



## GENETIC MODIFICATION AND FOOD

The Institute of Food Science & Technology has authorised the following Information Statement, dated September 2008, replacing the Statement of July 2004 and any previous version.

### SUMMARY

***Over the past 11 years, and in many parts of the world, genetically modified (GM) crops grown by 12 million farmers (of which 11 million are resource-poor farmers) have already provided significant improvements in the quantity and quality of the food supply while reducing economic cost, energy usage, pesticide usage, fuel usage, soil erosion and carbon emissions, with no scientifically-documented evidence of harm to human health.***

***In addition to the foregoing benefits, the “second generation” of GM crops and those in the research pipeline have the potential to deliver crops to provide much needed nutritional benefits; crops with more effective utilisation of fertiliser; crops that will grow under drought and other adverse climate conditions; and crops that will grow on previously inhospitable land.***

***Food scientists and technologists can support the responsible introduction of GM techniques provided that issues of product safety, environmental concerns, information and ethics are satisfactorily addressed. IFST considers that they are being addressed, and need even more intensively to continue to be so addressed. Only in this way may the benefits that this technology can confer become available, not least to help feed the world's escalating population in the coming decades.***

### INTRODUCTION AND DEFINITIONS

Food biotechnology is the application of biological techniques to food crops, animals and micro-organisms to improve the quality, quantity, safety, ease of processing and production economics of food. It thus includes the traditional food manufacturing processes used for bread, beer, cheese and various fermented milk products.

A relatively more recent (i.e. starting about 30 years ago) application of biotechnology to food is genetic modification (GM), also known as genetic engineering, genetic manipulation, gene technology and/or recombinant DNA technology. The collective term "Genetically Modified Organisms" or GMOs is used frequently in regulatory documents and in the scientific literature to describe the deliberate introduction of DNA by human intervention into plants, animals and micro-organisms.

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Random genetic variation occurs naturally in all living things and is the basis of evolution of new species through natural selection. Even before its scientific basis was understood, mankind took advantage of this natural variation by selectively breeding wild plants and animals and even micro-organisms such as yoghurt cultures and yeasts, to produce domesticated variants better suited to the needs of humans. Such selective breeding involves the transfer of unknown numbers and kinds of genes between individuals of the same species. Before the advent of GM technology, however, so-called "traditional" or "conventional" breeding technology involved far more than the foregoing. Over the past half-century it also included techniques involving polyploidisation and mutagenesis via x-rays, which are far more disruptive of the original plant genes than any GM modification. For example barley seeds (Golden Promise) were treated with x-rays in the Winfrith reactor in 1956 to yield the UK's favourite variety for brewing -- and this variety is also used in the production of organic beer.

Many changes to food materials brought about by gene technology are no different in essence from those which can take place in nature or by selective breeding, except that the gene technologist transfers a carefully targeted selected few specific genes, thus drastically reducing both their random nature and the time taken to produce an improvement.

Thus, within-species GM involves few fundamentally new issues. However, gene technology also makes it possible to move genes between different species. When first used, this property made the technique revolutionary in terms of the potential benefits that it may bring, but it also caused concern regarding issues of safety, ethics, environmental impact and consumer choice.

### TECHNIQUES OF GENETIC MODIFICATION

How is GM technology carried out? In simple terms, the gene technologist uses a "cutting-copying-pasting" approach to transfer genes from one organism to another. For this, bacterial enzymes are used that recognise, cut and join DNA at specific locations acting as molecular "scissors-and-tape". However, the selected gene is copied billions-fold, with the result that the amount of original genetic material in the modified organism is immeasurably small. Since DNA does not always readily move from one organism to another, "vehicles" such as plasmids (small rings of bacterial DNA) may be used; alternatively, some plant cells may be transformed by "shooting" small particles coated with the new DNA into the target cell using a special type of gun, the "Gene Gun". The modified cell can then be used to regenerate a new organism.

However, by currently available methods only small numbers of cells subjected to a genetic modification procedure are successfully modified. Furthermore, the regeneration of whole plants or animals from culture cells may take months or years. Consequently, it is necessary to identify the modified cells in a culture mix using "marker genes" closely linked to the genetic material to be transferred. Antibiotic resistance has often been used to "tag" genes so that they can be detected easily and rapidly at the cellular level in the laboratory, providing a basis for selection. The use of antibiotic resistance marker genes (ARMG) has, however, been a source of concern.

Although the transfer of antibiotic resistance from a marker gene contained in a GM plant to a microorganism normally present in the human gut has not been demonstrated

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experimentally, it has been suggested that the potential risk, however small, of spreading resistance to therapeutic antibiotics could have serious health consequences and therefore should be avoided. In the absence of reliable data, the UK Advisory Committee on Novel Foods and Processes (ACNFP) erred on the side of caution and recommended some years ago against the use of antibiotic resistance marker genes.

However, on 4 February 2004 a Working Party of the British Society for Antimicrobial Chemotherapy <http://www.bsac.org.uk/> stated

"There are no objective scientific grounds to believe that bacterial antibiotic resistance genes will migrate to bacteria to create new clinical problems."

They looked at various routes "but are unable to identify a credible scenario whereby new drug-resistant bacteria would be created". However they point out that the theoretical possibility of transfer by novel mechanisms cannot be entirely ruled out, and so consider whether transfer of the three drug resistance genes that have been used would pose a threat to antibiotic use in medical treatment. These 3 genes are common in bacteria, and found on mobile elements that move between DNA molecules and bacterial cells, and this gene mobility has already compromised clinical use of the antibiotics.

"The argument that occasional transfer of these particular resistance genes from GM plants to bacteria would pose an unacceptable risk to human or animal health has little substance. We conclude that the risk of transfer of AR genes from GM plants to bacteria is remote, and that the hazard arising from any such gene transfer is, at worst, slight."

The Working Party goes on to ask "Can a blanket ban on cultivation of GM plants carrying bacterial drug resistance genes be justified, even in part, because of extremely improbable, unquantifiable concerns?" They argue that a precautionary principle approach that argued that such a negligible risk must prevent the use of plants containing such genes, must be set against a pragmatic approach that takes account of the size of the risk and hazard and also the potential benefits of GM plants, such as reduced pesticide use. While the Working Party believes that the evidence means that most bacterial AR genes would be safe, they "consider it extremely undesirable and unnecessary to extend the list of AR genes approved for GM plant development. In particular, the use of any AR gene that if disseminated widely among bacteria would be likely to compromise use of a front-line or currently widely used antibiotic should be strongly discouraged, if not banned." They note that plant biotechnologists chose not to use AR genes in this category. And conclude, "The moratorium should continue, particularly as alternatives to AR genes are being developed".

On 16 April 2004 the European Food Safety Authority (EFSA) issued a scientific opinion [http://www.efsa.eu.int/press\\_room/press\\_release/386\\_en.html](http://www.efsa.eu.int/press_room/press_release/386_en.html) on the subject, classifying those evaluated into 3 groups based on their biological distribution and taking into account the current importance of the antibiotics concerned to human and veterinary medicine. The EFSA GMO Panel has proposed the following classification for ARMGs:

- Group 1 ARMGs contains antibiotic resistance genes which (a) are widely distributed among soil and enteric bacteria and (b) confer resistance to antibiotics which have no or only minor therapeutic relevance in human medicine and have only restricted use in

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defined areas of veterinary medicine. This refers to the antibiotic resistance genes *nptII* conferring resistance to the antibiotics kanamycin and neomycin with a 13-year history of safe use in food crops and the *hph* gene, which encodes for a protein that inactivates hygromycin, an antibiotic that is not utilised in human clinical medicine. No restrictions are required with this class of marker genes either for field experimentation or for placing on the market.

- Group 2 ARMGs contains antibiotic resistance genes which (a) are widely distributed in micro-organisms in the environment and (b) confer resistance to antibiotics which are used for therapy in defined areas of human and veterinary medicine. This group includes genes which confer resistance to chloramphenicol (*cmR* gene), ampicillin (*ampR* gene) and streptomycin and spectinomycin (*aadA* gene). The use of these genes should be restricted to field trial purposes and not be present in GM plants placed on the market.
- Group 3 ARMGs contains antibiotic resistance genes, which confer resistance to antibiotics highly relevant for human therapy like the *nptIII* gene conferring resistance to amikacin and the *tetA* gene conferring resistance to tetracyclines. Irrespective of considerations about the realistic importance of the health threat, these genes should be avoided in the genome of transgenic plants to ensure the highest standard of preventive health care. Therefore these ARMGs should not be present in GM plants placed on the market or in plants used for experimental field trials.

However, other methods are becoming available. In a development, reported in *Science* in May 1999, researchers at University of Hawaii demonstrated the use of sperm to transport "foreign" DNA into an egg. It has a relatively high rate of success, is technically simple to carry out, has potential for transferring larger pieces of DNA and is applicable to animals.

### ADVANTAGES AND POTENTIAL BENEFITS OF GENETIC MODIFICATION

For the development of improved food materials, GM has the following advantages over traditional selective breeding:

- Allows a much wider selection of traits for improvement: e.g. not only pest, disease and herbicide resistance (as achieved to date in plants) but also potentially drought resistance, halo tolerance, improved nutritional content (yield and quality of macro-nutrients, enhancement of micro-nutrients e.g. vitamin A, iron, enhancement of valuable phytochemical components, removal of allergens or toxic components) and improved sensory properties
- It is faster and lower in cost
- Desired change can be achieved in very few generations
- Allows greater precision in selecting characteristics
- Reduces risk of random occurrence of undesirable traits.

These advantages in turn lead to a number of potential benefits, especially in the longer-term, for the consumer, industry, agriculture and the environment:

- Improved agricultural performance (yields) with less labour and energy input and less cost input
- Benefits to the soil of "no-till" farming practice
- Reduced usage of pesticides and herbicides

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- Benefits to the environment in reducing the cost, energy usage, fuel usage and carbon emissions associated with tractor diesel fuel usage and pesticide spraying
- More efficient use of land
- Ability to grow crops in previously inhospitable environments (e.g. via increased ability of plants to grow in conditions of drought, soil salinity, extremes of temperature, consequences of global warming, etc.) leading to improved ability to feed an increasing world population at a reduced environmental cost
- Improved sensory attributes of food (e.g. flavour, texture, etc.)
- Removal of allergens or toxic components, such as the research on a non-allergenic GM peanut (University of Arkansas and University of Georgia) and a non-allergenic GM prawn (Tulane University); and in Japan, to produce a GM non-allergenic rice.
- Development of crop plants that take up and assimilate nitrogen more efficiently to improve the efficiency of utilisation, and hence reduce the application, of nitrogen fertilisers, resulting in lower production costs.
- Improving nitrogen fertilisation by transfer of nodulation properties from legumes to non-legumes (research at the UK John Innes Institute).
- Research indicates that there are also improved nutritional attributes such as:
  - increased Vitamin A content in rice, which will help to prevent blindness among children in Southeast Asia (Ingo Potrykus's EU research project jointly funded by the Rockefeller Foundation);
  - the announcement in September 2003 by Edgar Cahoon and his team at the Donald Danforth Plant Science Center in Missouri that by inserting a gene extracted from barley into a common type of field corn, they have created a strain that grows with six times the usual amount of vitamin E, a powerful antioxidant.
  - The BioCassava Plus Project by an international multi-centre research team led from Ohio State University, funded by a \$12 million grant from the Bill and Melinda Gates Foundation, to produce GM cassava with enough vitamins, minerals and protein to provide the poor and malnourished with a day's worth of nutrition in a single meal while reducing the cyanogen content; successful in greenhouse trials and now extending to field trials.
  - Research by Dow and Monsanto to develop a canola seed that produces omega-3 fatty acid, DHA (docosahexaenoic acid), thus minimising reliance on fish as source of omega-3.
- Improved processing characteristics leading to reduced waste and lower food costs to the consumer.
- Prevention of loss of species to endemic disease (e.g. the Cavendish dessert banana which is subject to two fungal diseases that have struck Africa, South America and Asia, but could be rerieved by GM development of a disease-resistant version).
- Chinese scientists have developed a genetically modified (GM) corn that could help improve the nutritional value of livestock feed and reduce pollution. The research is carried out by the Chinese Academy of Agricultural Sciences (CAAS). The corn has now entered pre-production field trials. The GM corn produces seeds containing high levels of the phytase enzyme. This enzyme helps livestock to digest phosphorus which is enclosed in the indigestible form of phytate. Animals lack phytase in their system. As a result, farmers add the enzyme to animal feed to help livestock digest phosphorus. The CAAS scientists isolated the gene that produces phytase from a species of the fungus *Aspergillus*, and inserted it into corn. Preliminary test have shown that compared to regular varieties, the rate of seed germination, growth speed and yield of the GM corn were no different. The scientists said that, under current

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industry criteria for feed additives, adding just a few grams of the GM corn seed per kilogram of animal feed would be enough to satisfy livestock's nutritional demand for phosphorus. If the technology is commercialised, Chinese farmers could save up to \$60 million per year in buying industrial phytase. Phosphorus pollution caused by animal waste is a serious problem in China, resulting in widespread algal blooms in the Chinese lakes. Better phosphorous digestibility could add to improvement of the environment. China has not yet approved any GM corn for commercial sale.

