

**FOOD STANDARDS  
AUSTRALIA NEW ZEALAND**

**APPLICATION HANDBOOK**

**1 October 2007**

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## ACRONYMS AND ABBREVIATIONS

ACCC	Australian Competition and Consumer Commission
ADI	Acceptable daily intake
ALARA	As low as reasonably achievable
AS	Australian Standard
CA	Chemical Abstracts
CCI	Confidential commercial information
Codex	Codex Alimentarius Commission
DBPCFC	Double blind placebo controlled food challenge
DIAMOND	<u>D</u> ietary <u>m</u> odelling of <u>n</u> utritional <u>d</u> ata
ECCB	Exclusive capturable commercial benefit
ERL	Extraneous residue limit
FAO	Food and Agricultural Organization
GM	Genetically modified
GMP	Good manufacturing practice
HACCP	Hazard assessment critical control point
IUPAC	International Union of Pure and Applied Chemists
ISO	International Standards Organization
JECFA	Joint (FAO/WHO) Expert Committee on Food Additives
ME	Metabolisable energy
ML	Maximum level
MRL	Maximum residue limit
NATA	National Association of Testing Authorities
NHMRC	National Health Medical Research Council
RIS	Regulatory impact statement
TPA	Trade Practices Act
WHO	World Health Organization
WTO	World Trade Organization

# **PART 1**

# **OVERVIEW**

## 1.1 INTRODUCTION

The Application Handbook provides the essential information required to make an application to vary the *Australia New Zealand Food Standards Code* (the Code). It provides background information on the Code and the role of Food Standards Australia New Zealand (FSANZ), as well as practical information on the procedure for making an application to FSANZ to vary the Code.

Under amendments to the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) in 2007, applications to vary the Code to contain the information specified in Part 3 of this *Application Handbook*. Applications which do not contain this information will not be accepted.

Potential applicants are encouraged to discuss their application with FSANZ prior to submission in order to clarify the nature of the application and to identify the information required in the application.

The *Application Handbook* is a 'living' document – it will change and be updated as required to reflect new information or to clarify the application information requirements. All changes to Part 3 of the *Application Handbook* will involve consultation and approval by the FSANZ Board.

## 1.2 THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

The Code contains food standards which have been developed, approved and gazetted by FSANZ. The Code applies to all food sold or prepared for sale in Australia and New Zealand (except where specified 'Australia only'). Any agency, body or person can make an application to vary the Code. In accordance with State, Territory and New Zealand food legislation, it is an offence to supply food that does not comply with the Code.

The Structure of the Code is as follows:

**Chapter 1 General Food Standards** – labelling requirements, permissions for use of substances added to food, permissions for use of new foods, maximum limits for chemical and microbiological contaminants, maximum residue limits for pesticides (Australia only), food processing requirements (Australia only).

**Chapter 2 Food Product Standards** – composition of cereals, fruits, vegetables, dairy products, beverages and special purpose foods.

**Chapter 3 Food Safety Standards (Australia only)** – food safety programs, food premises and equipment.

**Chapter 4 Primary Production Standards (Australia only)** – production and processing of seafood, poultry meat, meat and specific cheeses. As at June 2007, this Chapter is still largely under development.

The Code can be viewed on the FSANZ website at <http://www.foodstandards.gov.au/thecode/foodstandardscode.cfm>. Food produced only for export to countries other than Australia or New Zealand and food produced for personal use may not be required to comply with the Code.

## **1.3 FOOD STANDARDS AUSTRALIA NEW ZEALAND**

### **1.3.1 Role of FSANZ**

FSANZ is an Australian Commonwealth statutory authority established under the FSANZ Act and is an independent, expert scientific body. Its functions are stipulated in the FSANZ Act. These functions include developing food standards and variations to food standards that are included in the Code. Food standards are developed by FSANZ, either by application from any agency, body, or person, or by a proposal of its own initiative. Standards or variations to standards are approved by the FSANZ Board.

FSANZ also has a range of other functions under the FSANZ Act including facilitating harmonisation of State and Territory laws relating to food, coordinating national food surveillance and recall systems, conducting research, working with other national food agencies and international agencies, reviewing existing Standards, and developing codes of conduct with industry.

Standards approved by the FSANZ Board are subject to review by a council known as the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). The Ministerial Council comprises Health Ministers from all Australian States and Territories, the Australian and New Zealand Governments, as well as other Ministers from related portfolios where these have been nominated by their jurisdictions. Once the Ministerial Council process is finalised, the variations to the Standards are gazetted and then automatically adopted by reference under food legislation of the Commonwealth of Australia, the Australian States and Territories and New Zealand.

Although FSANZ develops food standards, responsibility for ensuring compliance with food standards for both domestically produced food and imported food rests with local government, States and Territory Governments in Australia and the New Zealand Government. Food imported into Australia is also subject to the *Imported Food Control Act 1992* (Cth).

### **1.3.2 FSANZ objectives**

Section 18 of the FSANZ Act sets out FSANZ's objectives (in descending priority order) in developing food regulatory measures and variations of food regulatory measures as:

- (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.

In developing food regulatory measures and variations of food regulatory measures, FSANZ 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; and

(e) any written policy guidelines formulated by the Ministerial Council.

## **1.4 NAVIGATING THE *APPLICATION HANDBOOK***

**Part 1** of the *Application Handbook* provides general introductory information.

**Part 2** of the *Application Handbook* provides practical information regarding the lodgement and processing of an application.

