CURRENT AWARENESS OF ISSUES RELATED TO GENETICALLY MODIFIED FOOD AND FOOD FROM CLONED ANIMALS

July – December 2004

Prepared as part of a New Zealand Food Safety Authority contract for scientific services

by

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Client Report FW0518

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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 and foods from cloned animals. This report covers developments in the period July to December 2004 and it is noted that during this period:

- The global planting area of GM crops continues to increase.

- There is an increasing commitment to and involvement in biotechnology research from developing countries.

- Codex Alimentarius has reconvened its task force on biotech food. The task force has a 4-year term and is due to report in 2009. The primary term of reference for the task force is stated in the report as "to elaborate standards, guidelines, or other principals, as appropriate, for foods derived from modern biotechnology, taking account in particular of the Principals for the Risk Analysis of Foods derived from Modern Biotechnology".

- Implementation of EU regulations to approve GMOs continues to be problematic. Inability of EU ministers to reach agreement on approvals has seen the EU Commission use a legal default option to make decisions.

- New GM varieties continue to be adopted in the USA, however, major biotechnology companies have withdrawn from the UK. Along with their withdrawl has been the withdrawl of applications for approvals for their GM lines. Due to current EU approval processes this now means that the time frame for any future approvals in the UK is likely to be a long one.

- New systems have been reported for the development of transgenic plants that contain no foreign DNA. This technology is likely to have implications for labelling regulations and testing systems should products from plants generated using these systems enter the market in the future.

- The US FDA has reported the establishment of a risk assessment system for analysing the consumption risks from foods derived from cloned animals. They are currently using this system to evaluate data on animal health and product composition from cloned animals prior to determining the food safety risks of these products.

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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) and foods from cloned animals. It is intended to include:

- scientific issues concerning safety, detection, and nutritional quality of genetically modified foods and foods from cloned animals;
- 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 enhancement of New Zealand's enforcement strategy on standards for genetically modified foods.

This is the first report for the 2004/2005 year and covers events from July to December 2004.

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 "canola" is used for this "double low" variety of rapeseed. .

An important source of information 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/

Abbreviations used throughout this document:

WTO: World Trade Organization
WHO: World Health Organization
FAO: Food and Agricultural Organization of the United Nations
ERMA: Environmental Risk Management Authority
FSANZ: Food Standards Australia New Zealand
NGO: Non-governmental Organisation

2 PART A: FOODS FROM GENETICALLY MODIFIED ORGANISMS

2.1 STATUS OF GM CROPS WORLDWIDE

2.1.1 GM Crops in the US

In August 2004 the Pew Initiative on Food and Biotechnology updated its facts sheet on the amount and types of genetically modified crops grown in the US to include 2004 data recently released by the USDA. Highlights from 2004 included:

- The portion of GM soybeans planted in the US increased from 81% of total plantings in 2003 to 85% in 2004. This represented an additional 3.9 million acres of plantings.
- The portion of GM corn planted increased from 40% of total plantings in 2003 to 45% in 2004. This represented an additional 4.9 million acres of plantings.
- Total plantings of GM cotton increased to 76% of the total cotton crop in 2004.

The full report can be accessed at http://pewagbiotech.org/resources/factsheets/

2.1.2 Global Planting of GM Crops

The Council for Biotechnology Information released a report in December 2004 outlining that research and production of biotech crops is now underway in 63 countries. The study, "The Global Diffusion of Plant Biotechnology: International Adoption and Research in 2004" reported that the global commercial value of biotech crops grown in the 3003-2004 crop-year was US$44 billion. The 5 countries leading this development are the US, Argentina, China, Canada, and Brazil.

However, while North America is still the epicentre for plant biotechnology research, more than half of the 63 countries engaged in biotech research, development and production are developing countries. Western Europe, China, Argentina, Brazil, South Africa, Australia and India are centres of influence that will help lead future developments. For example, India has at least 20 academic and research institutions involved in plant biotech research, covering 16 crops. The report contends that it is currently only the continued restricted activity within the EU that is slowing global diffusion of biotech.