- Perhaps a small benefit compared to the above-mentioned, but in January 2008, researchers at New Zealand Crop and Food Research announced the successful genetic modification of onion so that it does not make one cry! Normally when onions are cut or chopped, amino-acid sulphoxides and an enzyme are released to react and form the tear-causing volatile. The genetic modification blocks that enzyme action and redirects the reaction towards formation compounds responsible for flavour and health-giving properties.

GM has huge potential for mankind in medicine, agriculture and food. In food, the real benefits provided by the early instances that have been appearing so far, are surpassed by its longer-term benefit to the world - and especially the developing countries - its potential for developing crops of improved nutritional quality, and crops that will grow under previously inhospitable conditions (see above), thereby contributing to alleviating hunger and malnutrition, while helping to prevent the otherwise inevitable future pressure to encroach on natural resources. Even today, there are 860 million people (800 million of them in the developing countries and 200 million of them children) who regularly do not receive enough food to alleviate hunger, still less provide adequate nutrition. 24,000 people die of malnutrition-related causes daily. That situation will be greatly worsened as a result of the world's escalating population over the coming decades.

There are those who allege that "scientists claim that GM will solve the problem of world hunger". This is a familiar "straw man". It is frequently argued by some that there is more than enough food to feed the world and all that is needed is "fairer distribution" (which so far mankind has signally failed to achieve) – or a variant of that, "the real problem is not shortage of food, it is poverty". Whatever may be done by way of improved yields through conventional methods, attempted population control and more effective distribution would, however, be inadequate for the future. There are probably enough cereals to feed the present world population (if only they could be distributed to the right places at the right times and could be afforded). But there will be substantial shortfalls in cereals in the next two decades, especially if the present practice of diverting cereals from human food use to feedstock for ethanol biofuel production continues. Moreover, "world hunger" is a complex not only of inadequate quantity where it is needed but of inadequate quality i.e. for vast numbers of people the lack of foods with the necessary micronutrients and of clean water, for reasonable nutrition and health.

However, in decades to come, with the expected substantial increase in the world population, mostly in the poorest, least developed countries, the demand for increased agricultural land and for water will greatly increase. The important point is not only how to feed the world now but addressing and trying to solve the problem of "How shall mankind feed the world in a few decades from now?" Of course the problem that has huge political and economic dimensions will not be solved by GM alone, or even by science alone -- but will certainly not be solved without the contribution of science, including GM.

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Food scientists and technologists can support the responsible introduction of GM techniques provided that issues of product safety, environmental concerns, ethics and information are satisfactorily addressed. so that the benefits that this technology can confer become available both to improve the quality of the food supply and to help feed the world's escalating population in the coming decades.

### CURRENT GM FOODS AND FOOD INGREDIENTS

The "first generation" of GM food materials were those that were relatively easy to develop, chosen for their likelihood of rapid commercial success by providing traits that would commend themselves to farmers. Consequently, most of the 80+ crops that have been modified and the 25,000+ field trials that have taken place world-wide to date have involved crops engineered for agronomic traits. The first food plants to be grown successfully on a large commercial scale and put on the market were the GM maize resistant to the European corn-borer, a serious agricultural pest, and the soyabean genetically-modified to be tolerant of the herbicide glyphosate. The latter involves one or two applications of a less toxic, more rapidly broken down herbicide than the spraying regime that it replaces, that of several applications of different herbicides. Contrary to the widely held misconception, glyphosate is not a relatively new herbicide developed for GM crops. On the contrary it has been in use for over 30 years and has been a very popular broad-spectrum, safer and less soil-persistent herbicide, for many conventional crops. But it could not be used for soya because it killed the soya as well as the weeds. So soya farmers had to continue to use a "cocktail" of different herbicides at different stages of the growing season. The clever scientific trick was so to genetically modify soya that it was not killed by, but resistant to, glyphosate.

However, these GM products did not offer consumers a readily perceivable benefit "at the point of purchase"; and with intensified campaigns and media amplification in the early part of 1999 and thereafter highlighting problems and uncertainties (some real, some pure speculation, some spin-doctored and some urban myths), the UK public became turned against GM. Reacting to their customers' views, major retailers and manufacturers decided to exclude GM foods and ingredients.

An incidental victim was the canned tomato puree, prominently labelled "Produced from genetically modified tomatoes", on sale in stores of two major UK supermarket groups in competition with non-GM tomato puree. The GM tomato puree was of better flavour and consistency, cheaper, and consistently outsold the non-GM puree. It is now no longer available.

Chymosin, produced by GM micro-organisms, was developed to replace rennet, the milk-clotting enzyme used extensively in cheese-making, due to the severe shortage of the traditional source of the enzyme (i.e. calf stomachs). The GM enzyme, defined as a processing aid rather than a food additive in regulatory terms, has been in use since the late 1980s in the USA and in some European countries, including the UK

### WHAT ARE THE CONCERNS ABOUT GM?

Increasingly at the heart of the "concerns" debate about GM, is the fundamental matter of the role of science and society in relation to "new" science-based developments such as GM.

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There are two ways of dealing with new developments with associated problems and uncertainties. One is to reject or ban the developments. The other is to address and solve the problems, and to accept that there are no certainties in any aspect of life. Fortunately in the long run mankind has generally adopted the second course, otherwise we would still be living in the Stone Age. Looking at more recent times, there would be no electricity; the first passenger flight would not have taken place, so there would be no air travel; the first surgical operation would never have been carried out so there would be no surgery; the first anaesthesia would never have been used, so there would be no anaesthetics (it is worth recalling that the medical profession of the day prevented Queen Victoria from having anaesthesia with the difficult births of her first seven children ("not natural, not proven safe, not sufficiently tested, what about the long term effects?") -- the list could be endlessly extended. Exactly the same arguments were used in the early decades of the 20th century to try to prevent the legalisation of milk pasteurisation. Fortunately it was eventually legalised and over the last eight decades has saved untold numbers of lives that would otherwise have continued to be lost to milk-borne tuberculosis -- second only to clean water as the most important public health measure ever adopted.

Science depends on gaining knowledge, organising it into a coherent structure, hence improving understanding, and applying it. It is society's tool and method for doing so. However, we can never know everything there is to know about a topic. The one certain thing about life is that nothing in life is certain. Science cannot **prove** that anything is "safe" (i.e. absence of harm) because "absence of evidence" is not "evidence of absence". So any policy purportedly based on requiring science to **prove** safety is unrealistic.

In real life, decision and action by society to meet its needs has to be based, not on certainty but on using the best knowledge available at the time, and on skilful selection of areas for urgently needed research. In the absence of certainty it has to involve the combination of **risk analysis** and **the precautionary principle**, which are two inseparable sides of the same coin. These lie at the very crux of any discussion on the application of GM.

**Risk analysis (RA)** consists of

- **risk assessment**, a task for scientists who are experts both in the topic and in the methodology of risk assessment. Risk assessment should take account of the likelihood of a risk occurring and its seriousness if it does occur, and should be applied not only to a potential course of action, but also to failure to take that action and to alternative courses of action;
- **risk communication**, a multi-directional interchange of information between legislators, the scientific community and the rest of society, which should be an ongoing process; and
- **risk management**, for legislators to carry out on behalf of society in the light of i and ii.

The relationship involving these three activities is not a linear one but one of dynamic and ongoing interplay.

A precautionary approach is a concept familiar to, and used by, food scientists and technologists. Taking precautions in advance to identify foreseeable hazards and adopting



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measures to prevent harm from occurring is at the heart of the Hazard Analysis Critical Control Point (HACCP) preventive food safety system.

On 2 February 2000, the EU Commission issued a "Communication on the Precautionary Principle". It is on-line at

[http://europa.eu.int/comm/dgs/health\\_consumer/library/pub/pub07\\_en.pdf](http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf)

This includes

"The precautionary principle is not defined in the Treaty, which prescribes it only once - to protect the environment. But *in practice*, its scope is much wider, and specifically where preliminary objective scientific evaluation, indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community."

and

"The precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk.

The precautionary principle, which is essentially used by decision-makers in the management of risk, should not be confused with the element of caution that scientists apply in their assessment of scientific data.

Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty.

The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty.

Anti-GM activist groups have focused wholly on the phrases "...where preliminary objective scientific evaluation indicates that there are reasonable grounds for concern... and "and that scientific evaluation does not allow the risk to be determined with sufficient certainty" and have argued that these phrases justify opposing any and every GM activity.

This fails to recognise that science can never produce conclusive results and cannot deal in certainty. Moreover, experience teaches that the situation envisaged is most likely to arise in areas (such as biotechnology) where there are strong ideological agendas, in pursuit of which some individuals, including, unfortunately, some scientists, present unsubstantiated speculation, assumptions and guesswork as though they were "preliminary objective scientific evaluation". This sometimes takes the form of published purported "research papers" which on scrutiny turn out to be merely the authors' speculations and opinions, complete with references to similar papers by like-minded individuals.

If that sort of presentation is considered enough to bring a development to a halt, and, as we have seen, scientific evidence is always insufficient and science cannot prove anything to be safe, it can then be argued in perpetuity both by its ideological opponents and by scientists

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who see further research as a funding opportunity, that the development should not be implemented "until we know more".

Purported "preliminary objective scientific evaluation" should, therefore, always be very carefully and rigorously scrutinised to ensure that there is a broad scientific consensus that it is based on some hard scientific evidence.

Moreover, what is frequently overlooked – and always overlooked by the opponents of a development – is that PP should be applied not only to that development but to all alternative courses of action, including that of doing nothing.

On 8 July 2008 the European Food Safety Authority issued a Question and Answer Document, titled "EFSA GMO Risk Assessment FAQs" which addresses the EFSA role in GMO risk assessment. Some of the questions answered are: How does EFSA carry out GMO risk assessments? Why does EFSA not carry out its own studies? Can the public access GMO applications? How does EFSA take account of long-term effects for human health and the environment and assess potential impact on biodiversity? What about the issue of coexistence with conventional crops and uncertainties, assumptions and the precautionary principle? Why does EFSA keep getting asked to look again at its risk assessments? Why does EFSA consider that antibiotic resistance genes in some of the GM plants are not dangerous?

[http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_EFSAGMORiskFAQs.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_EFSAGMORiskFAQs.htm)

It is an oft-repeated environmental truism that we hold the world in trust for future generations. It would be a betrayal of that trust and an abdication of responsibility by the present generation if science were to limit itself to collecting and providing information about current biotechnology applications, or if society were to limit itself to arriving at verdicts about them. We (society and scientists as part of society) must not behave as disinterested spectators standing on the sidelines and observing problems that may stand in the way of providing future generations with the potential benefits that GM can offer. We have a duty to address and solve such problems. Science is society's tool for doing that.

"As for the future, your task is not to foresee it, but to enable it."  
[Antoine de Saint-Exupery, *The Wisdom of the Sands* (1948)]

Thus, the real questions to be answered are not "Is it safe? Is it environmentally friendly?" but "What do we have to do to make it safe? What do we have to do to make it environmentally friendly? " Recognition of these is the touchstone of sincerity and objectivity.

A joint report on "Transgenic Plants and World Agriculture" was published in July 2000 jointly by the Brazilian Academy of Sciences, the Chinese Academy of Sciences, The Indian National Science Academy, the Mexican Academy of Sciences, the National Academy of Sciences of the USA, The Royal Society (UK) and the Third World Academy of Sciences. It is available in printed form, published by The Royal Society, and it may be accessed on-line as a pdf file at <http://royalsociety.org/document.asp?tip=0&id=1448>

The US organization, the Center for Science in the Public Interest (CSPI), which is no friend of corporations or of US regulatory agencies, issued a report in November 2001, primarily

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from a US perspective, entitled "Genetically Engineered Foods: Are They Safe?" but which also included environmental considerations. It mainly took the form of Questions and Answers by the co-directors of the Biotechnology Project at CSPI. The full text can be accessed on-line at [http://www.cspinet.org/nah/11\\_01/](http://www.cspinet.org/nah/11_01/)

However, their "bottom line" conclusions were as follows:

- The genetically engineered foods that are currently on the market are safe. By increasing yields and reducing the use of pesticides, they benefit farmers and the environment.
- To ensure that new genetically engineered plants and animals are safe for humans and the environment, Congress should institute a mandatory government approval process that is open to public participation and review.
- The Environmental Protection Agency (EPA) should monitor the environmental impact of genetically engineered crops. It should require more field testing, enforce insect refuges for Bt crops, and adopt other environmental safeguards.
- The U.S. government should fund more research on genetic engineering, especially on fruits, vegetables, and other crops that are not of great commercial interest to the biotechnology companies.
- To enable developing nations to benefit from biotechnology, the U.S. government should:
  - fund research and the training of scientists,
  - help countries develop regulations to ensure the safe use of genetic engineering to produce food, and
  - press biotech companies to donate technologies and allow free access to patents that are used to produce genetically engineered seeds and animals.

