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 Ministry of Health with an independent source of current information on issues related to genetically modified foods. This report covers developments in the period January – June 2002.

1 INTRODUCTION

This project is intended to provide the Ministry of Health 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 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 report for the 2001/2002 year and covers events from 24 December 2001 to 19 June 2002.

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
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
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 Reviews

Two reviews of detection methods for genetically modified foods have been published recently. The first (Ahmed, 2002) discusses methodology in some detail and is less exhaustive in terms of published methods. The second (Anklam *et al*., 2002) provides extensive lists of methods for DNA isolation, qualitative and quantitative methods that have been published, in both the scientific literature as well as national legislation and standards.

2.2 Validated Test Methods for Foods and Ingredients from GM Plants

Immediately prior to the meeting of the Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology in Yokohama in March 2002, a Working Group on Analytical Methods held a meeting to consider a set of detection methods which are considered to be validated. The methods included immunoassays, qualitative and quantitative DNA based methods.

In the case of these methods, validation essentially means that they have each been the subject of a collaborative trial and their performance characteristics have been determined from the trial results. The methods will be submitted to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for consideration. The methods themselves can be found at the Codex website:

http://www.who.int/fsf/GMfood/codex_index.htm

2.3 Roundup Ready Corn Immunoassay

The first immunoassay test kit for the Roundup Ready trait in corn has been performance verified under the system administered by the USDA. The kit, made by Neogen, was found to be able to detect one Roundup Ready kernel (Variety NK603) in 800 kernels. The test can also detect one Roundup Ready soybean in 1000 beans (Source: http://www.usda.gov/gipsa/tech-servsup/metheqp/testkit.htm#Biotechnology).

2.4 Detection of DNA During Refining of Soybean Oil (Gryson *et al*., 2002)

It is generally accepted that, while DNA may sometimes be able to be isolated from crude or unrefined plant based oils, it cannot be recovered from refined oil. This study examined the steps involved in chemical and physical refining of plant based oils with respect to the ability to isolate and amplify DNA from soybean oil. The PCR used was for the lectin gene. It was found that degumming is the most important step for removing DNA. After degumming DNA was concentrated in the water fraction and after this step no DNA could be amplified in the oil fractions.

2.5 Testing Centres in India

The Indian Department of Biotechnology will spend $500,000 in 2002 to create two facilities to screen for transgenic sequences in crops and food products. The Centre for DNA Fingerprinting and Diagnostics in Hyderabad will concentrate on crops, while the Central Food Technology Research Institute in Mysore will focus on foods. The move was prompted in part by the discovery of illegally grown Bt cotton in Gujurat (Source: Nature Biotechnology 2002; 20: 109).

2.6 DNA-Based Testing Kits

As testing for genetically modified ingredients in foods becomes more well established, test kits are becoming increasingly common. An overview of kits available is at the AOAC International Research Institute kit database on their website at: http://216.55.34.180/testkits/gmo.html

Genescan kits were mentioned in the March 2001 report from this project (see: http:///www.genescan-europe.com). A range of kits have been produced for GM quantification by Roche for the Lightcycler instrument (see: http://www.roche-applied-science.com). Applied Biosystems have also released kits for detection and quantification of GMO using the Taqman instrument (see: http://home.appliedbiosystems.com/). Bionostra is a Spanish company who have released a range of screening and quantification kits for GM food products (see: http://www.bionostra.com/, New Zealand agent Innovative Sciences Ltd., PO Box 13108, Dunedin, isl@molbio.co.nz).

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

4 LEGISLATIVE POSITION OF OVERSEAS GOVERNMENTS REGARDING GENETICALLY MODIFIED FOODS

4.1 Food Use Approvals

4.1.1 Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology

The third meeting of this Task Force, in Yokohama in March 2002, finalised two important documents regarding internationally accepted procedures for undertaking risk assessments of GM organisms. The first document was a set of over-arching general "Principles for the risk analysis of foods derived from modern biotechnology", and the second document set out guidelines for safety assessment of foods from GM plants. Both these documents will be submitted for approval to the next meeting of the Codex Alimentarius Commission in July 2003. The documents and proceedings of the meeting can be viewed at:

http://www.who.int/fsf/GMfood/codex_index.htm

The Task Force has a limited time period, and will complete its work in early 2003. The intention is to complete a further document concerning the safety assessment of genetically modified micro-organisms.

4.1.2 European Union

The Environment Committee of the European Parliament voted in favour of more extensive labelling of foods and animal feeds containing GMOs in June 2002. This constitutes support for the proposed legislation before the EU, whereby animal feed, as well as highly refined foods derived from GM crops, would need to be labelled. The vote is only a preliminary however, as the measures need to also be considered by the European Parliament, reviewed by European capitals and the European Commission, followed by a second reading in the European Parliament (Source: Wall Street Journal 5 June 2002 via AgNet).

The UK House of Lords Select Committee on the European Union issued a report in April 2002 which examined the EU proposals to extend the labelling rules to all foods produced from GM crops, irrespective of whether GM material is detectable in the finished product, and to apply the regime to animal feed. Although the Committee endorsed the consumer's right to choose, it concluded that it is not practicable to legislate for the degree of traceability envisaged by the European Commission. The Committee also supported the current 1% rule for triggering labelling, and urged the Commission to lift the veto on approvals of new GMOs. The report is available from:

http://www.parliament.the-stationery-office.co.uk/pa/ld200102/ldselect/ldeucom/117/11701.htm

In February 2002 the EU Scientific Committee on Food released a report assessing the safety of genetically modified maize line GA21. The variety was first submitted to the Netherlands Competent Authority in 1998 and received a favourable opinion. However, a number of member states raised objections, including that the line should not receive clearance for food use ahead of a favourable decision for its Deliberate Release into the Environment. Such a

decision was delivered by the Scientific Committee on Plants in September 2000. This more recent opinion addressed other concerns from member states regarding food use, and concluded that grain from maize line GA21 and derived products was as safe as grain and derived products from conventional maize lines. The full opinion is available at:

http://europa.eu.int/comm/food/fs/sc/scf/out121_en.pdf

In April 2002 the same Committee released an opinion on a request to place genetically modified sweet maize Bt11 on the market. This transformation event, as field corn, was approved for human food use in 1998. Subsequently the transgene cassette was transferred to sweet corn using traditional methods. The Committee concluded that Bt11 sweet maize was as safe for human food use as its conventional counterparts. The full opinion is available at:

http://europa.eu.int/comm/food/fs/sc/scf/out129_en.pdf

4.1.3 United States General Accounting Office (GAO) review of safety assessment of genetically modified foods

The GAO is the investigative arm of the United States Congress and in July 2001 it was asked to examine the potential health risks from GM foods, and the adequacy of tests used to evaluate those risks, as well as the FDA's controls, future changes, and potential for long term health risk monitoring. It conducted its own review, as well as consulting with academic and commercial scientists, both in the US and overseas. Generally the GAO considered that the safety assessment process was adequate, and FDA controls appropriate. The FDA has issued a proposed rule making premarket assessment mandatory and identified the types of data required for such assessment. It is anticipated that this rule will be finalised during 2003, but in any case all the GM foods currently on the US market have been assessed by the FDA.

