**TE MANA WHAKARITE KAI MO AHITEREIRIA ME AOTEAROA**

# A SUBMISSION

**from the**

# AUSTRALIA NEW ZEALAND FOOD AUTHORITY

**to the**

# INQUIRY INTO PRIMARY PRODUCER ACCESS TO GENE TECHNOLOGY

**conducted by the**

## HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON PRIMARY INDUSTRIES AND REGIONAL SERVICES

## INTRODUCTION

The Australia New Zealand Food Authority (ANZFA), established by the *Australia New Zealand Food Authority Act 1991*, was created as the National Food Authority in 1991 following an inter–governmental agreement between the Commonwealth, States and Territories, to develop nationally uniform food standards. In 1996, as an extension of Australia's closer economic relationship with New Zealand, Australia and New Zealand entered into a Treaty establishing a joint food standards system underpinned by a joint *Australia New Zealand Food Standards Code*. The joint Code is due to be implemented in the year 2000.

Under the 1991 Agreement and the Treaty, decisions on the development or variation to food standards and other major food regulation issues are taken jointly by Ministers from all participating jurisdictions in their role as the Australia New Zealand Food Standards Council (ANZFSC). These decisions are based on recommendations from the ANZFA Board.

Enforcement of the *Food Standards Code* is undertaken by the State and Territory departments of health, and in many cases local governments, under their Food Act (or in some States, under the Public Health Act). ANZFA's role is limited to coordinating these activities despite a public perception that it is responsible for enforcement. [It is important to note that the Australian Constitution gives no direct powers over food regulation to the Commonwealth and the Commonwealth Government cannot set or vary food standards (other than jointly with a majority of other ANZFSC Ministers), nor can it enforce the standards in the States and Territories or require the States to enforce them.]

## BACKGROUND TO ANZFA's INVOLVEMENT IN GENE TECHNOLOGY

### Development of Standard A18

ANZFA has been involved in the issue of gene technology and its use in food production since about 1992 (as the then National Food Authority). This involvement culminated with a proposal for the development of a standard (Standard A18) for the regulation of such foods. This standard was finalised in February 1998 and was subsequently recommended to ANZFSC (Attachment 1). Standard A18 was adopted by ANZFSC on 30 July 1998 and came into effect on 13 May 1999.

The effect of Standard A18 is to prohibit the sale of food produced using gene technology unless an application for pre–market assessment has first been made to ANZFA with subsequent approval by ANZFSC. The assessment of the application is done according to ANZFA's statutory processes (Attachment 2) and generally involves two rounds of public comment plus a scientific risk assessment (Attachment 3).

There were essentially two reasons for ANZFA developing Standard A18. Firstly, to provide a mechanism whereby consumers can be confident that foods produced using gene technology are assessed as safe for human consumption before they are

permitted for sale. Secondly, to provide the agrifood sector with a clear regulatory pathway for the assessment and approval of food produced using gene technology.

**Labelling**

Standard A18 also contains a provision for labelling. Under that provision, food which has been significantly changed with respect to its nutritional quality, composition, allergenicity, or end use (that is, no longer substantially equivalent to its conventional counterpart) must be labelled to indicate the origin and nature of the characteristic that has been modified.

Some consumers have allergies to foods or need to keep a close watch on the nutritional content of their diet. For these reasons, it is vital that a label states where foods are different to their established counterparts. The need for this information to be on labels is generally accepted in Australia and New Zealand and internationally.

While it was accepted by ANZFSC, when it adopted Standard A18, that mandatory labelling is warranted for foods that are not substantially equivalent they deferred the question of whether so called substantially equivalent foods should also be labelled. At a later meeting of ANZFSC, held in December 1998, a majority of Health Ministers decided that the mandatory labelling requirements should be broadened to include foods that are substantially equivalent and directed ANZFA to develop a draft amendment to the *Food Standards Cod*e. The draft amendment is to take into account the need to:

(a) label if the manufacturer knows the food contains genetically modified material; and

(b) if the manufacturer is uncertain about the food's contents, the label must indicate that the food may contain genetically modified material.

If the manufacturer knows the product to be free of genetically modified material it is proposed that there will be no requirement to label the product, however it may be labelled as being free of such material if the manufacturer so wishes.

In addition, Health Ministers also asked ANZFA to develop for their further consideration a definition of the term 'genetically modified food', recognising that there are many food ingredients such as sugars and oils which can be made from genetically modified plants but are not themselves genetically modified.

ANZFA is currently in the process of developing draft amendments to the labelling provisions of Standard A18 in accordance with the direction of ANZFSC. These will be considered by ANZFSC at its August 1999 meeting. In addition, ANZFA has just completed a further round of public consultation on the issue of labelling. The results of this consultation will also be presented to ANZFSC.

**Interim arrangements**

Early in 1999 it became apparent that there were more foods produced using gene technology on the market than were first thought. As from 13 May 1999 these foods

would become illegal as ANZFA had yet to receive applications for their approval, nor would there be time to process any applications in time to meet the 13 May deadline. This could have resulted in severe market disruption because potentially a large number of finished foods would be affected, with businesses placed in the invidious situation of either having to remove their products from the marketplace - causing chaos in supermarkets - or risk prosecution for selling unapproved foods after 13 May 1999. It was ANZFA's assessment that this situation arose because of the failure of the developers of the genetically modified commodities to lodge applications with ANZFA for approval of their foods (approval of the commodity automatically gives approval to any foods derived from the commodity). The effects however would mainly be felt by other businesses, organisations and consumers.

As a matter of urgency ANZFA developed advice for addressing this problem and presented this to ANZFSC on 30 March 1999. ANZFSC agreed to interim arrangements for foods to remain on the market while they were undergoing assessment by ANZFA provided they met three requirements. These were:

(i) Companies must have submitted a comprehensive application for a safety assessment of their foods to ANZFA by 30 April 1999;

(ii) The food commodity must already be on the market lawfully overseas and be considered safe by an overseas regulatory agency; and

(iii) ANZFSC must have no evidence to indicate that the food commodity is unsafe.

Standard A18 was amended accordingly (Attachment 4) and ANZFA received and accepted an additional 14 applications under these interim arrangements making a total of 20 applications for approval of foods produced using gene technology (Attachment 5). ANZFA is now progressing each of these applications. ANZFA will also undertake an inquiry into the urgent variation to the standard to give the community an opportunity to provide comment and allow ANZFA to undertake further review of the action that was taken as a matter of urgency.

**INQUIRY TERMS OF REFERENCE**

ANZFA's comments will address only those terms of reference which impinge on matters of direct relevance to ANZFA. They are:

- opportunities to educate the community of the benefits of gene technology;
- the commercialisation and marketing of agricultural and livestock production varieties.

The other terms of reference relate primarily to agricultural production and as such are not directly relevant to ANZFA's role, therefore our comments will not specifically address them.

**Opportunities to educate the community of the benefits of gene technology**

Gene technology is a complex and sophisticated technology and one which is not readily understood by the community. The use of gene technology in food has captured the interest of the media who readily depict images of *Frankenstein foods* or *mutant foods*. To the community who lack sufficient knowledge about gene technology to distinguish fact from fiction, these images are quite troubling leading to the creation of an environment which, for the most part, is largely suspicious of the technology.

Given the ease with which misinformation is unquestioningly accepted by the community, ANZFA considers that there is an urgent need for balanced and factual information to be provided to the community, particularly about the use of gene technology in food.

There are three different levels of information ANZFA considers should be provided to the community.

The first level, forming the foundation of any community education, would be concerned with the regulatory aspects. Specifically, assuring the community that there are appropriate regulatory mechanisms in place to protect the health and safety of the population. As the food regulator one of ANZFA's roles is to provide this information to the community.

While ANZFA has been active in trying to inform the community about the measures the government has introduced to ensure the safety of foods produced using gene technology, this message is often lost among the more sensationalist negative images popular with the media today.

The second level of information would be concerned with the provision of information about gene technology in general. This information should be factual and, above all, easily understood by the community. ANZFA also has a role in providing this information, however, this should not be seen as primarily the responsibility of ANZFA. Other government bodies with an interest in gene technology, as well as scientific and research bodies who apply the technology, should carry the main responsibility for providing this information.

ANZFA has had few resources to devote to the provision of this sort of information. It is probably fair to say that, while efforts have been made by other organisations and government bodies to increase community knowledge and awareness, this has not been overly successful. The community remains largely ignorant about the technology and therefore open to misinformation. A balanced and reasoned debate about the risks versus the benefits will not be possible until the community is better informed. ANZFA anticipates that the proposed biotechnology public awareness program being developed by the newly formed Biotechnology Australia will better address the information needs of the community.

The third level of information would be concerned with the benefits of gene technology. Communicating the benefits of gene technology to the community is not ANZFA's role. ANZFA must maintain its neutrality with respect to the technology, whose end products it regulates. As a scientific organisation, however, ANZFA

recognises that there are many potential benefits (both to the agrifood sector and the consumer) to be gained from the use of gene technology in food production. ANZFA also recognises that, as with any new technology, there may be risks associated with its use and that the technology must be used with care and due responsibility. ANZFA's role is to develop appropriate mechanisms for minimising and managing the risks and to communicate this effectively to the community. Confidence in the Government's role in ensuring that the risks from the technology are minimised will generate an environment which is more receptive to learning about the benefits.

It is the responsibility of those who have invested in the technology (the agrifood sector, the scientific community, and those government bodies with a non–regulatory role) to promote the benefits of the technology. Thus far it would appear that positive messages about the technology are not being effectively conveyed to the community.

The risk to Australia from a failure to gain community acceptance for the responsible use of gene technology in agricultural production are great. All three levels of information are essential in order to effectively educate and inform the community. It is only through coordinating the provision of information at all three levels that the misinformation portrayed in the media will be effectively countered and the risk averted.