The study is available at: http://www.apec.umn.edu/faculty/frunge/globalbiotech04.pdf

2.2 LEGISLATIVE POSITION OF OVERSEAS GOVERNMENTS REGARDING GENETICALLY MODIFIED FOODS

2.2.1 European Union

- Decisions on national bans on GMOs within the EU have been referred to the EU Council of Ministers. This has involved a draft proposal to lift national bans currently in place in five EU Member States on certain authorised GMOs. The GMOs concerned are GM corn lines T25 and MON810 banned in Austria and Bt176 banned in Austria, Germany and Luxemborg, canola line MS1xRF1 banned in France and Topas 19/2 banned in France and Greece. The EU Regulatory Committee, which represents Member States, did not reach the qualifying majority needed to support the Commissions proposal to ask the five Member States to lift their national measures.

The Commission now formally transmits the proposals to the Council of Ministers for decision. If no decision is made within three months the file returns to the Commission who can then adopt it.
Source: European Commission Media Release 30 November 2004
http://europa.eu.int/

- Implementation of EU regulations to approve GMOs continues to be problematic. During the reporting period EU environmental ministers failed to agree on approvals for MON 863 corn and GT73 canola (Monsanto). Ministers must reach agreement within a three month time period or approvals have to pass back to the EU Commission, who then makes a decision whether or not to adopt them. However, the Commission has used this legal default procedure to overcome months of deadlock on approval of the Roundup Ready corn line NK603 (Monsanto), with approval being granted in October 2004.
  Source: Reuters via AgNet, 26 October, 29 November and 20 December 2004

2.2.2 Brazil

There have been ongoing delays and postponements in the creation of a Biosafety Bill to regulate biotechnology in Brazil. In October a draft modified bill was sent to the lower house for clearance before the President can signed it into law. A backlog of legislation in the lower house is now responsible for further delays in the bill's approval.

Meanwhile, Brazil's Biosafety Technical Commission has decided to allow up to 1% GM material in cotton seed lots. The comment made by the Commission's general co-ordinator was that the decision "was made to preserve the integrity of GMO restrictions, otherwise farmers would have disregarded the rules", and contaminated stocks with GMOs, "as they have done with soybeans".
Source AgNet 6 October and 18 November 2004

2.2.3 Mexico

In December 2004 Mexican legislators approved a new law to regulate GM crops. The legislation now ensures that GM crops undergo evaluation of any possible risk to human health and the environment.
Source: CropBiotech Update 22 December 2004 http://www.isaaa.org/kc

2.2.4 Thailand

In August 2004 the Thai government lifted a three-year ban on planting GMOs, by allowing crops to be grown in open field trials alongside non-GMO plants. The government is now expected to pass laws to regulate planting areas for GM crops and for the import of GM seeds, and for the labelling of other products containing GMOs.
Source: Reuters via AgNet 21 August 2004

2.2.5 Sri Lanka

The Sri Lankan Department for Environmental and Natural Resources has acknowledged the importance of introducing a Regulatory System to control the import of GMOs into the country and has stated that action is now being taken to introduce new laws to cover this area.
Source: AgNet 27 July 2004

2.2.6 South Africa

In July 2004 the South African Animal Feed Manufacturer's Association (AFMA) outlined five measures highlighted by the registrar of the GMO Act to address spillage or unintentional release during the importation of GM grain into South Africa. These measures relate to products with only commodity clearance and focus on issues associated with transportation and milling.
Information on importation of grain into South Africa can be found at:
http://www.isaaa.org/kc

2.2.7 Canada

The Canadian Council of Grocery Distributors (CCGD) in October lifted its two-year moratorium on labelling for GM ingredients. Association members can now label for GM content, provided they comply with the new standard published by the Canadian General Standards Board. In particular labelling for non-GE products must be able to be verified and manufacturers will need to be able to prove the product's history.
Source: BioCrop News via AgNet

2.3 GLOBAL REGULATORY INITIATIVES

2.3.1 Codex Alimentarius

The Codex Alimentarius Commission has reconvened its task force on biotech foods. The Joint FAO/WHO Foods Standards Programme 27th Session was held in Geneva from 29 June – 2 July 2004. The report of this meeting includes a section "Terms of Reference of the *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology". The task force has a term of four years, with a report to be tabled in 2009. The primary term of reference for the task force is stated in the report as "to elaborate standards, guidelines, or other principals, as appropriate, for foods derived from modern biotechnology, taking account in particular of the Principals for the Risk Analysis of Foods derived from Modern Biotechnology".
The full report from the 27th Session can be found at:
ftp://ftp.fao.org/codex/reports/al04_41e.pdf

