**22 August 2001**
**03/02**

# FULL ASSESSMENT REPORT

# PROPOSAL P249

# DEVELOPMENT OF "STOCK-IN-TRADE" PROVISIONS (GM LABELLING)

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## EXECUTIVE SUMMARY

On 24 November 2000, the Australia New Zealand Food Standards Council (ANZFSC) adopted an amended version of Standard A18 in Volume 1 of the *Food Standards Code* and Standard 1.5.2 for inclusion in Volume 2 of the *Food Standards Code*. Standard A18 and Standard 1.5.2 as adopted by Health Ministers included Division 2 (which extended labelling requirements for genetically modified (GM) foods) which is due to take legal effect on 7 December 2001; 12 months from the date of gazettal of the amended Standards.

It appears to date, that limited consideration has been given to the issue of whether food products produced lawfully prior to 7 December 2001. These GM foods would not comply with the labelling requirements in Division 2 and would be illegal to sell immediately following this date.

In New Zealand, subsection 42(4) of the *Food Act 1981* makes provision for the lawful sale of food which can be shown to have been "stock-in-trade" prior to the date of any change to food regulations. This provision only relates to "food regulations" and not to "food standards" contained with the *Food Standards* Code. Furthermore, no such provision exists in the food legislation of the Australian States and Territories.

The Authority's preliminary view is that it would be unreasonable to require the removal of GM foods produced and labelled in accordance with the requirements in place prior to 7 December 2001 (the date of commencement of the GM labelling requirements). The Authority therefore proposes to allow GM foods produced prior to 7 December 2001 to lawfully remain on the market for a further period of 12 months. GM foods produced or imported after 7 December 2001 will still be required to comply with Standard A18 or Standard 1.5.2 in their entirety.

# 1 INTRODUCTION

On 1 July 1996, an Agreement between Australia and New Zealand (the Treaty) came into force that established a joint Australian New Zealand Food Standards System, which served to underpin the development of Volume 2 of the *Food Standards Code* (Volume 2).

Under the Treaty, during the transition period to the joint system, products sold in New Zealand and Australia could comply with either the New Zealand *Food Regulations 1984* (NZFR), (if manufactured or imported into New Zealand) or Volume 1 of the *Food Standards Code* (Volume 1) (formerly known as the Australian *Food Standards Code*) until such time as Volume 2 had been developed and became the sole set of regulations for the two countries.

Volume 2 came into effect in Australia on 20 December 2000 and in New Zealand on 8 February 2001. It is expected that Volume 1 of the *Food Standards Code* and relevant parts of the New Zealand *Food Regulations 1984* will be repealed towards the end of 2002, leaving Volume 2 as the sole repository of food standards in Australia and New Zealand (under the joint food standards setting system).

# 2 BACKGROUND

## 2.1 Development of Standard for regulation of GM foods

The August 1999 meeting of the Australia New Zealand Food Standards Code (ANZFSC) resolved to adopt mandatory labelling of genetically modified foods (GMF) under Standard A18 – Foods Produced from Gene Technology. ANZFSC requested that ANZFA develop a draft Standard which provided a method of labelling that was practical, meaningful, and with the lowest possible compliance costs.

In October 1999, ANZFSC met to consider the draft Standard developed by an Inter-Governmental Task Force on Genetically Modified Food Labelling. The draft Standard consists of two parts. The first part (Division 1) relates to safety, and prohibits the sale of unapproved genetically modified (GM) foods. The second part (Division 2) relates to the labelling of GM food and food ingredients (whether packaged or unpackaged), additives, and processing aids. At this meeting, ANZFSC also requested that ANZFA publish (the then) draft StandardA18 for further public comment and consultation.

Ministers also requested that the Task Force produce a protocol of compliance and enforcement for the draft Standard with the principal objective of balancing effectiveness and cost efficiency.

