

**CURRENT AWARENESS OF GENETICALLY
MODIFIED FOOD ISSUES**

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**CURRENT AWARENESS OF GENETICALLY
MODIFIED FOOD ISSUES**



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SUMMARY

This report is one of a series intended to provide the New Zealand Food Safety Authority with an independent source of current information on issues related to genetically modified foods. This report covers developments in the period January to June 2003.

1 INTRODUCTION

This project is intended to provide the New Zealand Food Safety Authority with an independent source of current information on genetically modified foods (GMFs). 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 Authority 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 second report for the 2002/2003 year and covers events from January to June 2003.

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 New Zealand Food Safety Authority and Food Standards Australia New Zealand (FSANZ) 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

EPA: Environmental Protection Agency (US)

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

FSANZ: Food Standards Australia New Zealand

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 Traces of GM crops in wheat

Despite the fact that no GM wheat is commercially grown, traces of GM materials have been detected in both unmilled wheat and flour used to make bread and other foods. The source appears to be GM soy and corn particles mixed in with wheat supplies, and this illustrates the difficulty of maintaining complete segregation. A major UK milling company, Rank Hovis, has repeatedly found such traces of GM material using its own testing programme. Rank Hovis said cleaning techniques remove most if not all traces of foreign matter, though some small amounts are making it into flour (Source: Reuters 3 June 2003 via AgNet).

2.2 Quantification using hybrid amplicon standards

Current methods to quantitate the amount of a GM ingredient rely on either certified reference materials (available only for a range up to 5% w/w) or on plasmid preparations mass produced in GM bacteria. An alternative approach has been published (Pardigol *et al.*, 2003) which uses purified short sections of DNA which contain both the target gene and a reference gene. These are contained in a hybrid amplicon, generated from separate PCR reactions of the target and reference genes which generate amplicons which “overhang” i.e. when mixed, the tail sections of the 4 initial amplicons can bind and be extended to produce only two amplicons containing both genes. The hybrids are then quantified and used as standards in quantitative PCR determinations. Use of the hybrid amplicons was shown to successfully quantitate the amounts of GM ingredients in reference materials.

2.3 Starlink assay

A PCR reaction specific for the Starlink GM variety of corn has been published (Windels *et al.*, 2003). The method was demonstrated to be specific by its failure to amplify form DNA derived from MON810, T25, GA21m, Bt11, Bt176 and BtXtra corn.

3 GMF APPROVALS

Previous issues of this report have periodically included a table that listed approvals for human food use of GM transformation events. It has been decided to discontinue this table, in preference to the more extensive data at the AgBios database. This database covers human food use approvals as well as animal feed and environmental approvals, and some details about the genetic material inserted into each crop. The database is accessible at:

<http://www.agbios.com/default.asp>

Developments during the report period are summarised below.

3.1 Canada

In March 2003 Health Canada approved MON863 corn (rootworm resistant) for human consumption.

In January 2003 the Canadian government announced that it would accept Rainbow and Sunup GM papaya exported from Hawaii. The GM papaya are engineered for ringspot virus resistance, and have been exported to the US since 1998. The Hawaiian exporters are hoping for similar approval from Japan (Source: Honolulu Advertiser 28 January 2003 via AgNet).

3.2 USA

While GM corn variety MON863 engineered to be resistant to corn rootworm has been assessed and approved by both the USDA and the FDA, the EPA also needed to review this crop. This was because the crop is engineered to express a new variety of BT protein, Cry3Bb1. The release of such proteins are regulated by the EPA as they have jurisdiction over plant biopesticides. EPA approval was granted in February 2003 and this cleared the way for the crop to be planted commercially. Small areas are expected to be grown in 2003, with full production commencing in 2004. Most of the crop will be used as animal feed, although small amounts may be made into corn starch and oil for direct human consumption. It is also expected that the new variety will be crossed with other GM varieties, including those that confer protection against corn borer, and provide Roundup tolerance, to produce so-called "stacked" traits (Source: Washington Post 26 February 2003 via AgNet).

The EPA approval stipulated that farmers using MON863 corn must also plant an area of non-GM corn to act as a refuge for insects, in order to manage the build-up of insect Bt resistance. Despite calls by some organisations for the EPA approval to require equal (50%) non-GM corn plantings alongside the Bt corn, the EPA stipulated that such refuges need only be 20% of the GM area.

3.3 Spain

Spain has approved five new strains of GM Bt-corn for non-human consumption. Spain is one of the few European countries to commercially grow GM crops, but only 20,000 out of a total of 485,000 hectares of corn are GM varieties (Source: Reuters 13 March 2003 via AgNet).

4 LEGISLATIVE POSITION OF OVERSEAS GOVERNMENTS REGARDING GENETICALLY MODIFIED FOODS

4.1 Food Use Approvals

4.1.1 Codex

The fourth session of the Codex *ad hoc* Intergovernmental Task Force On Food Derived From Biotechnology was held in Yokohama in March 2003. The Task Force has already finalised (i.e. sent to the Codex Alimentarius Commission (CAC) for ratification) two documents; "Principles for the risk analysis of foods derived from modern biotechnology" and "Guidelines for the safety assessments of plant foods derived from modern biotechnology". The key business of the fourth (and final) meeting was to advance the "Draft guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms". This document was revised at the meeting and then it was agreed to advance the document to Step 8 i.e. to send it to the next meeting of the CAC.

The full report is available from:

<http://www.codexalimentarius.net/reports.asp>

4.1.2 European Union

Despite considerable anticipation, it appears that the EU moratorium on new approvals for GM crops will not be lifted until later in 2003. The EU Environment Commissioner announced that a new regulatory committee, which will decide whether GM organisms can be used in the EU, would not meet until October at the earliest. There is considerable opposition to allowing GM organisms onto the European market until new regulations were in place. As this "traceability and labeling" legislation, aimed at ensuring GM products can be withdrawn if environmental or health problems arise, is unlikely to be ready before October, EU markets will remain closed until then at the earliest. (Source: Reuters 4 march 2003 via AgNet).

The lifting of the moratorium is also dependent on the development of guidelines for GM crop co-existence with non-GM crops. At a meeting of Agriculture Ministers in February 2003 several member countries, led by Italy, added yet another obstacle by demanding that new rules be established for the coexistence of organic and GM agriculture before GMO approvals can resume. The European Commission (EC) is already formulating a strategy to manage coexistence, suggesting that Italy is simply using the issue of GM thresholds for organic products as another delaying tactic. Moreover, Italy is set to hold the EU presidency from July to December and will therefore set the EU agenda at the time when the latest pieces of GM legislation are expected to be approved (Source: Nature Biotechnology 2003; 21 (3): 346).

