Tabled document
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Labelling Genetically Modified Food

User Guide to Standard A18/1.5.2 – Food Produced Using Gene Technology

Contents

Background

On 28 July 2000 Health Ministers of the Australian States and Territories, Commonwealth and New Zealand agreed in principle to new labelling req genetically modified (GM) food under Standard A18 — Food Produced U Technology — in the Australian *Food Standards Code*. This standard also Standard 1.5.2 in the joint Australia New Zealand *Food Standards Code*.
The Ministerial Council formally approved the revised standard on 24 November 2000. It was gazetted on 7 December 2000 and comes into effect on 7 December 2001.
The standard requires that:

i. all foods produced using gene technology to be assessed and approved before sale and use; and
ii. all genetically modified food and ingredients, as defined in the standard, to be labelled where they
    a. contain novel DNA and/or novel protein in the final food, or
    b. have altered characteristics.

To do this, food businesses such as manufacturers, packers, importers and, where appropriate, retailers should take all reasonable steps to:

i. find out if their food or ingredients are produced using gene technology — this includes additives and processing aids;
ii. find out if the food or ingredient produced using gene technology is approved — this includes additives and processing aids; and
iii. determine what the labelling requirements are for the GM food or ingredient.

Purpose

This user guide has been developed in consultation with Australian and New Zealand government and industry representatives to help manufacturers and retailers interpret and apply Standard 1.5.2 – Food Produced Using Gene Technology of the Australia New Zealand *Food Standards Code*[1].
This user guide, unlike the standard itself, is not legally binding. If in any doubt about interpreting the standards, you should seek independent legal advice.
As well as complying with food standards requirements, you must also continue to comply with other legislation. In Australia, this legislation includes the *Trade Practices Act 1974,* the *Imported Food Control Act 1992,* and State and Territory Fair Trading Acts and Food Acts. In New Zealand, this legislation includes the *Food Act 1981* and *Fair Trading Act 1986.*

How is the user guide organised?

Standard A18/1.5.2 requires all foods produced using gene technology to be assessed and approved before sale and use. It also requires all genetically modified food and ingredients, as defined in the standard, to be labelled where they contain novel deoxyribonucleic acid (DNA) and/or novel protein in the final food or have altered characteristics.
To comply with the standard, food businesses such as manufacturers, packers, importers and, where appropriate, retailers should take all reasonable steps to find out whether a food or

[1] This standard also exists as Standard A18 in the Australian *Food Standards Code.*

ingredient (including additives and processing aids) is produced using gene technology, and if so, to:

- find out whether the food or ingredient produced using gene technology is permitted under the Code; and
- determine the labelling requirements for the GM food or ingredient.

It is the responsibility of the food business applying the food label (regarding labelling food, e.g. a food importer) or selling the food, to meet the requirements of the standard and ensure the accuracy of the label.

This user guide contains the following sections:

- *How the GM labelling requirements work* sets out a decision tree with a number of questions used to determine whether a food or ingredient requires GM labelling. It also explains the exemptions from GM labelling incorporated into Standard A18/1.5.2.
- *Documentation* explains how businesses can demonstrate having taken all reasonable steps in complying with food standards using a paper or audit trail similar to a quality assurance system.
- *Testing for the presence of novel DNA and/or novel protein* details how testing may be carried out if required.
- *Voluntary negative claims* provides advice for those wishing to use a voluntary negative claim on a label (e.g. 'GM free').
- *Examples of GM food labelling* provides a number of worked examples of foods and the GM labelling they may need to carry.
- *Where can I get more information?* lists relevant authorities in Australia and New Zealand that can provide further advice on compliance with the standard. It also lists various Internet sites with information on regulation of GM organisms and food in Australia and New Zealand, and internationally. Additional information can be found on the Australia New Zealand Food Authority (ANZFA) website at www.anzfa.gov.au.
- The *Attachments* list currently permitted GM food commodities, processing aids and the Table to Clause 2 of Standard A18/1.5.2.

How the GM labelling requirements work

In this user guide, 'food' or 'food ingredient' includes food additives and processing aids.

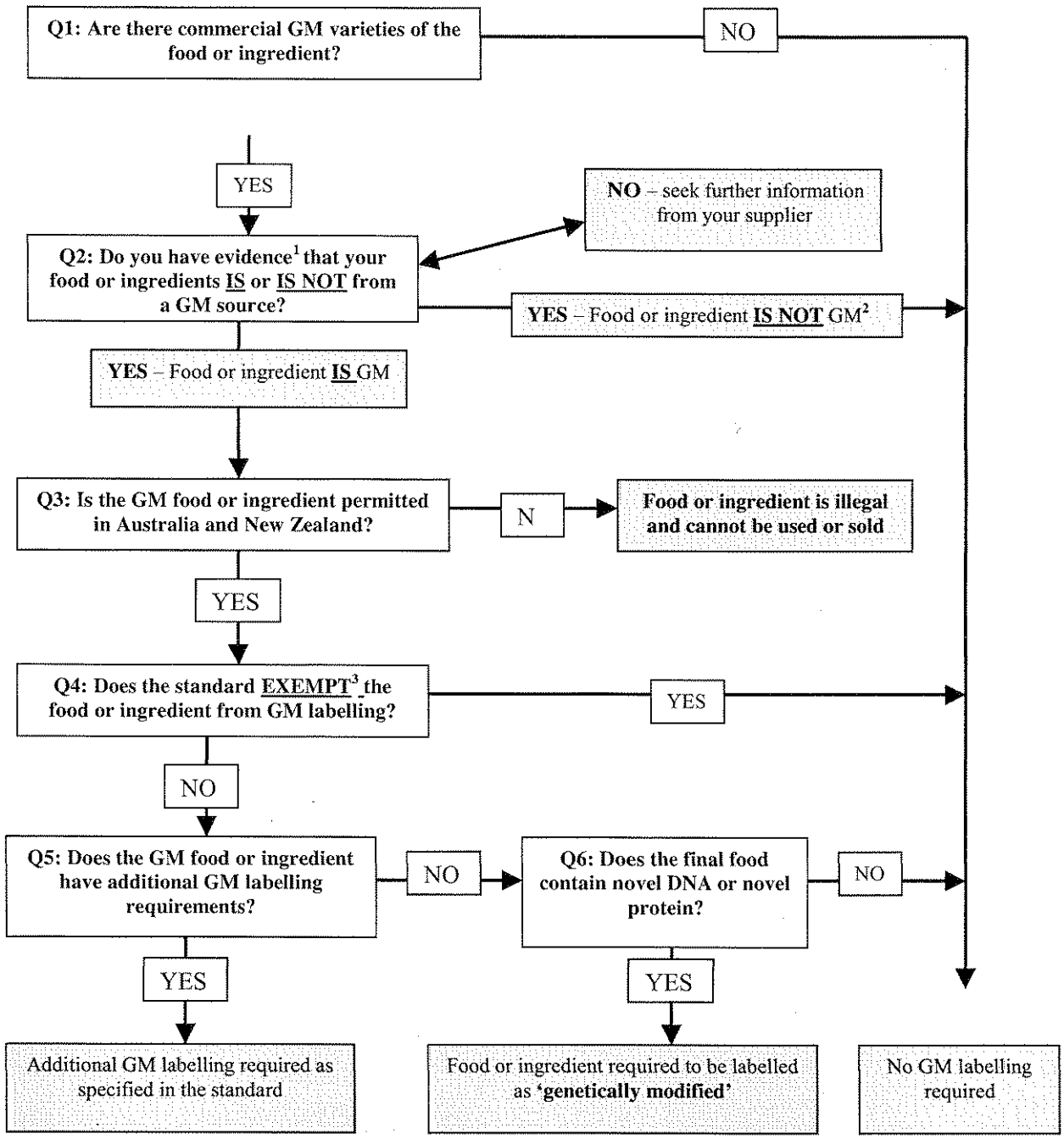
The standard requires that where a GM food or ingredient is present:

- for packaged foods the words '**genetically modified**' be used in conjunction with the name of the food, or in association with the specific ingredient within the ingredient list; and
- for unpackaged foods for retail sale (such as unpackaged fruit and vegetables, or unpackaged processed or semi-processed foods) the words '**genetically modified**' be displayed in association with the food, or in association with the particular ingredient within that food.

The standard does not require GM foods prepared for immediate consumption, such as restaurant and take-away food, and catered meals to be GM labelled. Consumers can, of course, request this information from these businesses.

The decision tree (below), together with the accompanying questions, will help you to determine what GM labelling may be required for a food.

Decision Tree: When to Label Foods as 'Genetically Modified'



[1] Evidence may be from a paper trail of verifiable documentation or from testing for novel DNA or novel protein.

[2] Where you have sought not to use a GM food or ingredients the standard allows up to 10 g/kg (1%) per ingredient of GM food where its presence is unintended.

[3] Exemptions from labelling are:
- flavourings at or below 1g/kg (0.1%) in final food;
- highly refined foods (from which novel DNA or novel protein is removed, e.g. refined sugars, oils etc.) - unless they have additional GM labelling requirements;
- additives and processing aids (which do not contain novel DNA or novel protein); and
- food intended for immediate consumption from the point of preparation (restaurants, take-aways etc.).

NOTE: foods or ingredients that are exempt still need to be approved under the standard.

QUESTION 1: ARE THERE COMMERCIAL GM VARIETIES OF THE FOOD OR INGREDIENT ON THE MARKET?

At the date of publication of this user guide, only a limited number of foods and ingredients on local and international markets come from GM sources. While limited in number, they may be used in a wide range of final foods.
Sources of information that can help you determine if a food or ingredient comes from a commercialised GM source include:

- the supplier of your food or ingredient;
- your State, Territory or New Zealand health or agricultural authority; or
- the ANZFA Internet site.

See *Where can I get more information?* for contact details of government agencies and Internet sites that can help you find this information.
A number of commercialised foods produced using gene technology on the international market are not approved for use in Australia and New Zealand. International information sources, such as Internet sites, can help answer this question.
If your food or ingredient comes exclusively from food commodities known not to have commercial GM varieties, then you do not need to consider GM labelling any further.

QUESTION 2: DO YOU HAVE EVIDENCE THAT YOUR FOOD OR INGREDIENT IS OR IS NOT FROM A GM SOURCE?

If the food or ingredient *could be* from a GM source, you will need to determine whether or not it is GM in order to comply with the standard. Evidence to show the GM status of the food or ingredient can be obtained from documentation or testing.
In the first instance, you should seek documentary evidence regarding the GM status of the food or ingredient from your supplier.
If you cannot resolve this question with their supplier, you may need to test the food or ingredient or seek other sources of supply to comply with the standard. (See *Documentation* and *Testing for the presence of novel DNA and/or novel protein* for recommendations regarding verifiable documentation and the applicability of testing.
If you conclude from documentation or testing that the food or ingredient is from a GM source, the next step is to determine:

- whether it is permitted (see *Question 3*); and
- if it is required to be labelled 'genetically modified' (see *Questions 4, 5* and *6*).

If you conclude from documentation or testing that the food or ingredient is not from a GM source, then no 'genetically modified' labelling is applicable (see also *Question 4* regarding exemption from GM labelling for GM food which is unintentionally present).

QUESTION 3: IS THE GM FOOD OR INGREDIENT FROM A VARIETY PERMITTED IN AUSTRALIA AND NEW ZEALAND?

It is important to find out if the food or ingredient (including food additives and processing aids) is derived from a permitted or approved GM variety in Australia and New Zealand. To do this, you will need to refer to:

- the list of GM food varieties approved or permitted under the standard (see *Attachment 1*);
- other food standards in the *Food Standards Code* that list food additives or processing aids including GM varieties (see *Attachment 2*); and/or
- the ANZFA Internet site (see *Where can I get more information?*).

These attachments are correct as of the date of publication of this user guide. You should consult the ANZFA Internet site or contact ANZFA (see *Where can I get more information?*) for an up-to-date list of permissions and approvals.