On 28 July 2000, the Australia New Zealand Food Standards Council (ANZFSC), agreed in principle to draft Standard A18, and a revised version of Standard 1.5.2. On 24 November, ANZFSC formally adopted draft Standard A18 in Volume 1 of the *Food Standards Code* and Standard 1.5.2 for inclusion in Volume 2 of the *Food Standards Code*. Standard A18 and Standard 1.5.2 as adopted by Health Ministers included Divisions 1 and Division 2 as described above. Division 2 includes the labelling provisions and is due to take legal effect on 7 December 2001, which is twelve months from the date of gazettal of the amended Standards.

## 2.2 Standard A18 and Standard 1.5.2

### *2.2.1 Division 1*

Division 1 of Standard A18 and Standard 1.5.2 prohibit the sale of foods produced using gene technology unless specifically permitted to do so. To this date, 12 foods produced using gene technology have been approved for sale.

### *2.2.2 Division 2*

Division 2 imposes labelling requirements on genetically modified foods and is due to come into legal effect on 7 December 2001 in both countries.

## 2.3 Application of Standard A18 and Standard 1.5.2

### *2.3.1 Australia*

The Food Acts of the Australian States and Territories and the *Imported Food Control Act 1992* (Commonwealth) require that food for sale or imported into Australia must comply with the requirements of Standard A18 or Standard 1.5.2.

There are no provisions in the Food Acts of the States and Territories, nor in the *Imported Food Control Act 1992* that specifically make allowance for the continued lawful sale of "stock-in-trade" when changes to food standards are made.

### *2.3.2 New Zealand*

In New Zealand, food for sale, or food imported into New Zealand, must comply with Standard A18 in Volume 1 or Standard 1.5.2 in Volume 2 of the *Food Standards Code*. On 20 December 2000, the Minister of Health under the *Food Act 1981* (New Zealand), issued the "*New Zealand Food Standard 2001*" in which Standard A18 and Standard 1.5.2 were declared to be mandatory food standards.

Subsections 42(4) and 42(5) of the *Food Act 1981* (New Zealand) provide –

> (4) Notwithstanding anything contained in any regulations made under this section, it shall be lawful for any person, at any time within 12 months after the date of the commencement of the regulations, to sell any food of which the sale is otherwise lawful, if he proves that at the said date the food was part of the existing stock-in-trade in New Zealand of any person carrying on business there, and that since the said date no act has been done whereby the food fails to conform to the regulations.
>
> (5) For the purposes of subsection (4) of this section, any goods purchased before the said date for importation into New Zealand shall be deemed to be part of the purchaser's stock-in-trade in New Zealand.

The effect of subsection 42(4) is to create a defence for stock-in-trade food that is made unlawful by any amendments to the *Food Regulations 1984* or *Dietary Supplements Regulations 1985*. Subsection 42(5) of the Act goes on to provide that, for the purposes of subsection (4), any goods purchased before the said date for importation into New Zealand shall be deemed to be part of the purchaser's "stock-in-trade" in New Zealand.

These "stock-in-trade" provisions do not apply to the *Food Standards Code*, as the Code is issued as a "food standard", under section 11C of the *Food Act 1981*, rather than as "regulations" under section 42.

## 2.4 Implementation of GM food labelling requirements

In the Intergovernmental Taskforce Report on the labelling of genetically modified foods provided to the ANZFSC meeting on 28 July 2000, the Task Force addressed the issue of implementation of the labelling provisions in the following manner -

> "26. Date of Implementation
>
> - Industry raised the issue of the timing of implementation and urged that the 12-month implementation period be extended to take into consideration long shelf-life products that would remain on the market, unlabelled, after the commencement date. Industry also urged that the revised Standard come into effect at the same time as the new Joint Code.
>
> - The Task Force considered that industry has had notification of the intended labelling regulations for over 18 months and that a 12-month implementation period is likely to be sufficient for the significant majority of products to be turned over and long shelf-life products should not be a major issue.
>
> - The Task Force recommended that 12-month implementation period be applied to the revised Standard.
>
> - If Ministers consider that this is still a significant issue they may agree that the revised Standard be applied to foods produced after the date of commencement."