The GAO recommended some improvements:

- occasionally the FDA could examine raw data rather than interpreted summaries of the data;
- randomly verifying some of the test data that companies provide; and,
- increasing the transparency of the evaluation process, in particular stating the scientific rationale for decision making.

The report is available from:

http://www.gao.gov

4.1.4 China

The rules for importing GM crops into China have been the subject of considerable confusion since they were first announced in June 2001. In January 2002 China's Ministry of Agriculture issued details of the rules on GM organisms, saying the policy would take effect on March 20. Overseas firms that export GMO products to China were required to obtain safety certificates from the Ministry certifying that the goods were harmless to humans, animals and the environment. All imported GMO soybeans, corn, rapeseed, cottonseed and

tomatoes were required to be clearly labelled as GMO products (Source: Reuters 7 January 2002 via AgNet). The new rules were seen as a means to protect China's farmers from imports after that country's entry into the World Trade Organisation. China produces approximately 100 million tonnes of corn per year, but only 15 million tonnes of soybeans. (Source: Reuters 11 January 2002 via AgNet).

The Chinese government has also announced rules preventing foreign investment in a number of sectors of the economy, including the production and development of GM seeds. This could affect companies like Monsanto, which is already developing GM cotton in China (Source: Reuters March 13, 2002 via AgNet).

During the period of uncertainty over how the new rules would work, the $US1 billion worth of soybean exports from the US to China largely ceased (Source: Dow Jones 20 February 2002 via AgNet). Following discussions between US and Chinese officials, an interim solution was achieved. Preliminary safety approvals would be issued within 30 days to importers that provide documents that certified the country of origin or safety of GMOs (Source: China Online 11 March 2002 via AgNet). Although this system provided a temporary means of resuming importation of soybeans, in May China's Ministry of Health announced that a new approval system would take effect on July 1, 2002. Producers of GMO products will have to request inclusion on an approved foods list and evaluation of submissions will take up to six months (Source: Dow Jones 8 May 2002 via AgNet).

The rules were later amended to say they only applied to soybeans imported for human consumption rather than crushing, but as the latter are used to produce oil for human consumption it was unclear whether these would need to be approved as well (Source: Reuters 14 May 2002 via AgNet).

In contrast Brazilian soybeans are exempt from the regulations as they are regarded as being non-GMO. China is Brazil's second largest soybean export market with about $US500 million in sales (Source: Dow Jones 31 May 2002 via AgNet).

4.1.5 Saudi Arabia

Import certification and labelling of GM products were announced in early 2002 (Source: AgWeb 9 January 2002 via AgNet). A report by the USDA Foreign Agricultural Service posted on the web indicates that the Saudi Arabian Ministry of Commerce has contracted with Genetic ID to do GM testing until its own laboratories are established. A 1% threshold has been set to account for cross contamination. The full report is available at:

http://www.fas.usda.gov/gainfiles/200203/135683674.pdf

4.1.6 Korea

In January 2002 Korea's Ministry of Agriculture and Forestry issued guidelines on GM agricultural products. Those seeking to sell GMO goods produced domestically or abroad on the local market must submit an application to the Rural Development Administration to verify that the products do not harm the environment (Source: Asia Pulse 11 January 2002 via AgNet). This follows the introduction of labelling requirements in September 2001. These

labelling rules require that certificates are produced to show that GMO items have been separated from non-GMO ones at each step of the production and marketing process. Such requirements are seen as impeding imports from the US, but complaints by US exporters have been rejected by Korea, which claims that there was a lengthy preparation process before the rules took effect (Source: Digital Chosun Choi Won-kyu 20 January 2002 via AgNet).

4.1.7 Croatia

The Croatian Environment Minister announced in January 2002 that legislation is being drafted to ban production and limit imports of food containing GM ingredients. The intention was to protect tourism and local organic farming. GM free status was seen as offering a competitive advantage to Croatian farming. As Croatia is a member of the WTO, the United States may challenge the legislation (Source: Reuters 15 January 2002).

4.1.8 Canada

In January 2001 an Expert Panel of the Royal Society in Canada released a report on food biotechnology called "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada". A year later, the Canadian government issued a progress report on what it was doing to address the recommendations. Many of the actions involve increasing the amount of information communicated to the general public. Others include updating safety assessment protocols, and developing new ones to address the safety assessment of food from transgenic animals and fish. Detection methods will also be required as part of the data submitted for approval of GM plants for human food use.

The various government agencies involved are reviewing international approaches to identify best practice. A relevant comment in the report is: "The system in place for the regulatory review of novel foods in Australia and New Zealand is considered a model of public transparency and expert consultation. Initial contact has been initiated between Health Canada and counterparts at the Australia New Zealand Food Authority and a meeting is being proposed for Spring of 2002."

The full report is available from:

http://www.hc-sc.gc.ca/english/protection/royalsociety/progress_report.html

4.1.9 Brazilian soybeans

Despite an official ban on commercial GM crop planting, it is well known that a proportion of the Brazilian soybean crop is Roundup Ready soy. The oilseed industry publication Oil World has estimated that 14% of the total Brazilian plantings may be GM. The total area of soybeans in Brazil is 15.5 million hectares, so approximately 2 million hectares are potentially GM (Source: Reuters 19 February 2002 via AgNet).

4.1.10 Philippines

The Philippines Department of Agriculture issued rules to cover the field testing, propagation, commercialisation and importation of GM crops in March 2002. The measures do not include labelling requirements, as this would require more interagency co-ordination. However, imported GMO containing crops will require certification that such crops are safe for human consumption (Source: Dow Jones 27 February 2002 via AgNet). The government will prepare by June 30 2003 a list of approved commodities that will be allowed entry into the country. After that date, any company importing a GMO not included on the list of the Bureau of Plant Industry will be required to secure a permit (Source: Reuters 3 April 2002 via AgNet).

4.1.11 Russia

A certificate for biological safety has been issued for two types of GM potatoes by the Russian Ministry of Industry, Science and Technology. The potatoes were developed by Monsanto, who announced that they only need a variety registration from the Agriculture Ministry to begin sales. This is expected to occur in early 2003. However, that date may be too optimistic as the sales would also require the approval of the State Environmental Assessment Commission which has responded negatively to such issues in the past. Russia has permitted the import of genetically modified soy, potato and corn since 1999 (Source: The Russia Journal 17 may 2002 via AgNet).