Note that if the food is or contains a non-permitted or non-approved GM food or ingredient it is illegal and must not be sold, and you will need to find another source of the food or ingredient.

QUESTION 4: DOES THE STANDARD EXEMPT THE FOOD OR INGREDIENT FROM GM LABELLING?

A food or ingredient does not need to be labelled as 'genetically modified' if it cannot possibly come from a GM source (see *Question 1*) or if it is specifically exempt from labelling by the standard.

If your food or ingredient falls into any of the following categories you do not need to apply a 'genetically modified' label:

- **Highly refined foods**, such as refined oils, sugars and starches that have undergone refining processes that have the effect of removing DNA and/or protein (see *Question 6* which considers processes that are typically known to remove DNA and protein). No 'genetically modified' label is required for highly refined foods *unless* they have additional GM labelling requirements under the standard. (See *Question 5*).
- **Additives and processing aids** that do not carry forward novel DNA or novel protein to the final food.
- **Flavourings** (including individual aromatic, carrier and other components) at no more than **1 g/kg (0.1%)** in the final food as consumed (see *Question 6* for more information on flavourings).
- **Food intended for immediate consumption that is prepared and sold from food premises and/or vending vehicles.** This includes food prepared and sold from outlets such as restaurants, take-away outlets, caterers, or self-catering institutions where consumers can request information on the GM status of their foods from the vendor.
- Where you have intended that GM food not be used or present in a food the standard allows for the **unintentional presence of a GM food not more than 10 g/kg (1%) per ingredient**.

Note that verification of the non-GM source of the food or ingredient may include documentation from identity preserved or other production systems that segregate or otherwise verify that it is not of GM origin.

Manufacturers should be cautious in applying voluntary negative claims, such as 'GM free', to foods which could unintentionally have GM content as it may breach false and misleading provisions within fair-trading and consumer protection laws (see *Voluntary negative claims* for further information).
Foods produced from conventional animals fed on GM stockfeed or crops do not have to be labelled as 'genetically modified' because they do not fall under the definition of a food produced using gene technology.

QUESTION 5: DOES THE GM FOOD OR INGREDIENT HAVE ADDITIONAL GM LABELLING REQUIREMENTS?

Some GM foods may require additional GM labelling under the standard. These requirements are listed in the table to clause 2 (see *Attachment 3*) in the standard against specific approvals. Additional GM labelling is required where the food has altered characteristics, or where the food carries identified ethical, cultural or religious concerns with respect to the genetic modification.
'Altered characteristics' means that when compared to matching conventional foods the GM food is different in relation to:

- composition or nutritional values;
- anti-nutritional factors or natural toxicants;
- factors known to cause allergic responses in particular sections of the population;

or

- its intended use.

If your food or ingredient is listed in the standard as requiring additional GM labelling, you must apply the labelling specified in column 2 of the table to clause 2 (see *Attachment 3*) of the standard in addition to the indication that the food is 'genetically modified'. This requirement applies even if it is otherwise exempt from the general labelling requirement.
An example of a food type requiring additional GM labelling is provided in the section *Examples of GM food labelling: refined oil with altered characteristics.*

QUESTION 6: DOES THE FINAL FOOD CONTAIN NOVEL DNA AND/OR NOVEL PROTEIN?

Novel DNA and/or novel protein means DNA or protein that, because of the use of gene technology, is different in chemical sequence or structure from that in the matching conventional food.
If you determine that the final food does contain novel DNA and/or novel protein, the words 'genetically modified' must be used in association with the name of the food or in the ingredient list.
If processing has had the effect of removing novel DNA and/or novel protein that may have been present in the original food or ingredient, then a 'genetically modified' label is not required unless additional GM labelling requirements are stipulated by the standard.
If you don't know the GM status of your food or ingredient you should either obtain evidence from your supplier or undertake testing for novel DNA and/or novel protein.

Below is an explanation of how to deal with some special cases:

(a) Highly refined foods

Highly refined foods are foods such as oils, sugars and starches, which undergo refining processes that result in purified products from which DNA and protein has been removed. Such refined foods do not require a 'genetically modified' label unless they have additional GM labelling requirements (see *Question 5*).

Refining processes do not always have the same effect and you may need to ask your supplier or test to confirm that the specific processes used have removed DNA and protein in the refined product.

Processes that may be used to purify foods or ingredients include, but are not limited to:

- high temperature extraction;
- filtration and centrifugation;
- solvent extraction (aqueous or organic);
- distillation;
- crystallisation;
- dialysis and fractionation;
- coagulation and precipitation;
- caustic, acidic or oxidative purification; and
- fermentation and enzymic digestion.

Examples of highly refined foods are:

- crystalline sugars and sugar syrups;
- purified oils and their derivatives; and
- purified starches and derivatives.

Semi- or minimally refined foods are produced using simple processes such as crushing or husking which may not remove DNA and/or protein. For example, cold pressed or crudely refined oils may contain proportions of DNA and/or protein and therefore labelling may be required. In these circumstances, you may need to request information from your supplier and/or undertake appropriate testing (see also *Testing for the presence of novel DNA and/or novel protein*).

(b) Food additives and processing aids

Food additives are substances intentionally added to foods to achieve a technological function and normally remain present in the final food. Examples are preservatives, antioxidants and thickeners.

Processing aids are used in small amounts to perform a technological function in the processing of raw materials, foods or food ingredients and are normally not present in the final food. An example is the enzyme amylase used in some processes to clarify fruit or sugar juices.

Both processing aids and food additives are not required to carry a 'genetically modified' label unless they themselves are, or they contain, novel DNA or novel protein and the novel DNA or novel protein remains in the final food.

Lists of food additives and processing aids approved for use in food production are contained within Standard A3 and A16 respectively in the Australian *Food Standards Code*. These are also listed respectively in Standards 1.3.1 and 1.3.3 of the Australia New Zealand *Food Standards Code*.