**The commercialisation and marketing of agricultural and livestock production varieties**

ANZFA has developed a regulatory framework for foods produced using gene technology which provides certainty to the agrifood sector that foods produced using gene technology can be commercialised. The approvals ultimately given by ANZFSC will indicate that the products are considered to be safe for human consumption. This regulatory framework can thus give confidence, both to the agrifood sector, who ultimately will market the products, and to the community, who ultimately will consume the products.

In the end, however, the success or otherwise of the commercialisation and marketing of agricultural and livestock production varieties will largely depend on the degree of acceptance by the consumer – the ultimate end user. Until the community is more accepting of the technology, in particular, its use in food, the agrifood sector will be reluctant to actively market its products as having been produced using gene technology for fear of market discrimination.

## CONCLUSIONS

One of the major impediments to the successful uptake of gene technology by primary producers is the apparent lack of widespread community understanding, support and acceptance of the technology. If this is not urgently addressed through active and coordinated community education by all sectors with an interest in gene technology, the potential exists for Australia, and Australian agriculture in particular, to miss capturing the benefits. A more coordinated approach to this issue

through the governments Biotechnology Strategy will address many of ANZFA's concerns.

## ATTACHMENTS

1. Statement of Reasons for recommending Standard A18-Food Produced using Gene Technology
2. The development of food standards
3. Guidelines for the safety assessment of foods to be included in Standard A18-Food Produced using Gene Technology
4. Standard A18, as amended
5. Current applications to amend Standard A18

**ATTACHMENT 1**

**25 February 1998**
**14/98**

**STATEMENT OF REASONS**

**PROPOSAL P97**

**FOR RECOMMENDING STANDARD A18 - FOODS PRODUCED USING GENE TECHNOLOGY**

The Australia New Zealand Food Authority has before it a proposal to vary the *Food Standards Code* by addition of Standard A18 - Food Produced using Gene Technology.

The proposed standard, as prepared after Full Assessment, is amended for the following reasons:

- to incorporate an additional provision in the standard specifically for the labelling of food produced using gene technology. This labelling provision relates to food that contains new or altered genetic material and which is not substantially equivalent in any characteristic or property of the food;

- to clarify and simplify the definitions of 'gene technology' and 'food produced using gene technology' used in the standard; and

- to reword clauses to reflect changes in the definitions.

The Authority has recommended to the Australia New Zealand Food Standards Council that it adopt the draft standard to the *Food Standards Code*, as amended, for the reasons below:

- the current regulatory framework is inadequate to ensure that foods produced using gene technology are required to undergo a safety assessment before they are released onto the market;

- the proposed standard will establish a mechanism whereby consumers can be confident that the safety for human consumption of foods produced using gene technology will be fully assessed before these products are made available for sale;

- industry will be provided with a clear regulatory pathway for the assessment of food produced using gene technology;

- consumers will have access to accurate information, including labelling, on foods produced using gene technology;

- the proposed standard does not regulate food additives and processing aids that are derived from genetically modified organisms (GMO). This is because other standards in the *Food Standards Code* require pre–market approval for these substances;

- the proposed standard will have the effect of prohibiting foods produced using gene technology unless they have been assessed by the Authority as safe for human consumption;

- the Authority has developed guidelines for the risk–based, case–by–case assessment of foods to be included in the standard. These guidelines are contained in the information paper *Safety Assessment guidelines for foods to be included in Standard A18 - Food Produced Using Gene Technology;*

- it would not be appropriate for the Authority to include in the proposed standard foods produced using gene technology that may currently be available for sale eg. soybean products from Roundup Ready® soybeans or cotton seed oil from INGARD® cotton. The assessment of these products will be progressed via the usual Authority application process if the proposed standard is adopted;

- the standard prescribes mandatory labelling for foods that contain new and altered genetic material and which are not substantially equivalent to their conventional counterparts in a characteristic or property of the food;

- where the standard specifies that a food produced using gene technology must be labelled, that label must indicate the biological origin and nature of the characteristic or property modified;

- a mandatory requirement to label foods that are substantially equivalent to their conventional counterparts is not prescribed as:

  (i) it cannot be justified on the basis of sound scientific principles;

  (ii) it is not necessary for the protection of public health and safety as food that is deemed by the Authority as unsafe for human consumption will not be permitted for sale; and

  (iii) it is more restrictive than necessary to achieve a legitimate outcome;

For these reasons, the mandatory labelling of food that is substantially equivalent to existing conventional foods is also unlikely to be consistent with Australia's and New Zealand's obligations as signatories to World Trade Organization (WTO) Agreements and therefore difficult to sustain in the

likely event of a challenge in that forum and it is also unlikely to be consistent with the regulatory policies of both Australia and New Zealand. In addition, in countries where labelling of substantially equivalent foods has been required, this is not delivering useful information to consumers.

- mandatory labelling for substantially equivalent foods is not regarded as practicable given:

    (i) the complexities associated with tracking individual food components through the food chain (eg, Roundup Ready® soybeans) and the reluctance of major producing countries to segregate commodities;

    (ii) that it is unlikely that enforcement agencies will be able to enforce mandatory labelling requirements for substantially equivalent foods; and

    (iii) that it is unlikely that mandatory labelling requirements for substantially equivalent foods could be enforced equally between imported and domestic products;

- negative claims (eg, that foods are not, or do not contain, products of a GMO) will not be prohibited.

- industry has a primary responsibility to develop and implement a communication strategy for the provision of information to consumers about such foods. To this end:

    (i) the Authority will cooperate with industry in the provision of information about gene technology;

    (ii) the Authority will commit to working with industry bodies, relevant government agencies and consumers in the development and provision of information to consumers; and

    (iii) the Authority draws attention to its public processes and the fact that information relating to any food produced using gene technology approved by the Authority will be available in the public domain.

The Australia New Zealand Food Standards Council consists of the Commonwealth of Australia, Australian State and Territory, and New Zealand Health Ministers who will now decide whether to accept, reject or amend ANZFA's recommendation to adopt the standard, as amended.

It has been recommended that the commencement date of the amended draft standard will be nine (9) months from the date of gazettal.

**REGULATORY IMPACT**

The Authority has satisfied the Australian Commonwealth Government's regulatory impact assessment requirements. That process concluded that the amendment to the

*Food Standards Code* is necessary, cost effective and of benefit to both producers and consumers.

## WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

Australia and New Zealand are members of the 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 agreement between the Governments of Australia and New Zealand on Uniform 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).

This matter was notified to the WTO because it was considered that the proposal raised matters relating to public health and safety and may be seen to constitute a technical barrier to trade.

**DRAFT VARIATION TO THE *FOOD STANDARDS CODE***

To Commence: 9 months after the date of Gazettal.

**The *Food Standards Code*** is varied by inserting –

## *"STANDARD A18*

## *FOOD PRODUCED USING GENE TECHNOLOGY*

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**Purpose**

This standard regulates the sale of foods and food ingredients, other than food additives and processing aids, which are produced using gene technology. The standard prohibits the sale 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 or class of food prior to its inclusion in the Table. The safety assessment will be done in accordance with the Authority's approved safety assessment criteria.

Food additives and processing aids which are produced using gene technology are not regulated in this standard. Other standards in this Code regulating food additives and processing aids require pre-market approval for these substances.

**Table of Provisions**



**Definitions**

**1.** In this standard –

a **food produced using gene technology** is a food which has been obtained from an organism which has been modified by gene technology, but does not include any substance regulated as a food additive or a processing aid.

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

**General prohibition on the sale of food produced using gene technology**

**2.** A food produced using gene technology must not be sold or used as an ingredient of another 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><br>**Food produced using gene technology** | **Column 2**<br><br>**Special conditions** |
|---|---|
| | |

**Labelling**

**3.** (1) A food that is, or contains as an ingredient, a food produced using gene technology that:

(a) contains new or altered genetic material; and

(b) is not substantially equivalent in any characteristic or property of the food;

must indicate on the label the biological origin and nature of the characteristic or property modified.

Editorial note:

**not substantially equivalent in any characteristic or property of the food** includes:

(a) where the modification results in one or more significant compositional or nutritional parameters having values outside of the normal range of values for the existing equivalent food or food ingredient; or

(b) where the level of anti–nutritional factors or natural toxicants are considered significantly different in comparison to the existing equivalent food or food ingredient; or

(c) where the food contains a new factor known to cause an allergic response in particular sections of the population; or

(d) where the intended use of the food or food ingredient is different to the existing equivalent food or food ingredient.

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## 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.

The Australia New Zealand Food Authority is now developing a joint *Australia New Zealand Food Standards Code* which will provide compositional and labelling standards for food in both Australia and New Zealand.

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

- Food sold in New Zealand (that has been manufactured in, or imported into, New Zealand either from Australia or from a third country) may comply with either the Australian *Food Standards Code* , as gazetted in New Zealand, or the New Zealand *Food Regulations*, but not a combination of both. However in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *Food Regulations.*

- Food manufactured in Australia and sold in Australia must for most products comply solely with the Australian *Food Standards Code*. However Standard T1 allows for certain specified foods to be manufactured in accordance with the relevant provisions of the New Zealand *Food Regulations.*

- Food imported into Australia from New Zealand must either comply with the Australian *Food Standards Code* or relevant provisions of the New Zealand *Food Regulations.* If they comply with the New Zealand *Food Regulations* they must also comply with Standard A14 and the maximum permitted concentrations for cadmium as set out in Standard A12 of the Australian *Food Standards Code*.

- Food imported into Australia from other than New Zealand must comply solely with the Australian *Food Standards Code.* The provisions set out in Standard T1 of the Australian *Food Standards Code* do not apply in this case.

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act* and all food sold in Australia must comply with the Australian *Trade Practices Act (1974).*

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

## FURTHER INFORMATION

Further information on this and other matters should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the following addresses:

PO Box 7186
Canberra Mail Centre ACT 2610
AUSTRALIA
Tel (02) 6271 2258 Fax (02) 6271 2278
mail: slo@anzfa.gov.au

P O Box 10559
WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942 Fax (04) 473 9855
email: anzfa.nz@anzfa.gov.au

Requests for copies of other information papers should be addressed to the Authority's Information Officer at the above address, or Email info@anzfa.gov.au

**ATTACHMENT 2**

# Development of food standards

Food standards may relate to any or all of the following:

- Composition of food, including:
  - maximum amounts of contaminants or residues in food;
  - its microbiological status and safety; and
  - the method of sampling and testing the food to determine its composition.
- Production of food including the maximum or minimum amounts of additives that must or may be used its preparation.
- Packaging, storing or handling food.
- Information about food, including labelling, promotion and advertising.
- Interpretation of other standards.
- Other public health matters relating to food as prescribed.

