Delta and Pine Land has been cancelled. (Source: Nature Biotechnology 2000; 18: 141)).

Aventis Life Sciences (formed by the merger of AgrEvo and Rhone Poulenc).

Dupont (this company has now acquired the seed producer Pioneer Hi-Bred which produces seed for many GM crops).

Syngenta (formed by the merger of AstraZeneca PLC of Britain, and Novartis AG of Switzerland).

Pesticides:

Glyphosate by Monsanto is known by the trade name Roundup (the monoisopropylammonium salt).

Glufosinate by Aventis (was AgrEvo) is also known as phosphinothricin. The salt glufosinate ammonium is also known as “Basta” and is produced by Hoechst AG.

Imidazolinone herbicides inhibit the acetolactate synthase enzyme, and include imazethapyr, the active ingredient in Cyanamid Canada’s “Pursuit” herbicide.

ANZFA Application Number	Plant	Company	Trait	Brand Names	Variety (Line) Names	Transform-ation event	Food Use Approvals and Consultations
	Cantaloupe	Agritope Inc.	Modified fruit ripening			A and B	USA: FDA 1999
	Chicory (*Radicchio rosso*)[1]	Bejo Zaden BV	Glufosinate tolerant (PAT), male sterile (bar)	Seedlink		RM3-3, RM3-4, RM3-6	EU: marketing for breeding authorised, human and animal food use under consideration USA: FDA 1997
A375	**Corn**	**Aventis (was AgrEvo)**	**Glufosinate-ammonium herbicide tolerant**	**Liberty Link**	**Pride and Pioneer lines**	**T25**	**EU: cultivation, importation, storage and processing for food, feed and industrial uses approved April 1998 (several derivatives also approved for food use as substantially equivalent)** **USA: FDA 1995** **UK: ACNFP Feb 1997** **Canada: 3 April 1997** **Japan: May 1997** **Argentina: June 1998**
	Corn[2]	Aventis (was AgrEvo)	Glufosinate-ammonium herbicide tolerant	Liberty Link		T14	USA: FDA 1995 UK: ACNFP Feb 1997 Canada: 3 April 1997 Japan: May 1997
	Corn	Aventis (was AgrEvo)	Glufosinate-ammonium herbicide tolerant and insect resistant (*cry9C* gene from *Bacillus thuringiensis* subsp. *tolworthi*)	StarLink		cbh351	EU: Application files in preparation USA: FDA 1998 for use as animal feed or as processed products where there is no dietary exposure to Cry9C protein.
	Corn[2]	Aventis (was AgrEvo and	Male sterility + Glufosinate-ammonium herbicide tolerant			MS3	USA: FDA 1996 Canada: July 1997

ANZFA Application Number	Plant	Company	Trait	Brand Names	Variety (Line) Names	Transform-ation event	Food Use Approvals and Consultations
		Plant Genetic Systems)					
	Corn	Aventis	Male sterile				USA: FDA 2000
	Corn	Aventis	Glufosinate tolerant (PAT), male sterile (bar)			MS6	US:FDA 2000
	Corn[3]	BASF Canada	Sethoxydim tolerant			DK404SR, DK412SR	Canada: Feb 1997
A380	**Corn**	**Monsanto (was DeKalb)**	**Lepidopteran insect (European corn borer) resistant (*cry1A(c)* gene from *Bacillus thuringiensis*) and Glufosinate-ammonium herbicide tolerant**			**DBT418 (BJ16)**	**EU: Importation for human food and animal feed under consideration USA: FDA 1997 Canada: April 1997 Japan: November 1999**
A362	**Corn**	**Monsanto**	**Glyphosate herbicide tolerant**	**Roundup Ready**		**GA 21**	**EU: Storage and processing to non-viable products and use for human and animal feed under consideration. Not used for cultivation. USA: FDA 1998 Canada: May 1999 Japan: November 1999 NZ/Australia: 2000**
A346	**Corn**	**Monsanto**	**Lepidopteran insect (European corn borer) resistant (*cry1A(b)* gene from *Bacillus thuringiensis* subsp. *kurstaki*)**	**Yieldgard**		**MON 810**	**EU: cultivation, importation, storage and processing for food, feed and industrial uses approved April 1998 (several derivatives also approved for food use as substantially equivalent) USA: FDA 1996 UK: ACNFP Feb 1997 Canada: Feb 1997**