On 21 February 2002, the US National Academy of Science (NAS) issued its report *Environmental Effects of Transgenic Plants*. The report, which was commissioned in January 2000 by USDA's Animal and Plant Health Inspection Service (APHIS), reviewed the scope and adequacy of the APHIS component of the Federal regulatory framework for biotechnology. As requested, the report evaluates the evolution of APHIS' regulatory program, assessed the effectiveness of changes that APHIS had made to improve the program over the years, and made recommendations for further refinements, particularly involving three processes: notification, permitting and petitioning for non-regulated status. On 2 August 2002, USDA's Animal and Plant Health Inspection Service (APHIS) announced the creation of the new "Biotechnology Regulatory Services" (BRS) Unit within APHIS "to focus on USDA's key role in regulating and facilitating biotechnology".

The full news release is at <http://www.aphis.usda.gov/lpa/news/2002/08/bioreorg.html>

The World Health Organization has issued "[20 Questions on Genetically Modified \(GM\) Foods](#)". These questions and answers have been prepared by WHO in response to questions and concerns by a number of WHO Member State Governments with regard to the nature and safety of genetically modified food.

### SAFETY CONSIDERATIONS

When introducing any new technology, including gene technology, into the food chain, there is a need to adopt appropriate safeguards to protect human health. Most countries in the

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Western hemisphere started developing regulatory controls well before any GM foods reached the market. These controls were put in place not because safety problems had been identified but because of a lack of familiarity with GMOs. Although many of the early concerns regarding the safety of GM foods have not materialised, the precautionary approach has continued as it remains important to ensure that no new hazards are created.

When considering safety in relation to GM, generalisations cannot validly be made. Instances have to be considered and studied in a case-by-case approach, and each case should be assessed in relation to the food involved, as ready for consumption, whether by man or by animals.

Regulations in most countries, including the UK, include the concept of substantial equivalence. This concept was developed in the late 1980s by several national regulators and refined and given international recognition by the Organisation for Economic Co-operation and Development (OECD) in 1993 and further developed by the FAO/WHO Consultation in 1996 with particular reference to foods produced by modern biotechnology (fully detailed on the Web sites of FAO and the UK Advisory Committee on Novel Foods and Processes (ACNFP)). The concept is based on the idea that existing organisms used as food or food sources can serve as a basis for comparison when assessing the safety for humans of modified foods or ingredients. If a new food or component is considered to be substantially equivalent to an existing food or component the theory is that it can be treated in the same manner with respect to its safety and nutritional assessments.

Acceptability or non-acceptability is established by determining whether a novel food is substantially equivalent to an analogous conventional food in terms of composition, nutritional properties, toxin and allergen content, the amount consumed, the type of processing (industrial or domestic) that the food might undergo and consumption by vulnerable groups of people (e.g. infants and the elderly). Foods are assigned to three categories:

- Products that are shown to be substantially equivalent to existing foods or food components
- Products that are substantially equivalent to existing foods or food components except for defined differences
- Products that are not substantially equivalent to existing foods or food components

Where differences are identified, extensive animal feeding and toxicological trials are required. The establishment of substantial equivalence is an analytical exercise which has to be approached carefully. The comparison may be a simple task, or very lengthy, depending upon the nature and experience with the foods or components being compared. It must also contain a dynamic element to take into account that the continuing modification of a food will require that the most recent novel food is compared with an appropriate former novel food and not necessarily with the original and traditional counterpart.

An understanding of substantial equivalence is key to understanding the basis of GM regulatory controls. This brief outline may be supplemented by studying the text of the Report of the Joint FAO/WHO Consultation on Biotechnology and Food Safety <http://www.fao.org/aq/agr/food/pdf/biotechnology.pdf>

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The question of **antibiotic resistance marker genes** (ARMGs) has been addressed above.

There are no inherent grounds for assuming that GM foods are more - or less - **allergenic** than traditional foods. However, when developing any novel foods, including GM foods, care must be taken that allergenicity is not inadvertently introduced into the diet. This requires assessment of the allergenicity of a new protein by predictive methods, experimental testing and a post-marketing surveillance based on traceability.

The testing of GM products for suspected allergens can be done by an IgE test with serum from sensitive individuals [e.g. Herian et al (1990)]. However, there is also a need to test products where genes have been inserted from sources not known to be allergenic. Astwood et al (1996) have developed a method. Stability of a protein or protein fragments to digestion in simulated gastric fluid (SGF) may be used to assess the potential allergenicity of a protein.

The British Medical Association (BMA) in its earlier (1999) "interim statement" on GM had been hostile to GM and called for an open-ended moratorium on all commercial planting of GM crops until more was known about their effects on human health. Indeed that had been one of the factors influencing the visiting party of Zambian scientists to return to Zambia with recommendations against GM. "Doubts over the safety of genetically modified foods voiced by the British Medical Association were the main reason behind Zambia's decision to reject food aid in 2002, says a Zambian scientist who visited Europe this week. Famine still threatens 2.4 million people in Zambia today". New Scientist, 29 January 2003. <http://www.newscientist.com/news/news.jsp?id=ns99993317>

However in March 2004 the BMA issued a new statement [http://uk.sitestat.com/bma/bma/s?RH%20GMFoods&ns\\_type=pdf&ns\\_url=http://www.bma.org.uk/ap.nsf/AttachmentsByTitle/PDFgmfoods/\\$FILE/GM.pdf](http://uk.sitestat.com/bma/bma/s?RH%20GMFoods&ns_type=pdf&ns_url=http://www.bma.org.uk/ap.nsf/AttachmentsByTitle/PDFgmfoods/$FILE/GM.pdf)

Announcing it they said

"The BMA produced an interim report in 1999 on the health implications of GM food crops. In accordance with our intention to keep the public informed, we held a round table meeting of experts in June 2003 and have recently reviewed the emerging evidence. In producing an update of our 1999 report, the BMA seeks to support balanced debate. As an organisation of doctors, we are not experts in agricultural techniques and crop science, but we are concerned with all issues of public health. The environment in which we live, the air we breathe, the water we drink and the food we eat, all have an impact on our health as individuals. It is this context that the statement has been prepared. The BMA shares the view of the Royal Society that that there is no robust evidence to prove that GM foods are unsafe. However, we endorse the call for further research and surveillance to provide convincing evidence of safety and benefit."

Numerous perceived concerns regarding the safety of GM foods have been aired, many of them speculative and without any scientific evidence, but three substantial concerns which have been most widely discussed are in fact urban myths. These are the L-tryptophan story, the brazil nut allergen story and the events surrounding Arpad Pusztai and his potato experiment.

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### THE L-TRYPTOPHAN STORY

A frequently repeated account alleges GM as the cause of the disease that caused 1500 illnesses and 37 deaths in USA in 1989. The story refers to the so-called Eosinophilia-Myalgia Syndrome (EMS syndrome) associated with some dietary supplements containing the amino acid L-tryptophan.

The illnesses and death did occur, but the rest of the story is untrue. In reality, extensive investigation traced the cause to an impurity in L-tryptophan made by just one of its several chemical manufacturers, all in Japan. The culprit was Showa Denko KK of Tokyo (the fourth largest chemical manufacturer in Japan, but which had some 80% of the market for L-tryptophan). There has been successful litigation by three plaintiffs against SD KK. The GM issue was not raised seriously by the plaintiffs because there was such overwhelming evidence against it being a factor.

The manufacture of L-tryptophan is by a fermentation which also results in the formation of a number of secondary substances. To produce L-tryptophan of a purity necessary for human ingestion, the fermentation product mixture has to go through purification processes to remove the impurities, by-products and cellular debris, including treatment with activated carbon and reverse osmosis. Investigation of the records of Showa Denko KK showed that in the critical period (December 1988 to June 1989) they made a number of simultaneous changes to the manufacturing protocols. One of these was the use of the fermentation organism *Bacillus amyloliquefaciens* that had been genetically altered to increase the production of L-tryptophan. But this was accompanied by the partial bypassing of the reverse osmosis purification procedure, and a halving of the amount of activated carbon used (both stupid and irresponsible things to have done), thus failing to carry out the purification effectively. Subsequent research showed that in consequence the procedure left behind some sixty impurities; and also found significant correlation between the development of EMS and the reduction of the activated charcoal.

There have been several attempts to explain the precise mechanism by which the syndrome occurred. One involves a residual impurity 1,1'-ethylidenebis-[tryptophan] (EBT), which then broke down to give 1-methyl-1,2,3,4-tetrahydro-beta-carboline-3-carboxylic acid (MTCA), a substance that was thought to have been involved in the EMS syndrome. Another suggests that it was the result of a reaction between two (or more) impurities. Like so many food poisoning outbreaks investigated after the event, the exact mechanism is unlikely now to be conclusively proved, but it was nothing to do with GM. Thus the "tryptophan" story was not a consequence of GM, nor of tryptophan itself, but an impurity or impurities left in as a result of irresponsible short-cutting by a particular chemical manufacturer.

### THE BRAZIL NUT ALLERGEN STORY

With the currently much greater recognition of food allergens as a food safety issue, the possible introduction of allergenicity by genetic modification is a concern; and the apocryphal story of "people made sick by a brazil nut gene transferred into soya" has become a widely believed urban myth.

In fact, such a product never came on the market, and nobody ever ate any such product. Soya protein is deficient in methionine, and a seed company, Pioneer Hi-Bred, wanted to

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investigate the possibility of producing a soyabean with increased methionine content (thereby improving the nutritional quality of soya protein), by transferring a brazil nut gene to soya. With any research involving any gene transfer, it is routine standard procedure to investigate whether any allergenicity could be thereby transferred. In this instance, many people are allergic (some very seriously so) to soya itself; but it was important to investigate whether such a transfer would make the resulting soya allergenic also to people who are allergic to brazil nuts. The research was carried out at the University of Nebraska, the leading centre for allergenicity research. Perhaps not surprisingly, the researchers found that brazil nut allergenicity was transferred to the experimental material. Pioneer Hi-Bred announced that the research project was discontinued, and the results were published in a peer-reviewed journal [Nordlee et al, (1995)].

### THE PUSZTAI POTATO EXPERIMENT

This has received considerable publicity. It relates to the purported adverse effects on rats of GM potatoes in which lectins had been inserted, and the associated TV programme and media interviews given by Dr Pusztai. Lectins, which are complex plant proteins, appear to act as pest deterrents in plants and lectin insertion into a crop plant by GM has been investigated as a means of enhancing pest resistance.

The story has been greatly confused by contradictory reports as to exactly what happened, and as to the supposed ill-treatment of the researcher concerned – mostly culled from the media and claims by Pusztai himself and activists keen to exploit the situation. Fortunately there is now a first-hand history available. In March/April 1999 the House of Commons Parliamentary Select Committee on Science and Technology investigated GM, and on Monday 8 March 1999 they held a Hearing at which Dr Pusztai and his friend Dr Stanley Ewen, and Professor Philip James, Director and Dr Andrew Chesson, Head of the Nutritional Chemistry Unit, both of the Rowett Research Institute (RRI), all appeared and were examined.

The written statement submitted by the RRI, which, incidentally, is considerably sympathetic to Pusztai, gives a first-hand historical account (and, incidentally, disposes of the various myths that have been put around about Pusztai and his treatment). For a verbatim account of all the evidence submitted by RRI and by Pusztai himself, and for the Select Committee's conclusions, see UK House of Commons, Select Committee on Science and Technology, <http://www.publications.parliament.uk/pa/cm199899/cmselect/cmsstech/286/9030801.htm> and <http://www.publications.parliament.uk/pa/cm199899/cmselect/cmsstech/286/28602.htm>

The study which caused the controversy has since been reviewed twice by the Audit Committee, by the Royal Society; by ACNFP; by the Committee on Toxicity; and by the Nuffield Council on Bioethics. All have found the experiment flawed, poorly designed, and incapable of leading to meaningful conclusions. There is, however, agreement that adequate *in vivo* tests need to be developed before a new GM crop with a lectin insert is released for either human or animal consumption.