The two new pieces of EU legislation made some progress in March 2003 with their approval by the Council of Agriculture Ministers. The Council agreed a common position on a separate proposal for a regulation, concerning the traceability and labelling of GMOs as well as food and feed products produced from GMOs. This regulation will establish a framework for the traceability of products consisting of or containing GMOs in order to facilitate their

accurate labelling and the monitoring of the effects on the environment and human health. Both common positions will now be forwarded to the European Parliament for a second reading (Source: Euractiv 20 March 2003 via AgNet).

In April 2003 the European Commission formally requested that France, Luxembourg, Belgium, Netherlands, Germany, Italy, Ireland, Greece, Spain, Portugal, Austria and Finland adopt and notify national legislation implementing EU law on the deliberate release of genetically modified organisms (GMOs) into the environment. The twelve Member States cited have failed to meet an agreed deadline of 17 October 2002 for the adoption and notification of such legislation. As of 17 October 2002, a new Directive revising the original framework for regulating the release of GMOs in the European Union came into force. The original regulatory framework, which was established by the 1990 Directive, was established in response to concerns that the release of GMOs might lead to irreversible damage to the environment. A 1996 review identified several aspects of the original framework that needed clarification and improvement. As a result, Directive 90/220/EEC was revised and replaced by Directive 2001/18/EC. The revised Directive maintains the structure of the old directive, but improves the strictness and transparency of the provisions, notably creating a more effective and efficient authorisation procedure. In particular, it introduces:

- Principles governing environmental risk assessment
- Mandatory post-market monitoring, including monitoring of possible long-term effects on the environment
- A requirement to communicate information to the public
- A requirement for Member States to ensure labelling and traceability at all stages of marketing
- A requirement that initial approvals of GMOs be limited to a maximum of ten years
- Obligatory consultation of the Scientific Committee(s)
- An obligation to consult the European Parliament on decisions to authorise the release of GMOs
- The possibility, under the new comitology procedure, for Council of Ministers to adopt or reject a Commission Proposal for authorisation of a GMO by qualified majority

(Source: European Commission press release April 10 2003 via AgNet).

In May 2003 the Committee on the Environment, Public Health and Consumer Policy of the European Union decided to toughen proposed laws regarding labelling and traceability. Two reports were adopted at the Committee's 21 May meeting. The effect of these reports was to amend the common position of the European Council and Parliament. The changes were to lower the threshold for labelling from 0.9% to 0.5%, to oppose a tolerance for unauthorised GM crops, and to create mandatory (rather than voluntary) requirements for co-existence between GM and non-GM crops. The proposed tolerance due to adventitious or technically unavoidable presence was to have been 0.5% for a three year time period for unauthorised (but still favorably assessed for safety) GM material, after which the tolerance would drop to zero. In effect the Committee set an immediate zero tolerance, and this has created concern amongst countries exporting to Europe, as such limits may be unachievable. These amendments to the common position will go to the European Parliament in July 2003.

For copies of these reports see:

<http://www.europarl.eu.int/meetdocs/committees/envi/20030521/envi20030521.htm>

An updated (March 2003) version of the useful document "Question and Answers on the Regulation of GMOs in the EU" March 27, 2003 is available at: http://europa.eu.int/comm/dgs/health_consumer/library/press/press279_en.pdf

4.1.3 Biosafety Protocol

On June 13 the Convention on Biological Diversity announced that the 50th nation (the Republic of Palau) had ratified the Cartagena Protocol on Biosafety. This ratification started a 90 day countdown , with the treaty coming into force on 11 September 2003. The requirements of the Protocol will be:

- Countries shipping living modified organisms (LMOs) for intentional introduction into the environment will have to give prior notification of the first shipment to an importing country that is a party to the Protocol under what is referred to as the "Advance Informed Agreement" procedure. Sufficient information will have to be provided to enable importing countries to make informed decisions on whether to accept the shipment.
- Member countries of the Protocol will also be required to use the Biosafety Clearinghouse (BCH) to fulfil a number of specific obligations. The BCH is a largely Internet- based facility established under the Protocol to ease communications and exchange of information between the Parties.
- All shipments containing LMOs for intentional introduction into the environment will be clearly identified as such in the accompanying documentation which must specify the identity and characteristics of the specific LMOs contained in each shipment.

New Zealand, Australia and the US have not ratified the Protocol.

In June the European Parliament approved in its second reading a proposed regulation for the transboundary movement of GM organisms. This agreement marked an important step towards the full implementation into Community legislation of the provisions of the Cartagena Protocol. The Proposal on the transboundary movements of GMOs is linked to the ratification in June by the European Community of the Cartagena Protocol on Biosafety.

The main elements of the proposal are:

- The obligation to notify exports of GMOs intended for deliberate release into the environment;
- The obligation to provide information to our international partners on Community practices, legislation and decisions on GMOs, as well as on accidental releases of GMOs;
- A set of rules for identifying GMOs for export.

(Source: European Commission 4 June 2003
http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/03/790|0|RAPID&lg=EN).

In June 2003 the Japanese Diet also enacted a bill for regulating the use of genetically modified organisms (GMOs) with the House of Representatives approving it at a plenary session following its earlier adoption by the House of Councillors. The GMO usage law, expected to take effect next year, provides Japan with a legal framework to ratify the 2000 Cartagena Protocol on Biosafety (Source: Japan Today 10 June 2003 via AgNet).

4.1.4 WTO

In May 2003 it was announced that the US had finally decided to challenge the EU moratorium on GM food approvals at the World Trade Organisation (Source: ABC News May 9 2003 via AgNet). The US case was jointly filed with Argentina, Canada, and Egypt, and supported as third parties by: Australia, Chile, Colombia, El Salvador, Honduras, Mexico, New Zealand, Peru and Uruguay. As a first step, the countries requested a 60-day consultation period at the WTO. If no resolution is found they may seek the formation of a WTO dispute settlement panel to hear arguments. Dispute settlement procedures, including any appeal, typically take 18 months (Source: Agence France Presse 13 May 2003 via AgNet).

On 29 May Egypt announced that it had withdrawn from the case (Source Reuters 29 May 2003 via AgNet).