**Part 3** of the *Application Handbook* contains details of the information required to be submitted with an application.

Applications to vary the Code will generally, but not exclusively, relate to one or more of the following groups of standards:

1. Standards related to labelling and other information requirements
2. Standards related to substances added to food
3. Standards related to contaminants and natural toxins
4. Standards related to new foods
5. Standards related to composition of food products
6. Standards related to food production

Each of these broad groups of standards contains a number of individual food standards which relates to specific food matters. For each, there will be different information requirements.

Part 3 of the *Application Handbook* begins with a section on general requirements which are common to all applications. The sections which follow contain more specific requirements related to each of the groups of Standards given above. Applicants will need to identify which parts of the *Application Handbook* are relevant to a specific application.

The flowchart diagram below may assist applicants to identify the relevant parts of the *Application Handbook*.

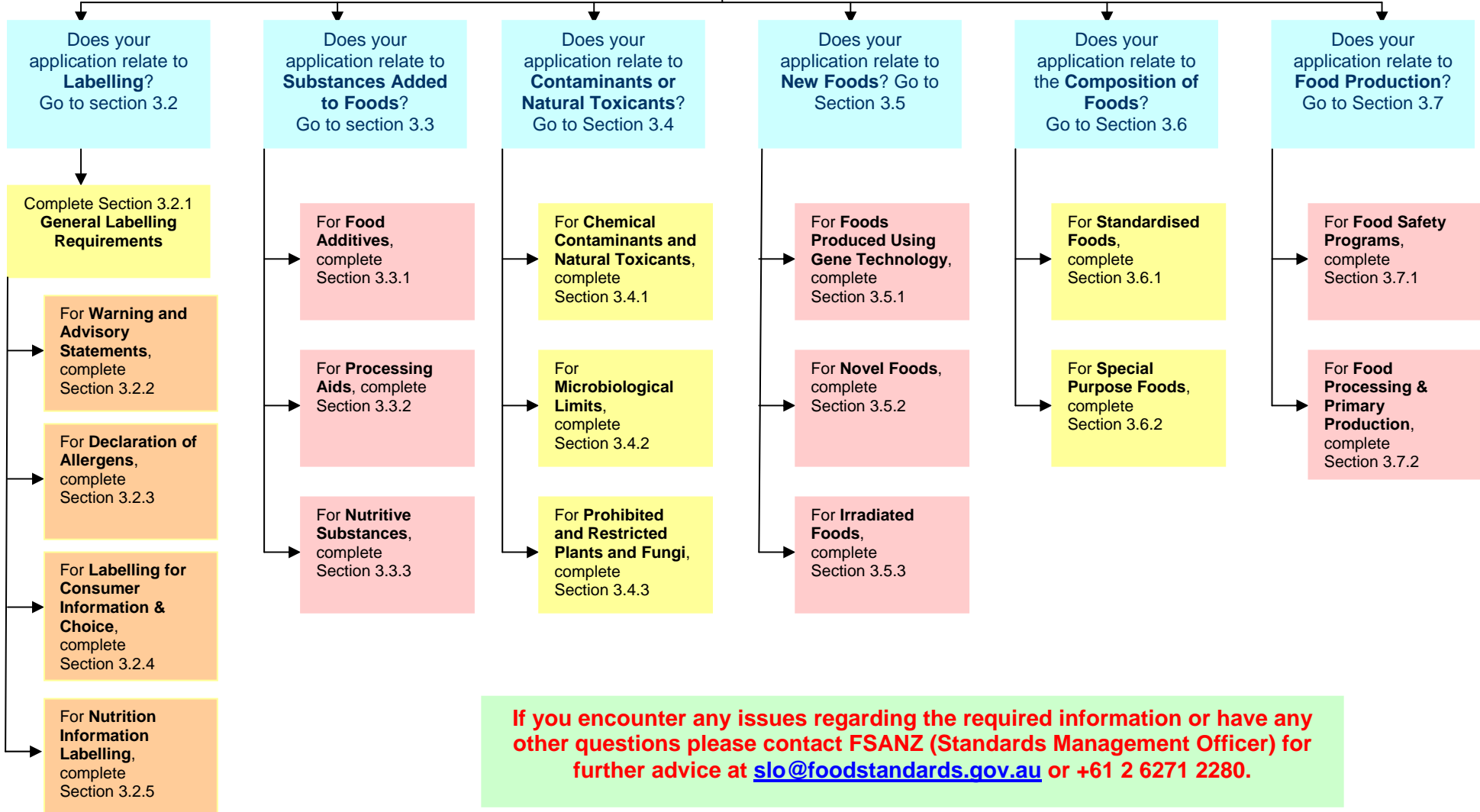
In the case of the *Standards Related to Labelling and Other Information Requirements*, applicants should begin with the section on *General Food Labelling*, which contains general requirements for an application related to labelling. The other sections relate to particular aspects of labelling, which may or may not be relevant to a particular application.

In the case of the other groups of Standards, applicants should identify the section which is relevant to their particular application.

The *Application Handbook* does not provide details regarding why specific information is required nor how the information will be used in the assessment process. This is beyond the scope of the *Application Handbook*. This information will be provided, where possible, in accompanying *Guidance Documents* (via references/links). Some of these are already available and others will be developed in the future.