(c) Flavourings

Flavourings are a class of food additive that are concentrated natural or synthetic preparations added to foods to give taste and/or odour. They are used in small concentrations and are not meant to be consumed alone. Flavourings are at a concentration of less than 1 g/kg (0.1%) in

the majority of foods in which they are used but may be above this level in some highly flavoured products.
Where a flavouring containing a permitted GM component (including individual carriers) is added to a food and the concentration of that flavouring is no more than 1 g/kg (0.1%) in the final food, no 'genetically modified' label of the flavouring is required.

Documentation

Food businesses are likely to have in place procedures such as paper trails to provide assurance that all ingredients supplied and used in food products meet the requirements of food legislation. For example, in order for foods to be correctly and lawfully labelled, information on the food additives in each in-going ingredient is required. Manufacturers must also ensure that permitted food additives are declared in the final product label. This enables consumers to make informed choices regarding the components in the food.

What constitutes a reliable paper trail for GM labelling?

Compliance with the standard can be based on verifiable documentation. For this, you will need a reliable paper trail for which:

- there is written documentation (e.g. requests on order forms, and declarations on invoices, packing slips etc.); and
- the documentation is provided by a person authorised by the supplier.

The required information regarding the GM status of the food will need to be carried forward from growers, processors, suppliers and importers to manufacturers and retailers along the supply chain.

Responsibilities

At each step of the supply chain, successive suppliers should provide accurate information with respect to the GM status of food and food ingredients being supplied. Businesses should be diligent in determining the accuracy of this information and confident that it is reliable.
As a first step in enforcement, enforcement agencies would review documentation in assessing compliance with the standard. Businesses should retain documentation for an appropriate period that should be no less than the shelf life of the food.
A retailer would not be expected to keep separate records for food received for retail sale in addition to the information regarding GM status already on the label.
If you are unsure about your responsibilities, you should contact your State, Territory or New Zealand health department for advice and/or seek independent legal opinion.

Identity preservation

Identity preservation (IP) systems may be designed to ensure the absence of GM components in a food or ingredient. This is achieved by separating non-GM components in the supply chain.
You may choose to use an IP system to assure the non-genetically modified status of ingredients and avoid the need to carry a 'genetically modified' label. While such steps may be appropriate when voluntary negative claims are made (see *Voluntary negative*

claims), the standard does not regulate such claims or make the use of IP systems mandatory in these situations.

Testing for the presence of novel DNA and/or novel protein

The standard requires that if novel DNA or novel protein is present in a final food, a GM label is required.
Testing should be done when the GM status of the food:

- cannot be established through a paper trail; or
- varies from batch to batch; and
- there are suitable test methods available.

In the case of highly refined foods, a one-off test may be required to confirm that novel DNA and/or novel protein is removed. It may be necessary to repeat this verification over time if, for example, processing methods or suppliers change.
Occasional testing may be necessary to confirm the validity or reliability of the paper trail to demonstrate that all reasonable steps have been taken; for example, where variation exists in the supply or use of the food or ingredient, or to assess the reliability of the supplier.
There are currently two main test methods applicable to determine the GM status of food and ingredients. These are:

- the polymerase chain reaction (PCR) test for DNA, and
- enzyme-linked immunosorbent assay (ELISA) for protein.

In considering testing, the following key points in relation to GM testing should be examined.

- *Availability:* in some cases there will be no currently available testing system to establish whether a GM food is present.
- *Reproducibility*: test methods chosen should be readily replicated and reviewable.
- *Confidence*: limits of detection are gradually being reduced, but false positive and false negative results occur at low levels in the final food.
- *Cost*: testing is generally expensive.
- *Reliability*: accreditation of laboratories is a reflection of their reliability.

If you decide that testing is necessary, you should seek advice from the health department in your State or Territory or New Zealand (see *Where can I get more information?* for contact details and Internet links).

Voluntary negative claims

The standard does not address negative label claims such as 'GM free'. If you choose to make a voluntary negative label claim, you may be called on to substantiate that claim and ensure that it is not false or does not mislead or deceive consumers. In order to be able to substantiate your claim you may need to exercise greater diligence than required for positive labelling. Negative claims are deliberate commercial decisions. Any costs associated with making such claims are also voluntarily incurred.
Laws pertaining to false, misleading and deceptive conduct exist in Australian State and Territory fair-trading and food laws and in the New Zealand *Food Act 1981*. Such conduct is also regulated through the Commonwealth *Trade Practices Act 1974* and the New Zealand *Fair Trading Act 1986*.
The Australian Competition and Consumer Commission (ACCC) and the New Zealand Commerce Commission advise that if you wish to use a negative claim, that claim must be

an accurate, unambiguous representation of the product. You must be able to support any claims that you make. You may need to adjust your ingredient supplies to ensure that you have used ingredients and/or processes that accurately reflect your claim.
If your food product contains novel DNA/novel protein and a negative claim leads consumers to believe that it does not, you may be in breach of the Australian *Trade Practices Act*, New Zealand *Fair Trading Act* and *Food Act*, and State and Territory fair-trading laws as described above.

Examples of GM food labelling

Several example scenarios for GM labelling are set out below. These examples use the decision tree on page 5. Note that each case would need to be assessed on an individual basis and there will be numerous variations within the overall guidelines.

Honey scenario

Question 1 – Are there commercial GM varieties of the food or ingredient on the market?

- Honey is not, by definition, a food produced using gene technology under the standard – see editorial note under clause 1 of the standard.

Please note: the standard allows a food or ingredient to have up to 10 g/kg (1%) of a GM food where its presence is unintentional. This applies to the presence of pollen from an approved GM food commodity.
Outcome: No GM labelling required.

Apple scenario

Question 1 – Are there commercial GM varieties of the food or ingredient on the market?

- No evidence supplied.
- You determine from the list of permitted GM food commodities, or from your local agricultural authority, or from some other source, that GM varieties of apple are NOT available in the international marketplace.

Outcome: No GM labelling required.

Packet of soybeans scenario

Question 1 – Are there commercial GM varieties of the food or ingredient on the market?

- You determine from the list of permitted GM food commodities or from your local agricultural authority, or from some other source, that GM varieties of soybean ARE available in the marketplace.