2.4 GMF APPROVALS

2.4.1 Widestrike Cotton Approved in US

The US Environmental Protection Agency (EPA) has approved the use of a new cotton line (Widestrike), containing two proteins Cry1Ac and Cry1F from *Bacillus thuringiensis* (Bt). The EPA has previously approved both of these Cry proteins for use. Approval for Widestrike use is until 30 September 2009. The line, from Dow AgroSciences, is intended to be resistant to a wide range of insect pests of cotton.
Source: US Environmental Protection Agency.
http://yosemite1.epa.gov/

2.4.2 Triple Trait Corn Available for First Time in US

Monsanto is offering US farmers their first opportunity to plant a triple trait corn variety. YieldGard Plus with Roundup Ready Corn 2 technology will be available for planting in the 2005 season. The line combines both above and below ground insect resistance with herbicide tolerance and brings together traits previously contained in separate products.
Source: http://www.monsanto.com/

2.4.3 FDA Approval for GM Wheat

In July 2004 the US Food and Drug Administration issued approval for use in food of Monsanto's biotech wheat, concluding there are no food safety risks associated with the variety. Regardless of the approval Monsanto maintains it is not going to commercialize the product until there is greater public acceptance of it.
Source: Reuters via AgNet 23 July 2004

2.4.4 Roundup Ready Corn Approved in Argentina

The Argentina government in July 2004 approved planting of Monsanto's Roundup Ready corn variety NK604. Roundup Ready soybeans and cotton and insect-protected corn and cotton are already approved for planting in Argentina.
Source: http://www.monsanto.com. Press release 13 July 2004

2.4.5 Summary Notifications to the EU

Updated notification of existing products is available in table format at :
www.europa.eu.int/comm/food/food/biotechnology/gmfood/notifications_existing_products

A summary of genetically modified food pending authorisation in the EU is available at:
www.europa.eu.int/comm/food/food/biotechnology/authorisation/app_pend_2004

An update of genetically modified feeds authorised in the EU can be found at:
www.europa.eu.int/comm/food/food/biotechnology/authorisation/feed_authorised

2.4.6 GM Approvals in the UK

Bayer CropScience has withdrawn the last two remaining applications to the UK government for approval to grow GM seeds in Britain. The applications were for a winter and a spring canola variety, both with herbicide tolerance. Any new applications for growing GM seeds in the UK will now have firstly to go through the EU approval process, followed by two years of trials in the UK and then final approval by the British government. Any such approvals are therefore likely to take a long time and Bayer CropScience has indicated that they will not put forward any further applications until the UK government can prevent crops being destroyed by protesters during trial periods.
Source: http://news.independent.co.uk/ 21 November 2004

2.5 DETECTION OF GENETICALLY MODIFIED FOODS – RECENT DEVELOPMENTS

2.5.1 Importance of Sampling in Testing for GM Foods

Researchers at the US Department of Agriculture, and collaborators, published results of a study to evaluate variances associated with sampling in the detection of GM content in foods. The study tested for the presence of the Cry9C protein contained in StarLink corn in corn flour and corn meal samples. Emphasis was placed on measuring sampling and analytical variance at each step in the testing procedure. Variances were found to be a function of the concentration of Cry9C in the sample and the particle size of the product being tested. A higher concentration of Cry9C lead to an increase in variance as did larger particle size. Sampling variance associated with corn meal was almost double that for corn flour, with the sampling variance for corn meal accounting for 92.6% of the total testing variability. This study re-iterates the importance of sampling appropriate amounts of products when testing and quantifying GM content, and demonstrates the effect of increasing sample size on reducing false positives (seller's risk) and false negatives (buyer's risk), when testing against a defined limit greater than zero.
Whitaker, T.B., Trucksess, M.W., Giesbrecht, F.G., Slate, A.B. and Thomas, F.S. (2004). Evaluation of Sampling Plans to Detect Cry9C Protein in Corn Flour and Meal. Journal of AOAC International 87(4): 950.

2.5.2 Black Seas Countries Establish Network of Labs to Test for GM Food

The newly established Black Seas Biotechnology Association (BSB) and is made up of Bulgaria, Romania, Russia, Turkey and the Ukraine. The BSB recently established a laboratory network for the analysis and control of foods containing genetically modified organisms. The laboratories will be part of the EU network of GMO laboratories and one of their main aims will be the monitoring and harmonizing of legislation of BSB member states with those of the EU.
Source: Crop Biotech Update November 2004. http://www.isaaa.org/kc

2.5.3 Korea to Adopt Standardized Test

The Korean Food and Drug Administration (KFDA) has announced that it will establish a standardized test in an effort to make GMO product testing more reliable. Draft legislation in place in Korea requires labelling by food manufacturers to indicate if there is any GMOs in

their products. As there is no government-designated standardized testing system to monitor labelling, concerns have arisen over the credibility of test results.
Source: The Korean Times via AgNet 29 November 2004.

