

National Compliance and Monitoring Strategy for Genetically Modified Foods

Aim

To enhance confidence in compliance with Standard 1.5.2 “Foods Produced Using Gene Technology” of the Australia New Zealand Food Standards Code (the Code), by establishing a framework that enables consistent and effective monitoring and surveillance across jurisdictions.

Background

Food Standards Code

A food or ingredient produced using gene technology can not be sold or used in foods unless it has been approved for use and listed in the Code. Before a genetically modified (GM) food is approved, Food Standards Australia New Zealand (FSANZ) conducts a pre-market safety assessment which is based on the concepts and principles of the Codex General Principles for the Risk Assessment of Foods Derived from Biotechnology¹. The primary purpose of the safety assessment is: to identify new or altered hazards associated with the food as a result of the genetic modification; to assess whether there is risk associated with these hazards under the intended conditions of use; and to determine if any conditions of use are needed to enable safe use of the food. Further information on the safety assessment process can be found in the guidance document published by FSANZ².

The use and sale of GM foods, with the exception of food additives and processing aids, is covered by Standard 1.5.2 “Food Produced Using Gene Technology” of the Code. The use of food additives and processing aids is covered by Standards 1.3.1 “Food Additives” and 1.3.3 “Processing Aids” of the Code respectively. GM foods (except food additives and processing aids) that can be sold or used are listed in the Table to Division 2 of Standard 1.5.2. The table includes any special conditions applied to the GM food, such as additional labelling requirements for GM foods with altered characteristics.

Division 2 of Standard 1.5.2 of the Code covers the labelling of GM foods. This Division applies to all foods produced using gene technology, including food additives and processing aids, and requires packaged food for sale to be labelled with the statement “genetically modified” where:

- The food contains novel DNA and/or novel proteins; or
- The food has altered characteristics.

This labelling requirement does not cover:

- Highly refined food (other than that with altered characteristics) where the processing has removed the novel DNA and/or novel protein;
- A processing aid or food additive, except where the novel DNA and/or novel protein from the processing aid or food additive remains in the food;
- Flavours present in the food at a concentration of no more than 1g/kg; or

¹ Codex (2004). Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003), Codex Alimentarius Commission, Rome.

² FSANZ (2007). Safety Assessment of Genetically Modified Foods, guidance document. Food Standards Australia New Zealand, Canberra.

- A food, ingredient or processing aid in which the genetically modified food is unintentionally present in a quantity of no more than 10g/kg (1%) per ingredient.

Where GM food is displayed for retail sale unpackaged, the statement “genetically modified” must be displayed on or in connection with the display of the food. The labelling requirements do not extend to foods intended for immediate consumption when prepared and sold from the same food premises or vending vehicles (including restaurants, take away outlet, caterers or self-catering institutions).

Genetically modified foods

Over 38 distinct GM crop lines³ are approved and listed in the Code. To date, the relevant commodities include canola, corn, cotton, lucerne, potato, soybean and sugarbeet. Of these, only GM canola and GM cotton are produced on a commercial agricultural scale in Australia and none are grown in New Zealand. Foods derived from the remaining GM crop lines are approved in the Code as they could be present in imported foods, either as refined food fractions for use in wholesale food manufacture, or as GM ingredients in processed foods manufactured overseas.

The majority of approved GM foods intended for human consumption contain agronomic traits, that is, traits that confer a benefit to farmers in terms of reduced production costs and/or increased yields. Three approved lines (high lysine corn, lucerne and thermophilic alpha amylase corn) were developed primarily as either an industrial product or specifically for animal feed, and therefore their presence in the food supply should not be expected. The majority of GM lines approved in the Code carry a single new trait for tolerance to herbicides such as glyphosate [RoundUp®] or glufosinate ammonium [Liberty®], or protection against specific insect attack. A smaller number carry two new traits that either combine herbicide tolerance with insect protection, or combine two similar traits to provide additional protection to the plants. Examples of two similar traits include dual herbicide tolerance, or insect-protection conferred by two different insecticidal proteins with different specificities. Potentially, future crops may contain multiple transformation events⁴. FSANZ is also aware of the development of new agronomic traits (e.g. tolerance to water stress) and crops with an altered nutritional profile that may be targeted to consumers. To date, no applications pertaining to GM animals or food-producing species other than plants have been received by FSANZ.

While some approved GM lines have been in production for some time (e.g. RoundUp Ready soy), it should be noted that it is highly likely that a number of lines have been superceded and are no longer produced. For example, Ingard Cotton is likely to have been replaced by newer GM cotton varieties that carry a dual trait to enhance protection against insect attack. An unknown number of the GM lines listed in the Code are therefore likely to be redundant approvals.