Question 2 – Do you have evidence that your food or ingredient is or is not from a GM source?

- You request information from your supplier to identify whether the soybeans are or include GM varieties.
- Supplier indicates that the soybeans:
  - are or may sometimes be GM; or
  - are from a non-GM source.

Question 3 – Is the GM food or ingredient permitted for sale in Australia and New Zealand?

- Supplier indicates that the soybeans are from an approved variety.

Please note: if the supplier cannot provide this information, you might need to resort to testing to determine if the GM soybeans are approved.

Question 4 – Does the standard exempt the food or ingredient from GM labelling?

- Packaged whole soybeans are not refined, nor fall into other exemption categories under the standard.

Question 5 – Does the GM food or ingredient have additional GM labelling requirements?

- You determine or your supplier provides information leading you to the conclusion that there are no additional GM labelling requirements listed for the soybeans under the standard.

Question 6 – Does the final food contain novel DNA and/or novel protein?

- Soybeans contain significant proportions of protein and DNA, including novel components, and it should be assumed these are present in the final food.

Outcome:

- If you determine that the soybeans are from a GM source the words 'genetically modified' must be used in conjunction with the name 'Soybean' on the packet.
- If you determine that the soybeans are not from a GM source, no GM labelling is required.

Soy flour scenarios

SCENARIO 1 – FLOUR NOT GM

Question 1 – Are there commercial GM varieties of the food or ingredient on the market?

- You determine from the list of permitted GM food commodities, or from your local agriculture authority, or from some other source that GM varieties of soybean are available in the marketplace.

Question 2 – Do you have evidence that your food or ingredient is or is not from a GM source?

- Supplier provides evidence that the soy flour is NOT GM. There is an identity preservation system in place or it is sourced from a region where GM soy is not permitted or grown.
- The standard provides a tolerance of up to 10 g/kg (1%) of the flour to be comprised of a permitted GM food (see *Question 3*), but only where it can be shown that the presence of the GM food is unintended.

Outcome: No 'genetically modified' label is required.

SCENARIO 2 – SOY FLOUR FROM UNKNOWN SOURCE

Question 1 – Are there commercial GM varieties of the food or ingredient on the market?

- You determine from the list of permitted GM food commodities, or from your local agricultural authority, or from some other source, that GM varieties of soybean are available in the marketplace.

Question 2 – Do you have evidence that your food or ingredient is or is not from a GM source?

- Supplier cannot determine GM status of individual batches or provides no documentation.

- You ask the supplier to investigate further to determine if the soy flour contains GM components OR you or the supplier undertake testing of representative batches to identify whether novel DNA or novel protein are present.
- Supplier responds that the soy flour is potentially GM OR testing shows presence of GM soy.

Question 3 – Is the GM food or ingredient permitted for sale in Australia and New Zealand?

- If the supplier indicates or tests show that the soy is from a permitted GM variety you should determine what labelling requirements are applicable (*Questions 5* and *6*).
- If tests show that the GM soy is from an unapproved variety the soy flour is illegal and cannot be used or sold.

Question 4 – Does the standard exempt the food or ingredient from GM labelling?

- Soy flour is only minimally refined and does not fall into other exemption categories under the standard.

Question 5 – Does the GM food or ingredient have additional GM labelling requirements?

- You determine or your supplier provides information leading you to the conclusion that there are no additional GM labelling requirements listed for the soybean flour under the standard.

Question 6 – Does the final food contain novel DNA and/or novel protein?

- You determine that novel DNA or novel protein from the soy flour will remain in the final food.

Outcome: Label soy flour in the ingredient list as 'genetically modified'.

Processing aid/additive scenarios

SCENARIO 1 - CHYMOSIN/CHEESE SCENARIO

Question 1 – Are there commercial GM varieties of the food or ingredient on the market?

- Supplier advises or you determine that the coagulating enzyme chymosin (a protein used as a processing aid in the production of some cheeses) can be derived from a GM source.

Question 2 – Do you have evidence that your food or ingredient is or is not from a GM source?

Question 3 – Is the GM food or ingredient approved in Australia and New Zealand?

- You determine or your supplier advises that the chymosin supplied is from an approved GM source. If this information is not provided, assess against permitted additives or resolve with your supplier.

Question 4 – Does the standard exempt the food or ingredient from GM labelling?

- Trace amounts of the chymosin may be present in the final food.
- You determine or your supplier advises that chymosin supplied is a purified enzyme protein from a GM source that:
  – contains no novel DNA; and

– is protein that is structurally and chemically identical to chymosin obtained from conventional sources (such as rennet) used in traditional cheese manufacture.

- The chymosin is not 'novel' as defined by the standard (see *Question 6*).

Outcome: No GM labelling required.

SCENARIO 2 - LECITHIN/FOOD ADDITIVE SCENARIO

Question 1 – Are there commercial GM varieties of the food or ingredient on the market?
Question 2 – Do you have evidence that your food or ingredient is or is not from a GM source?

Question 3 – Is the GM food or ingredient permitted for sale in Australia and New Zealand?

- You determine or your supplier advises that the additive lecithin (an oil derivative used as an emulsifier in a number of foods) supplied is a minimally refined extract from permitted GM soy.

Question 4 – Does the standard exempt the food or ingredient from GM labelling?

- You determine or your supplier advises that the soy lecithin is only minimally refined and does not fall into other exemption categories under the standard.

Question 5 – Does the GM food or ingredient have additional GM labelling requirements?

- None required for the specific GM soy variety.

Question 6 – Does the final food contain novel DNA and/or novel protein?

- You determine or supplier advises that novel DNA and/or novel protein occurs in the soy lecithin, and this remains in the final food after processing or manufacturing.

Outcome: The words 'genetically modified' must be used in conjunction with the ingredient lecithin in the ingredient list if the final food contains novel DNA and/or novel protein.

If you determine that the soy lecithin *is* highly refined and *does not* carry novel DNA and/or novel protein through to the final food, no 'genetically modified' label for this ingredient is required.