ANZFA Application Number	Plant	Company	Trait	Brand Names	Variety (Line) Names	Transform-ation event	Food Use Approvals and Consultations
							Japan: May 1997 **NZ/Australia: 2000**
A416	**Corn**	**Monsanto**	**Glyphosate tolerant**			**NK603**	**USA: FDA 2000** **Canada: February 2001**
A381 (application withdrawn, no longer available)	Corn	Monsanto (was DeKalb, DeKalb Genetics)	Glufosinate-ammonium herbicide tolerant			DLL25 (B16)	USA: FDA 1996 UK: ACNFP under consideration and application resubmitted under Novel Food Regulation Canada: Dec 1996 Japan: November 1999
	Corn	Monsanto	Glyphosate herbicide tolerant			MON 832	Canada: September 1997.
	Corn	Monsanto (was Pioneer Hi-Bred)	Lepidopteran insect (European corn borer) resistant (*cry1A(b)* gene from *Bacillus thuringiensis* subsp. *kurstaki*) (also includes glyphosate resistance gene but is only expressed at low levels)			MON 809	USA: Approvals applicable to MON810 also apply to MON809. This event has been licensed to another company. EU: Human food, animal feed and industrial uses under consideration (several derivatives also approved for food use as substantially equivalent) UK: ACNFP Feb 1997 Canada: Dec 1996
	Corn	Monsanto	Lepidopteran insect (European corn borer) resistant (Cry1Ab from *Bacillus thuringiensis* subsp. *kurstaki*)			MON810	USA: FDA 1996
	Corn	Monsanto	Glyphosate herbicide tolerant + Lepidopteran insect (European corn borer) resistant			MON 802	USA: FDA 1996 (also MON 805, 830, 831, 832) UK: ACNFP under consideration and application

ANZFA Application Number	Plant	Company	Trait	Brand Names	Variety (Line) Names	Transform-ation event	Food Use Approvals and Consultations
							resubmitted under Novel Food Regulation Canada: Sept 1997
A385	**Corn**	**Syngenta (was Novartis, was Ciba-Geigy)**	**Lepidopteran insect (European corn borer) resistant (*cry1A(b)* gene from *Bacillus thuringiensis* subsp. *kurstaki*)**			**Event 176**	**EU: cultivation and importation for use in animal feed and in processed foods approved Jan 1997** **USA: FDA 1995** **UK: ACNFP May 1996** **Canada: Dec 1995** **Japan: Sept 1996** **Argentina: 1998** **Denmark: 1997** **The Netherlands: 1997** **Switzerland: 1998**
A386	**Corn**	**Syngenta (was Novartis, was Northrup King)**	**Lepidopteran insect (European corn borer) resistant (*cry1A(b)* gene from *Bacillus thuringiensis* subsp. *kurstaki*)** **and glufosinate-ammonium herbicide tolerant**			**Bt 11**	**EU: importation (but not cultivation), storage and processing for food, feed and industrial uses approved April 1998 (several derivatives also approved for food use as substantially equivalent)[5]** **USA: FDA 1996** **UK: ACNFP Feb 1997** **Canada: Aug 1996** **Japan: Sept 1996** **Switzerland: 1998**
	Corn[3]	Pioneer Hi-Bred	Imidazolinone herbicide tolerant			Lines (XA17) 3751 IR, 3417IR	Canada: May 1994 (and June 1998)
	Corn	Pioneer Hi-Bred	Insect resistant and herbicide		38B22	MON810 x T25	EU: Under consideration

