



Food Safety
AUTHORITY OF IRELAND



Food Safety and
Genetically Modified Foods

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The debate surrounding genetically modified foods has left consumers confused and sceptical. Interest groups seem to produce experts whose views are so diametrically opposed that consumers simply don't know who to believe. Are genetically modified foods safe? Are they adequately tested and regulated? Are they adequately labelled? Are they good for you? Are they bad for you? Will they save the earth or destroy it? Will they result in the cornering of the global food market by multinationals or will they bring to Mankind the same benefits as genetically engineered medicines?

This leaflet aims to inform the reader about what Genetically Modified (GM) foods are and how they are controlled. It lists the products that are currently allowed on the market in the EU and how they got there. It addresses the issues surrounding food safety and consumer protection so that you – as a consumer – can make an informed choice the next time you go shopping.

What are genes?

Plants and animals are made up of millions of cells which contain, among other things, DNA (deoxyribonucleic acid) and proteins. Genes are made up of strands of DNA from which proteins (strands of amino acids) are indirectly produced.

All DNA is made up of four basic building blocks and it is the order of these building blocks in a gene that results in the production of a specific protein which ultimately creates various physical characteristics of the cell and in turn the plant or animal.

Just as the combination of DNA from both parents determines the colour of a child's eyes, so does the DNA in parent plants determine the characteristics of the offspring such as size, speed of maturation, vitamin content, flower colour etc.

What is selective breeding?

Alterations of a gene or how it's regulated may change the characteristics of a plant or animal and, if inherited, those of the offspring. Most of the food we eat today has been modified in some way. For centuries plant breeders have been selectively breeding crops to produce higher yields or greater disease resistance. Many varieties of fruit, vegetables and even animals that we produce today did not exist fifty years ago. Maize that is consumed in large amounts today bears little resemblance to its nearest ancestral relative Teosinte, the wild grass that still grows wild in Mexico. Seedless grapes, pipless oranges, fast maturing chicken and modern dairy and beef breeds of cattle are all examples of selective modification that may never have developed in nature without human intervention.

What is genetic engineering?

Scientists can now identify and isolate individual genes responsible for producing specific characteristics. By altering these genes, or transferring them to another organism, scientists can "engineer" the genetic makeup of that organism producing a new variety. This technology has been used for the production of medicines, pharmaceuticals and now GM plants and animals.

An insecticide gene found in a common soil bacterium, *Bacillus thuringiensis* (Bt) has been transferred from the bacterium into plants such as maize. These “transgenic” maize plants can now repel specific insect attack without the need for pesticide spraying.

The technique has also been used to insert herbicide tolerance, virus resistance, delayed ripening and other traits into plants for food use. Genetic engineering, genetic modification, genetic manipulation, gene splicing and gene technology are all terms used to describe the process of altering genes and their functions.

Is genetic engineering good or bad?

Genetic engineering is just a technology, a tool with which to manipulate living organisms. How it is used and regulated will determine any benefits or dangers it may bring to Mankind.

What are the potential benefits from this gene technology?

Considerable advances in medicine such as the development of new vaccines and medical treatments have, and continue to be brought about using this technology.

Currently the only apparent direct benefits of growing GM crops are to the farming and the biotechnology industries. Nonetheless, the technology has the potential to produce foods that could be of great consumer benefit, such as:

- tomatoes with increased vitamin content
- foods such as peanuts with reduced or no allergenicity
- potatoes with higher starch content which absorbs less oil in cooking
- wheat with increased levels of folic acid to prevent spina bifida
- wheat with increased fibre to reduce the risk of colon cancer
- tomatoes that can ripen on the vine for better taste, but with a longer shelf life
- rice with increased pro-vitamin A content to help combat blindness in rice-dependent developing countries

None of these genetically modified foods is currently on the market in the EU or Ireland.

While gene technology has the potential to generate healthier foods, it could also provide crops that are designed to survive in harsh climates or on land that has been rendered useless by high salt or mineral levels. These advances will help both developed and developing countries reclaim some food producing land and help increase food production to cater for the expanding global population.

What concerns have been expressed about this technology?

A number of concerns about the use of this technology have been expressed such as food safety, potential damage to the environment, disruption of ecosystems, as well as ethical and moral objections. Others may be against genetic modification in food production on socio-economic or marketing grounds, because they wish to promote alternative farming practices or they object to multinational companies gaining some control of the food sector.

What about antibiotic resistance and this technology?