As the RRI Audit Committee stated

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"The research was preliminary and not part of the process of testing specifically genetically modified crops destined for commercial use."

"However, the purpose of the research remains valid. It was part of a larger programme designed to identify possible candidate genes, and their implications, for possible future use in the genetic modification of crops to enhance the crops' resistance to pests."

Whilst investigations into this case have shown that the problems were not directly related to the genetic modification as originally claimed (and still perpetuated by some) they emphasise that a greater awareness of the possible areas of concern is needed when assessing the safety of GM foods.

### ENVIRONMENTAL CONSIDERATIONS

Early regulatory controls over the release of GM crops had, of necessity, been developed on an *ad hoc* basis due to the virtual absence in the 1980s of quantitative data on the ability of GM organisms to survive in the environment. However, in recent years evidence has accumulated so that regulations and guidelines can now be developed on a more rational basis; but there is a continuing need for studies on the possible risks of GM crops to the agricultural environment. In the last few years, the UK Government has responded to this need by funding over 20 projects in this area at a cost of over £6 million. Clearly, regulations will need continuous revision and updating as new data become available.

In the EU Member States, any release of GMOs into the environment was governed by national regulations implementing EU Directive 90/220/EEC (now superseded by Directive 2001/18/EC) (implemented in the UK as part of the Environment Protection Act). In the UK, at present there are no GM crops being commercially grown. An experimental release, such as a field trial of a food crop, requires consent from the Government. Applications for consent must include a considerable volume of data and a detailed assessment of the risk of harm to human health and the environment. If a risk is identified or there is some uncertainty about the level of risk, the applicant may propose measures to manage or eliminate the risk. The applications are scrutinised by the Advisory Committee on Releases into the Environment (ACRE), a group of independent experts who advise the Government on whether consent should be given and whether extra conditions should be imposed prior to giving consent. All releases are advertised locally and details are made available via a Public Register. Release sites are subject to inspection by the Health and Safety Inspectorate and those making the release are required to report any incidents that may occur during and after the completion of the trials. On the one hand this openness and transparency is admirable, but on the other hand the information made available has been seized on by organised extremists who invade and destroy the trials.

The EU objective has been to protect health and the environment when

- carrying out the deliberate release into the environment of GMOs for any purposes other than placing on the market within the European Community
- placing on the market GMOs as, or in, products within the European Community

Data required other than for higher plants:



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- Information relating to the GMO characteristics of donor, recipient (or where appropriate parental) organisms characteristics of vector characteristics of modified organism
- Information relating to the conditions of release and receiving environment information on the release information on the environment
- Information relating to the interactions between the GMO and the environment characteristics affecting survival, multiplication and dispersal interactions with the environment
- Information on monitoring, control, waste treatment and emergency response plans.

Data required for GM higher plants:

- Information relating to recipient and / or parental plant
- Information relating to the genetic modification
- Information relating to the GM plant
- Information relating to the site of release
- Information relating to the release
- Information on control, monitoring, post-release and waste treatment plans

Since 1987, more than 25,000 field trials of GM plants have been carried out in 45 countries without adverse environmental consequences. Furthermore, the rate of field-testing has increased rapidly especially in the USA where the number of trials has doubled each year since 1987. In terms of field releases, the European Union lags well behind North America. More than 70% of field trials were conducted in the USA and Canada followed in descending order by Europe, Latin America and Asia, with very few trials conducted in Africa. These trials represent considerable accumulated evidence in support of a favourable safety and environmental record for the new gene technology.

The relevance of environmental data obtained from small field trials to large-scale sowing on several million acres of land has been questioned. However, the present situation is reported in the International Service for the Acquisition of Agri-Biotech Information (ISAAA) Report issued 13 February 2008, "Biotech Crops Experience Remarkable Dozen Years of Double-Digit Growth" from which the following is extracted:

After a dozen years of commercialization, biotech crops are still gaining ground with another year of double-digit growth and new countries joining the list of supporters, according to a report released today by the International Service for the Acquisition of Agri-biotech Applications (ISAAA). In 2007, biotech crop area grew 12 percent or 12.3 million hectares to reach 114.3 million hectares, the second highest area increase in the past five years.

In addition to planting more biotech hectares, farmers are quickly adopting varieties with more than one biotech trait. These "trait hectares" grew at a swift 22 percent, or 26 million hectares, to reach 143.7 million hectares – more than double the area increase of 12.3 million hectares. New crops were also added to the list as China reported 250,000 biotech poplar trees planted. The insect-resistant trees can contribute to reforestation efforts.

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Further, 2 million more farmers planted biotech crops last year to total 12 million farmers globally enjoying the advantages from the improved technology. Notably, 9 out of 10, or 11 million of the benefiting farmers, were resource-poor farmers, exceeding the 10-million milestone for the first time. In fact, the number of developing countries (12) planting biotech crops surpassed the number of industrialized countries (11), and the growth rate in the developing world was three times that of industrialized nations (21 percent compared to 6 percent.)

“With increasing food prices globally, the benefits of biotech crops have never been more important,” said Clive James, chairman and founder of ISAAA and the report’s author. “Already those farmers who began adopting biotech crops a few years ago are beginning to see socio-economic advantages compared to their peers who haven’t adopted the crops. If we are to achieve the Millennium Development Goals (MDGs) of cutting hunger and poverty in half by 2015, biotech crops must play an even bigger role in the next decade.”

According to the report, biotech crops have delivered unprecedented benefits that contribute toward the MDGs, particularly in countries like China, India and South Africa. The potential in the second decade of biotech crop commercialization (2006-2015) is enormous.

Studies in India and China show Bt cotton has increased yields by up to 50 percent and 10 percent, respectively, and reduced insecticide use in both countries up to 50 percent or more. In India, growers increased income up to \$250 or more per hectare, increasing farmer income nationally from \$840 million to \$1.7 billion last year. Chinese farmers saw similar gains with incomes growing an average of \$220 per hectare, or more than \$800 million nationally. Importantly, these studies showed strong farmer confidence in the crops with 9 out of 10 Indian farmers replanting biotech cotton year on year, and 100 percent of Chinese farmers choosing to continue utilizing the technology.

While these types of economic benefits are well substantiated, the socio-economic benefits associated with biotech crops are starting to emerge. A study of 9,300 Bt cotton and non-Bt cotton-growing households in India indicated that women and children in Bt cotton households have slightly more access to social benefits than non-Bt cotton growers. These include slight increases in pre-natal visits, assistance with at-home births, higher school enrollment for children and a higher proportion of children vaccinated.

Rosalie Ellasus, a widowed mother of 3 children, found similar benefits, choosing farming as a way to support her family. “With the extra income generated from biotech maize, investing in farming made sense and allowed me to earn more than the medical technology field I was trained in,” she said. “The biotech maze gave me peace of mind and meant less time monitoring for pests. With stack corn, I also incur savings on cultivation and weeding costs. With the added income, I have been able to send all my children to college.”

“It’s these types of benefits that will make crop biotechnology a vital tool in achieving the U.N. Millennium Development Goals of cutting hunger and poverty in half and ensuring a more sustainable agriculture in the future,” James said. “To reach these goals, a

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continued broadening and deepening of biotech crop use is crucial to meeting food, feed, fiber and fuel needs in the future.”

In 2007, the United States, Argentina, Brazil, Canada, India and China continued to be the principal adopters of biotech crops globally. While the United States continues to be the largest user of the technology, its biotech crop area represents a declining share of the global area due to a broadening adoption.

“With a dozen years of accumulated knowledge and significant economic, environmental and socio-economic benefits, biotech crops are poised for even greater growth in coming years, particularly in developing countries that have the greatest need for this technology,” James said.

According to the report, Burkina Faso, Egypt and possibly Vietnam are the next mostly likely countries to approve biotech crops. Australia is field-testing drought-tolerant wheat and two states recently lifted a four-year ban on biotech canola. Finally, countries like India recognize the importance of using biotechnology to make the country self-sufficient in food grains, including rice, wheat and oil seed production with the first biotech food crop, biotech eggplant, expecting approval in the near-term.

“I predict the number of biotech countries, crops, traits, area and farmers will all grow substantially in the second decade of adoption,” James said. “More developing countries are likely to approve the technology as it’s now possible to design regulatory systems that are rigorous without being onerous given their limited resources. The current delay in timely approvals of biotech crops like golden rice with benefits for millions is a moral dilemma where the demands of regulatory systems have often become the end and not the means.”

The report is entirely funded by the Rockefeller Foundation, a U.S.-based philanthropic organization associated with the Green Revolution; Ibercaja, one of the largest Spanish banks headquartered in the maize growing region of Spain; and the Bussolera-Branca Foundation from Italy, which supports the open-sharing of knowledge on biotech crops to aid decision-making by global society.

<http://www.isaaa.org/resources/publications/briefs/37/pressrelease/default.html>

See also related slides

<http://www.isaaa.org/resources/publications/briefs/37/pptslides/Brief37slides.pdf>

ISAAA now has an excellent website, updated weekly, with a very large number of links grouped to cover Global, Africa, Americas, Asia and Pacific, Europe, Research, Energy Crops for Biofuels Production and Biofuels Processing. At the time of writing the current weekly issue is dated 5 June 2008, but there are previous and future issues can be accessed by changing the date at the end of the URL (note the US practice mm/dd/yyyy).  
<http://www.isaaa.org/kc/cropbiotechupdate/online/default.asp?Date=6/05/2008>

Past experience with introductions of new species to environments where they are not naturally present has shown that potential problems may take several generations to manifest themselves. Possible cross-pollination from GM crops to non-GM crops is of

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concern to organic farmers, who fear that, if it occurs, their produce could no longer be said to be "organic", and to those who wish to have the right to choose non-GM foods.

Three reports of trials in USA, Germany and Spain respectively have demonstrated effective co-existence.

- Byrne, P. & Fromherz, S. (2003). "Can GM and Non-GM Crops Coexist? Setting a Precedent in Boulder County, Colorado, USA.", *Journal of Food, Agriculture & Environment*, 1, pp 258-261.  
<http://www.botanischergarten.ch/Coexistence/Byrne-Fromherz-2003.pdf>
- Anonymous (2004). "Insights gained from the 2004 Test Crop Coexistence of Genetically Modified and Conventional Corn", *InnoPlanta*, pp 6 Nordharz/Börde.  
<http://www.botanischergarten.ch/Coexistence/InnoPlanta-Coexistence-2004.pdf>
- Brookes, G. & Barfoot, P. (2004). "Co-existence of GM and non GM crops: case study of maize grown in Spain, PG Economics Ltd, pp 13 Dorchester, UK."  
<http://www.botanischergarten.ch/Coexistence/Brookes-Coexistence-Casestudy-Spain-2004.pdf>

In July 2006, Defra carried out a consultation on proposals for managing the coexistence of GM and non-GM crops in England.

<http://www.defra.gov.uk/environment/gm/crops/pdf/gmcoexist-condoc.pdf>

IFST responded that it agreed with Defra's view of the governing principle of coexistence; to "*balance the interests of all farmers*. Farmers have a legitimate interest in growing their preferred crops (conventional, organic or GM), and a coexistence regime must be fair and reasonable to all parties.". This implies that there should be no additional discrimination against farmers growing GM crops. Thus, issues concerning possible crosspollination or other interactions in all cases should be reciprocal. Following this principle IFST commented on four points:

1. Regarding Statutory Notification and Liaison Requirement (paragraphs 90-100 and Table 5), IFST noted under "Other Key Points" the third bullet concerning statutory offences and penalties and suggested that it should also be a statutory offence for a neighbour to disclose to any third party information received under the terms of paragraphs 90-100. To do so would be tantamount to an invitation to fundamentalist activists to trash the GM crop.
2. Regarding organic production, IFST supported the Defra view. Moreover, if an organic producer makes specific claims about the GM-threshold of his product, the onus must be on him to carry out adequate testing to substantiate the claim.
3. The consultation document considered at some length (paragraphs 136-171) the compensation of conventional or organic farmers whose crops may be "contaminated" with GM. In paragraph 31, the consultation document recognised a possible scenario where "the GM crop trades at a premium price relative to the equivalent conventional crop as it has a novel quality trait. Farmers growing the GM crop may therefore need to minimise 'contamination' from non-GM crop impurities because it reduces the desired quality." IFST pointed out that equity and justice would require that in the scenario described, the GM farmer should be compensated for contamination of his crop with "non-GM impurities". This would be in keeping with the principle that "a coexistence regime must be fair and reasonable to all parties."