2.6 SURVEILLANCE AND POST-MARKET MONITORING

2.6.1 Labelling Surveillance in Brazil

Consumer Protection agencies from nine Brazilian states have conducted an inspection of supermarkets and gathered samples of 45 different types of soybean products. Testing of the products for GM content will be used to monitor labelling requirements. Brazil currently requires that foods or food ingredients containing more than 1% transgenic components be labelled.
Source: AgNet 27 August 2004

2.6.2 GM Contamination in Thai Papaya Crops

In September 2004 the Thai government announced that GM papaya in a state-run experimental centre had contaminated surrounding fruit farms. The contamination was found after the Agricultural Department tested fruit from less than 10% of the 2,600 farms in the province.
Source: AgNet

2.7 GMO SAFETY ISSUES

2.7.1 Safety of GM Foods and Human Health: General Papers

2.7.1.1 EU Network Safety Assessment of Genetically Modified Food Crops

In July 2004 the Journal of Food and Chemical Toxicology published the results of an EU funded study on the safety assessment of genetically modified crops. This outlines results from a number of studies subsidised by the European Commission through the 5th Framework Programme 'Quality of Life Management of Living Resources, Key Action 1'. The study was organized by ENTRANSFOOD, the EU funded Thematic Network on the Safety Assessment of Genetically Modified Crops. Five Research Projects and Working Groups were set up with more than 65 participants from academia, the food industry, regulatory agencies and consumer groups from within 13 European countries.
The studies covered:

- Assessment of the safety of foods derived from GM crops.
- Unintended effects and their detection in GM crops.
- The relevance of gene transfer to the safety of food and feed derived from GM plants.
- Detection and traceability of GMOs in the food production chain.
- Social aspects of GM foods.

The main conclusions drawn from the studies include:

- Post market monitoring of GM food might be considered useful for those foods with specifically altered nutritional properties and whose dietary intake can be followed through labelling

- A combination of targeted and non-targeted methods of analysis, to be decided on a case-by-case basis, is the best way forward to evaluate the safety of GM and conventionally bred crops.
- To reduce the risk of gene transfer to the microbial population in the gut, the use of bacterial DNA in constructing GM plants should be kept to a minimum.
- Marker genes which code for resistance to clinically important antibiotics should not be used. Some antibiotic resistance genes such as the *nptII* gene can be used without the risk of compromising important clinically used antibiotics.
- The use of traceability systems for post-marketing monitoring applications requires labelling systems that include all necessary information on the presence of individual GMO varieties to the reader.
- Research is needed to determine the most effective form of food labels. They should take account of cross-cultural differences in information preferences where they exist.

A summary of the project conclusions can be found at www.entransfood.com. It is also published in:
Kuiper, H.A., Kleter, G.A., Konig, A., Hammes, W.P. and Knudsen, I. (2004). Safety Assessment, Detection and Traceability, and Societal Aspects of Genetically Modified Foods. Food and Chemical Toxicology Vol 42, Issue7:

2.7.1.2 Feeding trial in pigs

Researcher at the University of Southern Illinois reported on studies they have performed feeding pigs with GM corn. The researchers found no traces of 'foreign' genetic material in the flesh or blood of the piglets fed the GM corn. While they did detect fragments of the transgene from the corn in the stomach contents of the pigs these were not carried through to the small intestine, colon or feces. This suggests the DNA is degraded by the time it is excreted and that no intact DNA is absorbed into the animal tissues from the gut. These results are consistent with other animal feeding studies which concluded that GM feed is as safe for the organism ingesting it and for the environment as conventional foods.
Source: AgNet 6 November 2004

2.7.2 National reports on GM food safety

2.7.2.1 Italy

Eighteen Italian scientific organisations have signed a consensus document on 'Food Safety and GMOs'. The document presents the current knowledge about the safety of GMOs worldwide. The major recommendation made in the report is that assessment of GMOs for safety should concentrate less on the technology used to produce them and more on their engineered feature, and these should be treated on a case-by-case basis.
The full document can be found at http://www.cedab.it/Documenti.asp