The process of transferring genes from one plant to another is complex and imprecise. Only a small fraction of the plant cells targeted with a new gene will actually incorporate that gene into their own genome making it difficult to identify altered cells. By linking an antibiotic resistance gene (marker) to the gene of interest, only cells that have incorporated the new genes will grow on media that contains the antibiotic while the other cells fail to grow.

Many concerns have been expressed about the possible transfer of antibiotic resistance genes to gut microorganisms which could reduce the efficacy of antibiotics in treating human and animal diseases. While this is a theoretical possibility, in practice the actual risk of this happening has been shown to be very low. Additionally, the use of antibiotic resistance markers in the production of GM plants is being phased out and replaced by other markers such as herbicide tolerance.

What is GM food?

Genetically modified food (GM food) differs from non-GM (conventional) food in that it contains or is produced from genetically modified organisms (GMOs). The majority of GM food ingredients available so far are derived from GM plants, particularly maize and soya bean. A GM food may comprise one ingredient, e.g. tomato, or alternatively may contain a number of ingredients, one or more of which are partially or wholly derived from a GMO.

Is GM food safe?

GM foods are subjected to an extensive range of analytical tests for food safety evaluation. Such tests include composition analysis, allergenicity tests, toxicological analysis, nutritional evaluation and many more. The GMO Sub-Committee of the FSAI evaluate each new GM food application separately to ensure that it complies with specified safety criteria. If the Sub-Committee advises the FSAI that a GM food is not safe, or it requires further information before forming an opinion, an objection can be raised and further information or analysis requested.

Based on advice from its' scientific experts, the FSAI is satisfied that GM food and ingredients currently on the market in Ireland are as safe as their conventional counterparts.

What about food allergies?

Concerns have been expressed that if a person is allergic to a particular food and a gene from it is transferred to another food, that person could also become allergic to the gene altered food.



GM foods seeking a market place in Europe are subjected to many stringent tests, including allergenicity tests, prior to authorisation. This greatly reduces the possibility of transferring an allergenic trait to a different food. The specificity of gene transfer associated with GM foods also means that compared to conventional breeding there is a reduced possibility of inadvertently transferring allergy related genes. However, until more detailed information is available on the precise compounds present in some foods that elicit allergenic responses in humans, it is prudent to avoid the use of known allergenic foods such as peanuts in the production of GM foods. This opinion is supported by the advice of the World Health Organization (WHO).

What GM foods can be found on the shop shelves?

In the US and Canada a wide variety of GM plants such as maize, soya bean, tomato, cantaloupe, papaya, potato, rice and oils from rape and cotton seed are used to produce GM foods. Of these foods, only those that have undergone the authorisation process in the European Union may be sold in Ireland. However, for a limited time period in the EU, certain GM ingredients already in the authorisation process and that have had a favourable safety assessment will be tolerated at no more than 0.5% of a total ingredient or food.

Ingredients derived from four types of GM crops may be found in foods on the Irish market:

- **Soya bean** that is resistant to herbicide
- **Maize** that is resistant to pest attack and/or resistant to herbicide
- Oil from **Rape seed** that is resistant to herbicide
- Oil from **Cotton seed** that is resistant to pest attack and/or herbicide tolerant

Soya beans are processed and used as an ingredient in a wide variety of foods. It is estimated that up to 60% of processed foods contain soya ingredients. An example of such an ingredient is soya lecithin, an additive (E322) which is frequently used as an emulsifier in processed foods.

Examples of processed foods that may contain GM soya derivatives

Bread	Biscuits
Confectionery	Cereals
Infant formula	Chocolate products

Maize is not as widely used as soya bean but processed maize can be found in many food products.

Examples of processed foods that may contain GM maize derivatives

Beer	Margarine
Bakery products	Taco shells
Salad dressing	Tortilla chips

Oil derived from maize, soya bean, rape and cotton is used in some foods and in vegetable cooking oil.

Who regulates GM Foods in Ireland?

The European Union (EU) has developed legislation to ensure stringent safety control of GM foods and Ireland, as a Member State, is bound by this legislation.

In Ireland the FSAI is the competent authority for GM foods while the Department of Health and Children (DoHC) is responsible for policy matters.

As the competent authority, the FSAI enforces GM food regulations and in doing so monitors the Irish market to ensure that only EU-authorized GM foods are on the market and that they are labelled appropriately. In making decisions on the safety of GM food the FSAI avails of the best scientific advice available.



How are GM foods authorised within the EU?