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4. IFST supported the arguments put forward in the document against creating a register of locations of GM crops. As past experience in the UK and events in July 2006 in France have shown, the existence of information on the locations of GM crops would be an open invitation to fundamentalist activists to destroy the crops. Moreover, there is no longer a legal sanction against such activity; a Court decision has created a legal precedent whereby such extreme activists can escape the legal consequences of destroying the property of others. Any assumption that a register could be kept confidential would be unrealistic.

There is also concern that traits such as herbicide resistance may spread to wild "relative" weeds (at present the only GM crops that have wild "relatives" are canola and squash) and that the problem of insect resistance may be aggravated. It has been suggested that the adoption of insect-resistant crops by farmers worldwide may lead to the extinction of certain insect species (e.g. Lepidoptera) thereby reducing the biodiversity of the planet. Environmental regulation is difficult to enforce when there are no clear standards against which the performance of a product can be measured (e.g. how many birds, butterflies and wild flowers should there be on a farm and to what extent can their numbers be affected before the environment is harmed?).

Concern has been expressed about the potential risk of GM crops hybridizing (i.e. sharing their genes) with wild closely related species and thereby creating herbicide resistant weeds. This has certainly happened with conventional crops but there is no evidence of it having occurred with GM crops. According to Rick Roush, director of the University of California Statewide Integrated Pest Management Program, reviewing the book "Dangerous Liaisons: When Cultivated Plants Mate with their Wild Relatives" by Norman C. Ellstrand Nature (Book Review) 427, 395 - 396; Jan. 29 2004):

"Ellstrand provides an introductory section for readers who are not population geneticists, before detailing hybridization between domesticated plants and their wild relatives, and then presenting his interpretation of these observations. Despite his effort to provide this broad context for hybridization between crops and wild plants, and its consequences, I suspect that most readers will focus on chapter 7, where Ellstrand contrasts his views with an opening quote from the Israeli plant scientist Jonny Gressel: "Most crops have no interbreeding relatives in most of the world." Ellstrand reviewed the data for the world's 25 most widely planted crops, summarized their interbreeding with wild plants in a single table, and showed that 22 of them do hybridize with wild relatives somewhere in the world. I suspect that this table will be the most widely referenced in the book, and wish that a few of the distributions were more precisely stated. For example, cotton, beans and potatoes are listed with a "multicontinental" distribution of hybridization; more precisely this refers to Latin America (and, for cotton, some islands in the Caribbean and Pacific). But what about Gressel's proposition, especially in the context of GM crops? Using statistics from the database of the Food and Agriculture Organization of the United Nations, cited by Ellstrand <http://www.ipfsaph.org/En/default.jsp>, I checked on the dominant GM crops. At least 87% of the world's soybean crop, and 95% of the world's maize and cotton, are grown in countries for which Ellstrand lists no hybridization — and even for those countries with hybridization, such as China for soybeans, wild relatives are found in only some areas. Many of the other crops are

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complicated to tabulate, but Gressel seems to be correct that most crops are not interbreeding locally with wild relatives. This still leaves the possibility that serious problems could arise in the few areas of the world where hybridization can occur. This currently seems possible for GM canola in Canada and the United States, and for transgenic maize that is probably growing illegally in Mexico (but has apparently escaped documentation in the refereed literature). But even after reading this book, I haven't seen any evidence of harm to human health or to the environment (including weediness) from such hybridization. Where are the super-weeds that were predicted to occur from the exchange of transgenes with wild relatives? In contrast to the lack of evidence for deleterious effects of gene flow from GM crops, there is evidence that conventional agriculture has adversely affected wild plants through genetic swamping of their populations, and that wild plants have generated weediness in crop--weed hybrids. As noted by Ellstrand, "problems associated with hybridization between conventional crops and their wild relatives received scant attention until potential gene-flow problems were described for transgenic crops". For example, hybridization with cultivated rice has been implicated in the near-extinction of an endemic Taiwanese wild rice. Hybridization of maize with its ancestor teosinte may be contributing to the extinction of teosinte populations. Indigenous cotton in the Galapagos Islands could be at risk of extinction or replacement as a result of hybridization with cultivated cotton. Ellstrand cites similar evidence for at least another nine species. He also documents in great detail the history of sugar beets in Europe, where hybrids between cultivated beets and their progenitors, the sea beets, have caused major weed problems."

However, the problem of gene flow, whether from GM to non-GM (or vice versa) or from hybridization of conventional crops with wild relatives may well be solved by -- genetic modification! The February 2004 issue of *The Scientist* [http://www.the-scientist.com/yr2004/feb/tech\\_040216.html](http://www.the-scientist.com/yr2004/feb/tech_040216.html) contains a report by Ivan Oransky as follows (courtesy of Henry Daniell):

### Self-Containment for GM Plants

Genetically engineered plants pose several major environmental concerns, according to Henry Daniell, a professor of molecular biology and microbiology at the University of Central Florida. When foreign genes are introduced into the nuclear genome, they end up in pollen, posing the risk of transfer to other species. And sometimes, expression levels are low.

Daniell and colleagues have come up with what he says is a solution: chloroplast genetic engineering. The method--the recipient of several patents, most recently US #6,680,426--offers two benefits, says Daniell. First, like mitochondria, chloroplast genes are maternal and therefore not passed through pollen. And because each cell has 10,000 copies of the chloroplast genome, expression levels are generally high. "This is absolutely a beautiful system," he says.

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The transgene construct is designed to minimize disruption of the chloroplast genome. The gene to be inserted is put under the control of chloroplast regulatory signals so that errant transgenes won't express in the nucleus, Daniell says. Those that do hit their mark in the chloroplasts integrate via homologous recombination into a non-coding spacer region, where, Daniell says, "they won't disrupt anything else. Gene delivery is achieved via a biolistic gene gun."

From there, it's typical transgenic manipulation--selection of cells that have modified chloroplasts, followed by testing the construct's maternal inheritance. Daniell has founded a company, Chlorogen, to license the method.

The US National Academies of Science, National Research Council on January 20 2004 issued a report about a study of methods of preventing GM plants from mating or spreading novel genes to other species, entitled "Biological Confinement of Genetically Engineered Organisms".

<http://www.america.gov/st/washfile-english/2004/January/20040122180302FJrelluF0.8825647.html>

In the UK, English Nature (which at the time was the Government's statutory adviser on wildlife and natural features) monitored developments which may affect wildlife and advised on how any damaging effects might be avoided. Its environmental concerns about GM crops were among those which led the UK Government to approve the holding of the UK Farm Scale Evaluations (FSEs) of GM crops and to delay commercial introduction of genetically modified herbicide tolerant (GMHT) and insect resistant (IR) crops until research was completed and the results assimilated.

In 1998, four genetically modified crops had cleared most of the regulatory hurdles before commercial growing could be allowed in the UK. While these crops had been assessed as safe in terms of human health and direct impacts upon the environment, there had been insufficient research to determine whether there might be any significant effects on farmland wildlife resulting from the way that the crops would be managed. The FSEs of these GMHT crops were established to bridge this important gap in our knowledge.

The results of three FSEs were issued on 16 October 2003. The presentations, by the authors, of the eight rigorously peer-reviewed research papers on the three spring-sown FSEs, between them constituting a huge, rigorously designed, rigorously conducted, epoch-making GM research project costing nearly six million pounds sterling. In their presentations the authors were at pains to point out that their findings did not relate to the fact that the GM herbicide tolerant (GMHT) crops were GM, but to the differing herbicides and herbicide management systems that accompanied the GM crops and the conventional crop controls respectively.

The eight research papers present the FSE findings for those spring sown crops (namely beet, maize and spring oilseed rape – the FSE trials results of winter-sown oilseed rape were not published until May 2005). The researchers analysed the effect of each crop and accompanying herbicide and herbicide management system on the plants and animals living in the vicinity. About 60 fields in different parts of the UK where these crops were normally

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grown, each were sown with beet, maize and spring oilseed rape. Each field was split, one half being sown with a conventional variety managed according to the farmer's normal practice, the other half being sown with a GMHT variety, with weeds controlled by a broad-spectrum herbicide (glufosinate-ammonium in maize and spring oilseed rape, and glyphosate in beet). There was stringent auditing of the farmers' adherence to the protocols. Comparisons in biodiversity were made by looking at the levels of weeds and invertebrates, such as beetles, butterflies and bees, in both the fields and the field margins immediately surrounding them. The results revealed significant differences in the effect on biodiversity when managing GMHT crops as compared to conventional varieties.

Predictably, activists of one sort or another, and the media, have been interpreting the results to fit in with their respective preconceived positions. For the scientist, the outcomes point to the importance of weeds and of soil seed-banks in sustaining farmland wild life. It has been axiomatic that with the present generation of GMHT crops the purpose was to get rid of weeds as thoroughly and effectively as possible with the minimum of labour and tillage and with minimum application (in quantity and frequency) of a relatively environmentally-friendly broad-spectrum herbicide. Purely from a farmland wild life aspect, it could be argued that in two of the three crops (beet and spring oilseed rape) the herbicides performed their function too well. These results seem to suggest that there is a case for organizing the provision of sufficient weeds to maintain the farmland wild life.

Put another way, a rational society wishing to take advantage of the agricultural benefits that each of these GMHT crop systems can provide would recognize the need for a trade-off, to establish for each crop and herbicide management system a point of equilibrium where the benefits can accrue alongside the sustaining of the farmland "natural communities".

Whilst the findings cannot answer all the questions resulting from the intense public interest and debate on the future of genetic modification in agriculture in the UK, they do provide a valuable model for the assessment of technological change. The FSEs also demonstrate that it is possible to design experiments at an adequate scale to help forecast the potential environmental impacts of new technologies and practices in agriculture - something that has never been done before.

On 13 January 2004 ACRE gave its verdict on the FSEs. The Committee noted that in the cases of beet and spring-sown oilseed rape FSEs, evidence showed that insect species and weeds declined in the trial areas, endangering birds that fed on them. However, it supported the growing of GM maize, saying it was better for the environment than conventional farming. It also suggested the other crops might be grown in future if measures were taken to protect wildlife.

Although the UK Government subsequently approved in principle the growing of the GM maize for animal feed, the approval was heavily hedged around with onerous conditions (including a four years repeat of the FSE trial but with a non-atrazine control). The company concerned (Bayer CropScience) regarded it as totally impracticable and "economically non-viable" and withdrew.

On 1 July 2004 it was announced that Syngenta, the last big biotechnology company working on GM crops in Britain, was to close its research facility in the UK and transfer its efforts to the United States.



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### SOCIO-ECONOMIC ASPECTS

In June 2008, Brookes G and Barfoot P (PG Economics Ltd UK) issued a report "GM crops: global socio-economic and environmental impacts 1996-2006".

This comprehensive study presents the findings of research into the global socio-economic and environmental impact of GM crops in the eleven years since they were first commercially planted on a significant area. It focuses on the farm level economic effects, the environmental impact resulting from changes in the use of insecticides and herbicides, and the contribution towards reducing greenhouse gas (GHG) emissions.

<http://www.pgeconomics.co.uk/pdf/globalimpactstudyjune2008PGEconomics.pdf>

Much of the vocal antagonism to GM expressed by its opponents appears to consist of ideological antipathy to large companies engaged in GM and to the socio-economic system which allows large companies to exist and thrive. This is, however, not specific to GM, for similar antipathy by the same groups is expressed about large companies engaged in other products and activities. A great deal has been said and written to the effect that the existence of GM seeds somehow denies the farmer the ability to practice in the traditional way -- as though farmers cannot choose whether to use GM seed or stick with non-GM.

One manifestation of this concern has been about the potential for misuse of the so-called terminator genes which prevent seeds from germinating. Although patents exist for terminator technology, it is not available commercially. There are fears that large corporations might use such genes in all their GM crops to prevent farmers from storing seed and that plants that produce barren seed could make life more difficult for poor farmers in the developing world. However, farmers would only buy these seeds if they found an overall advantage in doing so; otherwise they could continue to grow conventional cultivars and save the seed in the traditional way. Furthermore, some fear that if cross-pollination occurs, GM plants with terminator genes could transfer their sterility to other plants grown nearby. However, on the positive side, terminator technology could ensure that GM plants do not themselves become weeds.

Concerns have been expressed over the supposed problem of patents held by biotechnology companies preventing the use of beneficial GM crops in developing countries. Leaving aside the strange contradiction that these concerns are expressed in many cases by the same people who deny that there are GM benefits and leaving aside too that many of the original patents are already expiring, the fact is that today, over eleven million resource-poor farmers in South Africa, China, India, the Philippines and elsewhere already happily grow nearly one-third of the world's total GM hectareage because they have higher yields, require fewer inputs and raise income.