## History of food standards

From 1973 national food standards in Australia were developed under the auspices of the National Health and Medical Research Council (NHMRC). These standards were voluntarily adopted (sometimes with amendments) into State and Territory food legislation.

The need for greater national uniformity of food law led in 1980 to Health Ministers adopting a Model Food Act. This Model Act provided the skeleton for national uniformity, and it was envisaged that it would be followed by uniform food standards regulation (based on the NHMRC standards) and uniform food hygiene regulations.

Through the 1980s, the NHMRC continued to develop its food standards into a consolidated *Food Standards Code*. This Code was adopted by States and Territories under their respective implementations of the Model Food Act, albeit on a voluntary basis and with the potential for non-uniform standards to be introduced.

The potential for States and Territories to have differing food standards, a lack of clearly defined objectives for food standards regulation, and perceived inefficiencies in the NHMRC's handling of food standards, were identified by the then Industries Assistance Commission as significant obstacles to industry in the microeconomic reform agenda of the late 1980's and early 1990s. Commonwealth, State and Territory Heads of Government agreed that responsibility for developing the *Food Standards Code* should be

centralised with a single, national agency, and the recommendations of this agency, if approved by a Ministerial council should be uniformly implemented.

In 1991 the *National Food Authority Act 1991* (the NFA Act) established the National Food Authority as the agency responsible for developing the *Food Standards Code*. In 1995 New Zealand agreed to join Australia to develop uniform food standards for both countries, and the Australia New Zealand Food Authority came into being in July 1996. The NFA Act then became known as the *Australia New Zealand Food Authority Act 1991*.

## Procedures for developing food standards

The ANZFA Act sets out in detail the procedure by which the Authority assesses applications or internally-generated proposals for changes to existing food standards or for the development of new food standards.

The process by which the Authority assesses food standards matters is open, accountable, consultative and transparent.

New food standards, or variations to existing standards, can be sought by any person, whether industry, consumer, government or an association an **application** in writing to the Authority. The Authority has a number of application forms to assist applicants and potential applicants to provide sufficient information in the application to enable the Authority to assess the matter expeditiously. Where necessary, the Authority may request samples of the food from the applicant, or further information in relation to the application.

The Authority can itself develop a **proposal** to change the *Food Standards Code*, in which case procedures are similar as for an application.

Applications first undergo a **preliminary assessment**. This is not a substantive assessment of the merits of the application, but a check to ensure that the application raises an substantive food standards issue. Preliminary assessment looks at all relevant matters and ensures that the application:

(a) whether the application relates to a matter that may be developed as a standard, or that warrants a variation of a standard, as the case requires;

(b) whether the application is so similar to a previous application for the development or variation of a standard that it ought not to be accepted;

(c) any other relevant matters.

Following preliminary assessment, the application is either “accepted”, in which case the applicant is notified and public submissions sought, or else “rejected”, in which case the applicant is notified and provided with a statement of reasons for the rejection. The applicant whose application has been rejected at preliminary assessment has a right to

apply to the Administrative Appeals Tribunal for an independent review of the Authority's decision.

If an application is accepted, the Authority invites **public submissions** by notice sent to "appropriate government agencies". The notice is also published in Australian and New Zealand newspapers, the Commonwealth Gazette and New Zealand Gazette. This notice states that the application has been received and accepted following preliminary assessment, and advises that the Authority will make a full assessment of the application. The notice invites written submissions on matters relevant to the application, and specifies how to get further information on the application.

The purpose of inviting public submissions is to:

- seek additional information from people other than the applicant;
- obtain the views of interested parties on the merits of the application; and
- make known to the public that the application has been received and is being considered.

The Authority, after receiving public submissions, must make a **full assessment** of the application according to statutory criteria. Full assessment is the main consideration of the merits of the application, and must take into account:

- any submissions made to it within the specified period in response to a notice sent or published;
- the objectives listed in section 10, namely, in descending priority order:
  - (a) the protection of public health and safety;
  - (b) the provision of adequate information relating to food to enable consumers to make informed choices and to prevent fraud and deception;
  - (c) the promotion of fair trading in food;
  - (d) the promotion of trade and commerce in the food industry; and
  - (e) the promotion of consistency between domestic and international food standards where these are at variance.
- any relevant New Zealand standards; and
- any other relevant matters.

If the Authority then decides to reject the application a notice is sent to the applicant, those who made submissions and "appropriate government agencies" advising that the application has been rejected and giving reasons for the rejection. The notice is also

published in Australian and New Zealand newspapers, the Commonwealth Gazette and New Zealand Gazette. The applicant is entitled to ask the Administrative Appeals Tribunal to review the Authority's decision to reject the application.

If the Authority accepts the application it then prepares a draft variation to the *Food Standards Code.* A notice is prepared advising that an **inquiry** will be held into a draft variation. This notice is sent to the applicant, "appropriate government agencies" and to those who made submissions as part of the public comment process. The notice is also published in Australian and New Zealand newspapers, the Commonwealth Gazette and New Zealand Gazette. The notice advises that the Authority has prepared the draft variation, indicates how to get further information about the draft, and **invites written submission** for the purpose of the inquiry.

The purpose of the inquiry is to seek public consideration of and comment on the Authority's decision at full assessment and on the draft variation. Comments received are considered in formulating the Authority's final position and recommendation.

In conducting the inquiry, the Authority is not bound to act in a formal manner, but may inform itself and consult with anyone it thinks fit, and may receive either oral or written submissions. It is not bound by the rules of evidence, and may hold public hearings.

Following its inquiry, the Authority must make a **recommendation to the Ministerial Council** (and give reasons for its recommendation) that:

(a) that it adopt the draft standard or the draft variation of the standard; or

(b) that it adopt the draft standard or the draft variation of the standard subject to such amendments as the Authority considers necessary; or

(c) that it reject the draft standard or the draft variation of the standard; and give the Council its reasons for making that recommendation.

The Authority must then **notify the outcome** of its inquiry. A notice is sent to the applicant, to "appropriate government agencies" and to each person or body who made submissions to the application. The notice is also published in Australian and New Zealand newspapers, the Commonwealth Gazette and New Zealand Gazette. The notice sets out the Authority's recommendation to the Council and states how to get further information about the recommendation and the reasons for it.

The Ministerial Council that considers the Authority's recommendation is the Australia New Zealand Food Standards Council (ANZFSC) which consists of the Australian Federal, State and Territory Health Ministers and the New Zealand Health Minister. The ANZFSC must **deal with the recommendation** of the Authority by either:

(a) adopting the draft standard or the draft variation of the standard; or

(b) make any amendments that it considers necessary to the draft standard or the draft variation of the standard and adopt the draft as so amended; or

(c) rejecting the draft standard or the draft variation of the standard; or

(d) returning the draft standard or the draft variation of the standard to the Authority for reconsideration in whole or in part by the Authority.

Once approved by ANZFSC, a variation is published in the Commonwealth Gazette and the New Zealand Gazette. Under a 1991 Commonwealth State and Territory Agreement, food standards adopted by Council and published by the Authority in the Gazette are adopted by reference and without amendment into Australian State and Territory food law.

## Time allowed to be taken by the Authority

The Authority's processes must be completed within 12 months of the date on which the Authority received an application, although this period may be extended by the Authority up to a maximum of six months. The period does not include any time spent waiting for an applicant to provide additional information required by the Authority. No similar time restriction exists for proposals raised by the Authority.

The above process may be shortened by omitting some of the above steps in two situations:

- Where an application raises issues of minor significance or complexity only; and where it will not have a significant adverse effect affect the interests of any body or person. However, anyone who feels their interests have been so affected by the decision of the Authority may ask the Administrative Appeals Tribunal to review the decision.

- Where a recommendation should be made to ANZFSC as a matter of urgency in order to avoid compromising the objectives in section 10 of the ANZFA Act. However, if the Authority omits to hold an inquiry before making a recommendation to ANZFSC, it must hold the inquiry as soon as possible after making that recommendation.

**ATTACHMENT 3**

# Guidelines for the Safety assessment of foods to be included in Standard A18 – Food Produced Using Gene Technology

**For guidance in making an application to amend the *Food Standards Code***

**edition August 1998**

## 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. The Australia New Zealand Food Authority is now developing a joint *Australia New Zealand Food Standards Code* which will provide compositional and labelling standards for food in both Australia and New Zealand.

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

- Food sold in New Zealand (that has been manufactured in, or imported into, New Zealand either from Australia or from a third country) may comply with either the Australian *Food Standards Code* , as gazetted in New Zealand, or the New Zealand *Food Regulations*, but not a combination of both. However in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *Food Regulations.*

- Food manufactured in Australia and sold in Australia must for most products comply solely with the Australian *Food Standards Code*. However Standard T1 allows for certain specified foods to be manufactured in accordance with the relevant provisions of New Zealand *Food Regulations.*

- Food imported into Australia from New Zealand must either comply with the Australian *Food Standards Code* or relevant provisions of the New Zealand *Food Regulations.* If they comply with the New Zealand *Food Regulations* they must also comply with Standard A14 and the maximum permitted concentrations for cadmium as set out in Standard A12 of the Australian *Food Standards Code*.

- Food imported into Australia from other then New Zealand must comply solely with the Australian *Food Standards Code.* The provisions set out in Standard T1 of the Australian *Food Standards Code* do not apply in this case.

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act* and all food sold in Australia must comply with the Australian *Trade Practices Act (1974).*

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# INTRODUCTION

The purpose of this paper is to provide guidance for industry and the public on the Australia New Zealand Food Authority's (ANZFA's) assessment of foods to be included in Standard A18 - Foods Produced using Gene Technology.

