



Information Paper 3

GM food regulation

Food Standards Australia New Zealand (FSANZ) aims to protect the health and safety of the people in Australia and New Zealand by maintaining a safe food supply.

FSANZ's responsibilities include developing standards for food manufacturing and labelling, providing information to consumers, coordinating national food issues such as food recalls, and undertaking scientific assessments on both domestic and imported foods.

FSANZ works in partnership with Australia's Commonwealth, State and Territory governments and the New Zealand Government to develop food standards which regulate the food products sold in Australia and New Zealand.

Food standards specify the safe level for things such as additives, chemical residues or microbes in food. They also specify the composition of some foods and the labelling requirements for foods.

GM foods

In the context of genetically modified (GM) foods, FSANZ is responsible for carrying out safety assessments of GM foods on behalf of the governments of Australia and New Zealand to ensure they are safe for consumption. All GM foods must undergo assessment before they can be sold in Australia and New Zealand.

Setting the standards

Food produced using gene technology is regulated by Standard 1.5.2 of the Australian Food Standards Code. Under this Standard, food produced using gene technology will not be sold until it has undergone a rigorous safety assessment by FSANZ. The safety assessments are performed on a case-by-case basis according to FSANZ's approved safety assessment criteria.

Standard 1.5.2 covers both the health and safety requirements regulating the sale of GM food, and the labelling and other information requirements for foods (including food additives and processing aids) produced using gene technology.

Standard 1.5.2 defines a food produced using gene technology as 'a food which has been derived or developed from an organism which has been modified by gene technology'. This definition does not include a food derived from an animal or other organism which has been fed GM feed, unless the animal or organism itself is a product of gene technology. The Standard does not regulate the safety assessment of food additives or processing aids that have been produced using modern gene technology because they are already covered by other food standards.

The safety assessment process

FSANZ's safety assessment process for GM foods is based on concepts and principles that have been developed through international organisations such as the World Health Organisation (WHO). These concepts include:

- Cautious use of scientific, risk-based assessment methods
- The need for case-by-case safety assessments
- Consideration of new genetic material, new proteins and other characteristics of GM food
- Consideration of intended and unintended effects of the genetic modification.

All GM foods must be assessed by FSANZ, determined to be safe and approved by the FSANZ Board, before they can be legally sold in Australia or New Zealand. Also, producers of GM foods must apply to FSANZ to seek approval for food to enter the food supply in Australia and New Zealand. This application is made at the commodity level – as a new primary product. Until the commodity is approved, foods containing it or ingredients derived from it cannot lawfully be sold.

Those applying to have GM foods approved must provide a large amount of scientific information so that FSANZ can complete a full safety assessment. All scientific data is required to be generated according to international standards of Good Laboratory Practice in laboratories that are independently audited.

The safety assessment process is very detailed. Generally, a GM food is recommended as safe for human consumption if FSANZ is satisfied that:

- All new genetic material has been examined in detail
- The new genetic material stays the same and is passed on in a predictable way from generation to generation
- The new proteins have been examined in detail
- The new proteins are unlikely to be toxic or allergenic
- The potential transfer of new genetic material to cells in the human digestive tract will not have a significant impact on human health
- The levels of naturally occurring toxins, allergens and anti-nutrients in the GM food are not significantly increased compared to the non-GM food
- The composition of the food is not significantly altered compared to the non-GM food.

GM foods and animal testing

Genetically modified foods are not required to be tested in animal feeding studies by Australia's food regulator, as FSANZ considers that a comparative assessment of GM foods with their conventional counterparts can generally identify any potential adverse health effects or differences requiring further evaluation.

FSANZ acknowledges there may be future GM applications, particularly for foods with intentional modifications to composition, where the results of animal toxicity studies may be informative.

In June 2007, FSANZ convened an expert panel to provide input on this issue. The panel recommended that FSANZ should continue with its case-by-case assessment of GM foods on the basis of best available science.

GM food labelling

To allow consumers to identify foods with GM ingredients, a mandatory labelling regime for GM foods where introduced DNA or protein is present in the final food came into effect on 8 December, 2001.

There are eight GM commodities approved for the food supply in Australia and New Zealand. They are varieties of soybean, corn, cotton, canola, potato, sugar beet, lucerne and rice. Two of these, cotton and canola, are grown in Australia.

As new GM foods become approved, consumers will be able to identify these products and make purchasing decisions based on this knowledge.

Food or ingredients labelled "genetically modified" either contain new genetic material or protein as a

result of genetic modification or they have altered characteristics – for example changed nutritive values - compared to the conventional food. The labelling on or attached to a package of GM food must include the statement 'genetically modified' in conjunction with the name of that food, ingredient or processing aid.

Foods from animals fed GM animal feed, such as eggs, meat and milk, are not required to be labelled as GM products anywhere in the world because the introduced DNA or protein is not present in the final food. In Australia, and many other countries, this also applies to highly refined oils, such as canola and cottonseed oils, which do not contain any genetic material after the refinement process.

Where GM food is not sold in a package any information required about the gene technology status of the food must be displayed on the food or in connection with the food display. In the future, if any GM fruits or vegetables become available, they will require such a label.

Food intended for immediate consumption from places such as vending vehicles, restaurants and take away outlets does not have to be labelled. Ingredients are also exempt from GM labelling where they contain less than one per cent of GM material - but only where its presence is unintended.

Example for single ingredient genetically modified foods:

Soy Flour
Genetically Modified

Soy Flour
From genetically modified soya beans

Example for genetically modified food ingredients:

Ingredients: Soy Protein Isolate (genetically modified), Maltodextrin, Vegetable Oil; Food Acid (332), Emulsifier (471), Vegetable Gum (407), Water Added.

An example of a GM food label

Food labelling review

A review of GM food labelling released by FSANZ in 2004 found that Australia's labelling regime is one of the most comprehensive labelling regimes for GM foods in the world. Two separate compliance surveys conducted in 2003 found a high level of industry compliance with the labelling requirements.

Further information