The classic case is GM vitamin A rich golden rice developed by Ingo Potrykus (referred to earlier) and his colleague Peter Beyer. Here the research has involved the use of over 70 patents owned by biotechnology companies from whom they had to obtain permission before they could begin testing the golden rice in field trials. What the critics fail to mention, however, is that those patent holders granted Potrykus and Beyer exemptions for Golden Rice; and moreover have agreed to provide free licences for use by poor farmers in developing countries.

At the 12th World Congress of Food Science and Technology in Chicago in July 2003, Potrykus stated, in the course of a comprehensive presentation, that obtaining those

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exemptions was time-consuming, but the main reason why golden rice and other GM nutrient-enhanced crops have not yet begun to help resource-poor farmers is not patents but "regulatory obstacles based on undue paranoia." He has even argued that "those who oppose GM technologies for political advantage or self-interest [should be] held responsible for the unnecessary suffering of millions of people with vitamin A deficiency," which golden rice could help address. His most up-to-date presentation (April 2004) is at <http://tinyurl.co.uk/mkmx>.

A wider matter, however, involves the general question of patents in relation to GM, and, more particularly whether genes can or should be patentable. By analogy with computer language, the procedure of inserting a gene into an organism is not just "cut-and-paste" but "cut- copy (billions of times over)-and-paste". The laboratory-generated copies by that procedure are in every way exact copies of the copied original, but are not the original. Precise details of patent law vary from country to country, but in principle, patents are intended to protect inventions and give the inventor monopoly for a limited time to benefit from the invention. Whether it is the original gene or DNA fragment, or a lab-generated exact copy, these are not "inventions" and ought not to be patentable. A gene is a pre-existing thing, and identification of a gene and its function is a "discovery" rather than an "invention". However, an invention is often a novel combination of pre-existing things, and it is not those things but the combination of them which may be accepted as an invention and therefore patentable. Generally, patent law requires novelty and also that the novelty and its claimed benefits would not be obvious to those "skilled in the art". If these principles are valid, then someone inventing a novel combination involving a gene can patent the combination, but cannot use patent law to prevent someone else from using that gene for other purposes (or even patenting a different combination involving that gene).

### ETHICAL CONSIDERATIONS

The officially appointed UK Committee on the Ethics of Genetic Modification and Food Use, chaired by the Rev. John Polkinghorne, carried out a wide public consultation and issued a report in September 1993 on all of the moral and ethical issues involved. This was accepted by the UK Government and welcomed by the Institute of Food Science & Technology. The Committee found that the concerns were misconceptions rather than of real substance, arising from lack of knowledge, outside the scientific community, of just what was involved.

The Polkinghorne Committee pointed out that because any gene extracted from one species for copying into another, is not itself inserted but is copied in the laboratory and diluted millions of times before a single gene is transferred, the chance that the original gene would be found are much less than the chance of recovering a particular drop of water from all the oceans of the world. If this were widely understood fears of cannibalism or of contravening religious food taboos would be seen to be unwarranted. Unfortunately, this fact does not make good media copy, whereas sensational stories do.

The Polkinghorne Committee's conclusions were:

- genetic modification of food and medicines is here to stay. It is not something to be stopped, and it would not be ethically right or necessary that it should be;

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- there is no reason for any ban on the use of copy genes of human origin or from animals subject to dietary restrictions, but scientists working in this field should be discouraged from using such genes where alternatives would be equally effective;
- products containing such copy genes should be labelled to enable consumers to make informed choices;
- government and industry should look for ways of explaining genetic modification to the general public.

Because what is transferred to the "host" is not the DNA direct from the donor but a laboratory copy of it (in familiar terms, it is cut-copy (billions of times over)-and-paste rather than cut-and-paste) the perceived concerns are mistaken, but no less real for that.

As a matter of interest that not many people realise, we are in fact all cannibals - everyone is continuously shedding skin cells, which of course contain their DNA. We are all ingesting the DNA of people around us, or who, for example, have previously been in the same room or public transport.

It is noticeable that when "ethical aspects" of GM are raised it is mostly in terms of ethical objections. However, two major reports have included addressing the ethical and social imperatives involved in making the potential benefits of GM available to improve the present and future food supply, especially in developing countries.

A most thorough and balanced study of the ethics, environmental impacts and social aspects of GM was carried out in 1998 under the auspices of the Nuffield Foundation. The Nuffield Council on Bioethics carried out a widespread public consultation using a questionnaire posing the ethical, environmental and social issues and issued a comprehensive report on its conclusions and recommendations, "Genetically modified crops: the ethical and social issues".

<http://www.nuffieldbioethics.org/go/ourwork/gmcrops/introduction>

In June 2003 the Nuffield Council on Bioethics issued for public consultation a Discussion Paper on the use of GM in developing countries. This evoked a supportive response from IFST. Following the consultation, on 28 December 2003 the Nuffield Council on Bioethics issued its Report (described as a "Follow-up Discussion Paper") on "The use of genetically modified crops in developing countries".

[http://www.nuffieldbioethics.org/go/ourwork/developingcountries/publication\\_169.html](http://www.nuffieldbioethics.org/go/ourwork/developingcountries/publication_169.html)

### INFORMATION ASPECTS

Information (and particularly label information) about the GM status of foods or ingredients is a topic with polarised views that do not lend themselves to an intermediate position. On the one hand, it is argued that if a food or ingredient has been approved as "safe", the method of production is irrelevant and need not be stated. On the other hand, it is argued that provision of that information is necessary for informed consumer choice, including the consumer who wishes to choose GM, and the consumer who wishes to avoid GM for whatever reason – even an irrational reason or whim. The EU Commission adopts the latter position (which is supported by IFST) while the US FDA adopts the former.

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### FACTORS AFFECTING EU APPROACH TO REGULATING GM

In the EU, the general legislative approach throughout its existence has been that if anything can conceivably be regulated, regulate it. So it had built a comprehensive system and machinery for considering and approving (or otherwise) applications for approval of specific lines of GMOs, and for controlling the release of GMOs into the environment. Likewise, it adopted from the outset the principle of informed consumer choice, which has led to increasingly comprehensive measures, initially voluntary and then by more and more stringent legislation, to provide distinctive labelling of GM foods. In this, as in other aspects, the nature and extent of the regulatory provisions has been influenced by the governments of the Member States, reflecting a public opinion in turn influenced by activist campaigning. However, there may be signs that, despite continued intensity of anti-GM activism, a more rational public opinion may be developing. Across the EU, this is reflected in the most recent EuroBarometer on attitudes of EU consumers about the environment issued in March 2008 which had a specific question about GMOs and found that 20% of EU citizens picked out the use of GMOs in farming as a concern from a list of environmental issues, down from 24% in 2004. When unprompted, GM ranks low on the list of EU consumer concerns relative to other environmental issues. However, when prompted by a specific question, 58% said they were personally opposed to the use of GM).

[http://ec.europa.eu/public\\_opinion/archives/ebs/ebs\\_295\\_en.pdf](http://ec.europa.eu/public_opinion/archives/ebs/ebs_295_en.pdf)

In the UK, the annual Food Standards Agency consumer survey on all food issues showing a decrease since 2006 in concern over many food safety issues including additives (35% down from 38%), food poisoning (36% down from 42%), GM foods (20% down from 25%); by recent media articles and editorials and by the recent statement by the UK Environment Minister Phil Woolas to media about the need to look at GM technology positively in context of global food shortage.

### DIFFERENCES FROM THE US REGULATORY APPROACH

In contrast, in the USA the Food and Drug Administration (FDA) has, despite increasing pressure, refused to require distinctive labelling of GM materials, on the grounds that it has determined that they are substantially equivalent to the non-GM versions; and that being so, their method of production is irrelevant. The most comprehensive analysis of the approach and reasoning underlying the US position is given in the *Expert Panel Report on the Biotechnology of Foods* issued by the Institute of Food Technologists (IFT). The full text is available at <http://www.ift.org/cms/?pid=1000380>

The absence of distinctive labelling in USA has had a consequence that most US consumers have not had the presence of GM foods or ingredients drawn to their attention (although over the past few years this situation has been gradually changing). Most of those that have been aware of it, have evidently been reassured by approval on the part of both FDA and EPA. This has in turn has been one of the factors making US consumers much less susceptible (so far) than European consumers to the kind of activist campaign that has dramatically affected public opinion in the EU and especially in the UK.

A survey by the Pew Initiative on biotechnology and GM foods revealed that Americans' knowledge of GM foods remains low and their opinions about its safety is just as divided as it was two years ago. The survey also shows that knowing FDA reviewed and approved a GM

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product can increase public confidence and that public support for GM products decreases as uses of the technology shift from plants to animals.

Using data from a similar survey released by the Pew Initiative in March 2001, the survey was able to compare awareness levels over a two-year period and draw two major conclusions: Americans' knowledge about GM foods remains low, even as GM technology is increasingly applied to agriculture; and opposition to GM foods has softened somewhat in the last two years but opinions about safety remain split.

The survey also probed topics rarely explored in widely-available opinion polls about agricultural biotechnology, including how Americans feel about the way GM products are regulated in the US and the application of genetic engineering technology to animals. Key findings indicate that Americans oppose a ban on GM foods, but are strongly supportive of a regulatory process that directly involves the FDA. It was also determined that Americans are far more comfortable with genetic modifications to plants than animals, and are particularly supportive of genetic modifications that improve health. The nationwide survey, conducted August 5-10, 2003 by The Mellman Group and Public Opinion Strategies, consisted of telephone interviews of 1,000 American consumers. The margin of error for this survey is +/- 3.1%. The margin of error is higher for subgroups. Data from a similar survey, released by the Pew Initiative in March 2001, was used for tracking purposes. The full report is at <http://pewagbiotech.org/research/2003update/>

In September 2007, the International Food Information Council (IFIC) commissioned Cogent Research to conduct the 12th in a series (1997-2007) of quantitative assessments of U.S. adult consumer attitudes toward food biotechnology during July 2007. The survey had a sample size of 1,000 and the data were weighted on age and education to be nationally representative. The survey found that consumer familiarity and overall impression of food biotechnology remains little changed from a year ago in the United States, amidst major concern over food safety. There was little change in the American public's perception of food biotechnology, and those who have an opinion are twice as likely to have favourable - as opposed to unfavourable - impressions. The national survey represents the 12th time IFIC has commissioned a survey on public attitudes about food biotechnology since 1997.

Overall confidence in the food supply remained at a high level with 69 percent of Americans indicating they were "very" or "somewhat" confident in the food supply compared to 72 percent last year. However, the number of Americans selecting "very confident" decreased from 21 percent in 2006 to 15 percent this year.

25 percent cited no particular food safety concern. Of the three-quarters of respondents who listed a specific food safety concern, disease and contamination topped the list at 38 percent; however, the biggest increase was in the "source" category, where concern about country of origin caused this category to rise from 6 percent of those citing a specific concern with the food supply in 2006 to 20 percent this year. Handling and preparation decreased as a food safety concern, cited by 26 percent of those citing a specific concern this year, dropping nine percent from last year's survey.

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While the public's overall favorable impression of plant biotechnology remained little changed in the past year, favorable impressions of animal biotechnology increased from 19 percent in 2006 to 24 percent this year. Nearly half of Americans (46 percent) said they were "somewhat" or "very" likely to buy meat, milk and eggs from cloned animals if the Food and Drug Administration (FDA) determined they were safe. When the phrase "from cloned animals" was replaced with "from animals enhanced through genetic engineering" the number of Americans who were "very" or "somewhat" likely to buy these food products jumped to 61 percent. Both of these figures show an increase from the 2006 survey.

Increased awareness of potential positive impacts of animal biotechnology continues to correlate with increased support among consumers. Two-thirds of consumers (66 percent) said they had a positive impression of animal biotechnology when informed that "animal biotechnology can improve the quality and safety of food," up from 59 percent in 2006. More than half of Americans (53 percent) reacted positively to the statement "animal biotechnology can increase farm efficiency," up from 36 percent in 2005 and 47 percent in 2006.

Satisfaction with current information on food labels remained high in 2007. Only 16 percent of consumers mentioned information they felt was missing, with less than one percent specifically mentioning biotechnology.

FDA requires special labeling only when the use of biotechnology introduces an allergen, or when it substantially changes the food's nutritional content. Well over half of those polled (61 percent) "strongly" or "somewhat" support the FDA labeling requirements for food produced using biotechnology, while 24 percent were "neutral" which was unchanged from last year's survey.