4.1.12 Zimbabwe

In May 2002, despite facing food shortages, Zimbabwe turned away a US donation of 10,000 tons of corn because it wasn't certified as GM free. Instead the corn was delivered to neighbouring Zambia, Mozambique and Malawi. Alternative food aid was delivered to Zimbabwe (Source: The Wall Street Journal 31 May 2002 via AgNet).

4.2 Labelling

This section includes information on GM labelling regimes proposed or implemented overseas. Results of surveys to assess compliance with labelling requirements are also reported.

4.2.1 Codex Committee on Food Labelling

The 30th Session of the Codex Committee on Food Labelling was held in Canada in May 2002. Amongst the issues considered at the meeting was the labelling of GM foods, or "food obtained through certain techniques of genetic modification/genetic engineering". The Committee made relatively little progress with this issue and the definitions and labelling provisions were not progressed further through the Codex process.

The report from the meeting is available from:

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

4.2.2 Ireland

In January 2002 the Food Safety Authority of Ireland announced the results of a survey of foods for the presence of genetically modified soy. A total of 37 samples of dried soy products, soy substitutes for dairy products and soy infant formulae were tested and 18 were found to contain GM ingredients. However, all of the 18 positive samples had a GM level of less than the 1% threshold that triggers GM labelling in Europe. Six of the 18 samples were mislabelled: five indicated they had no GM ingredients while the sixth was labelled as organic. The retailers, suppliers and manufacturers were contacted and informed of the results, but were not prosecuted. The full report is available from:

http://www.fsai.ie

4.2.3 France

Also in January the French National Consumers Institute released the results of a survey of 103 foods containing maize and soy. Of these 36 were found to contain GM ingredients. Only one food had more than 1% GM ingredients, while 25 had less than 0.1% and the levels in the remainder were not able to be determined (Source: Agence France Presse 4 January 2002 via AgNet).

4.2.4 Japan

In January 2002 a shipment of papaya from Hawaii to Japan was found to contain a GM virus resistant variety, as part of testing by the Japanese Health Ministry. The GM variety is banned in Japan (Source: Reuters 28 January 2002 via AgNet).

4.2.5 United Kingdom

The UK Food Standards Agency released the results of a survey of foods for GM ingredients in January 2002. Tests on 203 samples of baked goods, including bread, cakes and buns, found that 15% had traces of GM soy, but just three of the samples would have required labelling under the EU 1% threshold (Reuters 31 January 2002 via AgNet). The full report is available from:

http://www.food.gov.uk/news/pressreleases/gmtesting

In what is believed to be the first prosecution regarding GM labelling, trading standards officials in Warwickshire prosecuted East End Foods Ltd. for failing to declare that their East End Soy Mince contained more than 50% GM material. The manufacturers pleaded guilty, and were fined 4,000 pounds with costs of 12,000 pounds (Source: PA News 13 March 2002 via AgNet).

4.2.6 Brazil

Brazil is in the process of developing labelling rules for GM crops, in order to clear the legal barriers that prevent the sale of such produce. The draft government decree requires that consumer labelling be present on packaged foods with more than 4% GMO content. The

regulations were to have been enforced from 31 December 2001 but introduction was delayed by a review by a pan-ministerial committee (Source: Dow Jones 7 February 2002 via AgNet).

As the last major soy growing country to not allow the use of GM crops, Brazil's exports of soybeans are increasingly required to have certificated non-GMO status. An extensive programme of testing and certification has been introduced, although margins are small ($4-$10 per ton) due to the ample availability of both certified soymeal and non-GMO soybeans in general (Source: Dow Jones 19 February 2002 via AgNet).

4.2.7 Indonesia

In 1999 the Indonesian government issued a regulation which stipulated that consumers have the right to information on, and protection against, GMO-based products. The regulation has yet to be widely implemented because the Ministries of Agriculture, Forestry, Food and Horticulture and Health have yet to decide on the level of GMOs that must be declared on the product's label (Source: Jakarta Post 11 February 2002 via AgNet). In March 2002 it was announced that every food product with a GMO content more than 5% would have to be labelled (Reuters 28 March 2002 via AgNet).

4.2.8 Korea

Labelling requirements for GM ingredients in raw commodities and foods have been promulgated by the Korean Ministry of Agriculture and Forestry and the Food and Drug Administration. Now the Korean Fair Trade Commission has also published requirements that statements regarding GM content are included with advertising for such products. The rules were announced on 5 March and will come into effect on 1 July 2002 (Source: Foreign Agricultural Report 18 March 2002 via AgNet).

4.2.9 GMO free labelling in the United States

In January 2001 the FDA issued a proposed rule on voluntary labelling for biotech-free foods. However, FDA officials have announced that it could take some time to finalise the rule. The main reason is that the FDA needs to determine how to monitor the labelling. Companies will need to have their food tested and federal inspectors will conduct checks. It is likely that no more than 1% genetically modified ingredients will be allowed in officially biotech-free foods. In the interim consumers can avoid bioengineered foods by buying organic products. This year the USDA will provide an official seal for organic foods which meet the government's standards for such products, including a bar on the use of GM ingredients (Source: Associated Press 21 March 2002 via AgNet).

4.2.10 Chile

According to a notification to the World Trade Organisation (G/TBT/N/CHL/18 15 June 2001) Chile has introduced a labelling regime for transgenic foods. Such foodstuffs that do not contain genetically modified material and are substantially equivalent to their common counterparts will not need to be labelled. If they are not substantially equivalent, they must be labelled as "transgenically derived product". A 2% threshold for labelling has been set.

5 CURRENT DEVELOPMENTS

5.1 Resources

5.1.1 ICGEB Risk assessment searching mechanism

The International Centre for Genetic Engineering and Biotechnology (ICGEB) is a United Nations affiliated organisation that conducts innovative research in life sciences for the benefit of developing countries. It is funded principally by the governments of Italy and India, where its main offices are located, with additional contributions by member countries. In addition to its role in research, ICGEB also provides information services. Two of these are particularly relevant to GM foods: the bibliography and the risk assessment searching mechanism.

The Biosafety Database is a scientific bibliographic collection of studies on "Biosafety and Risk assessment in biotechnology". The database is updated monthly and contains scientific articles (full reference + abstract), published on international scientific journals from 1990 onwards, selected and classified by ICGEB scientists.

The bibliography is available at:

http://www.icgeb.org/~bsafesrv/bsfdata1.htm

More recently established is the risk assessment searching mechanism (RASM). This tool provides an index of the official and technical documents on risk assessment of living modified organisms authored by biosafety competent national authorities. The database can be searched using selection criteria: taxonomical classification on the released organism; LMO identifier or Company identifier; trait; gene; year (assessment date), country and type of risk assessment document.