ANZFA Application Number	Plant	Company	Trait	Brand Names	Variety (Line) Names	Transform-ation event	Food Use Approvals and Consultations
			tolerant				
	Corn	Pioneer Hi-Bred	Glufosinate tolerant (PAT), male sterile (DAM)			676, 678, 680	US: FDA 1998
	Corn	Monsanto	Insect resistant and herbicide tolerant			MON810 x GA21	EU: Under consideration (lead country: Netherlands)
	Corn[3]	Zeneca Seeds	Imidazolinone herbicide tolerant			Exp1910 IT	Canada: July 1997
	Cotton	DuPont	Sulfonylurea herbicide tolerant			19-51a	USA: FDA 1996
A379	**Cotton**	**Monsanto (was Calgene)/ Aventis (was Rhone Poulenc)**	**Bromoxynil herbicide tolerant**	**BXN cotton**	**10109, 10211, 10215, 10222, 10224**		**USA: FDA 1994** **UK: ACNFP Jan 1997** **Canada: Aug 1996** **Japan: Dec 1997 (excludes 10109)**
	Cotton	Monsanto (was Calgene)	Bromoxynil tolerant/insect protected (Lepidopteran resistant) (*cry1A(c)* gene from *Bacillus thuringiensis* subsp. *kurstaki*)	BXN-Bollgard	31807, 31808		USA: FDA 1998 Canada: Dec 1998 Japan: November 1999 (Bollgard with BXN cotton 31807)
A355	**Cotton**	**Monsanto**	**Glyphosate herbicide tolerant**	**Roundup Ready**		**RRC line 1445**	**EU: Processing to non viable products for human food, animal feed and industrial uses under consideration** **USA: FDA 1995** **UK: ACNFP under consideration and application resubmitted under Novel Food Regulation** **Canada: Dec 1996** **Japan: Dec 1997** **NZ/Australia: 2000**
A341	**Cotton**	**Monsanto**	**Lepidopteran resistant (*cry1A(c)* gene from *Bacillus***	**Ingard (aka**	**Lines 531, 757, 1076**		**EU: Processing to non viable products for human food,**

ANZFA Application Number	Plant	Company	Trait	Brand Names	Variety (Line) Names	Transform-ation event	Food Use Approvals and Consultations
			***thuringiensis* subsp. *Kurstaki*)**	**Bollgard) cotton**			**animal feed and industrial uses under consideration USA: FDA 1995 UK: ACNFP under consideration and application resubmitted under Novel Food Regulation Canada: Nov 1996 (line 757) and April 1996 (line 531) Japan: May 1997 NZ/Australia: Unconfined planting approved in Australia, Food use approved 1999**
A389 (withdrawn July 1999)	Cotton	Monsanto	Lepidopteran resistant (*cry2A(a)* gene from *Bacillus thuringiensis* subsp. *kurstaki*)			1849	
	Papaya	Cornell University	Papaya Ringspot Virus resistant		Lines 55-1 and 63-1		USA: FDA 1997
	Potato	Amylogene	Starch modified			EH 92-527-1	EU: Production of seed potatoes and processing to starch under consideration
	Potato	AVEBE	Reduced amylose content	Cultivars Apriori and Apropos			EU: Application rejected due to concerns about antibiotic gene used. Application withdrawn.
A382	**Potato**	**Monsanto**	**Coleopteran insect resistant (*cryIIIA* gene from *Bacillus thuringiensis* subsp. *tenebrionis*)**	**New Leaf**	**Russet Burbank, Atlantic, Superior**	**Includes BT6 SPBT02-05, ATBT04-06, ATBT04-31,**	**USA: FDA 1996 and 1994 UK: ACNFP under consideration and application resubmitted**