Section 10 of the *Australia New Zealand Food Authority Act 1991* (the Act) states that when developing or amending food standards ANZFA must have regard to the following objectives, listed in descending priority order:

a) the protection of public health and safety;

b) the provision of adequate information relating to food to enable consumers to make informed choices and to prevent fraud and deception;

c) the promotion of fair trading in food;

d) the promotion of trade and commerce in the food industry; and

e) the promotion of consistency between domestic and international food standards where these are at variance.

In assessing applications for foods and food ingredients produced using gene technology the Authority will need to consider each application against these Section 10 objectives.

The safety assessment incorporates a scientific risk-based approach. Standard A18 leaves scope for this assessment process to become more generic and simplified as the Authority gains experience in the assessment of these products. In time, this could lead to the assessment being applied to classes or categories of food rather than to individual products. Therefore, these assessment guidelines might be expected to evolve over time as the community becomes more familiar with these products in the food supply.

## What is gene technology?

Gene technology as it relates to food refers to new techniques including recombinant DNA technology which alter, in a very specific way, the genetic characteristics of an organism in order to increase food production, improve nutrient content, processing or storage characteristics of food.

Gene technology, as opposed to traditional techniques of making genetic changes (such as selective breeding), involves the isolation and subsequent introduction of discrete DNA segments containing genes(s) of interest into the recipient organism. Many of these modifications could be achieved by traditional breeding methods, and the new technology merely provides a faster and more efficient method of achieving the same end. In contrast to traditional approaches, however, recombinant DNA

technology also facilitates the introduction of genes from very distantly related organisms, for example between bacteria and plants.

## The regulation of genetically modified organisms

The current regulatory environment for genetically modified organisms (GMOs) consists of a number of advisory and statutory bodies. The Genetic Manipulation Advisory Committee (GMAC) oversees the research, development and use of novel genetic manipulation techniques in Australia. Steps have been taken to create a regulatory body that will subsume the functions of GMAC, however such a body is yet to come into being and currently compliance with GMAC guidelines is on a voluntary basis. In New Zealand, the Advisory Committee on Novel Genetic Techniques (ACNGT) and the Interim Assessment Group (IAG) collectively fulfil a similar role to that of GMAC. However, a statutory body, the Environmental Risk Management Authority (ERMA), will replace the IAG and will come into operation on 1 July 1998.

ANZFA does not have the legislative framework to consider and evaluate many of the broader social, ethical and environmental issues, or to determine biosafety assessment principles in relation to applications for foods or food ingredients to be added to the standard for food produced using gene technology. ANZFA has neither the mandate nor the expertise to examine and assess the risks related to the use of recombinant DNA techniques or the risks associated with the release into the environment of GMOs.

The approval for general release of genetically modified crops, animals or microorganisms is a function of GMAC (or its successor) in Australia and in New Zealand the IAG or ERMA.

# SAFETY EVALUATION GUIDELINES FOR FOOD PRODUCED USING GENE TECHNOLOGY

## Background

The evaluation of the safety of foods and food ingredients produced using gene technology requires consideration of a variety of scientific and technological issues, some of which have not previously been part of a food safety assessment.

Traditional food safety assessment techniques, eg, those based on toxicological testing used for food additives, cannot be easily modified to apply to foods or food ingredients. Assessment of the safety of food has historically been based on a combination of human experience and, in more recent times, on controlled laboratory studies. The OECD Group of National Experts on Safety in Biotechnology (OECD, 1993)[1] stated the following:

> 'The safety of food for human consumption is based on the concept that there should be a reasonable certainty that no harm will result from intended use under the anticipated conditions. Historically, foods prepared and used in traditional ways have been considered safe on the basis of long-term experience, even though they may have contained natural

[1] OECD (1993) Safety evaluation of foods derived by modern biotechnology - Concepts and Principles. OECD, Paris.

toxicants or anti-nutritional substances. In principle, food has been presumed to be safe unless a significant hazard was identified.'

If it is accepted that all food should meet such a basic level of safety, then the purpose of a safety assessment of a food produced using gene technology is to provide this basic level of safety and to confirm the substance as a 'food', with all the benefits and risks normally associated with food. New technologies, therefore, can be assessed, to a large extent, in the context of a comparison to the benchmark of commonly consumed foods which are already regarded as safe. Both OECD and WHO/FAO have embraced this concept of 'substantial equivalence' as part of the safety assessment process. Equivalence relies on a comparison of molecular, compositional and nutritional data for the food produced using gene technology to those of its traditional counterpart, where such exists. When this equivalence can only be partially achieved, the safety assessment may be able to focus on the defined differences. Where substantial equivalence is established, the product is regarded to be as safe as its conventional counterpart.

The assessment process would focus on the new gene product(s), its properties and history of use as a food or food ingredient or other compositional differences. Where a potential problem is identified, toxicological and/or nutritional studies may be required. The studies would necessarily be tailored to the product under examination.

Where no equivalence to any conventional food or food ingredient can be shown, the safety assessment would have to focus on composition and properties of the product as for any other non-traditional food source. The testing requirements would also be tailored to the needs of the particular product, taking into account its specific properties and purpose. Where the new food or food ingredient is intended to replace a significant part of the diet, human nutritional data is likely to be required.

## Specific safety issues associated with the use of gene technology

The safety assessment of foods and food ingredients produced using gene technology must address both the intentional and the unintentional effects which may arise from the genetic modification. Unintended changes which may be difficult to detect include increases in the levels of natural toxicants or alterations in the concentrations of vital nutrients in the genetically modified food.

A number of food safety issues are consistently raised by consumers and these are outlined below. Similar food safety issues arising from gene technology were identified by a recent FAO/WHO consultation on 'Biotechnology and Food Safety' (FAO/WHO, 1996)[2] . It was noted that these effects may also arise in food produced using conventional breeding.

### (i) Direct consequences of new gene products in food encoded by genes introduced during genetic modification

[2] FAO/WHO (1996) Biotechnology and Food Safety. Report of a Joint FAO/WHO Consultation, Rome.

There are now a number of examples of genetically modified plants used as food, which contain genes inserted with the use of gene technology. Examples include the insertion of viral-coat proteins genes into potatoes to confer virus resistance, and the insertion of genes, isolated from fish, into strawberries to confer increased resistance to cold. Genetic modification of organisms which are used as food or food ingredients is not restricted to plants.

The direct consequences of the presence of these gene products in food include potential nutritional, toxic or allergenic effects and these effects must be considered during the safety assessment. A consideration of substantial equivalence of any genetically modified food may also include consideration of the nutritional profile of the food, and the level of known toxicants.

Allergenicity of foods is an issue of considerable concern to consumers and it was the subject of a recent FAO technical experts meeting (FAO, 1995)[3] . Prediction of allergenic potential of novel gene products, however, is not a simple matter. There are no reliable animal models for the assessment of the allergenicity of foods at present. However, potential allergenicity can be indicated by examination of a number of factors, including:

(i) source of the transferred genetic material (any known allergens);

(ii) physiochemical characteristics of the new proteins (most allergens are between 10,000 - 40,000 molecular weight and resistant to acid and protease degradation);

(iii) sequence homology with known allergens (database comparison); and

(iv) prevalence and processing of foods (eg, proteins expressed in non-edible portions of plants; proteins denatured by heat / processing).

One of the difficulties with predicting allergenicity is that of detecting an effect which will occur in only a very small percentage of the population. In cases where there is some doubt, therefore, precautionary warnings may be appropriate, at least until the food has had wide usage in the population. For example, regulatory concern might be appropriate where a new protein was expressed in a common food and exhibited the physiochemical properties of an allergen. Any precautionary warning statement, however, would need to be reviewed following a reasonable period of human exposure.

When new proteins are produced from genes derived from known allergenic foods, tests can be conducted both *in vitro* (using sera from sensitive individuals) and *in vivo* (using skin tests on sensitive individuals). In the case of negative results, no further action would be necessary. In the case of positive results from *in vitro* and *in vivo* tests, labelling or other appropriate methods of informing the public should be used.

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[3] FAO (1995) Report of the FAO technical consultation of food allergies. FAO, Rome.

Stepwise approaches to assessment of potential allergenicity have been recently published (Astwood, 1996; Metcalfe *et al.* ,1996)[4] .

**(ii) Direct consequences of altered levels of existing gene products encoded by genes introduced or modified during genetic modification**

Expression of existing genes (or their products) may be changed with the introduction of additional copies of these genes, or with the introduction of genes which modify the expression of existing genes / gene products. Examples include the introduction of a gene coding for antisense messenger RNA to a plant enzyme which is involved in fruit softening, thereby producing tomatoes with improved ripening characteristics, texture and flavour; and the introduction of additional copies of growth hormones into pigs, with the intent to speed up the growth and thus increase the efficiency of meat production.

The consequences of these types of modifications may (as above), include altered nutritional profile or altered levels of toxicants in the food and these effects would be included in any safety assessment of the modified food or food ingredient.

**(iii) Indirect consequences of the effects of any new gene or gene product(s)**

The introduction of a novel gene or an additional insertion of an existing gene into an organism may unintentionally modify the expression of another gene, either by activating or repressing its expression. Similarly, products of the introduced genes may inadvertently modify the metabolic pathways of other genes or their products, thereby altering the metabolism of the organism. The end product of such unintended action may result in the presence of new components, or altered levels of existing components.

Similar consequences may be generated by a mutation(s) caused by the process of genetic modification of the food source organism, caused by the interruption of coding or control sequences, or the activation of latent genes.

Examples of such indirect consequences may include increased levels of naturally occurring toxicants or anti-nutrients (eg. lectins, neurotoxins, protease inhibitor), significant alterations in levels of important nutrients, changes in bioavailability of nutrients, new molecules (eg. modified oils, carbohydrates) and increased levels or appearance of new allergens.