4.1.5 USA

The US FDA appears to be backing away from the proposed mandatory notification process for new GM crops intended for human food use. Statements by the Deputy Commissioner of the FDA in June 2003 to the US Congress indicated that the proposed rule was not a priority for the FDA. A spokesperson for the Biotechnology Industry Organisation indicated that the current 100% compliance with the voluntary system would continue and no company would bring a new GM crop to market without FDA review (Source: Associated Press June 17 2003 via AgNet).

4.1.6 Switzerland

The Swiss Parliament has approved a new law regulating GM crops in food production. The law follows the rejection of a five-year moratorium on commercial GM production, and will allow the planting of GM crops while protecting non-GM crops from cross fertilisation. Field trials must first be conducted under closed conditions and outdoor field trial planting will only be allowed if indoor trials cannot provide the needed results (Source: Crop Biotech Update March 21 2003 via AgNet).

4.1.7 United States post-market oversight

The Pew Initiative on Food and Biotechnology commissioned a report prepared by Resources for the Future on post-market oversight on biotech food in the US. It was released in April 2003 and the full report can be found at:

<http://pewagbiotech.org/research/postmarket/>

The question to be answered was: Is the system prepared for post-market oversight? The study concluded that this question cannot be answered until the objectives of such oversight are defined. The report considered that the objectives should include:

- Foster compliance with conditions of use or other restrictions imposed during the premarket review process;
- Detect non-compliance and unforeseen health and environmental problems;
- Take appropriate enforcement action to correct and penalise non-compliance; and,
- Manage follow-up investigations, market disruptions, and other consequences of non-compliance and unforeseen problems.

The report found that there was doubt about the preparedness of the current system to achieve these objectives. This consisted of the agencies USDA, EPA, and FDA, which were considered to lack programmes, data collection systems, and in some situations, a legislative mandate. However, there was no suggestion of widespread non-compliance at present, or any specific food safety or environmental problems. The Starlink and Prodigene incidents revealed some vulnerabilities, but also demonstrated that the agencies had considerable capability to react to problems when they arose.

It was anticipated that there would be a need for greater post-market oversight in the future as a wider range of GM food crops are planted, and stronger restrictions on biopharming are introduced.

More fundamentally, the report indicated that there needs to be a debate about the degree of post-market control desired by society. This is a values laden question that needs to be debated before public policy can be developed.

4.2 Labelling

4.2.1 UK

The UK Food Standards Agency published a report in June 2003 on a survey they had conducted to check the labelling of GM foods. A total of 91 samples were taken for testing: 45 containing soy, 42 containing corn, two rapeseed oils, and two containing tomatoes. Of these, 18 samples made “GM free” claims, three of which were found to contain undeclared GM ingredients (all soy). A further 5 samples were found to contain undeclared GM soy, but no label claims were made. For all the positive samples the level of GM ingredients was below the 1% threshold for labelling.

When GM free claims were made, local authority representatives visited manufacturers to remind them of their responsibilities to ensure label claims are correct. However, there is no specific legislation covering the use of “GM free” on food labels in the EU. Local authority

representatives also contacted the other manufacturers of positive product to make them aware of their labelling responsibilities.

Three of the foods sampled did make positive label claims for GM ingredients: all were cakes or baked goods.

The full report is available from:

<http://www.foodstandards.gov.uk/news/newsarchive/gmlabellingchecks20june2003>

4.2.2 Japan

The USDA Foreign Agricultural Service has published an overview of policies and labelling of biotechnology derived crops in Japan. Included in the report is a description of a survey of 59 products in Japan for GM ingredients. The samples were either labelled GM free or unlabelled. Biotech ingredients were detected in 11 of the 59 samples (6 of soy origin and 5 of corn origin), and in one sample the level of GM derived DNA exceeded the informal threshold for unintentional commingling of 5%. The Japanese authorities issued guidance to the company to require labelling to indicate the presence of GM ingredients.

The USDA report is available from:

http://www.fas.usda.gov/scriptsw/AttacheRep/gain_display_report.asp?Rep_ID=125681754

4.2.3 Canada

The Canadian General Standards Board has been working on a voluntary standard for labelling of GM food in Canada since late 1999. The draft standard was released in 2001, and proposed a 5% threshold for labelling that was the subject of considerable criticism. Now it appears that the Board has been unable to resolve internal differences regarding the standard and the effort may be discontinued. A letter from the Board's chair to other Board members expressed concern and indicated that the group should either resolve its differences or dissolve (Source: Globe and Mail 14 March 2003 via AgNet).

However, a further meeting of the Board in May made substantial progress towards resolution of the conflicts, and hope was expressed that a voluntary standard would be agreed in June (Source: Western Producer 6 June 2003 via AgNet).

4.2.4 Hong Kong

There are currently no labelling requirements for GM foods in Hong Kong. Despite calls from environmental groups for a mandatory labelling system, a paper presented to the Hong Kong Legislative Council advocated a system of pre-market safety assessment and voluntary labelling. The reasons given were significant costs to the food industry and the lack of international consensus on labelling. A study of the potential impact of introducing a GM food labelling system in Hong Kong shows that, in the case of a mandatory system, the food trade would incur costs of between \$16 million and \$91 million during the first year of implementation. The government would need to spend a further \$1 million to \$5 million per year on enforcement (Source: South China Morning Post 18 March 2003 via AgNet).

Despite the paper's arguments, the Council instead voted to urge the government to impose a mandatory labelling system (Associated Press 21 March 2003 via AgNet). The Legislative Council has the power to enact laws within Hong Kong but final authority rests with the Chief Executive of the Hong Kong Special Administrative Region.

4.2.5 Thailand

GM labelling of food in Thailand was scheduled to begin on 11 May 2003. A total of 22 products made from corn or soy are required to be labelled if the GM products are among the top three ingredients and the GM content is more than 5%, based on a 2002 Public Health Ministry announcement. The use of GM-free labelling is also banned. (Source: Thai Daily Digest 21 April 2003 via AgNet).

4.2.6 Ireland

A new study by the Food Safety Authority of Ireland, on labelling of foods for GM content, found that of 75 foods tested, 12 contained low levels (<1%) of GM ingredients. The 75 foods tested included breakfast cereals, baby foods, dried soya products as well as soya and corn flour products. Seven of the 12 products were inaccurately labelled to indicate that they contained no GM ingredients, or were organic products, or both.