ANZFA Application Number	Plant	Company	Trait	Brand Names	Variety (Line) Names	Transform-ation event	Food Use Approvals and Consultations
						ATBT04-36	under Novel Food Regulation Canada: Sept 1995 and Nov 1996 Japan: Sept 1996 (BT6, BT10, BT12, BT16, BT17, BT18, BT23) and May 1997 (SPBT02-05, SPBT02-07, ATBT04-06, ATBT04-30, ATBT04-31, ATBT04-36)
A383	Potato	Monsanto	Coleopteran (Colorado beetle) (Cry3A from *Bacillus thuringiensis* subsp. *Tenebrionis*) and virus (potato virus Y) protected	New Leaf Y	Russet Burbank, Shepoeity	RBK 101 SHE 15 SHE 02	USA: FDA some lines 1998 Canada: May 1999
A384	Potato	Monsanto	Coleopteran (Colorado beetle) (Cry3A from *Bacillus thuringiensis* subsp. *tenebrionis*) and virus (potato leafroll virus) protected (glyphosate tolerant gene is present but not expressed at high enough levels to be effective - selection marker only)	New Leaf Plus	Russet Burbank	RBK 129 RBK 350 RBK 082	USA: FDA some lines 1998 Canada: Some lines May and Nov 1999
A372	Rapeseed/canola	Aventis (was AgrEvo)	Glufosinate-ammonium herbicide tolerant	Liberty Link	HCN92, HCN 10, Independence, Innovator	Topas 19/2	EU: importation (but not cultivation), storage and processing for food, feed and industrial uses approved April 1998 (oil also approved for food use as substantially equivalent)

ANZFA Application Number	Plant	Company	Trait	Brand Names	Variety (Line) Names	Transform-ation event	Food Use Approvals and Consultations
							USA: FDA March 1995 UK: ACNFP May 1995 Canada: Feb 1995 Japan: Sept 1996 and Dec 1997
A372	**Rapeseed/canola**	**Aventis (was AgrEvo)**	**Glufosinate-ammonium herbicide tolerant**	**Liberty Link**	**HCN28, Phoenix, Exceed**	**T45**	**EU: Human food, animal feed and industrial uses under consideration (import and processing only) USA: FDA Sept 1997 Canada: Feb 1997 Japan: May 1997**
A372	**Rapeseed/canola**	**Aventis (was AgrEvo and Plant Genetic Systems)**	**Male sterility and fertility restorer system for hybrid seed production + Glufosinate-ammonium herbicide tolerant**	**SeedLink or InVigor**	**PGS1, PHY14, PHY35**	**MS1, RF1**	**EU: cultivation and seed production but not food or feed use approved Feb 1996 (oil approved for food use as substantially equivalent) UK: ACNFP Feb 1995 (B-94-2) USA: FDA April 1996 Canada: Sept 1994 Japan: Sept 1996/May 1997**
A372	**Rapeseed/canola**	**Aventis (was AgrEvo and Plant Genetic Systems)**	**Male sterility (barnase) and fertility restorer (barstar) system for hybrid seed production + Glufosinate-ammonium herbicide tolerant (PAT)**	**Seed Link or InVigor**	**PGS2 (hybrid) (=PGS3880), PHY36 (hybrid), 2163, 2273 PHY23**	**MS1, RF2**	**EU: cultivation and importation for oil production approved June 1997 (oil approved for food use as substantially equivalent) UK: ACNFP Sept 1995 (B94-2 second line) USA: FDA April 1996 Canada: Aug 1995**