**(iv) The possibility of gene transfer from ingested genetically modified organisms (and/or foods or food components derived from them)**

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[4] Astwood J., Fuchs R. (1996) Food Biotechnology and genetic engineering. In: Food Allergy: Adverse reactions to Foods and Food Additives, 2nd Ed. Blackwell Scientific Publications, Boston MA pp65-92.

Metcalfe D., Astwood R., Townsend H., Sampson S., Taylor R., Fuchs R. (1996) Assessment of the allergenicity potential of foods derived from genetically engineered crop plants. *Crit. Rev. in Food Sci. and Nutrition*. **36** (suppl): S165–S181.

An issue of concern, expressed by consumer groups, is the potential consequences of transfer of an introduced gene in food, to the microorganisms in the human gastrointestinal tract. The particular genes most commonly discussed in this context are marker genes used to identify genetically modified organisms during their development and include herbicide resistance and antibiotic resistance genes.

This issue was discussed at a WHO Workshop in 1993 (WHO, 1993)[5] with particular reference to antibiotic resistance genes, since transfer of these genes could affect the therapeutic efficacy of antibiotics. The WHO workshop concluded that there was no recorded evidence of transfer of genes from plants to microorganisms in the gut. The workshop also concluded that such transfers would be extremely unlikely given the complexity of the steps required for gene
transfer and gene expression, including release of the plant DNA from the plant cell, survival in the gastrointestinal tract, the need for competent microorganisms, the penetration of the cell membrane, survival of the microbial restriction system, and integration into the host genome or plasmid.

While the likelihood of such a gene transfer is remote, the possibility cannot be ruled out, and the use of certain antibiotic resistance genes with significant public health uses, eg, for vancomycin resistance, should be restricted.

There are well known mechanisms for the transfer of genetic material between microorganisms. The possibility of a gene transfer from a microorganism to a human pathogen can only be assessed with a full understanding of the nature of the gene construct and the genetically modified organism. The stability of a transferred gene will be enhanced if it confers a selective advantage to the host. This may include bacteriophage resistance, virulence, adherence, substrate utilisation or production of bacterial antibiotics.

The safety assessment of such a potential scenario may include consideration of whether the transferred gene enhances survival. If not, further safety assessment is unnecessary. In order to minimise the possibility of enhanced survival, vectors should be modified to minimise the likelihood of transfer, and marker genes which confer resistance to clinically useful antibiotics should not be used.

It is anticipated that consideration of the potential risks associated with transfer of genes from a GMO to an unintended host will be provided by GMAC or its successor. Indeed, such considerations are included in any proposed research involving genetic manipulation and are required by GMAC as well as the ethics committees involved in the vetting of research proposals. ANZFA does not propose to duplicate these processes.

### (v) Potential for adverse health effects associated with genetically modified microorganisms

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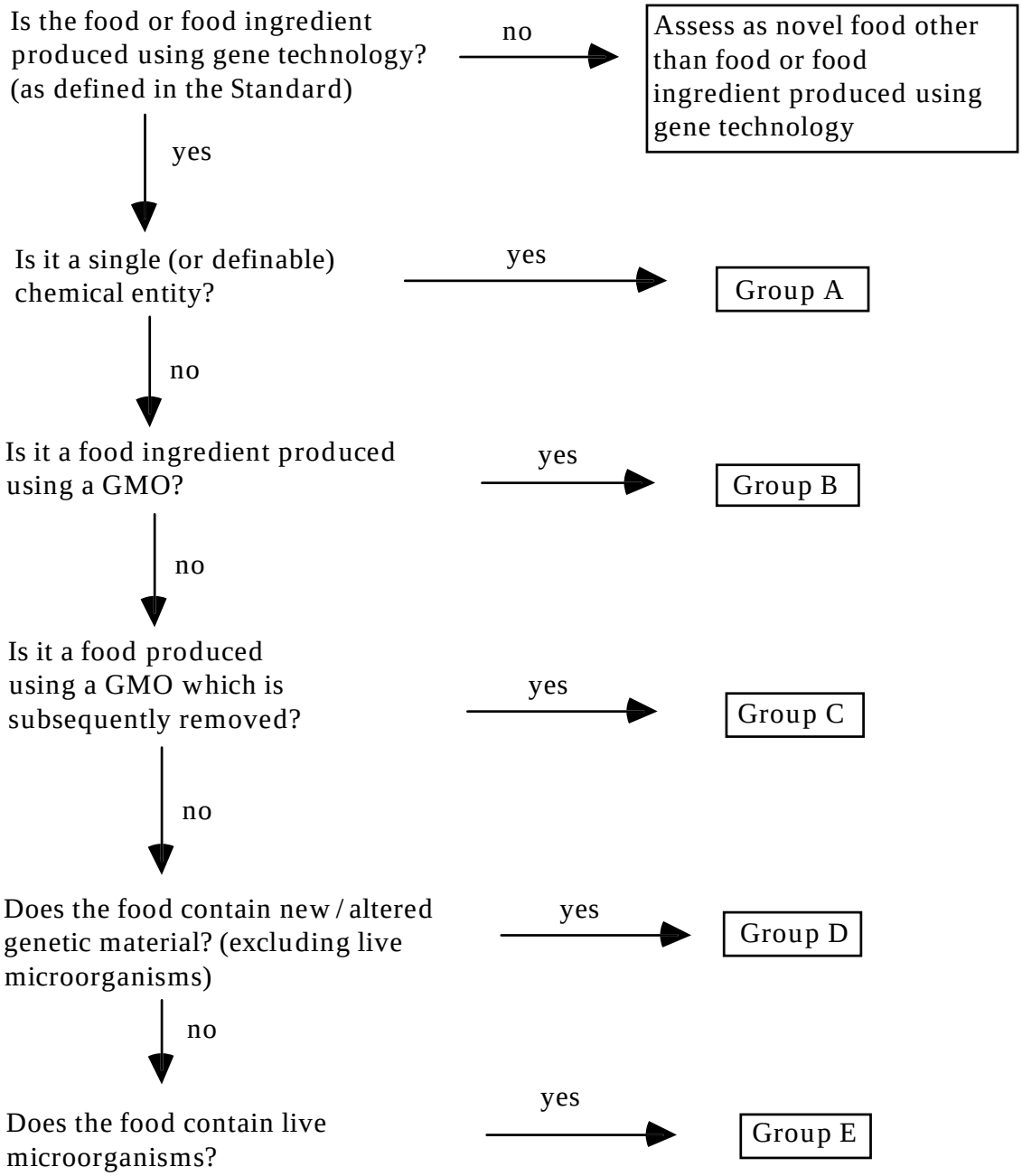
[5] WHO (1993) Health aspects of marker genes in genetically modified plants. Report of a WHO workshop. WHO, Geneva.

The potential for adverse health effects associated with the ingestion of genetically modified microorganisms may include their ability to compete for nutrients and to alter intestinal flora in humans, leading to unwanted gastrointestinal effects. Any safety assessment of food containing genetically modified microorganisms would take this issue into consideration.

## Classification of the food or food ingredient produced using gene technology

Foods or food ingredients produced using gene technology can generally be divided into five classes for the purpose of safety assessment as shown below. Each class possesses distinctive properties allowing a separate safety assessment approach. This assessment scheme provides a general guide only. In practice, the type and extent of the safety assessment will largely depend on the nature of the food being considered in an application.



**Group A** consists of chemically defined substances such as food additives, processing aids, and agricultural and veterinary chemicals.

*Examples:*
*enzymes such as α-amylases, chymosin, α-acetolactate decarboxylase; and*
*veterinary chemicals such as porcine somatotropin, bovine somatotropin.*

**Group B** consists of less well defined substances, such as oils, fats, starch and protein where the composition may or may not be slightly altered.

*Examples:*
*vegetable oil from pesticide-resistant seed plants;*
*sugar from insect-resistant sugar cane;*
*starch from insect-resistant maize;*
*vegetable oils with a modified fat composition from modified seed plants; and*
*mycoprotein from genetically modified yeast.*

**Group C** consists of foods produced using GMOs (generally microorganisms) where the GMO has been removed from the final product, such as beer and wine.

*Examples:*
*beer produced using yeast modified to ferment at a colder temperature; and*
*wine or beer produced using yeast modified to result in an altered flavour profile.*

**Group D** consists of transgenic plants or animals, ie, plants or animals which contain new or altered genetic material.

*Examples:*
*tomatoes containing the gene for Bt toxin;*
*soybeans containing a gene which confers herbicide resistance; potatoes in which genes have been altered to result in higher protein content;*
*pigs with altered growth characteristics; and*
*sheep resistant to blowfly strike.*

**Group E** consists of foods such as yogurt where the genetically modified fermentation microorganism remains in the food.

*Examples:*
*yogurt containing a fermentation organism with increased phage resistance; and*
*yogurt containing a modified fermentation organism which leads to increased vitamin content.*

## General data requirements

Safety assessment of food and food ingredients produced using gene technology needs to include the consideration of the intended and unintended effects arising from the genetic modification, together with a consideration of the equivalence of the modified food to its traditional food counterpart.

An important element in the safety assessment of these foods and food ingredients is the comparison of the final product with one having an acceptable standard of safety. The factors which need to be considered in this comparison will vary, depending on the nature of the food or food ingredient, and will change with time as better information becomes available.

Initially, assessments will be conducted on a case-by-case basis and the exact nature of the data requirements will depend on the particular circumstances. Data needed for the safety assessment will need to be tailored for the type of food or food ingredient to be assessed. As experience in this area grows, it may be possible to more clearly identify data requirements and to broaden the safety assessment to categories of products or to preclude certain products from detailed evaluation.

Data will be required in a broad range of areas, a number of which have overlapping requirements. The following provides an indication of the type of data required in each area. The exact data requirements will depend on the type of food or food ingredient being considered. An indication of which of these issues need to be addressed for each food type is provided in the decision tree charts shown below. For more detailed information about the application format refer to the Authority's '*Format for applying to amend the Australian Food Standards Code - Food Produced using Gene Technology'*.