ANZFSC decided that a 12 month implementation period was sufficient to allow industry to implement the revised labelling requirements. However, since this date, it has become apparent that industry will encounter significant difficulty in ensuring that food products manufactured prior to 7 December 2001 will comply with the labelling requirements being imposed after that date. During the 'Stakeholder Forum' discussions held by ANZFA at the time of its Board meeting in May 2001, a number of industry representatives raised the possibility of implementing a 'stock-in-trade' provision for the operation of the new GM food labelling requirements due to commence on 7 December 2001.

The Food Regulation Standing Committee recommended to the ANZFSC meeting of 31 July 2001, that ANZFA be requested to raise a proposal to consider the development of provisions relating to "stock-in-trade". This recommendation followed representations from the food industry advising that it was considered necessary to include provisions in the *Food Standards Code* which had the effect of allowing the continued sale of "stock-in-trade" in existence prior to 7 December 2001, the scheduled commencement date of the GM food labelling requirements.

Of particular concern was how long shelf life foods produced in the months prior to 7 December 2001 would be handled. It was argued that an explicit provision in he Food

Standards Code was necessary to permit products manufactured prior to 7 December 2001, but still legally available for sale after this date.

The Council of Health Ministers at their meeting in July 2001 requested that ANZFA prepare a proposal considering the development of provisions that permitted "stock-in-trade" manufactured or packed prior to 7 December 2001 to continue to be lawfully sold after that date.

### 2.5 International and World Trade Organization obligations

Australia and New Zealand are members of the World Trade Organization (WTO) and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the Treaty between the Governments of Australia and New Zealand on joint Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

### 2.6 International and Overseas Standards

#### *2.6.1 Codex Alimentarius*

Being investigated

#### *2.6.2 European Commission Directive*

Being investigated

#### *2.6.3 United States*

Being investigated

## 3 OBJECTIVES & POLICY

### 3.1 Objectives of Development of a "stock-in trade" provision

The development of all food standard(s) is predicated on fulfilling ANZFA's Section 10 objectives given below.

**ANZFA's statutory objectives in developing food regulatory measures and variations of food regulatory measures**

(1) The objectives (in descending priority order) of the Authority in developing food regulatory measures and variations of food regulatory measures are:
   (a) the protection of public health and safety; and

(b) the provision of adequate information relating to food to enable consumers to make informed choices; and
(c) the prevention of misleading or deceptive conduct.

(2) In developing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:
(a) the need for standards to be based on risk analysis using the best available scientific evidence;
(b) the promotion of consistency between domestic and international food standards;
(c) the desirability of an efficient and internationally competitive food industry;
(d) the promotion of fair trading in food.

The development of food standard(s) are also carried out in accordance with the competition policy principles which have been adopted by the Council of Australian Governments (COAG) and the draft Code of Good Regulatory Practice (New Zealand). These principles require the review of all business regulation to remove unnecessary obstacles to competition and an assessment of proposed regulation on all affected sectors of the community, and can be encapsulated in the phrase 'minimum effective regulation'.

The specific objectives for this Proposal are to:

1. Provide information to consumers to enable them to make informed choices about the consumption of GM foods and/or ingredients and to prevent misleading or deceptive conduct.

2. Not jeopardise the efficiency and international competitiveness of the food industry of Australia and New Zealand.

An assessment of this proposal must necessarily involve a balancing of these statutory objectives.

## 4 OPTIONS FOR REGULATION

There are two options for the implementation of the GM foods labelling requirements:

**4.1 Option 1**: Status Quo – Require all food prepared for sale, packed for sale, or imported for sale before and after 7 December 2001 to comply with the labelling requirements of Standard A18 and Standard 1.5.2

**4.2 Option 2**: Develop provisions that allow the continued lawful sale of foods produced prior to 7 December 2001, after that date.

## 5 AFFECTED PARTIES

The parties affected by this application are set out below.