ANZFA Application Number	Plant	Company	Trait	Brand Names	Variety (Line) Names	Transform-ation event	Food Use Approvals and Consultations
							Japan: May 1997 and Nov 1999
A372	**Rapeseed/canola**	**Aventis (was AgrEvo and Plant Genetic Systems)**	**Male sterility and fertility restorer system for hybrid seed production + Glufosinate-ammonium herbicide tolerant**	**Seed Link or InVigor**	**2363, 2463, 2473, 2373**	**MS8,RF3**	**EU: Human food, animal feed and industrial use under consideration. (oil approved for food use as substantially equivalent) USA: FDA Sept 1998 Canada: March 1997 Japan: Dec 1997 and 1998**
	Rapeseed/canola	Aventis (was AgrEvo)	Glufosinate-ammonium herbicide tolerant	Liberty Link		Topas19/2 and T45 combined	ANZFA: Individual transformation events approved; combination therefore also approved. USA: Approved Canada: Approved Japan: Approved
	Rapeseed/ Canola[2]	Aventis (was AgrEvo)	Glufosinate-ammonium herbicide tolerant/male sterile	Liberty Link/ Synergy	Liberator L62 Falcon GS40/90	T177 (pHoe6/Ac)	EU: Human food, animal feed and industrial uses under consideration (oil approved for food use as substantially equivalent) USA: FDA 1998 Canada: Feb 1995 Japan: Dec 1997
	Rapeseed/ Canola	BASF AG	Phytase gene from *Aspergillus niger* (to degrade phytate in animal feed)	Phytaseed canola		MPS961, 962, 963, 964, 965	USA: FDA 1999
A363	**Rapeseed/ Canola**	**Monsanto**	**Glyphosate herbicide tolerant**	**Roundup Ready**		**GT73 (G73, R73)**	**EU: oil approved for food use as substantially equivalent USA: FDA 1995**

ANZFA Application Number	Plant	Company	Trait	Brand Names	Variety (Line) Names	Transform-ation event	Food Use Approvals and Consultations
							UK: ACNFP Jan 1996 **Canada: Nov 1994** **Japan: Sept 1996** **NZ/Australia: 2000**
	Rapeseed/ canola	Monsanto (was Calgene)	Modified fatty acid profile (higher quantities of laurate and myristate)			Laurate canola 23-198, 23-18-17	USA: FDA 1995 UK: ACNFP Under consideration Canada: April 1996
	Rapeseed/ canola	Monsanto Canada Inc.	Glyphosate herbicide tolerant			GT 200	Canada: Sept 1997
	Rapeseed/ canola[3]	Pioneer Hi-Bred	High oleic/low linoleic			45A37 46A40	Canada: Aug 1996
	Rapeseed/ canola[3]	Pioneer Hi-Bred	Imidazolinone herbicide tolerant			Lines NS738, NS1471 and NS1473	Canada: April 1995
A388	**Rapeseed/ canola**	**Aventis (was Rhone Poulenc)**	**Bromoxynil tolerant**			**Westar Oxy-235**	**USA: FDA 1999** **Canada: July 1997** **Japan: November 1999**
	Rice	Aventis	Glufosinate-ammonium herbicide tolerant			LLRICE E06, LLRICE E62	USA: FDA 2000
	Soybean	Aventis (was AgrEvo)	Glufosinate-ammonium herbicide tolerant	Liberty Link		A2704-12, A5547-127	USA: FDA 1998 Canada: November 2000
A387	**Soybean**	**Dupont**	**High oleic acid**			**G94-1, G94-19, G94-168**	**USA: FDA 1997** **Canada: October 2000** **NZ/Australia: 2000**
A338	**Soybean**	**Monsanto**	**Glyphosate herbicide tolerant**	**Roundup Ready**		**GTS 40-3-2**	**EU: importation (but not cultivation), storage and processing for food, feed and industrial uses approved May 1996**