2.7.2.2 US Government Report on Biotech Food Safety

The investigative branch of the US Congress has published a report concluding that foods produced using biotechnology are as safe as conventional foods. Entitled "Genetically Modified Foods: Experts View Regimen of Safety Tests as Adequate, but FDA's Evaluation Process Could Be Enhanced", the report recommends modest changes to the process used by the US FDA to evaluate biotech foods. The overall conclusions of the report support the

consensus view that while biotech foods are not risk-free, the risks are similar to those posed by non-biotech food products and that the strict regime of testing of biotech products possibly makes them safer than conventional foods. The recommendations to enhance the FDA's evaluation process are that (i) the raw data provided by companies about new products be randomly verified and (ii) the FDA do a better job of informing the public about its evaluation process and the scientific rational behind its decisions.
Source: Council for Biotechnology Infromation via AgNet 3 November 2004

2.7.3 GM Crops and Environmental Safety Issues

During the period covered by this report results from a number of studies on aspects of GMOs and Environmental Safety have been released. These include:

- The UK Botanical and Rotational Implications of Genetically Modified Herbicide Tolerance (Bright) Link project released results of a four-year study on GM sugar beet and winter canola, and stated that there was no evidence that the crops were harmful to the environment. The study was sponsored in part by the Department for Environment, Food and Rural Affairs (Defra) and the Scottish Executive Environment and Rural Affairs Department. (Seerad) and The Home-Grown Cereals Authority (HGCA).
  Full report available at HGCA online, Report 353: http://www.hgca.com

- In July 2004 PE Economics (UK) released a paper on GM and non-GM crop co-existence, "Co-existence in North American agriculture: can GM crops be grown with conventional and organic crops?". Key findings of the report were that (i) GM crops are and have been grown in co-existence with conventional crops without causing any economic or marketing problems to non-GM or organic growers, and (ii) growth of GM crop area has not impeded the development of organic crops.
  Source: Agricultural Biotechnology Newsletter 9 July 2004 via AgNet

- The University of Bern published a review in August 2004, "The impact of agricultural biotechnology on biodiversity". This is a comprehensive review that covers the impact of a number of agricultural practices on biodiversity, and these included GM technology. It includes information about a number of controversial case histories, for example, "The British Farm Scale Experiment 2003" on herbicide application management.
  The full report can be found at:
  http://www.botanischergarten.ch/Biotech-Biodiv/Report-Biodiv-Biotech12.pdf

2.8 BIOTECH RESEARCH

2.8.1 New Crops in Development

During the period covered by this report a number of announcements were made by research groups and/or biotech companies relating to potential new GM crops being developed. These included:

- Egyptian scientists, who have produced drought-tolerant wheat by transferring a gene from barley into a local wheat variety. It is claimed that the new line can grow with one-eighth the irrigation requirements of the parent line and could be cultivated with rainfall alone in some desert areas.
- German researchers, who reported the engineering of linseed plants to produce significant levels of very long chain (omega-3) poly-unsaturated fatty acids (PUFAs) in the seed. This is the first report of the successful introduction of omega-3 PUFAs into an oilseed crop.
- US Department of Agriculture and University of Missouri scientists, who announced the development of a new soybean line resistant to two leading nematode pests. The new line S99-3181 is likely to be used as a parent line in breeding programmes.
- The International Institute for the Semi-Arid Tropics (ICRISAT), who announced the development of GM groundnuts (peanut) and GM pigeon peas.

2.8.2 New Systems for Generating Transgenic Plants that Contain No Foreign DNA

Generation of transgenic plants, whether via *Agrobacterium*-mediated transformation or using biolistic techniques has until now relied on the incorporation of foreign DNA into plant genomes. Much of the public concern about GM crops/foods stems from a concern about the perceived safety issues associated with this foreign DNA content. Much biotechnology research has therefore focussed on how to minimise the amount of foreign DNA transferred. Two groups have recently reported systems for the generation of genetically modified plants that contain no foreign DNA.

1. The May 2004 issue of the prestigious international journal, Plant Physiology, published results of a research project undertaken by the US group, Simplot Plant Sciences. This group has developed a method for the transformation of potato plants whereby a plant-derived (P-) DNA fragment is transferred into the plant alongside a conventional *Agrobacterium*-derived T-DNA that carries a selectable marker gene. Successful transformation is confirmed by determining the expression of the selectable marker gene in a system that inhibits its integration into the plant genome. They found that 29% of the regenerated plants derived using the system contained integrated P-DNA but no evidence of any inserted T-DNA. The method has been used to produce hundreds of T-DNA free potato plants that display reduced expression of a potato poly-phenol oxidase gene regulated by a gene inserted via P-DNA integration.