The mechanism is available from:

http://www.icgeb.org/~bsafesrv/rasm.html

5.1.2 AgBioForum

This online journal has published a series of articles in recent issues regarding communicating about agrobiotechnology. An article entitled “Language and persuasion in biotechnology communication” was published in Volume 4, Number 2, while all of Volume 4, Numbers 3 and 4 were a special issue devoted to the topic. The journal is available from:

http://www.agbioforum.org/

5.2 Human Health

5.2.1 UK Royal Society report on genetically modified plants for food use and human health

In February 2002 a report by the UK Royal Society entitled "Genetically modified plants for food use and human health – an update" was released. The report was a followup to a report issued in 1998. The new report focuses on the effects that GM food might have on human health and the use of the principle of substantial equivalence in GM food safety testing.

The group of experts had some concerns about the regulatory processes governing the development and use of GM plants. They agreed with a FAO/WHO report which stated that the criteria for safety assessments needed to be made explicit and objective, and that differences in the application of the principles of substantial equivalence, for example in the different member states of the EU, needed to be resolved. New profiling techniques for crop components are in development and their use was recommended.

It was also recommended that more detailed guidelines be developed for the safety assessment of GM crops with altered nutritional quality, though it was recognised that such alterations may also occur through conventional breeding. Safety assessment in relation to vulnerable groups such as infants was singled out as needing greater attention, and it was also recommended that the existing guidelines and legislation for foods for such groups be made complementary to the assessment of GM crops.

The allergenic risks posed by GM crops were deemed to be no greater than those from conventionally bred crops. However, a shortcoming in the current allergenicity assessment was noted: there is no formal assessment of the allergenic risks posed by inhalation of pollen and dusts from crop plants (particularly occupational exposure), and this should be added to current decision trees.

Although plant viral sequences are commonly used in the construction of the genes inserted into GM plants, after reviewing the evidence the group considered that the risks to human health were negligible. A review was also conducted of recent research on the potential for genes from GM plants to become incorporated into the consumer's genetic makeup. Given the long history of DNA consumption for a wide variety of sources, the group concluded that such consumption posed no significant risk to human health, and that additional ingestion of GM DNA has no effect.

The full report is available from:

http://www.royalsoc.ac.uk/files/statfiles/document-165.pdf

5.2.2 French report on human health effects of GM crops

The French food safety agency, Agence Française de Securite Sanitaire des Aliments (AFSSA), released a report in January 2002 which stated that more testing is needed to determine the possible health side-effects of GM organisms. Questions were raised about the possible side effects of long term exposure, including allergenicity, immune, hormonal and

reproductive effects (Source: Reuters 30 January 2002 via AgNet). The report identified a number of ways to improve the safety assessments of GM foods including:

- supply of the full sequence of the insert including junction regions; and,
- the use of 90 day sub-chronic toxicity testing of the gene product on laboratory animals.

However, the difficulty of testing systems still being developed (particularly for allergenicity) was acknowledged. The question of antibiotic resistance was also reviewed with the concluding comment that "as far as we know, the consumption by humans or animals of food products containing or consisting of genetically modified plants containing resistance genes to kanamycin and/or ampicillin does not, in consequence, pose any more than a theoretical, and in any case, negligible, risk to human health in terms of the presence of these antibiotic resistance genes in the environmental bacteria."

5.2.3 Society of Toxicology statement

The Society of Toxicology is a professional and scholarly organisation of 5,200 scientists from academic institutions, government, and industry representing professionals who practice toxicology in the U.S. and abroad. In March 2002 they issued a position paper on foods produced through biotechnology. The summary concludes that:

1. There is no reason to suppose that the process of food production through biotechnology leads to risks of a different nature than those already familiar to toxicologists or that cannot also be created by conventional breeding practices for plant, animal or microbial improvement. It is therefore important to recognise that it is the food product itself, rather than the process through which it is made, that should be the focus of attention in assessing safety.
2. We support the use of the substantial equivalence concept as part of the safety assessment of biotechnology-derived foods. This seeks to establish whether the new food is significantly different from existing foods that are generally considered to be safe for consumers, and it provides critical guidance as to the nature of any increased health hazards in the new food. To establish substantial equivalence, it is necessary to conduct extensive comparative studies of the chemical composition, nutritional quality, and levels of potentially toxic components in both the engineered and conventional crop or animal. Any notable differences between the existing and new organism would require further evaluation to determine whether there is a likely to be a higher level of risk from the consumption of the foods derived from the engineered form. Through this approach, the safety of current biotechnology-derived foods compared to their conventional counterparts can be assessed with reasonable certainty using established and accepted methods of analytical, nutritional and toxicological research.
3. Extensive studies of this type have established that the level of safety to consumers of current genetically engineered foods is likely to be equivalent to that of traditional foods. Verified records of adverse health effects are absent, although the current passive reporting system probably would not detect minor or rare adverse effects.
4. The changes in composition of existing foods produced through biotechnology are slight. Assessing safety may be more difficult in the future if genetic engineering projects cause more substantial and complex changes in a foodstuff. Toxicologists are currently limited in their ability to assess the risks presented by complex mixtures, and they have not yet

developed methods by which whole foods (as compared to single chemical components) can be fully evaluated for safety. Progress also needs to be made in developing definitive methods for the identification and characterisation of proteins that are potential allergens and this is currently a major focus of research. A continuing evolution of toxicological methodologies and regulatory strategies will be necessary to ensure that the present level of safety of biotechnology-derived foods is maintained in the future.

The full statement is available from:

http://www.agbioworld.org/biotech_info/articles/toxsoc.html

5.2.4 New GM crops with properties relevant to human health

5.2.4.1 Delayed ripening GM tomatoes in China

A tomato with an inserted gene that delays ripening has been developed by a Chinese government laboratory, Hong Kong Agritech Limited. The tomato has undergone field trials in Guangdong and Beijing, and also passed toxicity tests in mice, as required by the Ministry of Agriculture. Seeds have been freely distributed to farming co-operatives in Xinjiang, Shanxi, Guangxi, Shandong and Shanghai for tests. The tomato is expected to be on mainland Chinese shelves by next year (2003) (Source: Asia Africa Intelligence 7 January 2002 via AgNet).

5.2.4.2 Spinach gene in a pig

Japanese researchers at Kinki University in Osaka claim to have succeeded in transplanting a spinach gene into a pig in order to change pig fat to contain a higher proportion of linoleic acid (an unsaturated fatty acid found in plants). This is the first time that a plant gene has been made to function properly in a mammal. The GM pigs had a 20% higher linoleic acid content in their fat than non-modified pigs (Source: Associated Press 24 January 2002 via AgNet).