³ The Food Standards Code defines a line as a plant, of which the genetic material includes a transformation event or events and includes other plants derived from the original line.

⁴ The Food Standards Code defines a transformation event as a unique genetic modification arising from the use of gene technology.

Compliance with the Food Standards Code

Food businesses are required to comply with the Code and relevant jurisdictions are responsible for enforcing the requirements of the Code. When assessing compliance with Standard 1.5.2, document reviews and/or analytical testing has been undertaken in the past.

- Document review activities require the relevant jurisdictions to review the systems maintained by the food businesses and establish the likely level of compliance to the Code. Personnel resources are required from the relevant jurisdictions.
- Analytical testing can either be conducted separate to or as an adjunct to document review to verify that businesses are effectively managing the GM status of their food. Analytical testing requires specialised equipment and knowledge. As further GM foods are developed, enhanced testing capability needs to be maintained in order to detect new novel DNA proteins.

Document review and analytical testing surveillance activities are resource intensive for jurisdictions. In addition, many of the GM foods and ingredients are available in both New Zealand and Australia. This combined with the resource concerns of jurisdictions provides impetus to develop a national monitoring and surveillance strategy for GM foods.

Previous surveillance programs have been undertaken to assess compliance with Standard 1.5.2. Albeit that some were based on a small sample size, these activities have found a high level of compliance with Standard 1.5.2. Some of the findings of these activities include:

- Overall there is a high proportion of medium to large businesses that have implemented a management system for determining the GM status of foods;
- Generally, smaller businesses did not have management systems but showed a high level of compliance. Often this was due to them sourcing ingredients from wholesalers who supply the ingredients to larger companies with requirements for verification of GM status; and
- GM sequences have been infrequently detected in foods. Where GM sequences were detected, the level was less than the 10g/kg (1%) level for unintentional presence as stated in Standard 1.5.2 of the Code.

Analytical methodology

Since established protein detection methods are neither specific nor sensitive enough to measure very small amounts of a novel protein in a food product, the focus of attention for detecting GM material in foods has been to adapt or refine existing methods of DNA detection. However, there is no single test to determine whether food contains a GM ingredient.

The preferred method for DNA detection remains polymerase chain reaction (PCR) technology, which is capable of detecting the presence of extremely small amounts of DNA present in a sample. In theory, it is even possible to detect DNA that is degraded with time or by food processing. An initial PCR screening test can identify the presence of novel DNA in food by detecting regulatory elements⁵ commonly used in gene constructs (also referred to as gene

⁵ Regulatory elements are promoters (e.g. CaMV35S) and terminators (e.g. *nos*) that are sequences of DNA that control the expression of the inserted gene.

expression cassettes). This type of screen will detect a large number of GM lines non-specifically.

An event-specific PCR test exploits knowledge of the DNA sequence at junction regions, i.e. where the inserted novel DNA intersects with plant genomic DNA. As every insertion event is unique, the DNA sequence across the boundary between inserted and genomic DNA is specific for each GM line. Event-specific PCR tests are therefore able to discriminate a number of distinct lines containing the same gene constructs. Quantitative PCR is also possible using this information. The table below (reproduced from NMI presentation to FSANZ Science Network Forum, May 2008) provides an overview of the difference between screening and event-specific detection methods.

	Screen	Event-specific
Target DNA sequence	Occurs in nature	Not found in nature
Result outcome	Permits reasonable conclusion about presence or absence of novel DNA	Unambiguously identifies a specific GM event
Advantage	Provides maximum coverage (80% of commercial GMOs contain the CaMV 35S promoter and/or NOS terminator)	Can be used for quantification
Limitation	There is no single screen that will detect all GMOs	A separate test is required for each event

Scope

- As Standard 1.5.2 of the Code requires food available for sale to comply with GM labelling requirements, compliance monitoring will predominately focus on finished product expanding to raw commodities when further investigation is required.
- Both correct labelling of approved GM lines and the potential presence of foods derived from lines not permitted in the Food Standards Code are addressed by the strategy.
- Negative claims, such as “GM free” are not included in this strategy as negative claims are not covered by Standard 1.5.2. Any identified issues with negative claims should be referred to the appropriate enforcement agencies who enforce the Australian Trade Practices Act 1974 and the New Zealand Fair Trading Act 1986 (ACCC and NZCC respectively).
- This strategy is confined to monitoring for compliance to Standard 1.5.2 and does not address matters considered during the pre-market safety assessment of a GM food application.
- Enforcement action may require further activities with reference to the national enforcement policies and relevant jurisdictional policies, procedures and competing priorities.