This year, IFIC included questions about "sustainability" in the food biotechnology survey for the first time. Although Americans use a variety of terms to describe "sustainability," 83 percent equate the term to "long-lasting" or "self-sufficiency." Close to three-quarters of Americans (70 percent), however, say they have heard "nothing" about sustainable food production. When sustainability was defined as a method to "operate in a manner which does not jeopardize the availability of resources for future generations," 63 percent of Americans said they thought it was important. In a question where consumers were asked to rank 5 factors related to growing crops in a sustainable way, the factor ranked number one was "increasing the production of food staples in the world, thereby reducing world hunger", with "reducing the amount of pesticides needed to produce food" coming in second. Other eco-friendly factors like rainforest conservation and reducing green house gas emissions ranked lower. <http://ific.org/newsroom/releases/biotechresearchrelease2007.cfm>

Another major difference is that, in the definition of substantial equivalence, still used in many countries including the USA and Canada, the presence of degraded novel DNA or protein does not preclude a GM food from being considered substantially equivalent to a

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conventional food. However, in the EU, the concept of substantial equivalence was redefined in December 1997. Only highly processed foods derived from GM crops, such as highly refined oil, white sugar and starch hydrolysates, are considered substantially equivalent to their conventional counterparts on the grounds that neither DNA nor protein would be expected to be present following the processing that these foods receive. All other ingredients derived from GM crops, such as flour and protein extracts, require a full safety evaluation as they may contain novel DNA and/or protein, in either intact or degraded form. Thus, lecithin from GM soyabean, used extensively as an emulsifier in many processed foods, would be considered substantially equivalent to conventional lecithin in North America but not in the UK and the rest of the EU..

### DETECTION AND ANALYSIS OF GM MATERIALS

Effective regulatory control over GMOs is crucially dependent on the existence of reliable analytical methodology for detection and identification of specific genes, and for quantification where, for example, a threshold limit is set. Until the mid-1990s, in the absence of reliable analytical methods it was impossible to determine whether a food or food ingredient had been genetically modified. More recently, however, new methods have been developed based on the polymerase chain reaction (PCR) – a method for several-million-fold amplification *in vitro* of specific DNA sequences known as nucleotides or "primers". Compared with the millions of bases in the DNA in an organism, and 100 bases in an average gene, it has been discovered that primers as short as 21-24 bases in length can act as a unique "fingerprint" for a gene.

PCR-based assays involve the following three basic steps:

1. DNA extraction and purification
2. PCR amplification of DNA
3. Gel electrophoretic analysis of PCR reaction products

Within the framework of the development of EU legislation on GMOs in food and food ingredients, the Health and Consumer Protection Directorate General of the European Commission in December 1998 commissioned two studies on the development of qualitative as well as quantitative methods for the detection of GMOs in food, after an open call for tender procedure (Official Journal S 122 of 27 June 1998, p.34) to two leading institutions in the field of analytical methods:

- The German Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV – Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin) and;
- The Institute for Health and Consumer Protection (IHCP) of the Joint Research Centre of the European Commission in Ispra.

The studies were completed in October 2000 and executive summaries can be accessed at [http://europa.eu.int/comm/food/food/biotechnology/gmfood/biotech04\\_en.pdf](http://europa.eu.int/comm/food/food/biotechnology/gmfood/biotech04_en.pdf) and [http://europa.eu.int/comm/food/food/biotechnology/gmfood/biotech05\\_en.pdf](http://europa.eu.int/comm/food/food/biotechnology/gmfood/biotech05_en.pdf)

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Meanwhile, the World Health Organization on 1 August 2003 announced the availability of a guidance manual which is " ... used in the training courses organized jointly by the Joint Research Centre (JRC) of the European Commission and WHO/Europe, [which] provides the theoretical and practical information on methodologies and protocols followed during the courses. It covers a wide variety of techniques for GMOs detection, identification, characterization and quantification, and includes key background theoretical information for working in the field of GMO detection ..." Details are available at [http://www.euro.who.int/foodsafety/Assistance/20030728\\_1](http://www.euro.who.int/foodsafety/Assistance/20030728_1)

The course is intended to teach molecular detection techniques to laboratory personnel with a good level of analytical knowledge, but with no or little expertise in this specific domain. The Course Manual entitled "The analysis of food samples for the presence of genetically modified organisms", edited by M. Querci, M. Jermini and G. Van Den Eede, has now been made available on-line at <http://gmotraining.jrc.it/>

In March 2004 the European Committee for Standardization (CEN) issued European Standard EN ISO 21572: 2004 "Methods for detection of Genetically modified organisms and derived products – Protein based methods".

EU Commission Regulation (EC) No1981/2006 sets out detailed rules for implementation of Article 32 of Regulation EC (No) 1829/2003 regarding the Community Reference Laboratory (CRL) for GMOs. It sets out requirements for national laboratories that can engage on such work and lists national reference laboratories that may assist the CRL in testing and validating methods of detection.

### EU DIRECTIVES AND REGULATIONS CONCERNING GM

Relevant regulatory information has been given under various headings in the foregoing text, but for convenience is collected under this heading.

### RELEASES INTO THE ENVIRONMENT

Under Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [OJ L 117, 8 May 1990, p 15; amended by Commission Directive 94/15/EC (OJ L103, 22/4/94, p.20) and Commission Directive 97/35/EC (OJ L169, 27/6/97, p 72)] up to 29 October 2001, under the procedure set out in Directive 90/220/EEC and using the current risk assessment methodology, [18 GMOs](#) had been authorised in the EU. Two genetically modified plants, a variety of soya and a variety of maize were authorised for use in food. From October 1998 until the present no further authorisations were granted under Directive 90/220/EEC and as of 29 October 2001, 12 applications for authorisation were pending. The moratorium continued but (unless blocked by some Member States) was due to be lifted following the adoption of the new Directives. Directive 2001/18/EC provides for the deliberate release into the environment of genetically modified organisms and repealed Directive 90/220/EEC. It requires that introduction of GMOs into the environment should be carried out according to the step by step principle. This means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken.



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[http://eur-lex.europa.eu/LexUriServ/site/en/oj/2001/l\\_106/l\\_10620010417en00010038.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2001/l_106/l_10620010417en00010038.pdf)

Annexes to the Directive contain full details of the extensive information that must be submitted in support of any application.

### CONTAINMENT

EU Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms [OJ L117, 8 May 1990, pp 1-14], as amended by Council Directive 98/81/EC of 26/10/98 (OJ L330, 5 December 1998, p13).

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0081:EN:HTML>  
[http://ec.europa.eu/environment/biotechnology/pdf/dir98\\_81.pdf](http://ec.europa.eu/environment/biotechnology/pdf/dir98_81.pdf)

This Directive, which provides the circumstances and conditions under which GMOs (including fermentation organisms) require consent for contained use, is implemented in the UK by:

- The Environmental Protection Act 1990, Part VI, Genetically Modified Organisms, Sections 106-127. Section 106 states that this Part (i.e. Part VI) has effect for preventing or minimising any damage to the environment which may arise from the escape or release from human control or genetically modified organisms.
- The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996 (SI 1996/1106) restrict the import and acquisition of GMOs under Section 108 (l)(a) of this Act.
- The Genetically Modified Organisms (Contained Use) Regulations 1992 (SI 1992/3217)
- The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996 (SI 1996/967)
- The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996 (SI 1998/1548)

### PLACING ON THE MARKET AND LABELLING

Prior to May 1997, labelling of GM foods in many countries, including the UK, was not explicitly mandatory. Nevertheless, some food manufacturers and retailers labelled GM foods on a voluntary basis (e.g. the Co-op's vegetarian cheese prepared using GM chymosin and Sainsbury's and Safeway's GM tomato puree) to allow consumers to exercise choice and to gain consumer confidence. Labelling guidelines developed by a number of bodies including the independent Food Advisory Committee in 1993 (revised in 1996) and the Institute of Grocery Distribution in 1997. These guidelines took into account the need for labelling of novel foods, which contain material (e.g. allergens), which may have implications for the health of some sections of the population (e.g. infants or the elderly) as well as those, which contain "ethically sensitive genes". The latter include foods that contain copy genes originally derived from humans or from animals, which are the subject of religious dietary restrictions (e.g. pig genes for Muslims) or any animal genes for vegetarians and vegans. Much of the provision on ethically sensitive genes has been based on the findings of the UK Polkinghorne Committee, which reported on the ethics of genetic modification in 1993.

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On 15 May 1997, the EU Novel Foods Regulation (258/97) were made, controlling the placing on the market and the labelling of GM foods or foods obtained from GMOs mandatory in the European Union if, on the basis of a scientific assessment, they were judged not to be substantially equivalent to an existing food (for a definition of substantial equivalence, see section above on "Safety and regulation of GM foods").

Over the next three years there followed a succession of increasingly stringent measures, enforcement of which were carried out by Member States' authorities.

From July 2000 discussions and work proceeded in the Commission, the Council of Ministers and the European Parliament, to provide a new comprehensive and stringent regulatory regime, replacing the previous piecemeal measures covered in the various pieces of legislation. This would cover traceability of GMOs throughout the chain from farm to table, and labelling of GMOs and products produced from GMOs and regulating GM food and feed.

'Traceability' here means the ability to trace and follow a food, feed, food-producing animal or substance, through all stages from rearing or growing of primary products, through production, manufacture and distribution up to and including its sale or supply to the final consumer; and in the case of a food containing a GMO, or a food, food ingredient, additive, or flavouring derived from a GMO, an unique code identifier following it from "farm to fork", and provision to the authorities of information facilitating the detection and identification of a particular GM product including lodging of a sample of the GMO or its genetic material.

Of course traceability is highly important for all aspects of product food safety. But for any scheme that needs an effective system for authorization of specific GMOs, and labelling distinction between GM and non-GM products, not only analysis but also traceability is a must. However, this was the first time that a proposal had been made to establish mandatory traceability measures. Moreover, it would seem that the new approach placed emphasis on traceability of heritage rather than relying solely on analysis.

These proposals went through a long period of gestation and debate, but finally emerged from their second reading in the European Parliament in June 2003. The new legislation was given final approval by the Council of Ministers on 22 July 2003, published in the Official Journal of the European Union on 22 September 2003 and designated

- Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed;  
[http://eur-lex.europa.eu/pri/en/oj/dat/2003/l\\_268/l\\_26820031018en00010023.pdf](http://eur-lex.europa.eu/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf)  
and
- Regulation (EC) 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC .  
[http://eur-lex.europa.eu/pri/en/oj/dat/2003/l\\_268/l\\_26820031018en00240028.pdf](http://eur-lex.europa.eu/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf)

These mean that GM crops have to be kept separate from conventional crops and put strict limits on the accidental mixing of the two. The rules allow for no more than 0.9% accidental mixing of GM in non-GM shipments to the EU. All products containing more than 0.9%

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GMOs have to be distinctively labelled as genetically modified. Genetically modified material will also have to be traced at all stages of production.

In the UK, the Food Standards Agency carried out consultations on the enforcement and penalties in the UK of these two EU Regulations, and on draft Guidance Notes <http://www.food.gov.uk/multimedia/pdfs/gmconsultnotes.pdf>, although, as FSA points out, this is draft informal guidance for application of both Regulations in the UK and cannot modify the Regulations themselves.

Several countries in the EU had said they would keep the unofficial moratorium in place until the new legislation regarding labelling and traceability was introduced. Member States were divided in several votes since December 2003, which under EU rules sent the decision ultimately to the EU Commission.

On 2 October 2003 the EU Commission issued "Questions and Answers about GMOs in seeds," which provides answers to the following questions: What is the EU seeds legislation? Is there separate legislation on GM seeds? Why is there a need to set thresholds for GM-impurities in conventional seeds? What thresholds for GM-presence in conventional seeds will the Commission propose? What is the aim of such thresholds, what is the relationship between the seed thresholds and the labelling thresholds for food and feed products? What kind of GMOs will benefit from the thresholds proposed? and Will these thresholds be important for the co-existence of genetically modified crops with conventional and organic farming? It can be found at [http://europa.eu.int/comm/food/plant/gmplants/index\\_en.htm](http://europa.eu.int/comm/food/plant/gmplants/index_en.htm)

On 12 May 2004 the Commission decided to lift the 6-year-old unofficial moratorium by approving imports of an insect-resistant Bt11 strain of sweet corn for human consumption from Swiss-based Syngenta. This GM corn would only be imported and not grown in the EU, although an application for cultivation is pending. Any sold – whether canned or fresh - would have to be labelled in accordance with the new Directives.

David Byrne, EU Commissioner for Health and Consumer Protection, said the GM corn was approved after "the most rigorous pre-marketing assessment in the world".