**5.1 Consumers** in Australia and New Zealand;

**5.2 Food industry**, including New Zealand and Australian manufacturers, exporters to Australia and New Zealand including multi-national manufacturers, and New Zealand and Australian importers;

**5.3 Governments** of New Zealand, the States and Territories and the Commonwealth of Australia.

## 6 IMPACT ANALYSIS

### 6.1 Option 1

Status Quo – Require all food prepared for sale, packed for sale, or imported for sale before and after 7 December 2001 to comply with the labelling requirements of Standard A18 and Standard 1.5.2

***Government***

*Advantages*

- None identified

*Disadvantages*

- Food may need to be recalled to comply with labelling requirements.

***Consumers***

*Advantages*

- Foods available for sale will contain information relating to the genetically modified food content.

*Disadvantages*

- Substantial amount of food that is safe to consume may cease to be available due to the recall of such products. The costs of determining genetically modified food content of such foods and re-labelling if necessary is likely to be passed on to consumers.
- Potential for significant disruption to the market place.

***Industry***

*Advantages*

- None identified

*Disadvantages*

- Substantial costs of determining whether foods already packaged for sale contain genetically modified foods and if so, the costs of re-labelling these products.

- Potential for significant disruption to the market place.

### 6.2 Option 2

Develop provisions that allow the continued lawful sale of foods produced prior to 7 December 2001, after that date.

***Government***

*Advantages*

- Not incur additional costs of conducting a recall of non-compliant food products.

*Disadvantages*

- None identified.

***Consumers***

*Advantages*

- Food products lawfully produced prior to 7 December 2001 would remain available for sale.
- Avoiding the additional flow on costs of re-labelling foods produced prior to 7 December 2001.
- Removing the detrimental affects of a potentially disrupted food market.

*Disadvantages*

- Some foods may remain on the markets without the requirement of declaring the presence of GM foods.

***Industry***

*Advantages*

- Food products lawfully produced prior to 7 December 2001 would remain available for sale.
- Avoiding the additional costs of re-labelling foods produced prior to 7 December 2001.
- Avoid potential for significant disruption to the market place.

*Disadvantages*

- None

## 7 ASSESSMENT

### 7.1 Assessment against objectives set out section 10 of the ANZFA Act.

Division 1 of Standard A18 and Standard 1.5.2 was adopted by ANZFSC with a view to the protection of the public health and safety of the populations of New Zealand and Australia.

This is achieved by requiring that all foods produced using gene technology be approved for use as foods before being able to be lawfully sold in either jurisdiction.

Division 2 of Standard A18 and Standard 1.5.2 was adopted by ANZFSC with a view to providing information to consumers to enable informed choices about the food they choose to purchase and consume.

### 7.2 Implementation of Standard A18 and Standard 1.5.2

In developing and adopting standards, ANZFA and ANZFSC are obliged to do so in a manner that protects the public health and safety of consumers and provides adequate information to consumers to allow informed choice and prevent false or misleading conduct. This must however be done in a manner that does not unnecessarily impact upon the efficiency and international effectiveness of the food industry in New Zealand and Australia.

It appears that since the gazettal of the Standards, the issue of how food products manufactured or imported into Australia or New Zealand prior to 7 December 2001, had not been specifically considered. State and Territory enforcement agencies indicated at this time to the food industry that enforcement priorities would be focused on the date of manufacture of the product rather than the date of sale of the product. It has become apparent that this approach does not provide the certainty that the food industry requires in order to effectively carry on their business.

### 7.3 Conclusion

ANZFA's preliminary view is that it is unreasonable to require retailers to remove GM foods from their shelves on 7 December 2001 that were able to be lawfully sold the day before. To do so would potentially mean the removal of substantial quantities of food from retailers' shelves because the labelling requirements have changed from those in effect at the date of manufacture of the food. This could be considered an unwarranted and arbitrary imposition on industry and ultimately on consumers to do so. It is therefore proposed to provide an a defence to food manufactured or imported into Australia or New Zealand prior to 7 December 2001, with respect to the labelling requirements set out in Division 2 of Standard A18 and Standard 1.5.2.

However, ANZFA does not consider it reasonable, in the light of the objectives prescribed in section 10 of the ANZFA Act, to provide an open-ended exemption for food produced or imported into Australia or New Zealand prior to 7 December 2001. A balance must be struck between consumers' ability to access information under the operation of the Standard, and industry's ability to adapt in a reasonably cost effective manner to the new requirements.