Please note: All food additives need to be declared in ingredient lists under the general labelling provisions in other standards in the Australia New Zealand *Food Standards Code.*

A refined canola oil scenario

Question 1 – Are there commercial GM varieties of the food or ingredient on the market?

- You determine from the list of permitted GM food commodities or from your local agricultural authority, or from some other source that GM varieties of canola are available in the marketplace.

Question 2 – Do you have evidence that your food or ingredient is or is not from a GM source?
Question 3 – Is the GM food or ingredient permitted in Australia and New Zealand?

- You request information from your supplier to identify whether the oil is from an approved GM canola variety.
- Supplier indicates that it is or sometimes may be.

Question 4 – Does the standard exempt the food or ingredient from GM labelling?

- You determine or your supplier informs you that the refining process used to produce the canola oil removes DNA and protein.

Question 5 – Does the GM food or ingredient have additional GM labelling requirements?

- None are currently listed under the standard for this oil.

Question 6 – Does the final food contain novel DNA and/or novel protein?

- As determined at *Question 4*, soybean oil is a highly refined commodity that has undergone a process that removes DNA and protein.

Outcome: No GM labelling required.

Cold pressed/unrefined canola oil scenario

Question 1 – Are there commercial GM varieties of the food or ingredient on the market?
Question 2 – Do you have evidence that your food or ingredient is or is not from a GM source?

Question 3 – Is the GM food or ingredient permitted in Australia and New Zealand?

- Supplier advises that in-going canola seeds are from a permitted GM variety and that the oil is cold pressed.

Question 4 – Does the standard exempt the food or ingredient from GM labelling?

- You or your supplier is unable to determine if cold pressed/unrefined canola oil undergoes a process that removes DNA and/or protein.

Question 5 – Does the GM food or ingredient have additional GM labelling requirements?

- Supplier advises or you determine that no additional GM labelling requirements are required by the standard.

Question 6 – Does the final food contain novel DNA and/or novel protein?

- Supplier cannot provide verifiable documentation for individual batches as to the presence or absence of novel DNA and/or novel protein.
- You arrange for testing to be undertaken on representative batches.

Outcome:

- If novel DNA and/or novel protein found to be present routinely, label canola oil as 'genetically modified'.
- If no novel DNA and/or novel protein found routinely, no 'genetically modified' label is required.

Refined soy oil with altered characteristics

Question 1 – Are there commercial GM varieties of the food or ingredient on the market?
Question 2 – Do you have evidence that your food or ingredient is or is not from a GM source?

Question 3 – Is the GM food or ingredient permitted *in Australia and New Zealand?*

- Supplier provides documentation indicating that the refined soy oil supplied is from a GM soy variety approved in Australia and New Zealand.

Question 4 – Does the standard exempt the food or ingredient from GM labelling?

- You or your supplier determines the soy oil undergoes a process that removes DNA and/or protein.

Question 5 – Does the GM food or ingredient have additional GM labelling requirements?

- Supplier advises you that the oil has altered characteristics that require additional GM labelling under the standard (Table to clause 2).

Outcome: Label oil 'genetically modified' and include any additional labelling requirements specified in the standard.

Processed food scenario: bread

Typical ingredients of white bread:

wheat flour, yeast, soy flour, water, vegetable oil, sugar, salt, emulsifiers (471, 472E), preservative (282), enzyme (amylase).

- **Wheat**: Supplier indicates (*Questions 1 and 2*) that wheat flour is not GM or you determine that no GM wheat varieties exist in the marketplace.
- **Yeast:** Supplier indicates (*Questions 1 and 2*) yeast is not GM or you determine no GM yeasts exist in the marketplace.
- **Soy flour**: Supplier indicates (*Questions 1 and 2*) or you determine that GM soy varieties do exist on the market and that the ingredient supplied is a permitted GM soy flour (*Question 3*). GM soy flour is of a variety that requires no additional GM labelling (*Question 5*). You determine novel soy DNA or novel soy protein remains evident in the final food (*Question 6*).
  A 'genetically modified soy flour' label **is** required.
- **Vegetable oil**: Supplier indicates (*Questions 1, 2 and 3*) or you determine that it is canola oil, there are GM varieties of canola, and it is derived from an approved GM canola variety. You determine that it does not have any altered characteristics (*Question 5*), and that it is highly refined and contains no DNA or protein (*Question 6*).
  No 'genetically modified' label is required.
- **Sugar**: Supplier indicates (*Questions 1 and 2*) or you determine that the sugar is from a non-GM source or from a permitted GM source (*Question 3*) but is highly refined (*Question 4 and 6*).
  No 'genetically modified' label is required.
- **Salt**: Mineral ingredient – not GM.
- **Emulsifiers**: Supplier indicates (*Questions 1, 2 and 3*) that both emulsifiers are derived potentially from approved GM soy. Supplier advises or you determine that emulsifier is a highly processed synthetic additive containing no novel DNA or novel protein (*Question 6*).
- No 'genetically modified' label is required.
- **Preservative**: Supplier indicates (*Question 1*) that the preservative is a highly processed synthetic additive that has no GM varieties.
- No 'genetically modified' label is required.
- **Enzyme – amylase:** Supplier indicates (*Questions 1, 2 and 3*), or you determine that the amylase is a permitted GM processing aid that does not additional GM labelling (*Question 5*). The amylase is not in itself a novel protein, it does not contain novel DNA, and/or these components do not remain in final food (*Question 6*).
  No 'genetically modified' label is required.

Outcome: Final ingredient list would appear as:

wheat flour, yeast, soy flour (genetically modified), water, vegetable oil, sugar, salt, emulsifiers (471, 472E), preservative (282), enzyme (amylase).

Unpackaged processed food with GM ingredient scenario: sausages with GM soy protein isolate

Information is supplied to you through consignment documentation or on the package to the effect that the sausages you will display for unpackaged sale contain 'genetically modified soy protein isolate'.
Under clause 4(3) of the standard, where a food is GM or contains a GM ingredient and is displayed for retail sale other than in a package, any information that would have been required on the label or attached to the food if it was packaged must be displayed on or in connection with the display of the food.
Outcome: You must indicate that the sausages contain 'genetically modified soy protein isolate' on or in connection with the display of the food, for example, on the name/price tag or elsewhere in association with the display.