Read Part 1 & 2 of the *Application Handbook* which provide essential information for making an application.  
Arrange a meeting with FSANZ to discuss your application prior to submission (strongly recommended)

Begin the application by completing Section 3.1 – General Requirements.  
Proceed to specific sections listed below.



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# **PART 2**

# **GENERAL APPLICATION PROCEDURES**

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## **2.1 MAKING AN APPLICATION**

### **2.1.1 Application Inquiries**

Application inquiries must be directed to the Standards Management Officer by email to [slo@foodstandards.gov.au](mailto:slo@foodstandards.gov.au) or telephone: +61 2 6271 2280.

Applicants are strongly advised to consult with FSANZ prior to submitting an application to ensure that the application contains all the necessary information relevant to the proposed variation to the Code. This can be done via teleconference, video link or at a face-to-face meeting. Please contact the Standards Management Officer to make arrangements.

Applicants must ensure that their applications meet any requirements laid out in the relevant guidelines set out in Part 3 of this Handbook.

### **2.1.2 Lodging an Application**

Ideally, (if under 3 MB, or via a Zip file if larger than 3 MB) applications can be submitted electronically through the application form on the FSANZ website at [xxxxxxx \(site under development at 1 October 2007\)](#) or emailed to [slo@foodstandards.gov.au](mailto:slo@foodstandards.gov.au). Alternatively, applications may be submitted by email to the Standards Management Officer at [applications@foodstandards.gov.au](mailto:applications@foodstandards.gov.au) or by post or courier to the following address:

Food Standards Australia New Zealand  
PO Box 7186  
CANBERRA BC ACT 2610  
AUSTRALIA

Applications should be clearly identified with the word ‘Application’ and follow the stipulated form as prescribed in Part 3.1.1.

### **2.1.3 Information Requirements for an Application**

An application must contain the information specified in Part 3 of this *Application Handbook*.

For further details regarding the use of Part 3, please refer to Section 1.4 – Navigating the *Application Handbook*.

For further details in relation to the data quality, please refer to Section 3.1.5 – Information to support the Application.

## 2.1.4 Fees

### ***When do fees apply?***

FSANZ does not charge a fee for the assessment of an application unless either:

- FSANZ determines that an applicant has an exclusive capturable commercial benefit (ECCB) (*see below*); or
- an applicant wishes work to start on the assessment immediately, rather than according to the anticipated timeframes established as part of the Administrative Assessment.

### ***Applications with an Exclusive Capturable Commercial benefit***

Where an application is likely to result in an amendment to the Code that provides exclusive benefits to the applicant, the application is considered to confer an ‘exclusive capturable commercial benefit’ (ECCB) and the applicant is required to pay the full cost of processing their application..

Section 8 of the FSANZ Act provides

*An exclusive, capturable commercial benefit is conferred upon a person who applies for the development of a food regulatory measure or the variation of a food regulatory measure under section 22 if:*

- (a) the applicant can be identified as a person or body that may derive a financial gain from the coming into effect of the draft standard or draft variation of the standard that would be prepared in relation to the application; and*
- (b) any other unrelated persons or bodies, including unrelated commercial entities, would require the agreement of the applicant in order to benefit financially from the approval of the application.*

### ***When are fees payable?***

Fees are determined as part of the Administrative Assessment process. Fees are payable after the applicant has been formally notified of FSANZ’s decision in relation to the appropriate assessment Procedure under s.27 of the FSANZ Act.

The full cost-recovery charge for applications with an ECCB being considered under either the General or Minor Procedures must be paid within 20 business days after the above notification has issued. The application is rejected if payment is not received by FSANZ within the 20 days. In the case of applications being considered under the Major Procedure, the fees may either be paid in full or in two instalments of 25% and 75% of the full cost-recovery charge. If either the full charge or the 1<sup>st</sup> instalment of 25% of the full charge is not received within the 20 days, the application is rejected. Payment of the 2<sup>nd</sup> instalment of 75% of the full charge will be due on the date submissions for the first round of public comment close.

In circumstances where an applicant wishes FSANZ to expedite work on the assessment of an application being considered under either the General or Minor Procedures, FSANZ must receive the full cost recovery fees. Work will not commence on the application until the full cost-recovery charge is paid.

In the case of applications being considered under the Major Procedure, the fees may either be paid in full or in two instalments of 25% and 75% of the full cost-recovery charge. Work will not commence on the application until either the full cost-recovery charge or the 1<sup>st</sup> instalment of 25% of the full charge is paid. Payment of the 2<sup>nd</sup> instalment of 75% of the full charge will be due on the date submissions for the first round of public comment close.

In any case where the 2<sup>nd</sup> instalment of fees are owing, FSANZ will not work on the application until the 2<sup>nd</sup> instalment is paid.

Generally, fees must be paid in Australian dollars. However, New Zealand applicants may pay fees in New Zealand currency, the amount of which will be calculated using the official exchange rate on the day the fee is paid.

Fees will be partially refundable, in accordance with the FSANZ Regulations. The fees are exempt from GST. Fees are indicated in the table below:

Procedure	Hours	Total Fees \$AUD <sup>1</sup>	Indicative Total Fees \$NZ <sup>*</sup>
Minor Procedure	Up to 175 hours	\$18,725	\$21,535
General Procedure	Up to 500 hours	\$53,500	\$61,525
	Up to 850 hours	\$90,950	\$104,595
Major Procedure	more than 1050 hours <sup>**</sup>	\$112,350	\$129,205

\* The figures above are therefore only indicative, calculated on an exchange rate of \$AUD1 = \$NZ1.15.