ANZFA Application Number	**Plant**	**Company**	**Trait**	**Brand Names**	**Variety (Line) Names**	**Transform-ation event**	**Food Use Approvals and Consultations**
							USA: FDA 1994. **UK: ACNFP Feb 1995** **Canada: April 1996** **Japan: Sept 1996** **NZ/Australia: 1999** **Also approved in Mexico, Argentina, Switzerland**
ANZFA has been notified about these crops but they are not the subject of a formal application	Soybean	Syngenta (was Novartis)	Glyphosate herbicide tolerant			GTS 40-3-2 Monsanto	These plants were derived by conventional backcrossing the Monsanto Roundup Ready GTS 40-3-2 soy with Novartis soybean varieties. Approvals relevant to GTS 40-3-2 will also apply to these.
	Soybean	Agriculture and Agri-Food Canada	Low linoleic soybean				Canada: October 2000
	Squash	Seminis Vegetable Seeds	Cucumber mosaic virus (CMV), Watermelon Mosaic Virus 2 (WMV2) and Zucchini Yellow Mosaic Virus (ZYMV) resistant	Asgrow		ZW20 and CZW3 lines	USA: FDA 1994 (ZW20) and 1997 (CZW3) Canada: April 1998
	Sugar beet	Aventis (was AgrEvo)/KWS (product being developed by KWS in Germany, AgrEvo shares regulatory responsibilities for	Glufosinate-ammonium herbicide tolerant	Liberty Link		T120-7	USA: FDA: 1998 Japan: November 1999 Canada: November 2000

ANZFA Application Number	Plant	Company	Trait	Brand Names	Variety (Line) Names	Transform-ation event	Food Use Approvals and Consultations
		seeking approval)					
A378	**Sugar beet**	**Monsanto/ Syngenta (was Novartis)**	**Glyphosate tolerant**			**GTSB77**	**USA: FDA 1998**
	Tomato	Agritope	Fruit ripening delayed (S-adenosylmethionine hydrolase from *E. coli* bacteriophage T3)			35-1-N	USA: FDA 1996
	Tomato	DNA Plant Technology Corporation	Fruit ripening delayed (antisense amino cyclopropane carboxylic acid synthase suppression)			1345-4	USA: FDA 1994 Canada: Nov 1995
	Tomato	Monsanto (was Calgene)	Fruit ripening altered (Flavr Savr) (antisense polygalacturonase suppression)	Flavr Savr		CR3-613, CR3-623	USA: FDA 1994 UK: ACNFP Feb 1996 Canada: Feb 1995 Japan: Dec 1997
	Tomato	Monsanto (was Calgene)	Insect protected (*cryIA(c)* gene from *Bacillus thuringiensis* subsp. *kurstaki*)			5345	USA: FDA 1998 Canada: October 2000
	Tomato	Monsanto	Fruit ripening altered (1-aminocyclopropane-1-carboylic acid deaminase)			8338	USA: FDA 1995
	Tomato[4]	Zeneca	Fruit ripening altered/delayed softening (antisense polygalacturonase suppression)			TGT7-F	EU: Human food use under consideration USA: FDA 1994 UK: processed form (peeled and comminuted) ACNFP approved Jan 1998; processed form (tomato paste) ACNFP approved Feb 1995 and Feb 1996 (3 additional lines) Canada: June 1996

ANZFA Application Number	Plant	Company	Trait	Brand Names	Variety (Line) Names	Transform-ation event	Food Use Approvals and Consultations
	Wheat[4]	Cyanimid	Imidazolinone tolerant			SWP965001	Canada: Nov 1999

1. Has been approved by the FDA but not yet marketed in the US (Source: New Scientist 30 October 1999)
2. These products have been discontinued commercially.
3. Not a genetically modified product. Produced by mutation and traditional plant breeding, in vitro selection, or somaclonal variation. Canada requires such products with novel traits to be assessed so they appear on their approvals list. Approved in other countries including EU.
4. Approved by UK ACNFP as UK Competent Authority in May 1999 and by EU Scientific Committee on Food in October 1999 http://www.europa/eu.int/comm/dg24/health/sc/scf/index_en.html). Awaiting decision by European Commission.
5. This approval applies to field corn. An application from Novartis for approval of a GM variety of sweet corn is currently being considered by the Netherlands Competent Authority.