### (i) Data on donor and host organisms and vectors

Detailed information should be provided on the nature of the donor and host organisms, such as identification, pathogenicity, known toxin production, previous use in food and food production. In the case of the host, a full description is required of how the inserted gene will be regulated.

Full information should be provided on the introduced modified DNA, such as source, sequence information, characterisation of the vector, presence of marker genes, presence of DNA in addition to that intended, information on deletions or rearrangements.

If the result of the modification is the production of a novel protein, full characterisation will be required with regard to identity, functionality and similarity to existing proteins from traditional sources.

It is anticipated that, for all foods produced using gene technology, assessment of such issues as the appropriateness of the donor and vectors used, the adequacy of

the genetic technique used, and the stability of the genetic changes will be conducted by GMAC (or its successor). In this case, the general requirements for information on the donor, host, vector and genetic manipulation techniques used will be those now required by GMAC.

**(ii) Food product information**

Additional information required on a product which is a food or food ingredient produced using gene technology will depend on the nature of the food or ingredient. Apart from general information on proposed use, manufacturing process and quality assurance programs, information will be required to address the safety issues raised in the decision tree charts shown below.

This information may include history of use in food or food production and compositional analysis on major or novel constituents, nutrient constituents, endogenous toxins and anti-nutritional factors.

**(iii) Dietary intake**

In situations where the food produced using gene technology is of a different composition to a conventional counterpart, it may be necessary to provide an indication of the likely dietary intake. This could be determined, in the case of a plant, from the amount of plant material in the final food and the current daily intake of a particular food. The safety assessment will consider the anticipated intake of the modified food as compared to the conventional food.

**(iv) Nutritional data**

As indicated in the charts in the following section, the nature of the nutritional information required will depend on the nature of the food or food ingredient produced using gene technology. In general, information is sought in order to ensure that the nutritional status of the consumer is not compromised by the substitution of less nutritious food varieties or by affecting the level of nutrient intake through interactions causing poor absorption or an increased level of anti-nutritional factors in the food supply. Generally, this can be assured by careful compositional analysis of nutrients and potential anti-nutritional factors. In some cases, it may be necessary to examine nutrient bioavailability using animal models.

**(v) Toxicological data**

As with the nutritional issues, many concerns can be resolved by compositional analysis of the food or food ingredient produced using gene technology in order to ensure the levels of natural toxicants are within the range normally found in the traditional counterpart food or ingredient. If concerns remain or if further confirmatory data regarding the potential toxicity of the food is required, both *in vitro* or *in vivo* studies may be necessary. This might occur if the food is to be a major component of the diet or if the food contains new or altered components.

The difficulties of using traditional animal feeding studies to examine the potential toxicity of whole foods is recognised. However, useful information can be obtained

in well planned studies. These studies may also be used to provide nutritional information.

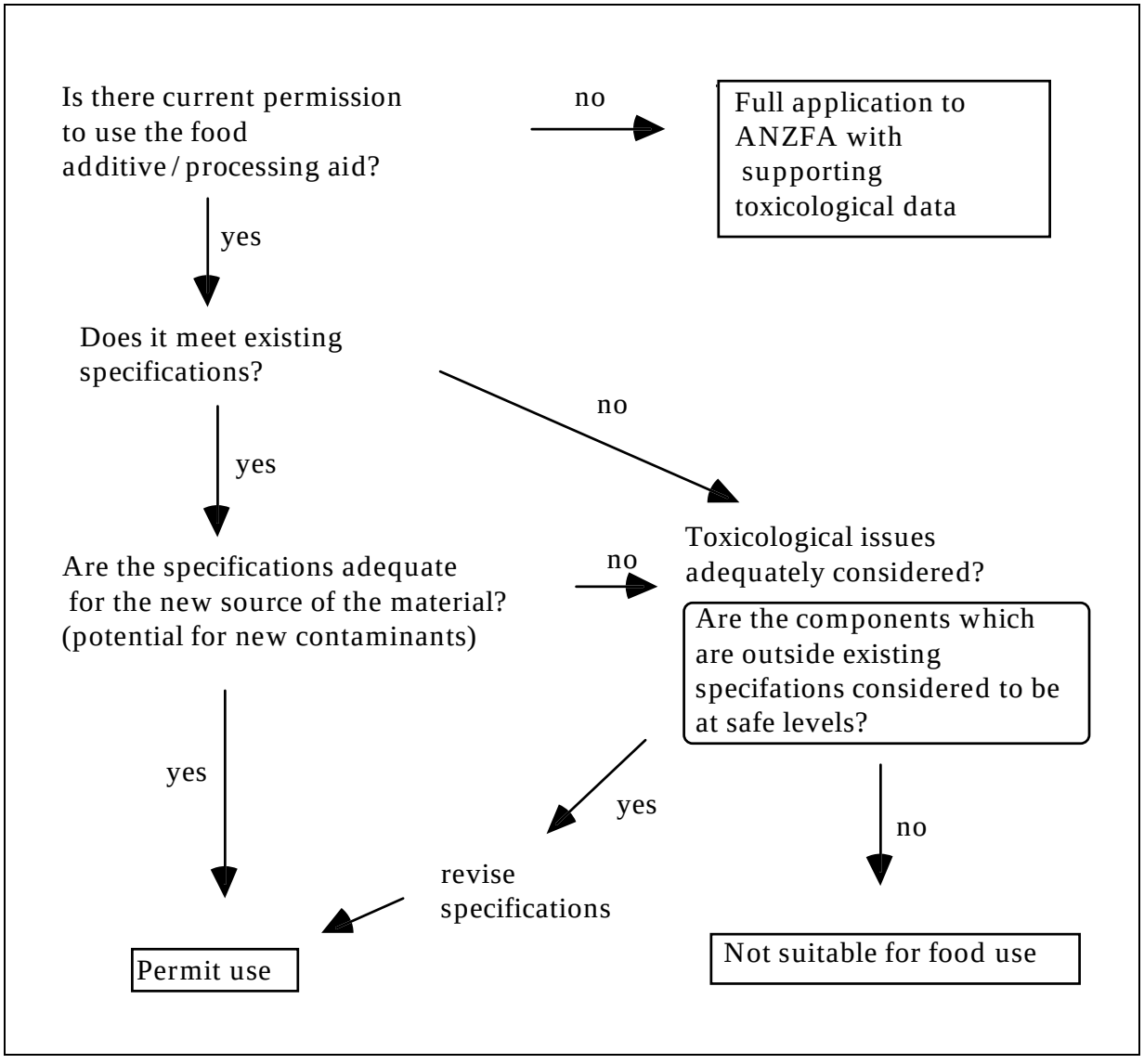
## Decision trees to assist safety assessment

### (i) Group A safety assessment

**Group A** consists of chemically defined substances such as food additives, processing aids, and agricultural and veterinary chemicals.

Issues for consideration in relation to substances in Group A:

1. Whether the substance meets the existing specifications.
2. Adequacy of existing specifications for a new source of the substance.
3. Potential toxicity of new contaminants.
4. Toxicity of substances outside existing specifications.

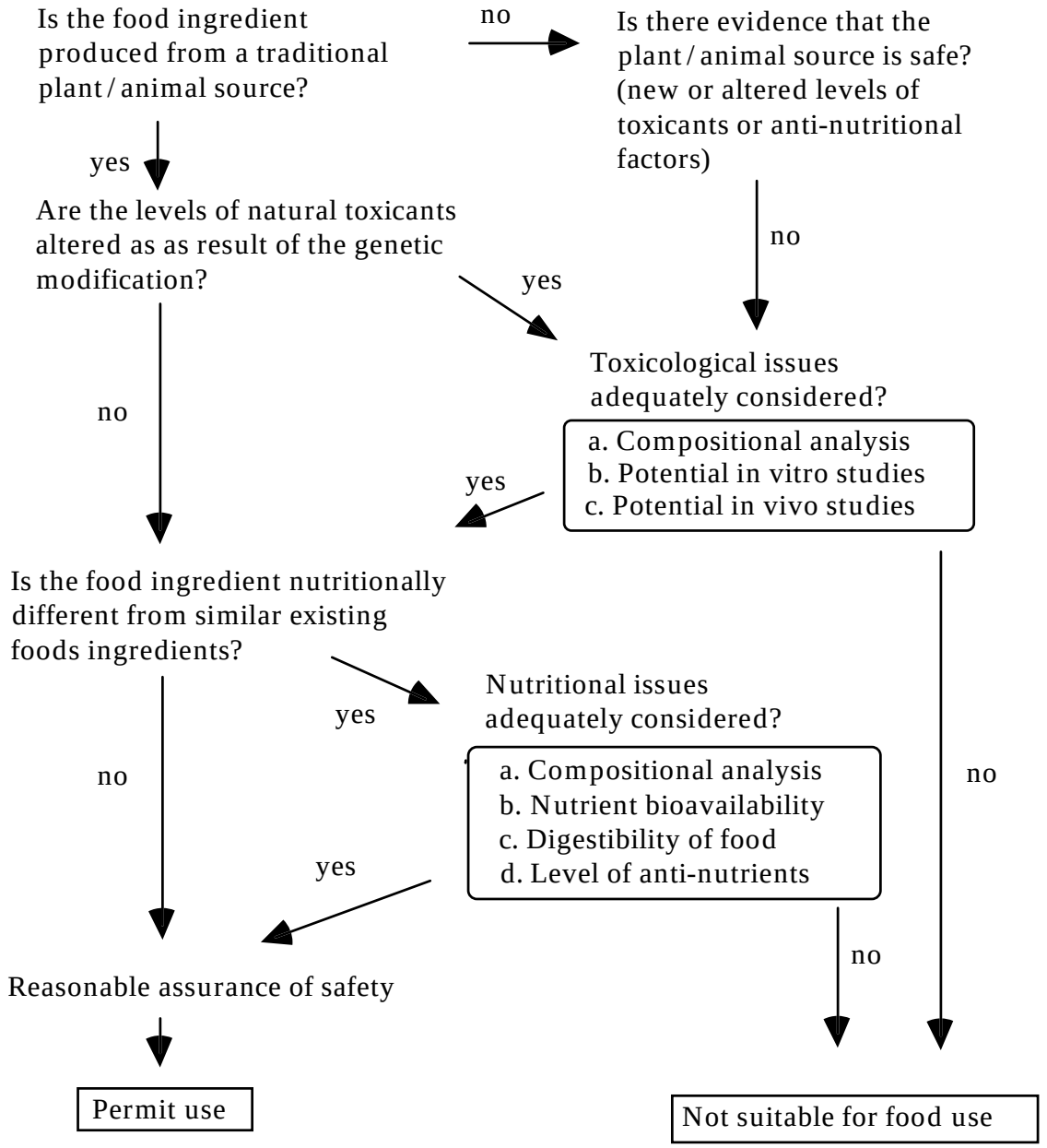


## (ii) Group B safety assessment

**Group B** consists of less well defined food ingredients such as oils, fats, starches, sugars, gums and proteins where the composition may or may not be slightly altered.