   Rommens, C.M., Humara, J.M., Ye, J., Yan, H., Richael, C., Zhang, L., Perry, R. and Swords, K. (2004). Crop Improvement through Modification of the Plant's Own Genome. Plant Physiology 135: 421.

2. In late 2004 the NZ researcher Dr Tony Connor announced the successfully generation of transformed plants without the use of any foreign DNA during the

transformation process. The system relies on the presence of sequences within a plant genome that are analogous to the regions of *Agrobacterium*-derived T-DNA that are necessary for the transfer of introduced DNA into the plant genome. By incorporating these plant-derived sequences alongside other plant sequences for the conferment of specific traits it has been possible to generate a transgenic plant that contains only DNA endogenous to that plant genome. Preliminary studies have been carried out in the model plant *Arabidopsis*, with ongoing work in potato and other crop plants.

Source: NZ Bio News Update 24 Nov 2004, and pers. com.

The development of both these methods should go some way towards allaying public concerns about the safety of foreign DNA inserted into GM foods. If these methods ultimately produce foods for the public market it will however result in labelling issues that will need to be addressed. For example, decisions will need to be made as to the classification of such products - whether or not they are technically GMOs and if they will need to comply with current labelling requirements for GMOs. The ability to test for such products would require the provision of specific information on their generation as the endogenous plant-derived nature of any introduced DNA will make it unlikely that any generic testing system will be able to used on these products. This will be an issue for ERMA, FSANZ and NZFSA to consider at the time if such products are likely to come onto the market.

2.9 MISCELLANEOUS

2.9.1 Monsanto to Leave Costa Rica

Monsanto has decided to withdraw its request to release GM corn in Costa Rica and will withdraw from the country.
Source: AgNet, 20 September 2004

2.9.2 US demands compensation from EU

The WTO has announced that they have put off until March 2005 a decision on whether the EU broke trade rules by not allowing imports of genetically modified foods. The decision had been expected in September or October 2004, but, WTO officials have said that they wish to allow more time for both sides to make their case and to allow the judges to question scientists.
Source: Reuter via AgNet 26 August 2004

2.9.3 Studies on Opinion and Support for GM Technologies

2.9.3.1 PEW Initiative on Food and Biotechnology

In September 2004 the US Pew Initiative on Food and Biotechnology conducted its third comprehensive survey of US consumers views about the application of genetic engineering to agriculture. The first survey was conducted in January 2001 and the second in August 2003. In summary the latest survey found:

- Americans remain relatively uninformed about genetically modified foods and their level of knowledge has not increased over the past three years.
- The knowledge that consumers do have seems to be driven mostly by the degree to which the media concentrates on the issue.
- Opinions formed during events such as the StarLink incident can be long lasting for some consumers.
- Support and opposition to the introduction of GM foods into the food supply has remained essentially the same over the last year.
- Whilst not knowing much about the regulation of GM foods, consumers support a strong regulatory system.
- Americans remain most comfortable with the genetic modification of plants, and least comfortable with the modification of humans.
- Consumers are most supportive of the use of biotechnology where they feel it will directly help them and their families.

The full survey report can be found at: http://pewagbiotech.org/

2.9.4 Genetically Modified Crops in Developing Countries

- In July 2004 India's Department of Biotechnology and the US Department for International Development signed a letter of intent to initiate enhanced cooperation in agricultural biotechnology research and development.
  Source: Agnet

- An Open Letter of support has been signed by more than 40 NGOs and stakeholders in civil society worldwide and sent to the UN FAO supporting the FAO's May 2004 report in favour of using agricultural biotechnology to help meet the needs of the poor and undernourished.
  The Open Letter and list of signatories can be found at:
  http://www.internationalconsumers.org

3 PART B: FOODS FROM CLONED ANIMALS

This section presents recent international information on the safety of foods from cloned animals. Issues associated with transgenic animals as foods are not covered in this report.