5.2.4.3 Freeze thaw stable potato starch (Jobling et al., 2002)

The use of unmodified starches in frozen foods is limited by the undesirable textural changes that occur after freezing and thawing (separation of starch gel and water phases). Currently this is circumvented by chemical modification. An alternative is to alter the starch composition. By using antisense techniques (where a reverse sequence of DNA inhibits production of enzymes by binding to the RNA intended to produce the enzyme) three isozymes of starch synthase were inhibited in potatoes. By removing amylose and reducing the chain length of amylopectin branches, a freeze thaw stable starch was produced.

5.2.5 WHO study on human health and modern food biotechnology

The Food Safety Programme of the World Health Organisation has commissioned an evidence-based study of the human health and development implications of GM organisms and products. The study aims to complement the efforts of other international agencies by collating already existing information and analysing it as it pertains to the WHO mandate. To

enhance transparency in the process, WHO will collaborate with FAO and involve an array of stakeholders and interest groups. The primary aim is to create an accessible knowledge base to assist Member States, international standards bodies and other stakeholders to achieve transparent and inclusive consensus on the evaluation and application of biotechnology.

The main issues on which evidence is invited are:

- Research and Development;
- Impact on human health (food safety and environmental effects);
- Food security, cost and access to the technology;
- Ethical, legal and social issues;
- Capacity-building initiatives.

The report produced from this consultation process will be used directly by WHO in planning its future activities with regard to the use and application of modern biotechnology in human health and development. WHO intends to complete the report early in 2003.

Further details are available from:

http://www.who.int/fsf/GMfood/mega_study_index.htm

5.3 Consumer Issues

5.3.1 Starlink situation improving

Detection rates for Starlink corn in shipments from the US to Japan are dropping. Japan imports more than 10 million tonnes of corn annually, and the US share of the market is over 95%. This should increase, provided the Starlink detection rate continues to fall to zero (Source: AgWeb 3 April 2002 via AgNet). In May 2002 Korea bought corn from the United States for human consumption for the first time since the Starlink issue arose in September 2000, on the condition that it was documented to be Starlink free (Source: Reuters 1 May 2002 via AgNet).

5.3.2 Unapproved canola seed

During 2001, trace amounts of the Roundup tolerant GM canola variety GT200 were found in canola seed in Canada. This variety was developed in the early 1990s, but was eventually dropped in favour of the alternate Roundup tolerant transformation event GT73 (RT73). In 2001 Monsanto recalled all of its Quest canola seed because it still contained traces of GT200.

Although GT200 had been approved for human food use in Canada at the time, it had not been approved in Japan or the United States, which are major export markets for Canada. The variety had not been detected in canola seed in the US. However, the GT200 variety had the potential to be present at low, adventitious levels in commercial canola varieties. Consequently in April 2002 as a precautionary measure Monsanto requested that the USDA grant an exemption for any GT200 that may appear in canola seed in the US (Source: AgWeb

15 April 2002 via AgNet). GT200 has now received food and feed use approval in Japan even though it is not on the commercial market.

5.3.3 Consumer behaviour

Although we do not usually cover consumer surveys in this report, some research on consumer behaviour with regard to labels in relevant. A joint US – French study (Noussair *et al*., 2002) used a survey technique called a Vickery auction. French consumers were given chocolate bars with GM or non-GM labels, then seated for 3 minutes to examine them, and then were asked to bid to purchase either of the types of bars. The study found that consumers generally didn't notice the GM content stated on the label, and commented that "What is not read in the laboratory will probably not be read in the supermarket". After the GM status of the products was pointed out to participants, the study found that most consumers were willing to buy the genetically modified foods, but only if the price was about one third lower than conventional products. For further information see:

http://www.mgmt.purdue.edu/faculty/noussair/working_papers/modified_organisms.pdf

5.3.4 Newspaper coverage of GM issues

The Institute for Food and Development Policy, also known as Food First, is a member-supported, non-profit 'peoples' think tank and education-for-action centre. In April 2002 they published a report claiming bias in media editorial and opinion pages of US newspapers and magazines in favour of GM foods. Of the 72 non-news articles considered, the ratio was four to one in favour of GM foods. Food First considers this to be a result of the media following the lead of industry advertising and public relations companies. The full report is available at:

http://www.foodfirst.org/media/press/2002/biotechbiasreport.html

5.3.5 Consumer information network in Canada winding down

The Food Biotechnology Communications Network was established in 1999 in Guelph, Ontario by a consortium of government, non-government and industry organisations to provide information to the public about agricultural biotechnology. They provided a website, a toll free hotline and email responses. Initially they were receiving 300 inquiries per month but now it has reduced to about 30 per month. The tone of the inquiries has also changed, from predominantly negative to neutral. The organisation will now be integrated into the Food Safety Network organised by Professor Powell at the University of Guelph (Source: Globe and Mail 2 May 2002 via AgNet).

5.4 Agricultural and Environmental Issues

5.4.1 Global Review of Commercialised Transgenic Crops: 2001

The latest in this series of publications by the International Service for the Acquisition of Agri-Biotech Applications (ISAAA) was published in January 2002. (For ordering see:

http://www.isaaa.org/). Selected data from the report are given in Tables 1 - 4. 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 2001)
	1998	1999	2000	2001	
Soybean	36.3	54.0	64.5	83.3	180 (46)
Corn	20.8	27.8	25.8	24.5	350 (7)
Cotton	6.3	9.3	13.3	17.0	85 (20)
Rapeseed/Canola	6.0	8.5	7.0	6.8	62.5 (11)
Potato	<0.3	<0.3	<0.3	<0.3	N/A
Total**	69.5	98.6	110.7	131.5	677.5 (19)

N/A = Not applicable
** Due to minor crops, rounding and conversion factors totals may not be exact.

The global area of GM soybeans and canola continues to increase, while the area of GM corn planted is static or declining.

Table 2: Global acreage of transgenic crops by trait

Trait	1999 (10^6 acres)	2000 (10^6 acres)	2001 (10^6 acres)
Herbicide tolerance	70.2	81.8	101.5
Insect resistance	22.2	20.8	19.5
Insect/herbicide resistance	7.2	8.0	10.5
Virus resistance/other	<0.3	<0.3	<0.3

Table 3: Global dominant transgenic crops by crop

Crop	% of total in 1999	% of total in 2000	% of total in 2001
Herbicide tolerant soybean	54	59	63
Insect resistant corn	19	15	11
Herbicide resistant rapeseed/canola	9	6	5
Insect/herbicide resistant cotton	5	4	5
Herbicide resistant corn	4	5	4

Table 4: Global acreage of transgenic crops by country

Country	1999 (10^6 acres)	2000 (10^6 acres)	2001 (10^6 acres)
USA	71.7	75.8	89.3
Argentina	16.7	25.0	29.5
Canada	10.0	7.5	8.0
Australia	0.3	0.5	0.5
China	0.75	1.25	3.8
South Africa	0.3	0.5	0.5

NA = not available

5.4.2 GM crop plantings internationally

5.4.2.1 United States

A survey by Reuters of more than 300 growers in the United States found that GM corn plantings would increase in 2002 by at least 13% while there would be a smaller 8% increase in the area of soybeans planted. However, plantings of GM cotton were predicted to fall by 2-8%, attributed to a global glut of cotton (Source: Reuters 9 January 2002 via AgNet).