In New Zealand, subsection 42(4) of the *Food Act 1981* (New Zealand), provides a 12 month limit on any concession being granted to food products which are part of the existing stock-in-trade in New Zealand of any person carrying on business there at the date of any amendments to the food regulations.

While subsection 42(4) does not apply in New Zealand in relation to food standards, this would appear to have provided a balance that the food industry has not to this date indicated was problematic. It would therefore seem reasonable in the circumstances to limit the proposed immunity to a period of 12 months. This further period would provide industry with the opportunity to identify affected products and re-label if necessary.

## 8 CONSULTATION NEED TO DISCUSS THIS PART

### 8.1 Invitation for Public Submissions

**Simplified procedures**

The Authority has decided, pursuant to section 36 of the *Australia New Zealand Food Authority Act 1991*, to omit to invite public submissions in relation to the proposal prior to making a full assessment. The Authority is satisfied that omitting to invite public submissions prior to making a full assessment (making a draft assessment) is warranted as the proposal deals raises matters of a mechanical nature that are of minor significance or complexity. Furthermore, the Authority considers that omitting to invite public submissions prior to making a full assessment, will not significantly adversely affect the interests of any person or body. Section 63 of the Act provides that, subject to the *Administrative Appeals Tribunal Act 1975*, an application for a review of the Authority's decision may be made to the Administrative Appeals Tribunal by a person whose interests are significantly affected by the decision to omit to invite public submissions in relation to the proposal.

The Authority has completed a full assessment of the proposal, developed draft variations to Standard A18 in Volume 1 and Standard 1.5.2 in Volume 2 of the *Food Standards Code* and will now conduct an inquiry to consider the draft variations and their regulatory impact.

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a final assessment on matters relevant to the proposal, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment. Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

### 8.2 Release for Public Consultation

This Proposal/ Full Assessment Report is released in August 2001 with a three-week consultation period. The views of the submitters will be incorporated into the development of the Inquiry Report.

**FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND**

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to

adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *(Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999.*

- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, but not a combination of the two.

- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the New Zealand *Food Regulations 1984.*

- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts.*

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the Australian *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

## 8.3 INVITATION FOR PUBLIC SUBMISSIONS

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a draft assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

Following its draft assessment of the application the Authority may prepare a draft standard or draft variation to a standard (and supporting draft regulatory impact statement), or decide to reject the application. If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the inquiry, which the Authority will hold to consider the draft standard or draft variation to a standard.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Proposal P249**at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra Mail Centre ACT 2610
AUSTRALIA
Tel (02) 6271 2222 Fax (02) 6271 2278

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Fax (04) 473 9942 Fax (04) 473 9855

Submissions should be received by the Authority by: **12 September 2001**.

## 9 CONCLUSION

This Proposal/Full Assessment Report discusses issues specific to the application of the GM food labelling provisions in Division 2 of Standard A18 and Standard 1.5.2 to “stock-in-trade”. This Report is accompanied by draft variations to Standard A18 and Standard 1.5.2 for which ANZFA seeks public comment. Responses to this Report will be used to develop

the next stage of the Proposal, including drafting an Inquiry Report and recommendation to the Australia New Zealand Food Standards Council.

## 10 ATTACHMENTS

1. Draft variations to Standard A18 in Volume 1 and Standard 1.5.2 in Volume 2 of the Food Standards Code
2. Current Standard A18 in Volume 1 of the *Food Standards Code*
3. Current Standard 1.5.2 in Volume 2 of the *Food Standards Code*

**To commence: On gazettal**

*Division 2 of Standard A18 of Volume 1 and Standard 1.5.2 of Volume 2 of the Food Standards Code is varied by inserting immediately after subclause 4(4) –*

(5) This Division does not apply to food packaged, manufactured or imported into Australia or New Zealand prior to 7 December 2001 for a period of 12 months after the commencement of that Division.