Where can I get more information?

Enforcement agencies

The Australia New Zealand *Food Standards Code* is adopted as regulations by reference in each State and Territory through relevant Food and Health Acts and similarly in New Zealand. It is the responsibility of government food/health agencies in these jurisdictions to enforce the standards. If you require further information on enforcement issues, contact the appropriate agency in your State, Territory or New Zealand. The list below provides contact details (see local phone books for relevant contact details if necessary):

Australian Capital Territory
Health Protection Services
ACT Department of Health, Housing and Community Care
Locked Bag No. 5
Weston Creek ACT 2611
Ph: 02 6205 1700 Fax: 02 6205 1705

Northern Territory

Territory Health Services
Environmental Health Program
PO Box 40596
Casuarina NT 0811
Ph: 08 8999 2939 Fax: 08 8999 2526

South Australia
Food Section
South Australia Department of Human Services
PO Box 6, Rundle Mall
Adelaide SA 5000
Ph: 08 8226 7100 Fax: 08 8226 7102

Victoria

Compliance and Standards
Department of Human Services
GPO Box 1670N
Melbourne VIC 3001
Ph: 03 9637 4211 Fax: 03 9637 5212

New South Wales
Food Unit
NSW Health Department
PO Box 798
Gladesville NSW 1675
Ph: 02 9816 0268 Fax: 02 9817 7596

Queensland

The Environmental Health Service of your relevant Queensland Public Health Unit network (refer local phonebook).
Also:
Food Services
Environmental Health Unit
Queensland Health
GPO Box 48
Brisbane QLD 4001
Ph: 07 3234 0938 Fax: 07 3234 1480

Tasmania

State Food Officer
Department of Health & Human Services
PO Box 125B
Hobart Tasmania 7000
Ph: 03 62 333753 Fax: 03 62 336620

Western Australia
Health Department of WA
PO Box 8172
Stirling St
Perth WA 6849
Ph: 08 9388 4999 Fax: 08 9382 8119

New Zealand
New Zealand Public Health Units are listed in local telephone books and on the Ministry of Health website at www.moh.govt.nz. Information can also be obtained from:

Food Group
Ministry of Health
PO Box 5013
Wellington, New Zealand
Ph: 04 496 2000 Fax: 04 496 2340

Enforcement of imported foods

Foods imported into Australia are subject to inspection by the Australian Quarantine and Inspection Service (AQIS). In New Zealand, imported foods are subject to inspection by local public health units.
If you have questions regarding the importation of foods that are genetically modified or contain genetically modified components, you should contact:

Australia

Imported Food Program
AQIS
Box 858
Canberra ACT 2601
Ph: 02 6272 5419 Fax: 02 6272 3682

New Zealand

Contact details for local public health units may be found in local telephone books or from the Food Group, Ministry of Health; Ph: 04 496 2000.

Organisations providing testing services for GM foods

Information on organisations that can provide testing services for GM foods may be obtained from enforcement agencies listed above.

Enquiries regarding voluntary negative claims about food

Contact your local health and/or fair-trading government agency. The Australian Consumer and Competition Commission (ACCC) and the New Zealand Commerce Commission (NZCC) regulate national trade practices laws.
In Australia, refer to your local phone book for ACCC contact details.
For New Zealand, contact details of the NZCC are:

Commerce Commission
http://www.comcom.govt.nz
Fair Trading Act inquiries:
PO Box 2351
Wellington, New Zealand
Ph: 04 498 0911

Enquires about primary production (food used as animal feed, export certification, organic certification)

Australia

Market Maintenance Group
AQIS
PO Box 858
Canberra ACT 2601
Ph: 02 6272 5254 Fax: 6272 6522

New Zealand

Ministry of Agriculture and Forestry (MAF)
http://www.maf.govt.nz

PO Box 2526
101 – 103 The Terrace
Wellington, New Zealand
Ph: 04 474 4100

Enquiries about the use GM organisms and their release into the environment

Australia

Office of the Gene Technology Regulator (OGTR)
Internet: www.ogtr.gov.au
Email: ogtr@health.gov.au
Free call: 1800 181 030
Fax: 02 6271 4202
Mail: Office of the Gene Technology Regulator (MDP 54)
PO Box 100
Woden ACT 2606

New Zealand

Environmental Risk Management Authority (ERMA)
http://www.ermanz.govt.nz
Ph: 04 473 8426
PO Box 131
20 Customhouse Quay
Wellington, New Zealand

ANZFA helpline and website

During the implementation period of this standard and also the new Australia New Zealand *Food Standard Code*, ANZFA is operating a helpline for small business that can assist with the interpretation of the standard. Local call cost phone numbers are:

Australia: 1300 652 166
New Zealand: 0800 441 571

The helpline also receives queries by email at advice@anzfa.gov.au.
The ANZFA website at http://www.anzfa.gov.au or http://www.anzfa.govt.nz, has a range of information regarding the regulation of foods produced using gene technology including extensive information on ANZFA's safety assessment. Links to international sources of information on GM foods can be also found on this site.

Attachment 1

GM food permitted in Australia and New Zealand as at August 2001[2]

CROP	TRAIT	APPLICANT	ANZFA APPLICATION NUMBER	POTENTIAL FOODS USES
SOYBEAN	**Herbicide tolerance:** Glyphosate **High oleic soybeans**[3]	Monsanto Optimum Quality Grains(DuPont/Pioneer)	A338 A387	Soy foods including, soy beverages, tofu, soy oil, soy flour, lecithin. Other products may include breads, pastries, snack foods, baked products, fried products, edible oil products and special purpose foods.
CANOLA (Oil seed rape)	**Herbicide tolerance:** Glufosinate ammonium and hybrid traits Glyphosate Bromoxynil	AgrEvo Monsanto Rhone Poulenc	A372 A363 A388	Canola oil. May include edible oil products, fried foods, and baked products, snack foods.