The USDA annual spring survey of US farmers' planting intentions also predicted an increase in plantings of GM crops. Approximately 74% of the soybean crop (54 million acres) is expected to be GM in 2002, up from 68% in 2001 and 54% in 2000. The area of GM corn is also expected to increase, to 32% of the total (25.3 million acres), up from 26% in 2001 and 25% in 2000. The area of GM cotton is also expected to increase, to 71% of the total crop (10.5 million acres), up from 69% in 2001 (Source: Associated Press 28 March 2002 via AgNet).

5.4.2.2 Canada

The area of transgenic canola in Canada in 2001 was approximately 55% of the total area planted in rapeseed/canola, compared to 1% in 1995. Herbicide tolerant GM canola represents 84% of the transgenic crop, with the remaining area being herbicide resistant varieties created using non-recombinant technologies. The GM canola area is mainly Roundup Ready canola (40%), while transgenic Liberty (glufosinate tolerant) and non-GM Pursuit or Clearfield (imadazilinone tolerant) canola each make up about 15% of the crop. The recently introduced bromoxynil tolerant system makes up a relatively small production area (Source: The West Australian 28 February 2002 via AgNet).

5.4.2.3 India

In March 2002 the first commercial release of a GM crop was approved in India. Three lines of Bt cotton were approved by the Genetic Engineering Approval Committee under certain conditions and for a 3 year time period (Source: Times of India 26 March 2002 via AgNet). India has the largest area of cotton under cultivation of any country in the world (25% of the global area), but its yields per hectare are low by international standards (12.3% of global cotton production). Conditions were imposed on the developer of the cotton, Monsanto

Mahyco Biotech India (a joint venture between the US Monsanto and India's Maharashtra Hybrid Seeds), and farmers, in the form of controlled operations (surrounding areas of non-GM cotton at the edges of fields) and the monitoring of environmental effects (Source; Agence France Presse 27 March 2002 via AgNet). Bt cotton will be grown on approximately 150,000 acres during 2002-2003. It has been found in field trials that Bt cotton gives an extra benefit of approximately 5,000 rupees ($US100) per acre from elimination of pesticide use and productivity and quality improvement (Source: Financial Times 9 May 2002 via AgNet).

The next GM crop to be approved in India is expected to be a GM mustard. The company Aventis, through its Indian branch ProAgro, is preparing to apply for permission to introduce a GM mustard that contains soil bacterial genes to increase yields (Source: Economic Times 28 March 2002 via AgNet).

5.4.2.4 Australia

Both Monsanto and Aventis have lodged applications with Australia's Office of the Gene Technology Regulator (OGTR) for extensive field trials of GM canola. Both companies can anticipate tough conditions on the trials, if approved, including monitoring for contamination of surrounding properties. Details of the applications are available at the OGTR website, along with a background document on the biology and ecology of canola:

http://www.ogtr.gov.au

5.4.3 Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation (NAS, 2002)

This book was written by a committee of the US National Academy of Sciences and reviews the scientific basis and adequacy of the USDA's oversight of environmental issues related to current and anticipated transgenic plants and their products. Some of the recommendations are particular to the regulatory system as set-up in the United States. The recommendations included (Fox, 2002):

- Tougher reviews of transgenic plants;
- Deferring to other federal agencies in cases where environmental assessments would be more rigorous;
- Conducting post-market surveillance; and,
- Augmenting scientific inputs into reviews and making the processes more transparent.

It is also of interest to note that the committee felt that risk analysis of transgenic plants fulfilled two distinct roles: (1) technical support for regulatory decision making and (2) establishment and maintenance of regulatory legitimacy. The second role is related to public confidence in the risk analysis process and such confidence is established by transparency, degree of public involvement and responsiveness to public concerns, scientific rigor, and the seriousness with which environmental risks are addressed.

5.4.4 Bt in St Lawrence river water

In late December 2001 a Quebec newspaper published a story that claimed that large quantities of Bt toxin had been found in water in the St Lawrence river, and quoted a toxicologist who speculated that soil bacteria had picked up DNA for the Bt gene from root exudates of Bt corn plants. A response to this information by Krista Thomas and Doug Powell at the University of Guelph was published in the Ontario Farmer newspaper. The results quoted were preliminary data from a 3 year study by researchers from the St Lawrence Centre, operated by Environment Canada. Samples of river sediment collected downstream from Bt corn fields were found to contain higher levels of Bt toxin than soil samples taken inside Bt corn fields. But the amounts found in each type of soil were at trace levels, and it was unclear whether they originated from naturally occurring Bt toxin or from GM crops as there are baseline levels of Bt toxin in soil (Source: AgNet 4 January 2002).

5.4.5 DNA from GM corn in local corn varieties in Mexico

Following the publication of a paper in the journal Nature reporting the detection of DNA from GM corn in Mexican landrace corn (Quist and Chapela, 2001), there has been considerable reaction and discussion. A website devoted to the topic has been established by Ag Biotech Infonet which has links to many of the relevant publications on the topic. The website is: http://www.biotech-info.net/mexican_bt_flow.html

Numerous responses to the original article have been published, including an editorial in the journal Transgenic Research (Christou, 2002). The editors claimed that in the original paper:

- sample contamination is the most likely explanation for the observed results;
- plants alleged to contain introgressed DNA should have been grown out and subjected to more reliable confirming studies;
- the inverse PCR results were technically flawed; and,
- cross pollination and introgression would not produce these results.

Much of the criticism of the original paper concerns that fact that the authors were not able to show the presence of intact inserts, and instead suggested that this is the result of sequence rearrangements during the transformation event or recombination. However, inserted DNA in GM crop plants is assessed for stability over several generations prior to release.

The original article also claimed to have detected portions of the alcohol dehydrogenase (adh1) gene which is included in the insert of the Bt11 variety of GM corn. However, one of the scientists involved in developing Bt11 corn has asserted that the sequence detected was from a completely different segment of the adh1 gene, and not part of the insert introduced into Bt11 corn (Source: AgBioView at http://www.agbioworld.org).