**Editorial Note:**

Subclause 4(5) will cease to operate on 7 December 2002. From this date all food will need to comply with the labelling requirements in Division 2.

**ATTACHMENT 2**

# *STANDARD A18*

# *FOOD PRODUCED USING GENE TECHNOLOGY*

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**Purpose**

Division 1 of this Standard addresses health and safety requirements, regulating the sale of food produced using gene technology, other than additives and processing aids. The Standard prohibits the sale and use of these foods unless they are included in the Table to clause 2 and comply with any special conditions in that Table.

The Authority will assess the safety for human consumption of each food produced using gene technology or such class of food prior to its inclusion in the Table. The safety assessment will be performed according to the Authority's approved safety assessment criteria.

Additives and processing aids which are produced using gene technology are not regulated in Division 1 of this Standard. Other Standards in this Code regulate additives and processing aids and require pre-market approval for these substances.

Division 2 of this Standard specifies labelling and other information requirements for foods, including food additives and processing aids, produced using gene technology.

**Table of Provisions**



**Clauses**

## Division 1 – Sale and use of food produced using gene technology

### 1 Interpretation

For the purposes of this Standard -

**a food produced using gene technology** means a food which has been derived or developed from an organism which has been modified by gene technology.

**Editorial note:**
This definition does not include a food derived from an animal or other organism which has been fed food produced using gene technology, unless the animal or organism itself is a product of gene technology.

**gene technology** means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.

## 2 General prohibition on the sale and use of food produced using gene technology

A food produced using gene technology, other than a substance regulated as a food additive or processing aid, must not be sold or used as an ingredient or component of any food unless it is listed in Column 1 of the Table to this clause and complies with the conditions, if any, specified in Column 2.

**TABLE TO CLAUSE 2**

| **Column 1**<br>**Food produced using gene technology** | **Column 2**<br>**Special conditions** |
|---|---|
| Oil derived from glyphosate-tolerant canola line GT73<br>Food derived from glyphosate-tolerant corn line GA21<br>Food derived from insect-protected corn line MON 810<br>Oil and linters derived from glyphosate-tolerant cotton line 1445<br>Oil and linters derived from insect-protected cotton lines 531, 757 and 1076<br>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 |

## 3 Exemption to general prohibition on sale and use

(1) For the purposes of this clause -

(a) the Act means the Australia New Zealand Food Authority Act 1991;
(b) the Authority means the Australia New Zealand Food Authority established under the Act;
(c) the Council means the Australia New Zealand Food Standards Council.

(2) The prohibition in clause 2 does not apply to a food produced using gene technology where -

(a) that food is the subject of an application under section 12 of the Act to vary the Table to that clause;
(b) the application has been accepted in accordance with section 13 of the Act by the Authority on or before 30 April 1999;

(c) the Authority has evidence that that food, in one or more countries, other than Australia or New Zealand, is lawfully permitted to be sold or used as an ingredient or component, by a national food regulatory agency; and

(d) the Council has not become aware of evidence that that food poses a significant risk to public health and safety.

## Division 2 - Labelling etc of food produced using gene technology

### 4 Interpretation and Application

(1) For the purposes of this Division -

**genetically modified food** means food which is, or contains as an ingredient, including a processing aid, a food produced using gene technology which -

(a) contains novel DNA and/or novel protein; or

(b) has altered characteristics;

but does not include -

(c) highly refined food, other than that with altered characteristics, where the effect of the refining process is to remove novel DNA and/or novel protein;

(d) a processing aid or food additive, except where novel DNA and/or novel protein from the processing aid or food additive remains present in the food to which it has been added;

(e) flavours present in the food in a concentration no more than 1g/kg; or

(f) a food, ingredient, or processing aid in which genetically modified food is unintentionally present in a quantity no more than 10g/kg per ingredient.

**altered characteristics** means any of the matters specified in paragraphs 7(a), (b), (c) or (d) of this Standard.

**novel DNA and/or novel protein** means DNA or a protein which, as a result of the use of gene technology, is different in chemical sequence or structure from DNA or protein present in counterpart food which has not been produced using gene technology.