For a new GM food to be placed on the market in the EU, an application must be placed with the competent authority of a Member State which then makes the application, and supplementary information, available to the European Food Safety Authority (EFSA) to carry out a safety assessment. EFSA makes the application available to all Member States and provides a summary of the dossier for the public. Within six months EFSA delivers an opinion on the application, after which the public will have 30 days to comment. Three months after delivery of the EFSA opinion, the Commission provides a draft Decision to the Standing Committee for the Food Chain and Animal Health. If the Commission proposal does not receive a qualified majority in favour, it is referred to the Council of Ministers. If the Council fails to deliver a decision within three months the Commission may adopt the draft proposal.

GM food ingredients authorised within the EU

Products from 17 GMOs can legally be marketed in the EU. These are:

One GM soy and one GM maize were approved under Directive 90/220/EEC prior to the entering into force of the Novel Food Regulation. Bt11 sweet corn was authorised in 2004 under the Novel Food Regulation EC 258/97. The other products were authorised under Article 5 of the Novel Food Regulation by virtue of substantial equivalence to products already on the market. A paste from a GM tomato (Zeneca) was authorised in the UK in 1995 prior to the novel food regulation.



Currently only ingredients from the following GM plants are approved for food use in the EU:

GM Maize lines Aventis (T25), Monsanto (Mon 810), Novartis (Bt176) Syngenta (Bt11), Pioneer (MON809).

GM Oilseed rape lines AgrEvo (Topas 19/2), Hoechst/AgrEvo (Falcon GS 40/90) and (Liberator L62), Monsanto (GT 73), Plant Genetic Systems (MS1 / RF1), (MS1 / RF2) (MS8 / RF3).

GM soya bean line Monsanto Roundup Ready 40-3-2.

GM Tomato from, Zeneca Nema 1401F, H282F (tomato paste only approved in UK in 1995).

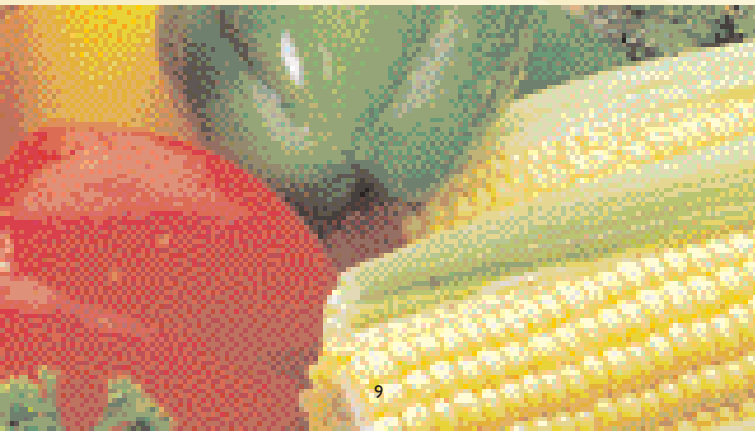
GM Cottonseed from Monsanto Insect Protected line 531 and Monsanto Roundup Ready line 1445.

See also inside back page for link to full list of GMO products approved under Directive 90/220 EEC.

Are all GM foods and ingredients labelled?

Under current EU legislation if more than 0.9% of a food or ingredient is derived from a GM source then it must be labelled accordingly.

Even if the GM ingredient is present in a food at below the 0.9% threshold level, operators must be in a position to demonstrate that they tried to obtain the food or ingredient from a non-GM source and thus its presence is due to cross contamination possibly during production, processing, transport or storage.



GM foods or ingredients that are not authorised within the EU are generally not permitted at any level. However, for a limited time period, GM foods and ingredients that are in the authorisation process and which have had a favourable safety assessment will be permitted at levels no greater than 0.5%.

Labelling of GM foods in the EU is required regardless of whether DNA or protein from the original GMO is detectable.

A food labelled to indicate that no GM ingredients are present, such as “GM free”, must not contain any level of GM ingredients. Similarly, any food on the EU market labelled as “organic” must not contain any level of GM ingredients.

Though GM foods currently on the EU market are considered as safe as their traditional counterparts, the FSAI believes in the right of the consumer to appropriate information regarding GM foods.

Clear, unambiguous labelling that facilitates an informed purchase choice is what is prescribed by law and expected by consumers and the FSAI.

GM food monitoring in Ireland

As the competent authority for GM foods in Ireland, the FSAI carries out routine surveys on the food supply to monitor GM ingredients. The first survey carried out in 2000 focused on the maize based products tortilla chips and taco shells. The results of this survey, published in May 2001 revealed that 19 out of the 26 samples tested were found to contain GM ingredients.