The International Maize and Wheat Improvement Centre (CIMMYT) in Mexico has been conducting tests, both on maize landrace seeds stored in its gene bank, and field samples. No traces of the 35S promotor have been found (Hodgson, 2002). The latest set of results, on gene bank samples, can be found at:

http://www.cimmyt.org/whatiscimmyt/Transgenic/furthertest_7feb02.htm

Finally, in the 4 April 2002 issue, the journal Nature published two critical letters regarding the original publication, with a reply by Quist and Chapela. The accompanying editorial note stated that the journal had concluded "that the evidence available is not sufficient to justify the publication of the original article. As the authors nevertheless wish to stand by their conclusions, we feel it best simply to make these circumstances clear, to publish the criticisms, the authors' response and the new data, and to allow our readers to judge the science for themselves."

The Information Systems for Biotechnology (ISB) News Report for May contained additional discussion of the methodology in the original paper and suggested alternatives. This is available at:

http://www.isb.vt.edu/news/2002/news02.may.html#may0201

5.4.6 New GM crops with properties relevant to agriculture

5.4.6.1 Bt cotton

Dow Agrosciences have announced their intention to bring a new broad spectrum insect resistance trait to the cotton market in time for the 2004 growing season. The new variety will contain the Cry1F and the Cry1Ac types of the Bt toxin. This will provide resistance to the major lepidopteran pests in cotton: bollworms, tobacco budworms and pink bollworms. The company will submit a registration package to the EPA during 2002 and receive approval for marketing during 2003. (Source: Newsedge Corporation 15 February 2002 via AgNet).

5.4.6.2 Roundup Ready wheat

The introduction of this crop appears to be delayed, with a Monsanto announcement that the regulatory approval for planting in the US is taking longer than expected. The company will also file for regulatory approval in Canada, Japan and the European Union in 2002, but market introduction is not expected before 2005 (Source: Reuters 20 February 2002 via AgNet).

5.4.6.3 India

There is an active research effort into transgenic plants being undertaken by several institutions under the Indian Council of Agricultural Research. The Delhi based Indian Agricultural Research Institute (Pusa Institute) has developed and tested transgenic brinjal (eggplant), tomato, cabbage, rice (including Basmati), Brassica (Indian mustard) and potato. Genes for Bt toxins have been inserted into mustard and several strains of rice, while drought-tolerant potatoes and related ripening tomatoes have also been developed. These crops are generally at the stage of being ready for field trials (Source: Business Standard 12 February 2002 via AgNet).

5.4.7 GM crop trials in the United Kingdom

Large scale trials with GM crops have been underway in the United Kingdom since 2000. These are called Farm Scale Evaluations and are scheduled to end in 2002 for spring sown

crops and 2003 for winter sown crops. However, commercial planting could still be some time away, as the UK government has signalled that the results from these trials would not be enough to justify lifting the moratorium on commercial releases. The Rural Affairs Secretary announced that there would be further independent review to satisfy the government that GM technology had no adverse effects on human health or the environment (Source: The Times 19 January 2002 via AgNet).

5.4.8 Plant biotechnology in China

An article published in the journal Science in January 2002 provided considerable background on China's research efforts in biotechnology (Huang *et al*., 2002). Government funding of approximately $112 million from 1986 to 1999 has resulted in the development of 251 GM plants, animals and recombinant micro-organisms which have been approved for field trials, environmental release or commercialisation. The most successful and large scale crop has been a Bt cotton which was approved for commercial release in 1997. Prior to that small scale releases of virus resistant tomatoes and sweet peppers, as well as colour altered petunias, had been approved. Virus resistant tobacco was commercialised in the early 1990s but was removed from production because of pressure from an international tobacco importer. The greatest benefit has been to farmers through the reduced need for pesticides, which has economic benefits, as well as improved health of workers through reduced exposure to herbicides.

5.4.9 Benefits of GM crops to farmers

There have been several recent studies of this topic, with often conflicting results.

A study by the Iowa States Leopold Centre for Sustainable Agriculture found that there was no significant difference in financial returns for Iowa farmers from GM crops compared with traditional crops. Reduced herbicide and weed management costs were offset by higher seed costs and slightly lower yields. However, farmers were adopting the GM crops because they can plant more acres in a shorter time frame, didn't have to worry about weed management as much, and using Bt corn was an insurance policy against possible insect infestation (Source: Chicago Tribune 7 January 2002 via AgNet).

A 3 year study of corn in Dakota found that under high corn borer pressure in 1997 Bt corn hybrids and insecticide (permethrin) treated isolines usually provided better yields than untreated lines. However in 1998 and 1999, when corn borer pressures were lower, yields from GM or insecticide treated corn lines were similar to untreated lines (Catangui and Berg, 2002).

Another study used published data to estimate what effects GM crops have had on a global basis, and then predicted what effect they would have if grown widely in the European Union (Phipps and Park, 2002). On a global basis it was estimated that GM varieties of soy, oilseed rape, cotton and maize had reduced pesticide use by a total of 22.3 million kilograms of formulated product in the year 2000. Estimates indicated that if 50% of the same crops grown in the EU were GM, pesticide use would decrease by 14.5 million kilograms of formulated product (4.4. million kilograms of active ingredient). In addition there would be a

reduction of 7.5 million hectares sprayed which would save 20.5 million litres of diesel and a reduction of 73,000 tonnes of carbon dioxide released into the atmosphere.

In June 2002 a Government funded report on the impact of GM Bt cotton strains in China was released. It was alleged that the GM crop, which is principally varieties developed by Monsanto, had damaged the environment and provided few long term benefits. The report was written jointly by the Nanjing Institute of Environmental Sciences in collaboration with Greenpeace (Source: Dow Jones 4 June 2002 via AgNet). The report is available from:

http://www.botanischergarten.ch/debate/GMcottonDamage.pdf

The China Academy of Sciences is reported to be preparing a paper that refutes the allegations, and chastises the State Environment Protection Agency for working with Greenpeace. A separate rebuttal of this report was written by Patrick Moore (co-founder of Greenpeace and now an environmental consultant) and is available from:

http://comet.sparklist.com/scripts/lyris.pl?visit=agbioview&id=183445739

The US National Centre for Food and Agricultural Policy describes itself as a non-profit, non-advocacy group. A study by them, funded by the Rockefeller Foundation, Council for Biotechnology Information, Grocery Manufacturers of America and Crop Life America, was released in June, and estimated the benefits from biotech crops in the United States based on 40 case studies. Overall the benefit during 2001 was estimated as:

- higher yields: 4 billion pounds of food and fibre compared to conventional varieties;
- increased incomes for farmers: $1.5 billion; and,
- reduced pesticide use: 46 million pounds..