(2) Any statement required by clause 5 may be contained in the statement of ingredients where the genetically modified food is an ingredient or processing aid.

(3) Where genetically modified food is displayed for retail sale other than in a package, any information that would have been required under clause 5 of this Standard on the label on or attached to the food if it was packaged, must be displayed on or in connection with the display of the food.

(4) This Division does not apply to food intended for immediate consumption which is prepared and sold from food premises and vending vehicles, including restaurants, take away outlets, caterers, or self-catering institutions.

## 5 Labelling of genetically modified food

The label on or attached to a package of genetically modified food must include the statement 'genetically modified' in conjunction with the name of that food or ingredient or processing aid.

**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.

## 6 Labelling of food which is not genetically modified

The label on or attached to a package of food which is not defined as 'genetically modified food' in clause 4 of this Standard is not required to include any statement about the genetic status of the food.

## 7 Additional labelling/information requirements

Notwithstanding the provisions of this Division, Column 2 of the Table to clause 2 may specify labelling or other information requirements in relation to food produced using gene technology listed in Column 1 of the Table where -

(a) the genetic modification has resulted in one or more significant composition or nutritional parameters having values outside the normal range of values for existing counterpart food not produced using gene technology;
(b) the level of anti-nutritional factors or natural toxicants are significantly different in comparison to the existing counterpart food not produced using gene technology;
(c) the food produced using gene technology contains a new factor known to cause an allergic response in particular sections of the population;
(d) the intended use of the food produced using gene technology is different to the existing counterpart food not produced using gene technology; or
(e) the genetic modification raises significant ethical, cultural and religious concerns regarding the origin of the genetic material used in the genetic modification.

**Editorial notes:**

The Compliance Guide for Standard A18 as published by the Australia New Zealand Food Authority should be read in conjunction with this Standard.

Claims about genetic modification or its absence are subject to the Australian Trade Practices Act 1974 and State and Territory Food Acts, and the Western Australian Health Act, and the New Zealand Fair Trading Act 1986 and Food Act.

Division 2 of this Standard is to be reviewed 3 years from its date of gazettal.

**ATTACHMENT 3**

# *STANDARD 1.5.2*

# *FOOD PRODUCED USING GENE TECHNOLOGY*

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**Purpose**

Division 1 of this Standard addresses health and safety requirements, regulating the sale of food produced using gene technology, other than additives and processing aids. The Standard prohibits the sale and use of these foods unless they are included in the Table to clause 2 and comply with any special conditions in that Table.

The Authority will assess the safety for human consumption of each food produced using gene technology or such class of food prior to its inclusion in the Table. The safety assessment will be performed according to the Authority's approved safety assessment criteria.

Additives and processing aids which are produced using gene technology are not regulated in Division 1 of this Standard. Other Standards in this Code regulate additives and processing aids and require pre-market approval for these substances.

Division 2 of this Standard specifies labelling and other information requirements for foods, including food additives and processing aids, produced using gene technology.

**Table of Provisions**



**Clauses**

## Division 1 – Sale and use of food produced using gene technology

### 1 Interpretation

For the purposes of this Standard -

**a food produced using gene technology** means a food which has been derived or developed from an organism which has been modified by gene technology.

**Editorial note:**

This definition does not include a food derived from an animal or other organism which has been fed food produced using gene technology, unless the animal or organism itself is a product of gene technology.

**gene technology** means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.

## 2 General prohibition on the sale and use of food produced using gene technology

A food produced using gene technology, other than a substance regulated as a food additive or processing aid, must not be sold or used as an ingredient or component of any food unless it is listed in Column 1 of the Table to this clause and complies with the conditions, if any, specified in Column 2.

**Table to clause 2**

| Column 1 | Column 2 |
|---|---|
| **Food produced using gene technology** | **Special conditions** |
| Oil derived from glyphosate-tolerant canola line GT73<br><br>Food derived from glyphosate-tolerant corn line GA21<br><br>Food derived from insect-protected corn line MON810<br><br>Oil and linters derived from glyphosate-tolerant cotton line 1445<br><br>Oil and linters derived from insect-protected cotton lines 531, 757 and 1076<br><br>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 |

## 3 Exemption to general prohibition on sale and use

(1) For the purposes of this clause -

(a) the Act means the *Australia New Zealand Food Authority Act 1991*;
(b) the Authority means the Australia New Zealand Food Authority established under the Act;
(c) the Council means the Australia New Zealand Food Standards Council.