\*\* If FSANZ determines, under the FSANZ Regulations, that the complete assessment of the application is likely to require more than 1050 hours, a surcharge of \$A107 per hour will apply for each completed hour.

### ***How to pay Fees***

Payment of fees can be made by direct deposit (preferred) or by cheque. **Direct deposits** should be directed to:

Commonwealth Bank of Australia  
84 Giles Street  
KINGSTON ACT 2604  
**BSB:** 062-910  
Account No.: 1000 8279  
Account Name: Food Standards Australia New Zealand (AXXXX)

**Cheques** should be made payable to *Food Standards Australia New Zealand (AXXXX)* and sent to:

Finance Department  
Food Standards Australia New Zealand  
PO Box 7186  
CANBERRA BC ACT 2610  
AUSTRALIA

### 2.1.5 Confidential Commercial Information

Applicants may ask FSANZ to treat all or part of the information that they supply as confidential commercial information. Subsection 4(1) of the FSANZ Act provides that:

*confidential commercial information, in relation to food, means:*

- (a) *a trade secret relating to food; or*
- (b) *any other information relating to food that has a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.*

Generally, the types of information regarded as confidential commercial information relates to trade secrets, manufacturing processes, innovative new products or marketing strategies. In most cases, only specific, limited sections of an application are regarded as confidential commercial information.

Applicants must request that material is treated as confidential, and justify why it should be considered to be confidential commercial information. **The information must be separated from other application documents (both electronically and in hard copy).** FSANZ will consider any requests made and may seek further information from an applicant. FSANZ may, in part or in total, refuse any request for confidentiality, if the information does not meet the definition contained in the Act. The relevant FSANZ General Manager makes the decision about what material should be treated as confidential commercial information in the first instance, on advice from FSANZ's Office of Legal Counsel.

If such a request is refused, applicants then have the option of withdrawing their application in full or the relevant information, as all information (other than confidential commercial material) provided in an application is placed on the public record.

Unless applicants make a specific request for information to be treated as confidential commercial information, all information pertaining to an application will be available to any interested party and will be accessible by the public via the FSANZ website or the Public Register.

### 2.1.6 Food Standards Development Work Plan

In recognition of the fact that FSANZ has limited resources and it is not possible to process unlimited numbers of applications within a fixed period, FSANZ prioritises its work through the creation of the Food Standards Development Work Plan. The development of a Work Plan is required under section 20 of the FSANZ Act. FSANZ must consult interested persons in developing the Work Plan and FSANZ must review and update the Work Plan at least every three months.

Once the Administrative Assessment has been carried out and an application is accepted by FSANZ, the application is assigned a number and placed on Work Plan. Commencement of the formal assessment of unpaid applications depends on their place on the Work Plan, based on the order of receipt.

Details provided on the Work Plan include:

- the application number and title;

- the applicant;
- a brief description of the purpose of the application;
- date received;
- the statutory start and finish dates for the assessment process;
- the assessment Procedure to be undertaken and the complexity of assessment; and
- an indication of the anticipated timeframes for the steps in the assessment process.

Links to the application, and where relevant, assessment reports and submissions will be included.

Commencement of the formal assessment of unpaid applications depends on the place the application occupies on the Work Plan, based on its order of receipt.

The Work Plan can be viewed on the FSANZ website at <http://www.foodstandards.gov.au/standardsdevelopment/standardsworkplan.cfm> or it can be obtained from the FSANZ Information Officer on +61 2 6271 2222. The Work Plan on the website is regularly updated.

### **2.1.7 FSANZ’s Obligations to Applicants**

FSANZ will keep applicants informed of the progress of the application throughout its assessment. FSANZ is obliged to formally notify applicants in writing of its decisions at certain parts of the assessment process including:

- on completion of the Administrative Assessment of an application where FSANZ has decided whether to accept or reject an application;
- on completion of the ‘Preparation of a draft variation’ stage;
- on completion of the ‘Assessment’ stage; and
- after the completion of the ‘Approval’ stage.

Applicants are also advised of other matters during the assessment process such as:

- receipt of an application;
- any decision by the Ministerial Council; or
- when an amendment to the Code resulting from an application is to be gazetted, as well as being included in any public notification of a call for submissions.

The Project Coordinator who is allocated to an application, will also remain in regular contact with the applicant.

If an application is rejected, FSANZ will notify the applicant in writing and outlining the reasons for rejection. An applicant can apply to the Administrative Appeals Tribunal for a review of that decision within 28 days of notification of the rejection.