Full results of the survey are available from:

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

4.2.7 Brazil

Measure 113 introduced by the Brazilian government to help it manage illegal planting of Roundup Ready soy, also appears to mandate labelling in that country. Information is unclear, but it seems that the threshold for labelling has been set at 1% and food ingredients that do not contain DNA or protein are exempt (Source: Planet Ark 1 May 2003 via AgNet).

5 CURRENT DEVELOPMENTS

5.1 Resources

5.1.1 US overview of biotechnology and trade

In January 2003 the US Department of State published an overview of the status of trade of biotechnology food products in the journal *International Economic Review*. It covers the status of such crops in international regulatory organisations, the status of biotechnology food products in a variety of countries and US exports to those countries. The article is also available on line at:

<http://usinfo.state.gov/topical/global/biotech/03011501.htm>

5.1.2 Reviews of the effect of GM crops on the environment

Two major reviews of the effect of GM crops on the environment have been published by “The Plant Journal”. The reviews are:

- The release of genetically modified crops into the environment. Part 1. Overview of current status and regulations
- The release of genetically modified crops into the environment. Part 2: Overview of ecological risk assessment.

Both articles are available from:

<http://www.blackwellpublishing.com/static/plantgm.asp>

5.1.3 Overview of biotechnology industry and its regulation

The International Food Policy Research Institute (IFPRI) has produced a series of briefs which give a useful summary of the biotechnology industry, its regulation, and intellectual property issues. See:

<http://www.ifpri.org/pubs/rag/br1001.pdf>

5.1.4 FAIBioDeC (FAO Database on Biotechnologies in Developing Countries)

This new database gathers, stores, organises and disseminates updated baseline information on the state-of-the-art of crop biotechnology products and techniques, which are in use, or in the pipeline in developing countries. The database includes about 2000 entries from 70 developing countries, including countries with economies in transition. While the available data at present are limited, it appears to be a very useful collation of crops in development, field trials, and commercialisation.

http://www.fao.org/biotech/inventory_admin/dep/default.asp

5.1.5 International Council for Science (ICSU)

The ICSU is an international UN affiliated cooperative group of 73 national science organisations, including the New Zealand Royal Society and the US National Academy of Sciences. In June 2003 it released a report entitled "New Genetics, Food and Agriculture: Scientific Discoveries - Societal Dilemmas" that was described as a synthesis of more than 50 science based reviews which assesses the risks and benefits of applying new genetic discoveries to food and agriculture. The report is based on an examination of reviews prepared by national academies of sciences, international organisations, and private agencies over the past three years (1999-2002), and identifies areas of scientific convergence, scientific divergence, and gaps in knowledge. In relation to societal concerns about genetically modified foods and other genetically modified organisms, the report addresses five key questions: Who needs GM foods? Are GM foods safe to eat? Will GMOs affect the environment? Are the regulations adequate? Will GMOs affect trade?

The complete report can be found at:

<http://www.icsu.org/>

5.2 Human Health

5.2.1 Milk from animals fed GM feed

It has generally been accepted that food derived from animals fed GM crops as feed does not contain any trace of novel DNA. Experiments with chickens and cows fed GM food (Espanier *et al.*, 2001) showed that chloroplast DNA could be briefly detected at low levels in animal blood, internal organs and milk, but not the transgene itself. Chloroplast DNA is 10^3 - 10^4 more abundant than the single copy transgene in plant material.

This has now been reinforced by scientists in Austria who fed dairy cows both soy and corn based feed (Poms *et al.*, 2003). Milk derived from these cows was tested for short fragments of DNA derived from the corn invertase and soy lectin genes. None could be detected. Another experiment involved the injection of purified DNA directly into the animal's bloodstream. The injected DNA could be detected after 2 minutes, but not after 10 minutes.

These results demonstrated that analysis of milk from dairy cows could not be used to determine whether the animals had been fed GM plant crops as feed.

5.2.2 Allergenicity Assessment

Another overview of the status of allergenicity assessment of genetically modified crops has been published (Ladics *et al.*, 2003). This derives from a workshop convened by the Society of Toxicology in March 2002, and contains a useful overview of the current status of animal models. The Society has also published a position paper regarding the safety of GM foods (see: <http://toxsci.oupjournals.org/cgi/content/full/71/1/2>).

Another discussion article has been published which addresses non-IgE mediated food sensitivity in more detail (Haslberger, 2003). The full article is available from:

<http://www.biotech-info.net/hypersensitivity.html>

5.3 Consumer Issues

5.3.1 British Medical Association

In 1999 the British Medical Association (BMA) published a report which expressed concern about the long term effects of GM crops on human health. This report has been widely cited by anti-GM groups, and was linked as a cause of the rejection of GM food aid by African countries in early 2003. In January 2003 it was announced that the BMA would revisit the issue in a review meeting to be held later this year. A spokesman for the BMA stated: "The BMA's report from 1999 was an interim report reflecting the early stage of scientific evidence reviewed. A round table meeting with scientists with knowledge of the developments in research and other parts of the evidence base is planned for later this year. That meeting might lead to a new report from the BMA - a second Interim statement - if the Board agrees there is sufficient new evidence to merit such a report (Source: BBC News and BMA statement 31 January 2003 via AgNet).

5.3.2 Bar codes for GM crops

An article in New Scientist (15 February 2003) describes how a patent has been granted to the UK National Institute of Agricultural Biology for a method to add a unique sequence to all GM organisms. This would allow a single test to identify any product as GM if it contains intact DNA. Additional sequences might contain information to identify the specific modification and the company involved. These sequences could remove the need to conduct multiple tests to determine the presence and identification of GM material, as well as preserving commercially confidential information about the modification. Inclusion of the sequences could be made compulsory under EU legislation.

Another system that has been proposed uses an artificial triplet codon set to represent letters of the alphabet and numbers (Marillonnet *et al.*, 2003). This would enable information to be included in the genome of the transgenic organism, without affecting the normal function of the rest of the genetic material. It is also suggested that a gene for a short "universal" polypeptide (with no safety issues) could be included in the genetic code to provide a marker for genetic modification.

A subsequent letter (Pauli, 2003) argued against the value of such systems, for GM food crops at least. Chief concerns were the need for additional risk assessment to examine the effect of any such tag on a case by case basis, and the fact that such a tag would still not allow analysis of food derivatives such as plant based oils.