(2) The prohibition in clause 2 does not apply to a food produced using gene technology where -

(a) that food is the subject of an application under section 12 of the Act to vary the Table to that clause;
(b) the application has been accepted in accordance with section 13 of the Act by the Authority on or before 30 April 1999;
(c) the Authority has evidence that that food, in one or more countries, other than Australia or New Zealand, is lawfully permitted to be sold or used as an ingredient or component, by a national food regulatory agency; and
(d) the Council has not become aware of evidence that that food poses a significant risk to public health and safety.

## Division 2 - Labelling etc of food produced using gene technology

### 4 Interpretation and Application

(1) For the purposes of this Division -

**genetically modified food** means food that is, or contains as an ingredient, including a processing aid, a food produced using gene technology which -

(a) contains novel DNA and/or novel protein; or
(b) has altered characteristics;

but does not include –

(c) highly refined food, other than that with altered characteristics, where the effect of the refining process is to remove novel DNA and/or novel protein;
(d) a processing aid or food additive, except where novel DNA and/or novel protein from the processing aid or food additive remains present in the food to which it has been added;
(e) flavours present in the food in a concentration no more than 1g/kg; or
(f) a food, ingredient, or processing aid in which genetically modified food is unintentionally present in a quantity of no more than 10g/kg per ingredient.

**altered characteristics** means any of the matters specified in paragraphs 7(a), (b), (c) or (d) of this Standard.

**novel DNA and/or novel protein** means DNA or a protein which, as a result of the use of gene technology, is different in chemical sequence or structure from DNA or protein present in counterpart food which has not been produced using gene technology.

(2) Any statement required by clause 5 may be contained in the statement of ingredients where the genetically modified food is an ingredient or processing aid.

(3) Where genetically modified food is displayed for retail sale other than in a package, any information that would have been required under clause 5 of this Standard on the label on the food if it was packaged, must be displayed on or in connection with the display of the food.

(4) This Division does not apply to food intended for immediate consumption which is prepared and sold from food premises and vending vehicles, including restaurants, take away outlets, caterers, or self-catering institutions.

## 5 Labelling of genetically modified food

The label on a package of genetically modified food must include the statement 'genetically modified' in conjunction with the name of that food or ingredient or processing aid.

**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.

## 6 Labelling of food which is not genetically modified

The label on a package of food which is not defined as 'genetically modified food' in clause 4 of this Standard is not required to include any statement about the genetic status of the food.

## 7 Additional labelling/information requirements

Notwithstanding the provisions of this Division, Column 2 of the Table to clause 2 may specify labelling or other information requirements in relation to food produced using gene technology listed in Column 1 of the Table where –

(a) the genetic modification has resulted in one or more significant composition or nutritional parameters having values outside the normal range of values for existing counterpart food not produced using gene technology;
(b) the level of anti-nutritional factors or natural toxicants are significantly different in comparison to the existing counterpart food not produced using gene technology;
(c) the food produced using gene technology contains a new factor known to cause an allergic response in particular sections of the population;
(d) the intended use of the food produced using gene technology is different to the existing counterpart food not produced using gene technology; or

(e) the genetic modification raises significant ethical, cultural and religious concerns regarding the origin of the genetic material used in the genetic modification.

**Editorial notes:**

The Compliance Guide for Standard 1.5.2 as published by the Australia New Zealand Food Authority should be read in conjunction with this Standard.

Claims about genetic modification or its absence are subject to the *Australian Trade Practices Act 1974* and State and Territory Food Acts, and the Western Australian Health Act, and the *New Zealand Fair Trading Act 1986* and Food Act.

Division 2 of this Standard is to be reviewed 3 years from its date of gazettal.