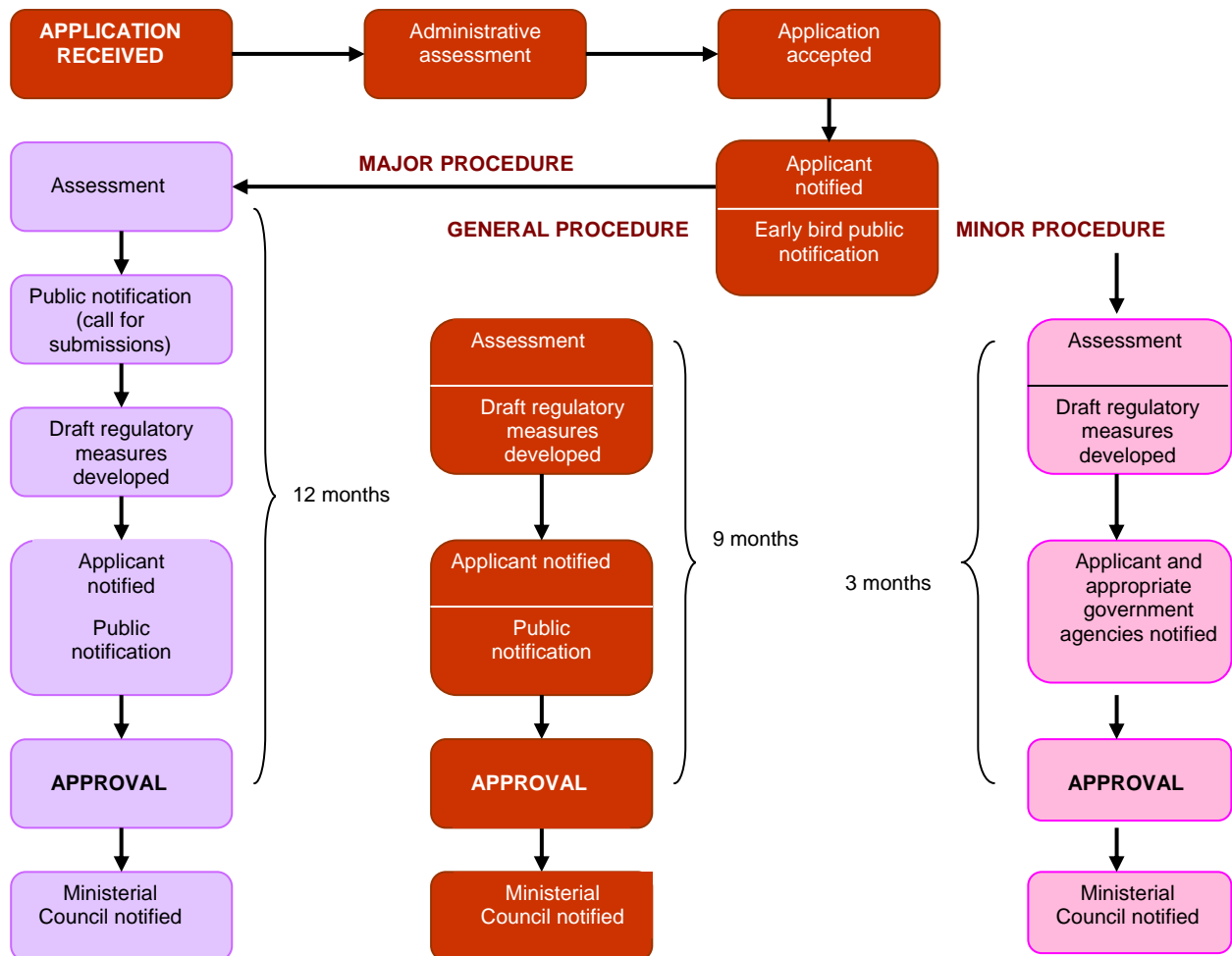
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## 2.2 PROCESSING APPLICATIONS

### 2.2.1 Assessment Procedures

All applications are subject to an ‘Administrative Assessment’ on receipt by FSANZ. The main purpose of the Administrative Assessment is to determine whether the application meets the application requirements and the Procedure by which it should be assessed.

Applications are then assessed under one of three Procedures – General (see Part 2.2.5), Minor (see Part 2.2.6) or Major (see Part 2.2.7).



### 2.2.2 Community Involvement and Consultation

FSANZ has a commitment towards community involvement and recognises that community involvement is a two-way process. Effective consultation begins with FSANZ being very open about food standards under development and informing the community about the processes and issues pertinent to each application and proposal.

FSANZ is also very welcoming of comments on each application and proposal, either as formal submissions on assessment reports or through participation at stakeholder forums.

This commitment has its basis in the FSANZ Act and reflects the need to ensure that consultation informs the assessment of applications.

The aim of FSANZ's approach to consultation is to adopt a flexible approach, varying the scope and intensity of community involvement to suit the circumstances and importance of the issues under consideration. A variety of community involvement techniques are used to best suit the diverse needs of those being consulted and people and organisations are encouraged to use a variety of methods to make their views known.

Interest groups and individuals have differing resources and this affects their ability to become involved in the consultation process.

New Zealand has its own statutory obligations under the New Zealand Food Act 1981 when issuing food standards. Whilst they differ slightly, these requirements are accommodated in FSANZ's stated consultation processes.

The views of Maori and indigenous peoples also have to be addressed in FSANZ's community involvement processes.

The process by which FSANZ considers food standards matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the application and the impacts of regulatory options. The issues raised in the public submissions are evaluated and addressed in FSANZ's assessment reports.

In many cases there will be strong conflicting views expressed by submitters. It can be expected that some of the views expressed will be subjective, with no supporting evidence provided, or maybe a selective use of evidence or references. The FSANZ approach has to be consistent and decisions have to be based on the best available scientific evidence.

FSANZ needs to ensure that it has collected sufficient evidence, including from outside experts if necessary, in order to be able to undertake a rigorous analysis of each case. In some situations the best available scientific evidence is irrefutable. In others there might be conflicting scientific views, a lack of evidence or some uncertainty in the science. Where the evidence is in dispute, FSANZ will ensure that it sets out the reasoning and logic used to reach its decision/s.