Principles

- A national and coordinated approach will be taken.
- Existing recognised national and bi-national structures, protocols and principles will be utilised to assist with a consistent and coordinated approach.
- Activities will take into account the potential for foods to contain GM material and compliance behaviour of businesses.

Elements

The national monitoring and compliance strategy will consist of the following elements:

- Education – provide the food industry with information to assist with complying with Standard 1.5.2
- Surveillance – monitor and verify compliance to Standard 1.5.2
- Complaint and Incident Response – respond to reports where it is suspected a food does not comply with Standard 1.5.2
- Communication – have information available on the level of compliance and government activities in respect to compliance with Standard 1.5.2
- Evaluation – assessment and refining the national monitoring and compliance strategy for GM foods

Education

Jurisdictions will endeavour to promote awareness of the Standard 1.5.2 by:

- providing information to businesses (e.g. compliance protocol) to assist compliance to the Standard;
- promoting compliance with Standard 1.5.2 through websites and publications;
- communicating to businesses the requirements of the Standard and their responsibility in regard to compliance; and
- engaging with industry groups about compliance to the Standard and information available.

Surveillance

A surveillance program will be developed and implemented by the Implementation Sub Committee (ISC) to assess industry compliance with Standard 1.5.2. The surveillance program will consider:

- the principles of this strategy;
- developing an initial baseline of data (based on previous activities) to assess future levels of compliance;
- the appropriate balance of utilising document review and analytical testing as compliance tools based on the above elements;
- developing a priority matrix that considers factors such as the commercial status of the GM line, primary use of the GM line and the potential for GM material to be present in a final food product (food or ingredient) ;
- both long-term and short-term activities;

- efficiencies in pooling resources for activities undertaken (e.g. analysis of foods, document review of businesses);
- the use of expert advice when required; and
- the level of activity required to confirm non-compliance.

A surveillance program will be established under ISC Component 1 – Monitoring and Surveillance and included on the national ISC Coordinated Food Survey Plan. The surveillance program will be developed based on the current “*Protocol and Strategy for the Establishment and Operation of a Coordinated Food Survey Plan*” including nomination of a lead agency to coordinate the survey. The Food Surveillance Network (FSN), among other activities, coordinates national and bi-national food surveillance activities. The participating FSN members together with the lead agency will be responsible for:

- implementing the surveillance program; and
- documenting the activities undertaken and the results when available.

The FSN will also be used as an avenue for information sharing between Australia and New Zealand.

The lead agency may seek expert advice or assistance from groups such as NMI, FSANZ and industry. The type of information sought could cover activities such as:

- keeping abreast of technologies for both qualitative and quantitative analysis; and
- determining the potential foods likely to contain GM material, including the reasoning.

Complaint and Incident Response

Complaints will be investigated through individual jurisdiction’s complaints resolution mechanism based on the evidence provided and the risk to food safety. The subject of the complaint may be considered for inclusion in the education or surveillance activities of this strategy.

The National Food Incident Response Protocol may be triggered, if appropriate, in situations where a local or international incident becomes apparent. As stated in the National Food Incident Response Protocol, a food incident is a situation within the food supply chain where there is a risk, potential risk or perceived risk of illness or confirmed illness associated with the consumption of a food or foods. In respect to GM foods, this is likely to only occur where a non-approved GM food not approved by regulators following the Codex Guideline has the potential to be present in the food supply and no information on its safety is available.

Communication Elements

Communication of the surveillance program will occur through the Food Surveillance Network as per the current “*Protocol and Strategy for the Establishment and Operation of a Coordinated Food Survey Plan*”. In line with the *Protocol*, communication and media materials will be prepared by the lead agency.

A common communication message should be developed to respond to requests for information. The message should be developed in participation with the Government Food Communicators Group and the lead agency together with participating FSN members. The communication message should be updated as required and should contain the following concepts:

- a coordinated national approach for monitoring compliance to Standard 1.5.2 is taken for the effective utilisation of government resources;
- this collaborative effort has analysed X foods over Y period and has reviewed the documentation for Z food businesses;
- the level of compliance to date has been ...%; and
- a coordinated collaborative response to incidents involving GM foods will be instigated if and when food safety incidents arise.

Evaluation

The strategy will be reviewed within five years or sooner if required. The review will at least consider:

- past level of compliance to Standard 1.5.2;
- advances in analytical testing methodology relevant to compliance monitoring;
- any amendments to Standard 1.5.2;
- new methods for developing GM foods that have implications for compliance monitoring;
- effectiveness, including consistency, of enforcement activities; and
- resources available for enforcement activities.

Any advances or changes in the above points may also be a trigger for a review of the strategy.