Issues for consideration in relation to substances in Group B:

1. History of use of the plant / animal source for the food ingredient.
2. Safety of any new source of the food ingredient.
3. Effect of genetic modification in the source organism on the levels of natural toxicants or anti-nutritional factors.
4. Need to conduct compositional analysis to compare with traditional source.

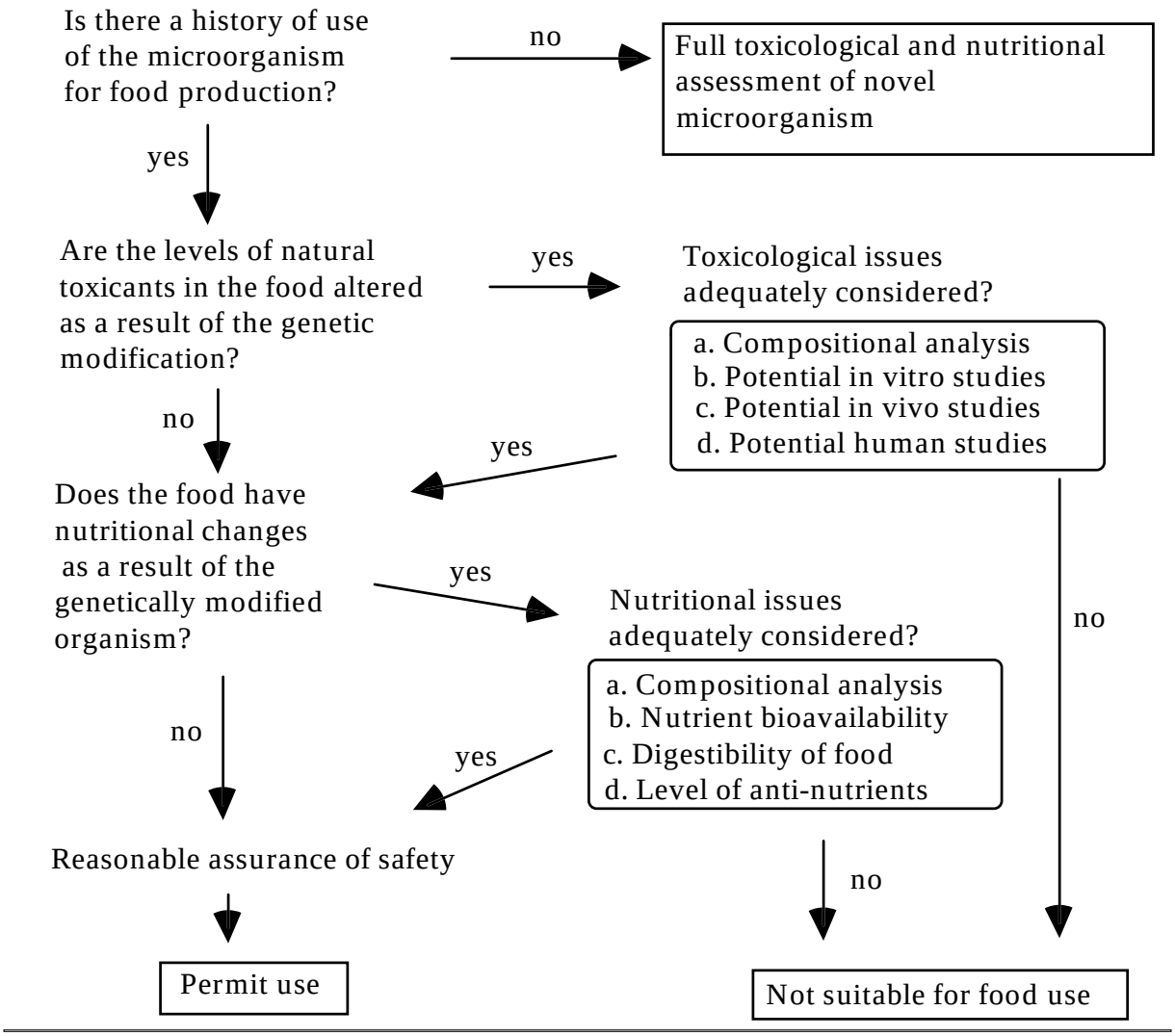


### (iii) Group C safety assessment

**Group C** consists of foods produced used GMOs (generally microorganisms) where the GMO has been removed from the final product such as beer and wine.

Issues in relation to foods in Group C:

1. History of use of the microorganism in food production.
2. Safety of any new microorganism used in food production.
3. Assurance that the GMO has been removed from the food, particularly if carrying genes which confer antibiotic resistance.
4. Effect of genetic modification in the microorganism on the levels of natural toxicants or anti-nutritional factors in the food.
5. Need to conduct compositional analysis to compare with traditional source.

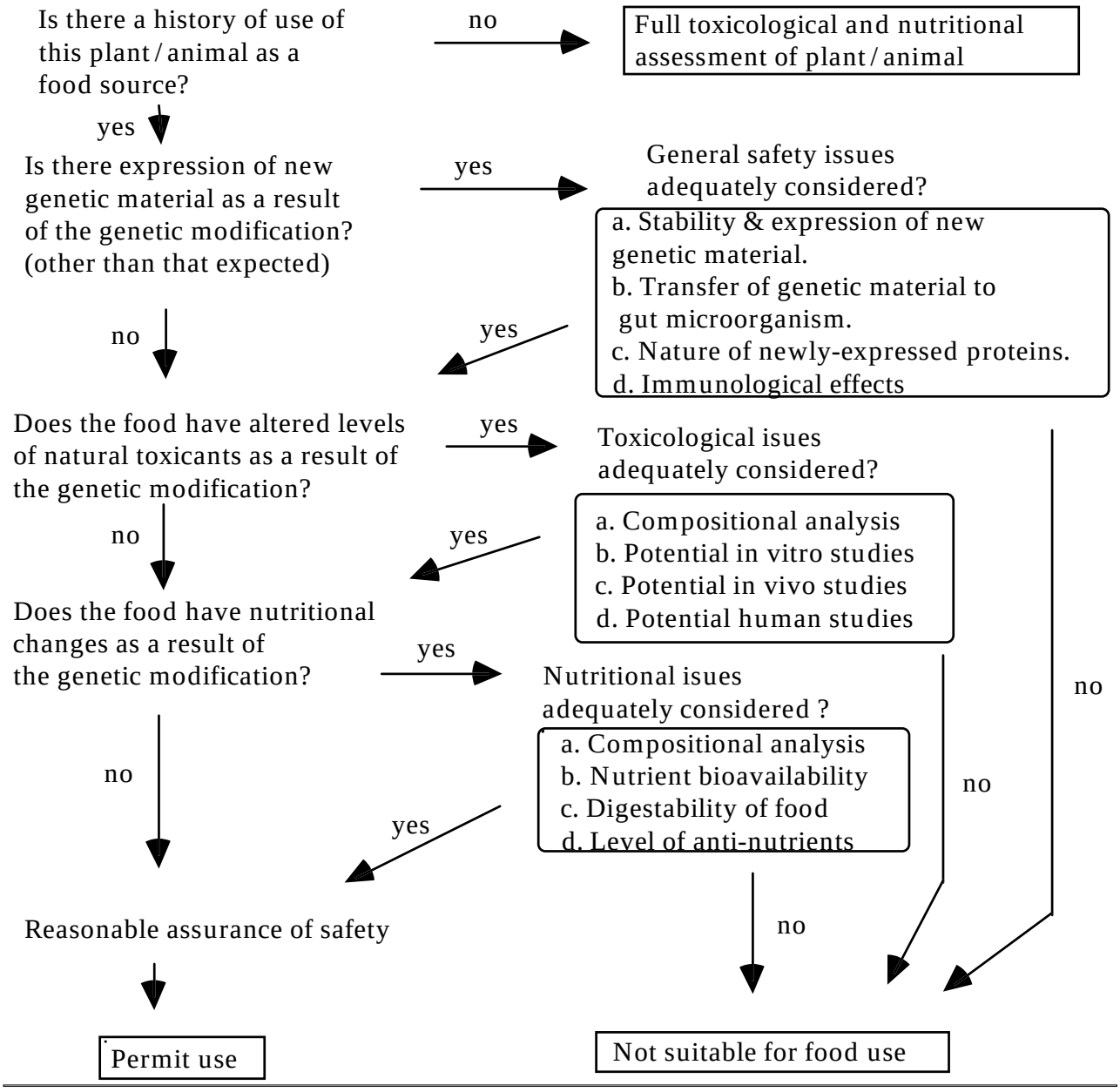


## (iv) Group D safety assessment

**Group D** consists of transgenic plants or animals, ie, plants or animals which contain new or altered genetic material.

Issues in relation to foods in Group D:

1. History of use of the plant / animal in food production.
2. Safety of any new plant / animal used in food production.
3. Expression of new genetic material other than the intended change.
4. The levels of natural toxicants or anti-nutritional factors in the transgenic food.
5. The nutritional status of the transgenic food.
6. Need to conduct compositional analysis to compare with traditional source.