### **2.2.3 Statutory Timeframes**

The FSANZ Act and the associated Regulation require FSANZ to make its decisions relating to applications within stipulated periods of time, depending on the Procedure into which an application has been placed:

- Administrative Assessment 15 business days (from receipt of application to decision to accept or reject application).
- General Procedure (Subdivision D of the FSANZ Act – 9 months (from commencement of assessment or receipt of fees to the date of approval of the draft food regulatory measure).
- Minor Procedure (Subdivision E of the FSANZ Act – 3 months (from commencement of assessment or receipt of fees to the date of approval of the draft food regulatory measure).

- Major Procedure (Subdivision F of the FSANZ Act – 12 months (from commencement of assessment or receipt of fees to the date of approval of the draft food regulatory measure)).

The statutory timeframe for applications being considered under the Major Procedure only can be extended for up to six months by FSANZ. This statutory timeframe does not include time taken for an applicant to provide additional information or fees (where applicable). FSANZ is required to indicate where it has extended the timeframe for completion of an assessment or where it has failed to meet its statutory timeframes and the reasons why in its Annual Report.

FSANZ also has the discretion to ‘stop the clock’ if it needs more information in order to complete an assessment of an application (s.108 of the FSANZ Act).

If an applicant fails or refuses to comply with FSANZ’s request for further information under s.108 of the FSANZ Act without reasonable excuse, the application is taken to have been withdrawn.

#### **2.2.4 Administrative Assessment**

An Administrative Assessment of an application is made by FSANZ within 15 business days after an application is given to FSANZ. The purpose of the Administrative Assessment stage is to determine whether an application is accepted or rejected under s.26 of the FSANZ Act.

In undertaking an Administrative Assessment, FSANZ must have regard to:

- whether the application meets the application requirements (including such information as is specified in writing by FSANZ in the *Application Handbook*;
- whether the application relates to a matter that may be developed as a food regulatory measure, or that warrants the variation of a food regulatory measure;
- whether the application is so similar to a previous application or proposal for the development or variation of a food regulatory measure that it ought to be rejected;
- any other relevant matter.

After undertaking an Administrative Assessment FSANZ must either accept or reject an application:

- if the application is rejected, FSANZ notifies the applicant with a statement of reasons;
- or
- if the application is accepted:
  - determines the assessment Procedure to be applied;
  - determines whether or not the proposed development or variation of the food regulatory measure would confer an exclusive, capturable commercial benefit on the applicant; and
  - notifies the applicant that the application has been accepted and the assessment Procedure that the application will be assessed under.

If the application is accepted, it is placed on the Work Plan (*see Part 2.1.6*).

### **2.2.5 General Procedure**

The General Procedure is the default assessment process and involves one round of public comment. For the purposes of cost-recovery under the Regulations, the General Procedure is split into two levels.

#### ***Level 1 (up to 500 hours)***

For example, an application for a variation of a food regulatory measure involving:

- (a) allowing a processing aid that is currently not permitted;
- (b) extending permission for use of a food or a food additive;
- (c) making a minor change to a labelling requirement;
- (d) making a minor change to a compositional requirement for a food;
- (e) granting a permission involving a pre-market safety assessment similar to a previous assessment; or
- (f) reducing a maximum residue limit.

This kind of application is likely to:

- (a) involve an assessment of the risk to public health and safety of average complexity; or
- (b) have only a limited social or economic impact; or
- (c) require a simple toxicological, nutritional, food technology, dietary modelling or microbiological assessment; or
- (d) require a simple assessment of risk management requirements; or
- (e) involve any other matter of similar complexity.

#### ***Level 2 (up to 850 hours)***

For example, an application for a variation of a food regulatory measure involving:

- (a) allowing a food or food additive that is not currently permitted;
- (b) changing a compositional requirement for a food;
- (c) establishing or increasing a maximum permitted concentration for an environmental contaminant or heavy metal;
- (d) changing permission to add a nutritive substance;
- (e) changing a labelling requirement for a food;
- (f) granting a permission involving a pre-market safety assessment similar to a previous assessment;
- (g) regulating a new micro-organism.

This kind of application is likely to:

- (a) involve a more complex assessment of the risk to public health and safety; or
- (b) have a broader social or economic impact; or
- (c) require a complete toxicological, nutritional, food technology, dietary modelling or microbiological assessment; or
- (d) require targeted consultation with key stakeholders, special interest groups; or
- (f) may require comprehensive consideration of risk management requirements; or
- (g) insert and amend maximum residue limits; or