5.3.3 Debate on genetically modified foods in the United Kingdom

As described in the January 2003 report from this project, the UK Agriculture and Environment Biotechnology Commission was set up in June 2000 with a remit to provide the UK Government and Devolved Administrations with independent, strategic advice on

developments in biotechnology and their implications for agriculture and the environment. It looks at the broad picture taking ethical and social issues into account as well as the science.

In July 2002 the Commission was charged with undertaking a national public dialogue on genetically modified crops, prior to their commercial release. The suggestion that there should be a national debate stemmed from the report "Crops on Trial" published by the Agriculture and Environment Biotechnology Commission (AEBC) in September 2001. The dialogue was launched in September 2002 and has three main parts: a science review, a public debate and an economics study.

Details of the public debate were announced in February 2003. It will include:

- six national and regional conferences - three in England and one each in Scotland, Wales and Northern Ireland;
- smaller county-level meetings;
- a 'toolkit' to encourage discussion at village and local group level; and,
- a film.

The campaign will run during May – July 2003 and cost 500,000 pounds. There has been concern that the debate is being held before the results of the extensive field trials of GM crops in the UK are known, and the debate is concurrent with possible further approvals of GM crops as new EU legislation comes into force.

The official website is:

<http://www.gmpublicdebate.org.uk/>

The science debate is being held concurrently. The source web page can be found at:

<http://www.gmsciencedebate.org.uk/>

Several Royal Society submissions on the debate can be found at:

<http://www.royalsoc.ac.uk/gmplants/>

Another public debate was officially announced in February 2003 by the UK Food Standards Agency. A number of communication initiatives are involved including:

- a citizen's jury (the FSA Citizens' Jury decided on 7 April that GM foods should be available to buy in the UK, although a sizeable minority (6 out of 15) disagreed, believing that the UK is not yet ready for GM foods. Their final report is available from <http://www.foodstandards.gov.uk/news/newsarchive/citizensjuryfinalreport/>);
- sponsorship of a schools debating competition at Durham University (the motion 'This house would eat GM food' was passed by a majority of the students attending the competition on 23 March);
- a video about genetically modified foods made by school students;
- discussion groups with young people and consumers on low incomes in Scotland;
- a new FSA website about genetically modified food; and,

- publication of a new booklet providing factual information to consumers about GM food.

Further details are available from:

http://www.foodstandards.gov.uk/gmdebate/gmpress/gm_pr

In another contribution to the debate in the UK, the Nuffield Council on Bioethics has announced that it will re-assess the conclusions and recommendations of its 1999 report, entitled "Genetically Modified Crops: Ethical and Social Issues". This is being done in the light of recent developments particularly in developing countries. GM crops have been grown on a considerable number of smallholding farms in developing countries over the last three years. Recent trends in poverty and hunger in developing countries also need to be considered. Rural poverty has become an increasing concern, while at the same time improvements in crop yields have slowed. The potential application of GM technology will be considered in the context of developments in regulation, trade, intellectual property rights and consumer attitudes. The Council published a draft discussion paper on the topic for consultation in June 2003. This stated that the European Union is ignoring a "moral imperative" to promote genetically modified crops for their great potential for helping the developing world, and that tough EU import and labelling regulations are deterring poor countries from growing GM produce, even though their farmers stand to gain more from the technology than any other group.

More information is available from: <http://www.nuffieldfoundation.org/home>

5.3.4 Information and effects on consumer acceptance

The USDA Economic Research Service has released the results of a study on influences on consumer acceptance of GM foods. "The Effects of information on consumer demand for biotech foods: evidence from experimental auctions" describes a series of experiments in 2001. During each auction of various food items, some GM and some non-GM, the participants were given one of a series of information packs about biotechnology from a variety of sources. It was found that participant's bids (the amount they were "willing to pay") were affected by the information packs they received. ProGM and anti GM packs produced expected higher and lower bids as expected, while packs with a mixture of information produced lower bids, confirming expectations that consumers place more weight on negative information. However, pro-GM information from science based organisations (as opposed to biotechnology companies) resulted in higher bids, and strongly offset anti-GM information. This is consistent with other studies which show that the information source is as important as the information itself.

The full report is available from:

<http://www.ers.usda.gov/publications/tb1903/tb1903.pdf>

5.3.5 Bans on GM materials by retailers in Europe

A review article has been published which discusses the dynamic of the bans on GM foods by major retailers in Europe (Kalaitzandonakes and Bijman, 2003). Although these are usually attributed to consumer demands, the authors argue that in fact there are other market related motives. For example, the proliferation of “in house” brands had led some retailers to seek competitive advantage through advertising an absence of GM ingredients. The introduction of such bans, initially of GM ingredients and more recently of products from animals fed on GM feed, has been led by smaller retailers, who may be seeking advantage against their larger rivals. These bans also pre-empt and often exceed the requirements of EU legislation.

5.4 Agricultural and Environmental Issues

5.4.1 Global Review of Commercialised Transgenic Crops: 2002

The latest in this series of publications by the International Service for the Acquisition of Agri-Biotech Applications (ISAAA) is for the year 2002. (For ordering see: <http://www.isaaa.org/>). Selected data from the report are given in Tables 1 - 3. Hectare areas were converted to acres using approximately 2.5 acres in a hectare.

Table 1: Global acreage of transgenic crops and total global acres by crop

Crop	GM area (10 ⁶ acres)				Global area (10 ⁶ acres) (% GM in 2002)
	1999	2000	2001	2002	
Soybean	54.0	64.5	83.3	91.3	180 (51)
Corn	27.8	25.8	24.5	31.0	350 (9)
Cotton	9.3	13.3	17.0	17.0	85 (20)
Rapeseed/Canola	8.5	7.0	6.8	7.5	62.5 (12)
Potato	<0.3	<0.3	<0.3	-	N/A
Total**	98.6	110.7	131.5	146.8	677.5 (22)

N/A = Not applicable

** Due to minor crops, rounding and conversion factors totals may not be exact.

The 12% increase in area of transgenic corn was predicted in a June 2002 survey of US farmers by the USDA.