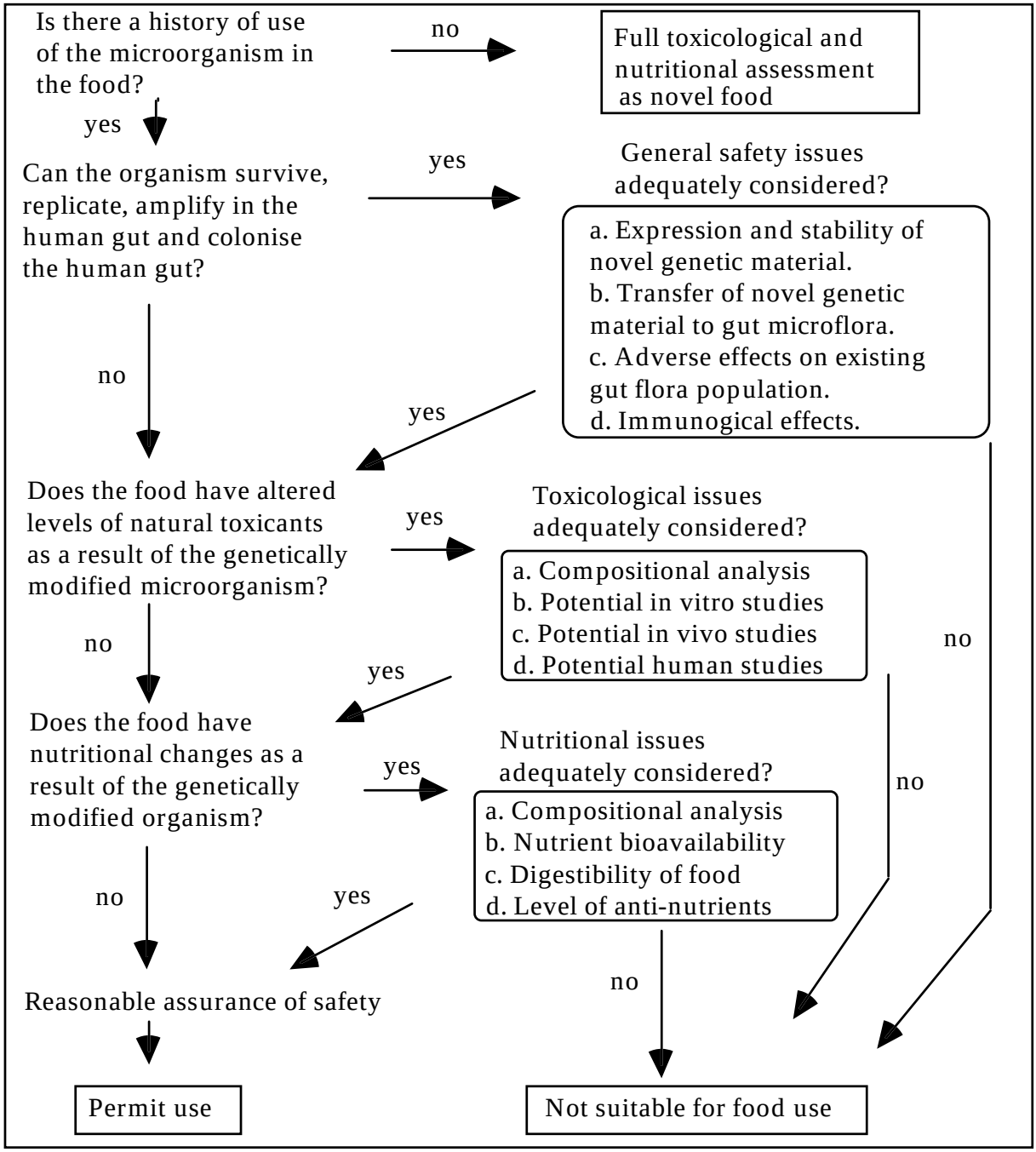


## (v) Group E safety assessment

**Group E** consists of foods such as yogurt where the genetically modified fermentation microorganism remains in the food.

Issues in relation to foods in Group E:

1. History of use of the microorganism in food production.
2. Safety of any new microorganism used in food production.
3. Expression of new genetic material other than the intended change.
4. The levels of natural toxicants or anti-nutritional factors in the food.
5. The nutritional status of the food.



**ATTACHMENT 4**

# *STANDARD A18*

# *FOOD PRODUCED USING GENE TECHNOLOGY*

## Purpose

This Standard regulates the sale of foods and food ingredients, other than additives and processing aids, which are produced using gene technology. The Standard prohibits the sale 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 or class of food prior to its inclusion in the Table. The safety assessment will be done in accordance with the Authority's approved safety assessment criteria.

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

## Table of Provisions



## Definitions

**1.** In this Standard -

a 'food produced using gene technology' is a food which has been derived from an organism which has been modified by gene technology, but does not include any substance regulated as a food additive or a processing aid.

'gene technology' refers to recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.

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

**2.** A food produced using gene technology must not be sold or used as an ingredient or component of another 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><br>**Food produced using gene technology** | **Column 2**<br><br>**Special conditions** |
|---|---|

| | |
|---|---|
| | |

**Exemption to general prohibition on sale**

2A. (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 as defined by the Act.

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

(a) the 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 the food, in one or more countries, other than Australia or New Zealand, is lawfully permitted as a food, by a national food regulatory agency; and
(d) the Council has not become aware of evidence that the food poses a significant risk to public health and safety.

**Labelling**

**3.** (1) A food that is, or contains as an ingredient or component, a food produced using gene technology that -

(a) contains new or altered genetic material; and
(b) is not substantially equivalent in any characteristic or property of the food;

must indicate on the label the origin and nature of the characteristic or property modified.

**Editorial note:**

**"not substantially equivalent" in any characteristic or property of the food** includes-

(a) where the modification results in one or more significant compositional or nutritional parameters having values outside of the normal range of values for the existing equivalent food or food ingredient; or

(b) where the level of anti–nutritional factors or natural toxicants are considered significantly different in comparison to the existing equivalent food or food ingredient; or

(c) where the food contains a new factor known to cause an allergic response in particular sections of the population; or

(d) where the intended use of the food or food ingredient is different to the existing equivalent food or food ingredient.

**ATTACHMENT 5**

# CURRENT APPLICATIONS TO AMEND STANDARD A18

Under Standard A18, the sale of foods or food ingredients produced using gene technology is prohibited unless they are included in the Table to clause 2 (subject to any special conditions so listed) or, as a result of clause 2A, exempted from the operation of clause 2.

The assessment of applications to amend the new standard will be conducted according to the *ANZFA Safety Assessment Guidelines for Food Produced Using Gene Technology* . The safety assessment looks at the direct consequences of the genetic modification on the nutritional profile and composition of the food as well as any potential toxic or allergenic effects. As well as the intentional changes, the assessment also considers any unintended effects which may arise from the genetic modification.

The Authority has received the following applications to approve the addition of the following foods derived from genetically modified crops to the Table to clause 2 of *Standard A18 - Food Produced Using Gene Technology*:

| CROP | TRAIT | APPLICANT | ANZFA APPLICATION NUMBER | POTENTIAL FOODS USES |
|---|---|---|---|---|
| **SOYBEAN** | **Herbicide tolerance:** | | | 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. |
| | Glyphosate | Monsanto | A338 | |
| | **High oleic soybeans** | Optimum Quality Grains (DuPont / Pioneer) | A387 | |
| **CANOLA (Oil seed rape)** | **Herbicide tolerance:** | | | Canola oil. May include edible oil products, fried foods, baked products, snack foods. |
| | Glufosinate ammonium and hybrid traits | AgrEvo | A372 | |
| | Glyphosate | Monsanto | A363 | |
| | Bromoxynil | Rhone Poulenc | A388 | |

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|---|---|---|---|---|
| **CORN** | **Insect resistance:** | | | |
| | Bt | Monsanto | A346 | |
| | **Herbicide tolerance:** | | | |
| | Glufosinate ammonium | AgrEvo | A375 | Corn oil, flour, sugar or syrup. |
| | Glufosinate ammonium (DLL25) | Monsanto | A381 | May include snack foods, baked goods, fried foods, edible oil products, confectionery, special purpose foods, soft drinks. |
| | Glyphosate | Monsanto | A362 | |
| | **Herbicide tolerance & insect resistance:** | | | |
| | Glufosinate ammonium & Bt | | | |
| | (DBT418) | Monsanto | A380 | |
| | (Bt-176 Maize) | Novartis | A385 | |
| | (Bt-11 Maize) | Novartis | A386 | |
| **POTATO** | **Insect resistance:** | | | |
| | Bt | Monsanto | A382 | |
| | **Insect resistance & virus resistance:** | | | |
| | Bt & potato virus Y (PVY) resistant | Monsanto | A383 | May include snack foods, processed potato products and other processed foods. |
| | Bt & potato leaf roll virus (PLRV) resistant | Monsanto | A384 | |
| **SUGAR-BEET** | **Herbicide tolerance:** | | | |
| | Glyphosate | Monsanto / Novartis | A378 | May include any processed foods containing sugar. |

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|---|---|---|---|---|
| **COTTON** | **Insect resistance:** | | | |
| | Bt - Cry1Ac gene | Monsanto | A341 | Cottonseed oil and linters. |
| | Bt - Cry2Aa gene | Monsanto | A389 | Products may include blended vegetable oils, fried foods, baked foods, snack foods, edible oil products, small goods casings. |
| | **Herbicide tolerance:** | | | |
| | Glyphosate | Monsanto | A355 | |
| | Bromoxynil | Monsanto / Rhone Poulenc | A379 | |

ANZFA considers that these twenty applications substantially cover the genetically modified crops likely to be imported as foods into Australia and New Zealand. All applications have met regulatory requirements for foods produced using gene technology in one or more of the following countries: USA, Canada, Japan and the European Union.

The Authority is now progressing each of these applications, which are in varying stages of completion.