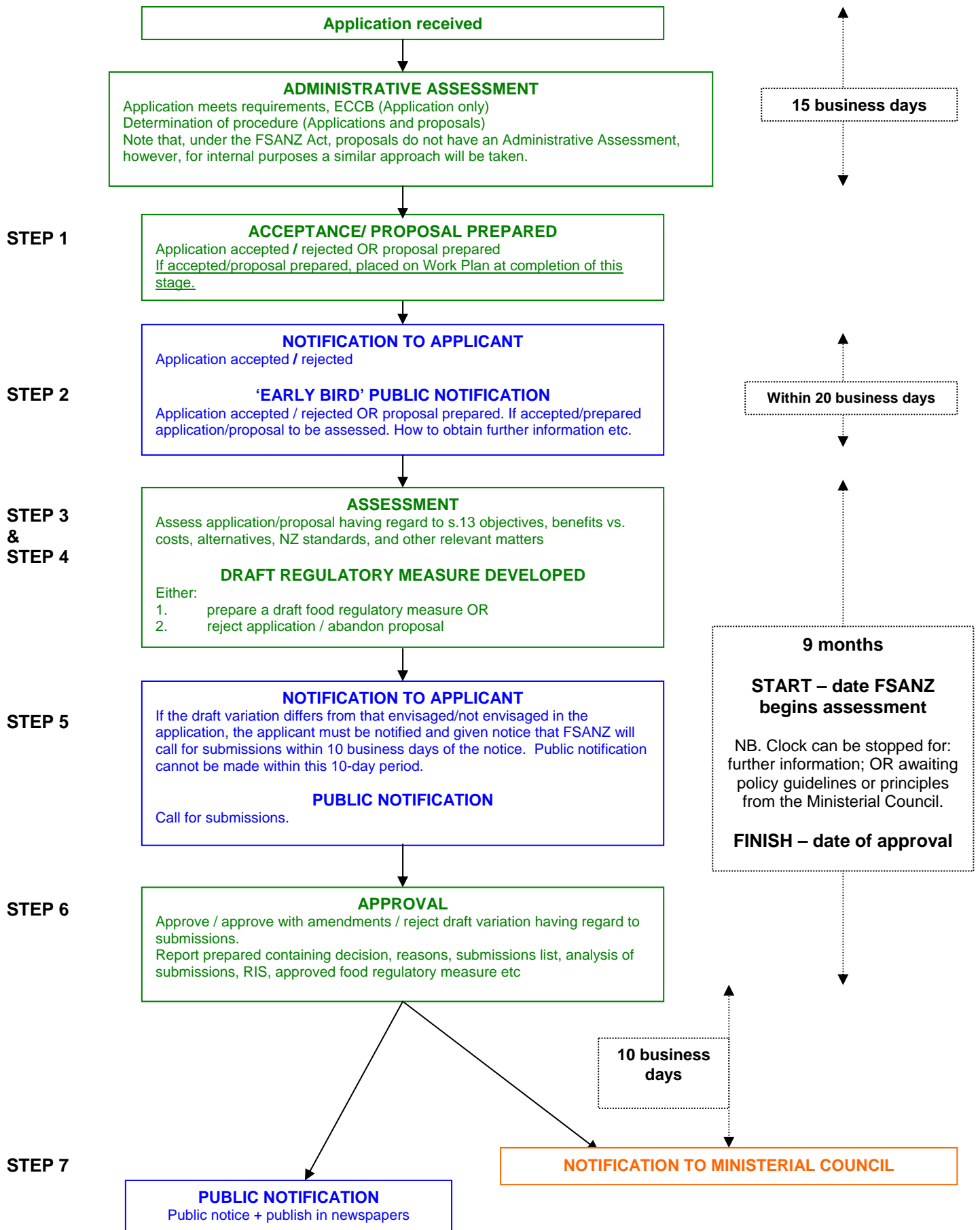
- (h) require the establishment of high level advisory groups to discuss and interpret scientific evidence and social perceptions; or
- (i) involve the development of a community communications strategy to address public concern; or
- (j) involve any other matter of similar complexity.

***Key Procedural Steps***

- Step 1            Acceptance or rejection of application
- Step 2            Notification to applicant & ‘Early Bird’ public notice
- Step 3 &  
Step 4            Assessment & draft food regulatory measure developed
- Step 5            Notification to applicant and call for public submissions
- Step 6            Approval of draft food regulatory measure
- Step 7            Notification of approval of draft food regulatory measure to Ministerial Council
- Step 8            Gazettal following advice from Ministerial Council to not review the approval decision

# GENERAL PROCEDURE (Subdivision D)

Default – Unpaid applications or proposals – cannot be used for a new food regulatory measure



## 2.2.6 Minor Procedure

Assessment under the Minor Procedure applies to an application for the variation of a food regulatory measure that, if made, would not directly or indirectly:

- (a) impose, vary or remove an obligation on any person; or
- (b) create, vary or remove a right of any person; or
- (c) otherwise alter the legal effect of the measure.

One round of consultation is carried out with Government agencies only. A application would fall within this Procedure if its only effect would be:

- (a) correcting a typographical error; or
- (b) updating a reference to another document; or
- (c) amending a cross-reference within a food regulatory measure; or
- (d) omitting provisions of a food regulatory measure that has ceased to have effect; or
- (e) any other matter of similar complexity