The full report is available from:

http://www.ncfap.org/40CaseStudies.htm

5.4.10 Pollen mediated gene flow report by European Environment Agency

The European Science Foundation (ESF) is the European association of research funding agencies, national research organisations and national academies of science and letters from 24 European countries. In 1999 it initiated the "Assessing the Impact of GM Plants" (AIGM) research programme. The European Environment Agency established a partnership with the ESF, and their first joint report is "Genetically modified organisms (GMOs): The significance of gene flow through pollen transfer". The report considers and interprets published research on gene flow from six major crop types that have been genetically modified and are close to commercial release in the European Union. Of the six crops, oilseed rape, sugar beet and maize were regarded as high risk for crop to crop gene flow and for crop to wild relatives gene flow, while potato, barley and wheat were considered low risk. Recommendations were made regarding future research and monitoring. The full report is available from:

http://reports.eea.eu.int/environmental_issue_report_2002_28/en

5.4.11 Co-existence of GM crops with conventional and organic crops

This study by the EU Joint Research Centre was an initial project addressing questions about co-existence of the different crops and trying to evaluate the introduction of GM crops to Europe. The study used computer modelling to estimate the effects of the introduction of GM crops (oilseed rape, grain maize, and potato) into Europe, with respect to levels of adventitious contamination of non-GM varieties. The report suggested that a 0.1% limit for adventitious presence would be difficult to meet, but the 1% labelling threshold should be achievable. However, the report also stated that any conclusions should be treated with caution as the models used have not been validated. Overall, the study identified the need for better information on gene flow.

An overview document is available from:

http://www.jrc.cec.eu.int/default.asp?sIdSz=our_work&sIdStSz=focus_on

and the full report is available from:

http://www.jrc.cec.eu.int/download/GMCrops_coexistence.pdf

5.5 GM Animal Feed

5.5.1 DNA carryover from GM crops to animals (Klotz *et al*., 2002)

This study examined pigs fed conventional and recombinant (Bt) maize. Various tissues were examined by PCR for the presence of plant chloroplast genes, a maize specific gene (zein), and the Cry1A gene from Bt maize. While short chloroplast-specific DNA could be successfully amplified from the intestinal juices of pigs up to 12 hours after feeding, this gene could not be detected in samples from pig organs. Specific gene fragments from the transgenic maize were not detected in any pig samples.

An associated field study examining supermarket poultry tissue samples frequently found the short chloroplast DNA fragment, as well as faint signals for the maize specific zein gene.

The authors commented that these diverse results may be caused by different digestion systems, but it would be difficult to control future regulations regarding labelling of animals fed GM feed.

5.5.2 Livestock Production Science

The April 2002 issue of this journal contained a number of papers concerning GM organisms in the food chain with respect to animal products. A review (Aumaitre *et al*., 2002) commented that to date GM plants have been equivalent to isogenic plants in compositional analyses and also animal performance. Chloroplast specific gene fragments have been detected in lymphocytes and duodenal juice of the dairy cow, and in muscle, liver, kidney and spleen of broilers. However, transgenic DNA could not be detected in milk, tissue samples or eggs of livestock fed Bt maize. This was reinforced in another study (Phipps *et al*., 2002) in

which ten cows were fed a mix that included Roundup Ready soy over several weeks. Transgenic DNA could not be detected in milk samples from these cows.

5.6 Miscellaneous

5.6.1 GM carnations in Australia

A company in Victoria called Tesselaar Bulbs and Flowers are selling GM carnations (which have altered flower colour). The range of GM plants is selling well across Australia according to the company, except in Tasmania where the state's GE free status prevent sales. The company has a website at: http://www.tesselaar.net.au (Source: New Zealand Life Sciences Network 16 January 2002 via AgNet).

5.6.2 Low nicotine GM tobacco

The US company, Vector Group, have developed a tobacco which has been genetically modified to block production of nicotine in the plant. The USDA has confirmed the low levels of nicotine and found that the crop poses little threat to the environment. The company has asked the USDA to remove restrictions on commercial release of the plant (Source: Associated Press, 16 February 2002 via AgNet).

5.6.3 EU food safety law defines precautionary principle

A new European regulation, Directive 178/2002, that entered into force on 21 February 2002 defines the controversial precautionary principle. Article 7 states that in cases where the possibility of harmful effects have been identified "but scientific uncertainty persists, risk management measures….may be adopted, pending further scientific information for a more comprehensive risk assessment". This enables the European Commission to directly intervene when food or feed is thought to pose a serious risk, and allows such interventions to be co-ordinated across the EU instead of *ad hoc* actions by member countries. The new regulation also establishes the European Food Safety Authority which will provide scientific and technical support to EU policy makers and disseminate risk related information (Source: ICTSD 26 February 2002 via AgNet).

5.6.4 Trypsin from GM corn

The proteolytic enzyme trypsin is used in a variety of industrial and pharmaceutical processes, including insulin production. Normally derived from animal sources, trypsin can now be commercially produced in GM corn. The corn is being grown in test plots in the Midwest of the United States, and was developed by ProdiGene Inc., a spinoff company of Pioneer Hi-Bred International. It will be on the market by the end of 2002 and scaled up to commercial production in 2003 (Source: Associated Press 17 March 2002 via AgNet).

5.6.5 Indigo production in bacteria

Indigo is a dye used for blue jeans. Originally extracted from plants, it is now made from coal or oil. A Californian company, Genencor, has developed a modified version of the *Escherichia coli* bacteria that produces indigo. The modification involves the addition of an extra enzyme that converts the naturally produced amino acid, tryptophan, into indigo. Tryptophan production by the bacteria was also enhanced (Source: CBC Online 4 April 2002 via AgNet).

5.6.6 Transgenic sequence excision (Keenan and Stemmer, 2002)

Although tissue specific promotors can reduce or eliminate expression of transgenes in certain parts of a GM plant, the transgene sequence is still present throughout all plant parts. The ability to excise a transgenic sequence from a plant could have important advantages: in perceived food safety (removal of encoded proteins from parts of the plant used for food), reduction of gene dispersal (through excision of the transgene from pollen or seeds) and replanting (saved seed with the deleted transgene could be saved and replanted).

A system to make such excisions has been proposed by the use of inducible promotors and site specific recombinases. Basically a tissue specific or chemically inducible promotor drives the expression of a recombinase enzyme that excises a transgene cassette placed between two recombinase sites. Also between these sites is the promotor and gene that expresses the desired trait. When induced in the specific tissue, the entire cassette is excised, apart from the recombinase recognition site.

There are a number of practical difficulties before this idea can be realised, but already systems such as the Cre recombinase plus the *loxP* recombinase sites are in active research.

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