All GM positive samples contained significantly less than the 1% labelling threshold at the time and thus GM labelling was not required for these products.

A second survey carried out in 2001 looked at the GM content of a range of soy based foods and was published early in 2002.

See inside back page for complete list of links to these surveys.

While no breaches of the GM legislation were uncovered, the results of this survey identified a problem in that 5 out of the 18 samples that contained traces of GM ingredients carried labels to indicate they had no GM ingredients.

A survey completed in 2002 formed part of the EU Co-ordinated Program for the Official Control of Food and the 75 samples included both maize and soya-containing foods.

The results of this survey, published in 2003, identified no breaches of the GM food legislation. However, 6 of the 12 foods that were found to contain traces of GM material carried labels to indicate they contained no GM ingredients. Such labelling constitutes a possible breach of the general labelling regulation in so far as it misleads the consumer to believe that no GM ingredients are present in the food.

The main goal of this monitoring campaign is to ensure that any GM food products available in Ireland are licensed for marketing within the EU and that those products on the market are labelled appropriately allowing consumers to be able to choose between GM and non-GM foods.



International focus on foods derived from biotechnology

Ireland is represented at international fora where issues on GM food are discussed and where globally harmonised standards for food derived from biotechnology are developed.

The Organisation for Economic Co-operation and Development (OECD) has a Task Force for the Safety of Novel Foods and Feeds. This Task Force has developed Consensus Documents that contain technical information for use in the regulatory assessment of food and feed produced using biotechnology.

The Codex Alimentarius Commission was set up in 1963 jointly by the World Health Organisation (WHO) and the Food and Agriculture Organisation (FAO) of the United Nations. It is dedicated to protecting the health of consumers while harmonising food hygiene guidelines globally to prevent food trade disputes resulting from variations in food standards. One of the Codex Task Forces at which Ireland is represented by the FSAI is the ad hoc Intergovernmental Task Force on Food Derived from Biotechnology. This task force, chaired by Japan, has developed a set of general principles for the risk analysis of food derived from biotechnology, as well as guidelines for the safety assessment of food derived from recombinant-DNA plants and foods derived from recombinant-DNA microorganisms.

EU GM food legislation

GM food is governed mainly by the GM Food and Feed Regulation (EC 1829/2003) which sets out the process by which GM food and feed is authorised and labelled within the EU. The other central piece of legislation is the Traceability and Labelling Regulation (EC 1830/2003) which ensures that GMOs and any derived products are labelled and traceable from the first and subsequent stages of placing on the market.

Regulation of GMOs in Ireland

In Ireland, GMOs and derived products are regulated by a number of Government Departments and Agencies that meet regularly. These include the Food Safety Authority of Ireland (food), Department of Health and Children (food), Department of Agriculture and Food (feed and seed), Department of the Environment, Heritage and Local Government (viable GMOs), the Environmental Protection Agency (viable GMOs) and the Irish Medicines Board (medicines). The Environmental Protection Agency is responsible for controlling the deliberate release of live GMOs whether for research purposes, field trials or commercial production. The State Laboratory along with other commercial laboratories are utilised by the regulatory bodies to detect and quantify GM material in food, feed and seed.

The FSAI does not give a blanket approval to all GM food. After scientific evaluation of each new application, an opinion on the safety of that food is formed and communicated to the European Commission.

A list of links for further information on GMOs is on the next page.

USEFUL LINKS

"Food Safety and Genetically Modified Foods" FSAI GMO Sub-Committee document on GMOs and food

http://www.fsai.ie/publications/reports/gmfood_report.pdf

FSAI GM Surveys

http://www.fsai.ie/surveillance/food/tortilla_survey.pdf

http://www.fsai.ie/surveillance/food/surveillance_food_surveygm.asp

http://www.fsai.ie/surveillance/food/GM_survey_2002.pdf

European Commission

http://europa.eu.int/comm/food/food/biotechnology/index_en.htm

List of authorised GM foods

<http://europa.eu.int/comm/food/food/biotechnology/>

[authorisation/list_author_gmo_en.pdf](http://europa.eu.int/comm/food/food/biotechnology/authorisation/list_author_gmo_en.pdf)

EU Joint Research Centre - Biotechnology section, the Commissions own expert people

<http://biotech.jrc.it>

The European Food Safety Authority (EFSA) that carries out safety assessments of GM food

www.efsa.eu.int/

EFSA public web page on GM Food and Feed applications

http://www.efsa.eu.int/science/gmo/gm_ff_applications/485_en.html.

The Irish Council for Bioethics which has a working group on GMOs

www.bioethics.ie

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