Table 2: Global dominant transgenic crops by crop

Crop	% of total in 2000	% of total in 2001	% of total in 2002
Herbicide tolerant soybean	59	63	62
Insect resistant corn	15	11	13
Herbicide resistant rapeseed/canola	6	5	5
Insect/herbicide resistant cotton	4	5	4
Herbicide resistant corn	5	4	4

Table 3: Global acreage of transgenic crops by country

Country	2000 (10 ⁶ acres)	2001 (10 ⁶ acres)	2002 (10 ⁶ acres)
USA	75.8	89.3	97.5
Argentina	25.0	29.5	33.8
Canada	7.5	8.0	8.8
Australia	0.5	0.5	0.3
China	1.25	3.8	5.3
South Africa	0.5	0.5	0.8

5.4.2 GM crop plantings

5.4.2.1 *USA*

A survey of US farmers published by Reuters in January predicted that US plantings of GM crops would again increase in 2003. Plantings of Roundup Ready soy were predicted to increase by 8.4%, while Roundup Ready corn would increase by 9.9%. Bt corn plantings were predicted to decline by 3.8%. GM cotton was also predicted to increase, with Roundup Ready cotton rising by 4.0% and Bt cotton by 5.2% (Source: Reuters 22 January 2003 via AgNet).

The annual survey of farmers by the USDA also predicts an increase in the area of GM crop planted in the US. Predictions were that 38% of the 79 million acres of corn planted in 2003 probably will be GM, up by 4% from 2002 and 13% from 2000. Approximately 80% of the 73.2 million acres of soybeans is predicted to be Roundup Ready soy in 2003, up by 5% from 2002 and 16% from 2000. The National Agricultural Statistics Survey is based on interviews with 75,000 growers in 48 corn states and 31 soybean states (Source: Associated Press 31 March 2003 and <http://www.usda.gov/nass/PUBS/TODAYRPT/pspl0303.pdf>).

5.4.2.2 *Canada*

In Ontario in 2002 45-50% of the corn grown was from GM varieties and more than 90% of the canola was GM. These proportions are expected to increase in 2003 (Source: The Record 7 April 2003 via AgNet).

The Canadian government has updated their Regulatory Directive Dir94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits. The full document is available from:

<http://www.inspection.gc.ca/english/plaveg/pbo/dir/dir9408de.shtml>

5.4.2.3 *Paraguay*

Paraguay is the third largest exporter of soy in South America (after Brazil and Argentina). It has yet to approve commercial production of GM soybeans, but it is expected to closely follow Brazil when that country approves the GM crop. However, as in Brazil, Paraguayan farmers are smuggling GM soy seeds from Argentina, and the demand is so great that the market for conventional soy seed is collapsing (Source: Reuters 14 January 2003 via AgNet).

5.4.2.4 *Australia*

Ingard insect protected Bt cotton has already been grown in Australia for a number of years. It was previously approved for commercial release under the voluntary system, but in February 2003 an application for continued use was submitted to the new mandatory approval process of the Australian Office of the Gene Technology Regulator (OGTR press release 4 February 2003 via AgNet).

Another variety of GM cotton, Roundup Ready, is being rapidly adopted by Australian farmers, and now represents 38% of the total area of GM cotton planted. One reason for this is the voluntary cap placed on plantings of Bt cotton by the industry, in order to reduce the risk of insect resistance development. A second factor was the ability of farmers planting Roundup Ready cotton to use low tillage farming, which limits wind and water erosion (Source: Australian Biotechnology News 31 January 2003 via AgNet).

The continued commercial release of both these cotton varieties was approved by the OGTR in June 2003.

In April 2003 the OGTR released the Risk Assessment and Risk Management Plan for the Invigor variety of GM canola from Bayer for an 8 week period of public comment. The Regulator stated that she had found that "GM canola poses no higher risk to human health and safety or the environment than is currently posed by the farming of conventional, non-genetically modified canola." However, in June 2003 the application 'clock' was stopped on the Bayer GM canola application (DIR21) to enable the thorough examination of all relevant procedural issues. It is anticipated that the clock will be stopped for approximately one month.

The application clock has also been stopped on Monsanto Roundup Ready canola, pending advice on herbicide use. When this is received a similar Plan will also be released for public comment.

The situation regarding commercial release of GM canola in Australia has been complicated by moratoria in GM crops by New South Wales (three years from 2003), Victoria, Tasmania (five years from 2003), and Western Australia State governments (this leaves Northern Territories and Queensland as the only States that might grow GM canola in 2003). The purpose of the moratoria is to allow more time to assess marketing and trade implications (which are outside the scope of the OGTR assessment). Even if the OGTR approves commercial release in 2003, no plantings will be allowed by those States, beyond existing field trials.

The OGTR has also given approval for field trials of CSIRO-developed GM grapevines in Victoria. The purpose of the trials is to evaluate the performance of grapevines containing additional copies of grapevine genes, modified to improve colour, flavour, sugar composition, flowering and fruit quality. Pollen flow of GM grapevines containing green fluorescent protein will also be studied. All grapevines were approved for trial under the former voluntary system overseen by the Genetic Manipulation Advisory Committee, and licences issued under the transitional arrangements of the Gene Technology Act 2000. These licences will expire in June 2003. There have been no reports of adverse effects on human health and safety or the environment resulting from these previous releases and approval of this application will enable trials to be continued.

Other decisions by the OGTR in June 2003 were to license the continued commercial release of Florigene GM blue carnations (originally licensed under the previous voluntary system) and to approve a limited field trial of GM papaya with delayed fruit ripening on a one hectare site in Redlands, Queensland.

See OGTR website: <http://www.health.gov.au/ogtr/index.htm>

5.4.2.5 China

The Chinese government has announced continued support for the development of biotechnology derived crops. During the tenth Five-Year Plan period (2001-2005), the central government will invest 6 billion yuan (\$726 million US) in basic and application research in the life sciences, as well as in some high-tech research and development. Statistics from the Ministry of Science and Technology show that in the past five years, China has developed a total of 600 new crop varieties and 1,000 new products, and built nearly 2,000 test bases and 5,000 pilot sites (Source: Xinhua News Agency February 20, 2003 Via Agnet).

5.4.2.6 Thailand

Thailand has announced that it will allow field testing of genetically modified crops but continue to ban bio-engineered products from being sold. Thailand currently bans the import of genetically modified food and other products and only allows testing of bio-engineered cotton seed in laboratories (Source: Reuters February 26, 2003)

5.4.2.7 Brazil

The Brazilian lower house of Congress has approved a provisional measure (Measure 113) which allows the sale of soybeans that may contain GM material until the end of March 2004, provided they are labelled as such. The impetus for this move appears to have been the recognition that an estimated 80% of the soybean crop in Rio Grande do Sul, and 12% of the national crop, is GM. This is despite the fact that transgenic crops are still banned in Brazil while a federal court considers whether the government's commission on biotechnology, CTN Bio, has the authority to approve their commercial planting and sale. The provisional measure is intended to facilitate trade (Source: Reuters 27 March and 14 May 2003 via AgNet).