3.1 INTRODUCTION TO CLONING OF FOOD ANIMALS

Assisted reproductive technologies (ARTs) have been used in animal production systems for over a century. One of the more recent developments within this area is nuclear transfer technology (NTT), or more colloquially 'cloning'. Nuclear transfer techniques can be divided into two types:

1. Embryonic nuclear transfer (ENT), where the nucleus from a very early embryo (blastocyte) is taken and transferred into the cytoplasm of a recipient cell that has had its own nucleus removed (e-nucleated host cell). The blastocyte stage from which the nucleus is taken is prior to morphologically distinct differentiation of cell types in the embryo and directs the recipient cell on to develop into an embryo.

2. Somatic cell nuclear transfer (SCNT), where a differentiated animal cell nucleus is transferred into an e-nucleated recipient cell. In this system the nucleus from the partially or terminally differentiated cell re-programmes the e-nucleus back to a de-differentiated state, which then directs development of the cell into an embryo.

Both of these systems have been used to successfully generate cloned animals, however, it should be noted that the vast majority of embryos reconstructed by nuclear transfer either die before birth or produce unhealthy offspring. This suggests that a normal developmental outcome is more of an exception than the rule. The technology however has potential to enhance agricultural practise, as elite animals are likely to be used as nuclear donors for the increased production of desirable characteristics in stock.

3.2 FOOD CONSUMPTION RISKS AND EVALUATION OF PRODUCTS FROM CLONED ANIMALS

As the techniques for efficient and successful animal cloning are still being developed and optimised in the laboratory/field trials the animals produced are generally not entering the food chain. However, as the technology develops and foods are produced for the market there will be a need for governmental and public acceptance of these foods. An assurance of safety aspects associated with foods from cloned animals is likely to be required. Some beef from cloned animals has been released onto the food market in Japan, with almost all of the products being labelled as cloned beef. In 2001 the US FDA requested producers of cloned animals to refrain from putting edible products on the market until the safety of those foods had been evaluated.

During this reporting period two major studies were published in the journal Cloning and Stem Cells that deal with aspects of food safety risks associated with food from cloned animals.

1. The Centre for Veterinary Medicine (CVM) of the US FDA has reported on its development of an approach for evaluating food consumption risks associated with animal clones. The risk assessment developed is a qualitative, comparative analysis in which outcomes are expressed relative to comparators of known or inferred safety. In this case, the comparator is foods derived from conventional animals. This approach assumes animal clones from species used for foods and their progeny to be subject to the same regulatory strictures as conventional animals and that edible products from clones and progeny would also be subject to the same scrutiny as products from their conventional counterparts. This translates to (i) healthy animals are likely to produce safe food, and (ii) if there is no material difference between the foods derived from cloned animals and their conventional alternatives then no additional risk is likely to be encountered from the foods from cloned animals. The overall risk assessment process takes two approaches. The first evaluates the health of animal clones and the second looks at the composition of meat and milk from animal clones. Having established this risk assessment and developed an approach for evaluating food consumption risks the CVM is now in the process of evaluating health data and compositional information from cloned animals and is expected to release the final results of this analysis at a later date.
   Publication: Rudenko, L., Matheson, J.C., Adams, A.L., Dubbin, E.S. and Greenlees, K.J. (2004). Food Consumption Risks Associated with Animal Clones: What Should Be Investigated? Cloning and Stem Cells 6(2): 79.

2. Researchers in Japan have reported results of a detailed evaluation of meat products from cloned cattle. Meat samples were obtained from both embryonic and somatic transfer cloned cattle and were compared with meat from non-cloned counterparts. Samples were analyzed for protein, lipids, carbohydrates, ash, cholesterol, amino acids and fatty acids. Digestibility, allergenicity and mutagenicity of meat were also assessed. Results indicated no significant biological differences between meat from cloned or non-cloned animals. A feeding trial was also performed where rats were fed meat from the cloned and non-cloned animals. No abnormalities were detected in body growth, general physical condition, locomotor activity, reflexes, sexual cycle, urinalysis, haematology, blood chemistry or histology in rats fed meat from either non-cloned or cloned cattle. Such equivalence results in food composition would suggest that the meat from the cloned animals studied should not pose any food safety risks not encountered in the products from the non-cloned counterpart animals. This data should add to that being obtained by such agencies as the US FDA from which to determine food safety risk for products from cloned animals.
   Publication: Takahashi, S and Ito, Y. (2004). Evaluation of Meat Products from Cloned Cattle: Biological and Biochemical Properties. Cloning and Stem Cells 6(2): 165.