"It has been scientifically assessed as being as safe as any conventional maize. Food safety is therefore not an issue, it is a question of consumer choice. Labelling provides consumers with the information they need to make up their own mind. They are therefore free to choose what they want to buy."

Events showed, however, that in the prevailing engendered climate of European consumer fears, importers and retailers in the EU Member States considered it too commercially risky to offer consumers that choice.

The report of the 36th Session of the Codex Committee on Food Labelling (CCFL), that took place from 28 April to 2 May 2008 in Ottawa, Canada, is now available. Agenda Item 5, on "Labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering", is covered in paragraphs 75-93 of the report. <http://www.codexalimentarius.net/web/archives.jsp?lang=en>

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On 6 January 2005, CORDIS (Community Research and Development Information Service), the EU's official online information platform for scientific research, issued a News Release, "EU project publishes conclusions and recommendations on GM foods," which states in part that " ... the European Commission funded a thematic network on the safety assessment of genetically modified food crops, the ENTRANSFOOD project ... Funded under the Fifth Framework Programme (FP5), ENTRANSFOOD sought to identify prerequisites for introducing agricultural biotechnology products in a way that is largely acceptable to European society ... the consortium ... consists of 65 partners from 13 different European countries, including representatives from academia, regulatory agencies, food manufacturers, retailers and consumer groups ... The project found that existing test methods for safety assessment of genetically modified organisms (GMOs) are efficient and ensure that GM foods that have passed the test are as safe and nutritious as plant-derived foods ... ENTRANSFOOD also noted that process-based labelling of all foods containing GM crops is a necessity in order to dispel the fears of EU citizens, but recognised that difficulties are unavoidable in implementing the EU's labelling requirements ... On the subject of detection of unintended effects and gene transfer, ENTRANSFOOD emphasised that there is no indication that unintended effects are more likely to occur in GM foods or that there is any inherent risk in the transfer of DNA between organisms, since DNA is not toxic ... ENTRANSFOOD recommended the creation of an evaluation and discussion platform combining a range of diverse perspectives on new food technology to formalise public engagement and consultation in the GM debate ..."

- The complete text of the CORDIS news release is at

[http://cordis.europa.eu/fetch?CALLER=EN\\_NEWS&ACTION=D&DOC=1&CAT=NEWS&QUERY=1173302230405&RCN=23144](http://cordis.europa.eu/fetch?CALLER=EN_NEWS&ACTION=D&DOC=1&CAT=NEWS&QUERY=1173302230405&RCN=23144)

Information about the ENTRANSFOOD project is at <http://www.entransfood.com>

Regulation (EC) No 1946/2003 of the European Parliament and of the Council on transboundary movements of GMOs came into force in November 2004.

[http://ec.europa.eu/environment/biotechnology/pdf/requ1946\\_2003.pdf](http://ec.europa.eu/environment/biotechnology/pdf/requ1946_2003.pdf)

The laws also allow EU Member States to take "appropriate measures" to ensure GM crops planted in the EU do not cross-pollinate with conventional crops. However, on 26 January 2004, EU Agriculture Commissioner Franz Fischler warned delegates at a conference on organic farming that food which is completely free of GMOs is a thing of the past. When it comes to setting acceptable thresholds for the levels of GMOs in organic and conventional products, the Commissioner said that Europe must take guidance from scientists, rather than politicians. 'We have been banished from paradise. The idea of a zero per cent threshold was no doubt possible in the Garden of Eden, but not in the real world,' said Dr Fischler. Then on 23 February 2004 a report was issued by the (US) Union of Concerned Scientists entitled "Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply". It described tests carried out in USA on supposedly unmodified corn, soy and canola seeds, all purchased commercially. Of 18 seed varieties tested, 16 seemed to contain some GM elements.

On 27 February 2004 the 87 member states of the Cartagena Protocol on Biosafety, which entered into force in September 2003, adopted documentation requirements and other procedures for promoting the safety of international trade in GMOs

<http://www.biodiv.org/doc/press/2004/pr-2004-02-27-bs-en.pdf>

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The new legislation did not, however, stop the US from going ahead with its WTO case against the EU. Although favouring the lifting of the moratorium, the US considered such stringent labelling laws unworkable and in practice as trade barriers.

On 7 February 2006 the preliminary confidential verdict of the World Trade Organisation (WTO) over genetically modified foods and crops was sent to the EU and the three WTO member countries that brought the trade complaint - Argentina, Canada and USA.

Then on 28 September 2006 the WTO issued the 1000 pages of reports of the panel that had examined complaints by the United States, Canada and Argentina, respectively, against "European Communities —Measures affecting the approval and marketing of biotech products" (DS291, DS292 and DS293).

These can be found at [http://www.wto.org/english/news\\_e/news06\\_e/291r\\_e.htm](http://www.wto.org/english/news_e/news06_e/291r_e.htm)

The WTO Panel's 21 pages report on its Recommendations and Conclusions can be found at [http://www.wto.org/english/tratop\\_e/dispu\\_e/291r\\_conc\\_e.pdf](http://www.wto.org/english/tratop_e/dispu_e/291r_conc_e.pdf)

The main conclusions of the panel of WTO judges, were as follows

- The panel found that the EU operated a *de facto* moratorium on considering new GMO imports between June 1999 and August 29 2003. This moratorium resulted in a failure to complete "approval procedures without undue delay" and so violated WTO rules. But as the moratorium has since been lifted, the panel made no recommendations for action.
- Separately, it also found that undue delay existed in 24 of the 27 individual product applications on which the three complainants had sought a ruling.
- It asked the WTO's dispute settlement body to request the EU to bring the measures into line with the rules. But according to trade sources, virtually all of these products have either since been approved or their applications withdrawn.
- The judges also found that bans imposed by six EU states - France, Germany, Luxembourg, Austria, Italy and Belgium - on products already approved by the EU violated trade rules and need to be revised. The individual states had failed to provide adequate scientific evidence of the risks to human health or the environment.
- The panel made no overall assessment of whether biotech products are generally safe or not.

The *de facto* EU moratorium, which operated between 1998 and 2004, has been lifted, since when 10 GM products have been authorised, according to the European Commission. More than 30 applications are being examined.

On 6 February 2006, the EU Commission issued its latest updated Questions-and-Answers fact sheet on the regulation of GMOs in the EU, It can be found at <http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/06/58&format=HTML&aged=0&language=EN&guiLanguage=en>

USDA Foreign Agricultural Service has a large number of GAIN Reports from FAS overseas Attaches regarding the biotechnology situation in individual countries. These are contained in a database accessed at <http://www.fas.usda.gov/scriptsw/attacherep/default.asp>. To read these FAS Attaché Reports, search by date and choose "Biotechnology" under "All

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Commodities” and “All Countries” under “Countries” or choose a specific country or countries.

A statement released on 20 July 2007 by the European Food Safety Authority (EFSA) concludes that

“ ... Biologically active genes and proteins are common constituents of foods and feed in varying amounts. After ingestion, a rapid degradation into short DNA or peptide fragments is observed in the gastrointestinal tract of animals and humans ... To date a large number of experimental studies with livestock have shown that recombinant DNA fragments or proteins derived from GM plants have not been detected in tissues, fluids or edible products of farm animals like broilers, cattle, pigs or quails ...”

[http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178623095798.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623095798.htm)

Animal feed is the most widespread use of GM crops in the food chain in the EU; some 85% of compound feeds in EU contain some GM material. In this connection the EU Directorate General Agriculture report of August 2007 on the “Economic impact of unapproved GMOs on EU feed imports and livestock production”. highlights the current serious concerns on asynchronous approvals (i.e. EU being so much slower than major GM crop growing and exporting countries) and zero tolerance of GMOs not yet approved in the EU (but that might be grown and traded commercially in third countries).

[http://ec.europa.eu/agriculture/envir/gmo/economic\\_impactGMOs\\_en.pdf](http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf)

EFSA is working closely with Member States on GMO risk assessment. At a meeting in November 2007 organised by EFSA, more than 60 GMO experts from national regulatory risk assessment bodies from across the European Union discussed best scientific approaches to evaluate the safety of GMOs at national and European level.

Scientists from the European food safety watchdog, including a number from its GMO Panel, and the national experts nominated by the national food safety agencies met in November 2007 to examine EFSA’s risk assessment procedures and its Guidance Documents. EFSA subjects each individual GMO application to rigorous review carried out according to internationally agreed guidelines.

Most experts agreed at the meeting on the general approach on risk assessment methodologies and approaches to GMOs. EFSA is building on the exchange of views to continue to strengthen its risk assessment approach and will take a number of recommendations to the Advisory Forum for further discussion.

One key issue addressed at the meeting was the Environmental Risk Assessment of GM plants intended for cultivation in Europe. Several experts asked EFSA to develop guidance further, particularly concerning field trials, regional specificity and potential effects on non-target organisms. EFSA will pursue its work in this area in co-operation with Member States and in light of a question recently received from the European Commission (DG Environment) on Environmental Risk Assessment.

The use of statistics in GMO risk assessments, to estimate biological differences between a GM plant and its conventional counterpart, was discussed in detail. EFSA has a working group looking at new statistical methods that could help further advance harmonisation in risk assessment. The majority of Member State experts agreed that

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statistics had an important role to play in GMO risk assessment but emphasised that biological relevance should drive the dynamics of the risk assessment rather than statistical significance.

On animal feeding trials, the majority of Member State experts was satisfied with present EFSA risk assessment guidance which requires a 90-day feeding trial study whenever evidence indicates significant differences in the GM plant which requires further investigation. However, one Member State expert asked for animal feeding trials to be conducted as a matter of routine. EFSA's GMO Panel has adopted a Report on animal feeding trials which will be published in a peer-reviewed scientific journal.

[http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178682961414.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178682961414.htm)

### Conclusions

The exercise of informed choice by consumers requires that they have accurate and unbiased information. The reverse is currently the case. The provision of such information will be a key factor in the acceptance of food applications of gene technology.

IFST fully supports the notion that academic and industrial scientists, professional bodies, learned societies, food retailers, governments and consumer organisations must all play an active role in communicating both the benefits of, and concerns about, GM foods to the public. The realisation of the potential benefits of gene technology will depend both on the further work of scientists in addressing and solving the above-mentioned potential problems and on effective communication between scientists and the rest of society, including the lay public.

Food scientists and technologists can support the responsible introduction of GM techniques provided that issues of product safety, environmental concerns, information and ethics are satisfactorily addressed. IFST considers that they are being addressed, and need even more intensively to continue to be so addressed. Only in this way may the benefits that this technology can confer become available, not least to help feed the world's escalating population in the coming decades.

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[http://europa.eu.int/comm/dgs/health\\_consumer/library/press/press298\\_en.pdf](http://europa.eu.int/comm/dgs/health_consumer/library/press/press298_en.pdf)

European Union: Questions and Answers on the European Food Safety Authority

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May be obtained through the worldwide Sales Agents, see <http://www.fao.org/> or [Publication-sales@fao.org](mailto:Publication-sales@fao.org) (cost around \$7).

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**The Institute of Food Science & Technology (IFST)** is the independent professional qualifying body for food scientists and technologists. It is totally independent of government, of industry, and of any lobbying groups or special interest groups. Its professional members are elected by virtue of their academic qualifications and their relevant experience, and their signed undertaking to comply with the Institute's ethical Code of Professional Conduct. They are elected solely in their personal capacities and in no way representing organisations where they may be employed. They work in a variety of areas, including universities and other centres of higher education, research institutions, food and related industries, consultancy, food law enforcement authorities, and in government departments and agencies. The nature of the Institute and the mixture of these backgrounds on the working groups drafting IFST Information Statements, and on the two Committees responsible for finalising and approving them, ensure that the contents are entirely objective. IFST recognises that research is constantly bringing new knowledge. However, collectively the profession is the repository of existing knowledge in its field. It includes researchers expanding the boundaries of knowledge and experts seeking to apply it for the public benefit.

Competence, integrity, and serving the public benefit lie at the heart of IFST philosophy. At all times IFST aims to:

- Benefit the public supply of safe, wholesome, nutritious, tasty and attractive food through the application of sound science and technology;
- Improve public knowledge and awareness of important issues relating to the supply, production, safety and quality of food;
- Develop and communicate the knowledge underlying food science and technology, and further the education of food scientists and technologists;
- Safeguard the public by defining, promoting, and upholding professional standards of competence, integrity and ethical behaviour; and
- Maintain these standards by encouraging members to continue their professional education and development throughout their careers.

In serving the public benefit IFST takes into account the many elements that are important for the efficient and responsible supply, manufacture and distribution of safe, wholesome, nutritious, and affordable foods with due regard for the environment, animal welfare and the rights of consumers.

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