Along with the agreement to allow properly labelled GM soy to be traded, Brazilian growers are also in the process of negotiating agreements to pay Monsanto royalties for use of the illegally planted GM soybeans (Source: Reuters 11 June 2003 via AgNet).

5.4.2.8 India

GM cotton was approved for commercial release in India in 2002. There has been a number of claims about the yield and economic performance of the crop. An overview of results from field trials conducted in India in 2001 has now been published (Qaim and Zilberman, 2003). Prior studies in India showed that crop damage from bollworm attacks averaged 50 to 60 percent. In the study, the researchers found that average yields for Bt cotton were 80 percent greater than their non-Bt counterparts, and 87 percent greater than the local cotton hybrids. In

addition, the Bt cotton crops were sprayed against bollworms three times less often than both the non-Bt and local cotton crops.

These results are in contrast to the United States and China, where yield increases have been modest (10%), and the major benefits being in pest management. The difference was attributed to the unaffordability and inefficient application of pesticide treatments on India, resulting in greater pest damage to traditional crops.

According to a report in *Nature Biotechnology* (2003; 21: 117), India has also given support for the development of GM rice varieties. A workshop held by the Indian National Academy of Agricultural Sciences endorsed the development of rice varieties tolerant to drought, submergence, salinity, and rich in micronutrients. However, work on transgenic rice for biopharming was discouraged.

5.4.3 Field scale trials of GM crops in the UK

There is considerable interest in the results of these trials which are to be published as scientific papers over the next few months. In April 2003 the Royal Society published details of how the results will be assessed and released, in an article by its President, Lord May. From the article:

“May states that an area much greater than the total land area of Great Britain has been under cultivation with GM crops in the United States, Canada, China and elsewhere, for several years, with no adverse effects having yet been identified, whereas benefits from reduced pesticide use have been demonstrated. Even so, the special nature of the British countryside with its intimate patchwork of woodland and hill farms, cropland and pasture, meant most people agreed that the FSEs were necessary here. The Government appointed an independent group, the scientific steering committee, to oversee the conduct of the FSEs. The committee undertook to have the results of the FSEs published in reputable peer-reviewed scientific journals and decided to submit them in two tranches, the first to include the corn, beet and spring-sown oilseed rape trials, the second to include the autumn-sown oilseed rape trials. The first tranche has already been submitted to *Philosophical Transactions of the Royal Society*. This is the world's longest established scientific journal and publishes sets of papers on single themes. The second tranche will be submitted to a journal later this year.”

Further information is available from the Royal Society website at:

<http://www.royalsoc.ac.uk/templates/search/websearch.cfm?mainpage=/gmplants/intro.htm>

5.4.4 Roundup Ready wheat

The process towards the introduction of the first GM variety of wheat is proceeding, with applications for approval for commercial release and food use lodged by Monsanto in the US, Japan and Canada. Despite concern amongst many US wheat farmers that their markets may reject wheat from a country that grows GM varieties, the Egyptian Foreign Minister announced that his government would not do so. Egypt is the second largest importer of wheat in the world (6.1 million tons in 2002-2003) after Brazil (6.3 million tons) (Source: Dow Jones 6 February 2003 via AgNet).

The USDA is expected to place strong controls on the commercialisation of Roundup Ready wheat. Even if the wheat is approved by the United States, Monsanto has promised not to sell it until at least Canada and Japan accept it and a secure segregation system is in place. US wheat exporters currently sell their wheat to foreign markets with a USDA-approved statement saying no biotech wheat is commercialised in the United States (Source: Reuters 16 March 2003 via AgNet).

5.4.5 Long term pest control

One concern about the use of Bt crops is the potential for emergence of insect resistance. A 10 year study of Bt cotton crops in Arizona has shown that the pink bollworm pest was suppressed in regions where Bt cotton was abundant (Carriere *et al.*, 2003) This suppression was not observed with regions using insecticide sprays, and demonstrates that Bt crops have value over this time period.

5.4.6 New GM crops with properties relevant to agriculture

5.4.6.1 *Pulses*

After commercial cultivation of transgenic cotton, and field evaluation of mustard, the next GM crop development in India is likely to involve pigeon pea and chick pea pulses engineered to be resistant to the pod borer insect *Haliverpa armgera*. India produces 90% and 73% of the world crop of these two pulses respectively (Source: Deepika Global New Delhi 13 January 2003 via AgNet). Field trials of the chickpea, which has been made insect resistant by introducing genes from *Bacillus thuringiensis* and soya trypsin inhibitor, are planned for 2004 (Source: The Hindu Business Line 19 January 2003 via AgNet).

5.4.6.2 *New GM wheat*

To date, most of the interest in GM wheat has revolved around the Roundup Ready variety developed by Monsanto. Now Syngenta has announced that it is seeking contracts with US universities to help it develop a GM wheat that is resistant to Fusarium head blight (or “scab”). This fungal disease can damage wheat crops, as well as produce mycotoxins dangerous to human health. The wheat is moving into advanced development but is not expected to be launched commercially until 2007 (Source: Reuters 21 February 2003 via AgNet). Syngenta has also applied for permission to conduct field trials of the wheat in Germany and the UK (Sources: Reuters March 14 and April 8 2003 via AgNet).

5.4.6.3 *GM orange trees in Brazil*

Despite the ban on commercialised GM crops in Brazil, researchers there are in the process of developing a virus-resistant transgenic orange tree. The intention is to develop a tree resistant to the citrus tristeza virus (CTV) which causes sudden death. The viral disease is a virulent mutation of an older plague that wiped out Brazil's orchards in the 1950s, and has surfaced across an area holding about 22 million trees in Brazil's main orange state of Sao Paulo (Source: Reuters 14 April 2003 via AgNet).

5.4.6.4 *Corn in France*

Despite Europe's moratorium on approvals for new GM food crops, biotechnology companies continue to develop new products. Field trials in France have been announced by the European Commission for three new GM corn varieties: Syngenta Seeds SA: insect resistant corn, Biogemma: GM corn with improved photosynthesis performance under drought conditions and GM corn modified for the lignin biosynthesis pathway. (Source: Life Sciences Network 1 April 2003 via AgNet)

5.4.7 Starlink corn settlement

A total of \$110 million (US) has been agreed by a court in the US to compensate farmers for the effects of the Starlink contamination incident. The money will be used to compensate not only farmers whose crops actually contained Starlink, but also other corn farmers who lost money through the disruption of the corn market (Source: Press release 16 April 2003 via AgNet).