2 This list is subject to change. Consult the ANZFA Internet site to determine if this table is still current.
3 This commodity is the only currently permitted food produced using gene technology that has 'altered characteristics' requiring additional GM labelling. The table to clause 2 in the standard stipulates that for this commodity *'The label on or attached to a package of food derived from high oleic acid soy bean lines G94-1, G94-19 and G168 must include the statement to the effect that the food has been genetically modified to contain high levels of oleic acid.'*

CORN	**Insect resistance:** Bt	Monsanto	A346	
	Herbicide tolerance: Glufosinate ammonium	AgrEvo	A375	Corn oil, flour, sugar or syrup. May include snack foods, baked goods, fried foods, edible oil products, confectionery, special purpose foods, and soft drinks.
	Glufosinate ammonium (DLL25)	Monsanto	A381	
	Glyphosate	Monsanto	A362	
	Herbicide tolerance & insect resistance: Glufosinate ammonium & Bt (DBT418)	Monsanto Novartis	A380 A385	
	(Bt-176 Maize) (Bt-11 Maize)	Novartis	A386	
POTATO	**Insect resistance:** Bt	Monsanto	A382	
	Insect resistance & virus resistance: Bt & potato virus Y (PVY) resistant (known as New Leaf Y)	Monsanto	A384	May include snack foods, processed potato products and other processed foods.
	Bt & potato leaf roll virus (PLRV) resistant (known as New Leaf Plus)	Monsanto	A383	
SUGAR-BEET	**Herbicide tolerance:** Glyphosate	Monsanto/Novartis	A378	May include any processed foods containing sugar.
COTTON	**Insect resistance:** Bt - Cry1Ac gene	Monsanto	A341	Cottonseed oil and linters. Products may include blended vegetable oils, fried foods, baked foods, snack foods, edible oil products, and smallgoods casings.
	Herbicide tolerance: Glyphosate	Monsanto	A355	
	Bromoxynil	Monsanto/Rhone Poulenc	A379	

Attachment 2

Permitted processing aids derived from GM varieties as at June 2001[1]

1. α-Acetolactate decarboxylase is produced by a genetically manipulated strain of *Bacillus subtilis* containing the gene for α-acetolactate decarboxylase isolated from *Bacillus brevis* and inserted using plasmid pUW235.
   Applicant: Novozymes Australia Pty Ltd.
   Date approved: 09/03/94
2. α-Amylase produced from a genetically manipulated strain of *Bacillus licheniformis* containing the gene for α-amylase isolated from *Bacillus stearothermophilus* and inserted using plasmid pPL1117.
   Applicant: Novozymes Australia Pty Ltd.
   Date approved: 09/03/94
3. α-Amylase produced from a genetically manipulated strain of *Bacillus subtilus* containing the gene for α-amylase isolated from *Bacillus stearothermophilus* and inserted using plasmid pPN1413.
   Applicant: Novozymes Australia Pty Ltd.
   Date approved: 18/01/94
4. Lipase produced from a genetically manipulated strain of *Aspergillus oryzae* containing the gene for lipase isolated from *Humicola lanuginosa* and inserted using plasmids pBoe1960 and p3SR2.
   Applicant: Novozymes Australia Pty Ltd.
   Date approved: 18/07/96
5. Hemicellulose endo-1,4-ß-xylanase produced from a genetically manipulated strain of *Aspergillus oryzae* containing the gene for hemicellulase isolated from *Thermomyces lanuginosus* and inserted using plasmids pA2X1T1 and pToC90.
   Applicant: Novozymes Australia Pty Ltd.
   Date approved: 5/05/97
6. Hemicellulose endo-1,4-ß-xylanase produced from a genetically manipulated strain of *Aspergillus oryzae* containing the gene for hemicellulase isolated from *Aspergillus aculeatus* and inserted using plasmid pToC237.
   Applicant: Novozymes Australia Pty Ltd.
   Date approved: 5/05/97
7. Mucorpepsin produced from genetically manipulated strain of the fungus *Aspergillus oryzae* containing the gene for aspartic proteinase isolated from *Rhizomucor miehei* and inserted using the vector *Escherichia coli* K12.
   Applicant: Novozymes Australia Pty Ltd.
   Date approved: 25/10/95
8. Chymosin produced from genetically manipulated organisms *Aspergillus niger var. awamori*, *Escherichia coli* K12 strain GE81 or *Kluyveromyces lactis* CHY1.
   Date approved: 14/08/91.

1 This list is subject to change. Consult the ANZFA Internet site for updates.

Attachment 3

Table to Clause 2 of Standard A18/1.5.2[1]

Column 1 Food produced using gene technology	Column 2 Special conditions
Oil derived from glyphosate-tolerant canola line GT73 Food derived from glyphosate-tolerant corn line GA21 Food derived from insect-protected corn line MON 810 Oil and linters derived from glyphosate-tolerant cotton line 1445 Oil and linters derived from insect-protected cotton lines 531, 757 and 1076 Food derived from glyphosate-tolerant soybean line 40-3-2	
Food derived from high oleic acid soybean lines G94-1, G94-19 and G168	The label on or attached to a package of a food derived from high oleic acid soy bean lines G94-1, G94-19 and G168 must include a statement to the effect that the food has been genetically modified to contain high levels of oleic acid.
Food derived from insect protected, glufosinate ammonium-tolerant Bt-11 corn*. Food derived from insect protected Bt-176 corn*. Food derived from insect and potato virus Y-protected potato lines RBMT15-101, SEM15-02 and SEM15-15*.	

1 This list incorporates all GM food commodities approved by the Ministerial Council to August 2001. Those asterisked (*) were approved on 31 July 2001. The list is subject to change. Consult the ANZFA Internet site for updates.

Food derived from insect and potato leafroll virus-protected potato lines RBMT21-129, RBMT21-350, and RBMT22-82*. Food derived from insect-protected potato lines BT-06, ATBT04-06, ATBT04-31, ATBT04-36, and SPBT02-05*.	