5.4.8 GM rape/canola in mustard seed

A consignment of brown mustard seed from the Canadian 2002 harvest, imported into France from Canada, has been discovered to contain low levels of seed from three varieties of GM oilseed rape: Roundup Ready, Liberty Link and Seed Link. While the oil from these three varieties of GM oilseed rape is licensed by the EU for food use, approval for the use of the seed from the GM oilseed was not sought. Safety assessments have been carried out on the oil and the seed of these three varieties of GM oilseed rape and as a result the GM oilseed rape seed is not considered a health risk to consumers. The Agency does not consider the presence of the GM oilseed rape seed in mustard to present a health risk. The level of GM oilseed rape seed present in the mustard seed is approximately 0.0018-0.003%. Nevertheless the UK FSA issued a reminder to seed importers that they have a responsibility to carry out appropriate checks for the possible presence of non-EU authorised GM varieties in food produce imported into Europe (Source: UKFSA 16 May 2003 <http://www.foodstandards.gov.uk/news/newsarchive/gmreminder>).

5.5 **GM Animal Feed**

5.5.1 Fate of feed ingested foreign DNA in pigs

A study of the fate of foreign DNA in pigs has been published by a research group in Germany (Reuter and Aulrich, 2003). Pigs were fed transgenic (Bt) corn and then slaughtered at various times following feeding. DNA was extracted from tissues and gut contents and examined by PCR for both plant DNA and any transgenic material.

Recombinant DNA was detected in intestinal contents up to 48 hours after the last feeding. Recombinant or corn specific DNA were not detectable in tissue samples. However, a generic plant DNA fragment (rubisco) was detected in some tissue DNA samples in both control and Bt group pigs. This contrasted with an earlier study (Klotz *et al.*, 2002) which

failed to detect different generic plant gene material (chloroplast DNA) in DNA from pig tissues.

5.5.2 Resources

A review of studies of the safety of GM feed for livestock has concluded that current herbicide tolerant and Bt constructs represent no threat to the health of animals or humans consuming the products of such animals (Beever *et al.*, 2003).

Another collation of references regarding the feeding of GM crop plants as animal feedstock is available at:

www.fass.org/Factsheet2.htm

5.6 **Biopharming**

5.6.1 USDA new rules

In March 2003 the USDA released new rules strengthening permit conditions for field tests of crop plants engineered to produce pharmaceuticals and industrial compounds. The new conditions include increased inspections, greater segregation of test plants from others that might cross pollinate, fallow periods following harvest, and the use of dedicated harvest and processing equipment. Further details are available from:

<http://www.usda.gov/news/releases/2003/03/aphis030603.htm>

The new requirements appear to have forced biotechnology companies to revise their strategies for development. The USDA's Animal and Plant Health Inspection Service (APHIS) reported that only two biotech companies have sought federal approval to plant pharmaceutical crops this year, compared to 20 permits approved to plant medicine crops on about 130 acres of land in 9 states in 2002 (Source: Reuters 2 May 2003 via AgNet).

5.6.2 Molecular farming

Molecularfarming.com is a website set up by an Irish farmer to act as a register of farmers worldwide who have facilities (e.g enclosed greenhouses) which might be used for growing plants engineered to produce pharmaceuticals or other compounds. So far one New Zealand farmer has registered.

See: <http://www.molecularfarming.com/database.html>

5.6.3 Algae as an option for biopharming

Scientists at the Scripps Research Institute in California have been able to introduce a gene for an antibody that targets herpes virus into algae (Mayfield *et al.*, 2003). The unicellular green algae was able to produce the antibody and also assemble it into a functional structure (bacteria cannot complete the assembly process). Algae are able to be cultured in large

quantities and may present an alternative to crop plants as a large scale production mechanisms for complex pharmaceuticals.

5.7 Miscellaneous

5.7.1 Genetically modified nicotine-reduced tobacco cigarettes

The US company Vector Tobacco Inc. has now launched their Quest cigarettes containing tobacco from plants engineered to reduce their nicotine content. However, the product is not being advertised as a smoking cessation product, and thus will not be subject to FDA oversight (Source: Associated Press 27 January 2003 via AgNet).

5.7.2 Bt toxins and nematodes

A research group in California has discovered that certain Bt toxins can affect nematodes (Wei *et al.*, 2003). Nematodes include parasitic roundworms that affect people (ascariasis, hookworm), animals, and plants. Control is difficult due to expense and increasing drug resistance. The scientists found that Cry5B destroyed the intestines of the common laboratory nematode, *C. elegans*, while two other Bt crystal proteins, Cry6A and Cry14A, had the ability to significantly reduce the ability of *C. elegans* to produce numerous young. Although this discovery might offer options for control, the Bt proteins might also affect beneficial soil dwelling nematodes which control insect pests.

Further information is available from the website: <http://www.btcryystal.org>

5.7.3 Biosafety tool kit

In 2001 the International Service for National Agricultural Research (ISNAR) (in association with FAO) convened an expert consultation to develop a conceptual framework to address biosafety regulatory implementation and capacity-building needs of developing countries. The effort was partly driven by the difficulties experienced in Africa when GM crops as food aid created difficulties for certain countries without an existing biosafety assessment process.

The framework has now been released at:

<http://www.isnar.cgiar.org/ibs/biosafety/index.htm>

5.7.4 Biotechnology research in Europe

A report by the EU Joint Research Centre has found that plant biotechnology research has dropped in the EU by 76% since 1998. The fall was attributed to the Environment Ministers' decision in 1999 to block any new approvals of genetically modified (GM) products in Europe (Source: Joint Research Centre press release 21 March 2003 via AgNet). This has been paralleled by an 80% decrease in field trials of GM plants in Europe between 1998 and 2003, attributed to the same reason (Source: Life Science Weekly 12 May 2003 via AgNet).

The full Joint Research Centre report is available from: <http://www.jrc.es/gmoreview.pdf>

5.7.5 Improper disposal of offspring from GM pigs

A research programme using GM pigs at the University of Illinois apparently released the offspring of those pigs into the food supply. Although the pigs do not inherit the transgenes, this event is being investigated by the FDA, to determine why the pigs were not destroyed by incineration or rendering (Source: Nature Biotechnology 2003; 21: 219).

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