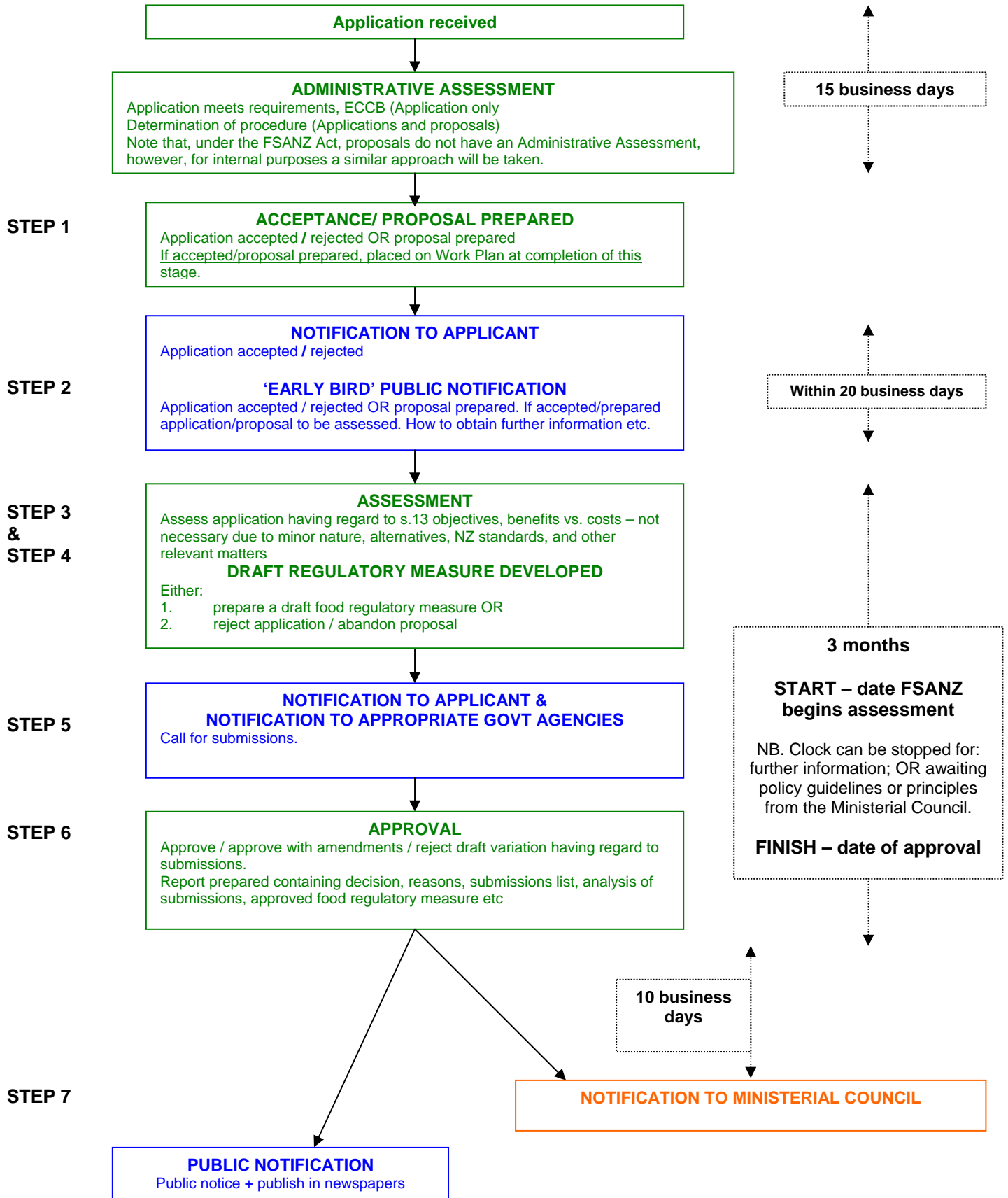
### ***Key Procedural Steps***

- |                    |  |
|--------------------|--|
| Step 1             | Acceptance of application  |
| Step 2             | Notification to applicant & 'Early Bird' public notice                                 |
| Step 3 &<br>Step 4 | Assessment & draft food regulatory measure developed                                   |
| Step 5             | Notification to applicant and call for submissions from government agencies            |
| Step 6             | Approval of draft food regulatory measure  |
| Step 7             | Notification of approval of draft food regulatory measure to Ministerial Council       |
| Step 8             | Gazettal following advice from Ministerial Council to not review the approval decision |

Where the proposed amendment will potentially affect the interests or rights of any parties, FSANZ will consult with these parties and take into account their views in making a decision on the matter.

# MINOR PROCEDURE (Subdivision E)

Unpaid applications or proposals – cannot be used for a new food regulatory measure



## 2.2.7 Major Procedure

Assessment under the Major Procedure applies to:

- (a) an application for the development of a new food regulatory measure; and
- (b) an application for the variation of a food regulatory measure that:
  - (i) involves such scientific or technical complexity that it is necessary to adopt this procedure in considering it; or
  - (ii) involves such a significant change to the scope of the food regulatory measure that it is necessary to adopt this procedure in considering it.

An application for the development of, or a major variation to, a new food regulatory measure involving:

- (a) the development of a new Standard; or
- (b) a change to a labelling requirement affecting a wide range of foods; or
- (c) a change to a compositional requirement for a food affecting a wide range of foods; or
- (d) a change to a nutritive substance permissions affecting a wide range of foods; or
- (e) the granting a permission involving a pre-market safety assessment, with no similar previous assessments; or
- (f) any other matter of similar complexity.

This kind of application is likely to:

- (a) require the use of community meetings including public hearings; or
- (b) involve the development of a complete community communications strategy to address public concern; or
- (c) require the development and distribution of community education material; or
- (d) require representation at international forums; or
- (e) require extensive consultation with government agencies, industry, health professionals and consumer groups; or
- (f) require establishment of external working parties and advisory groups; or
- (g) require a comprehensive assessment of risk management requirements; or
- (h) involve any other matter of similar complexity.

A minimum of two rounds of public comment would be required and consultation might also require the establishment of external working parties or advisory groups to assist with the assessment.

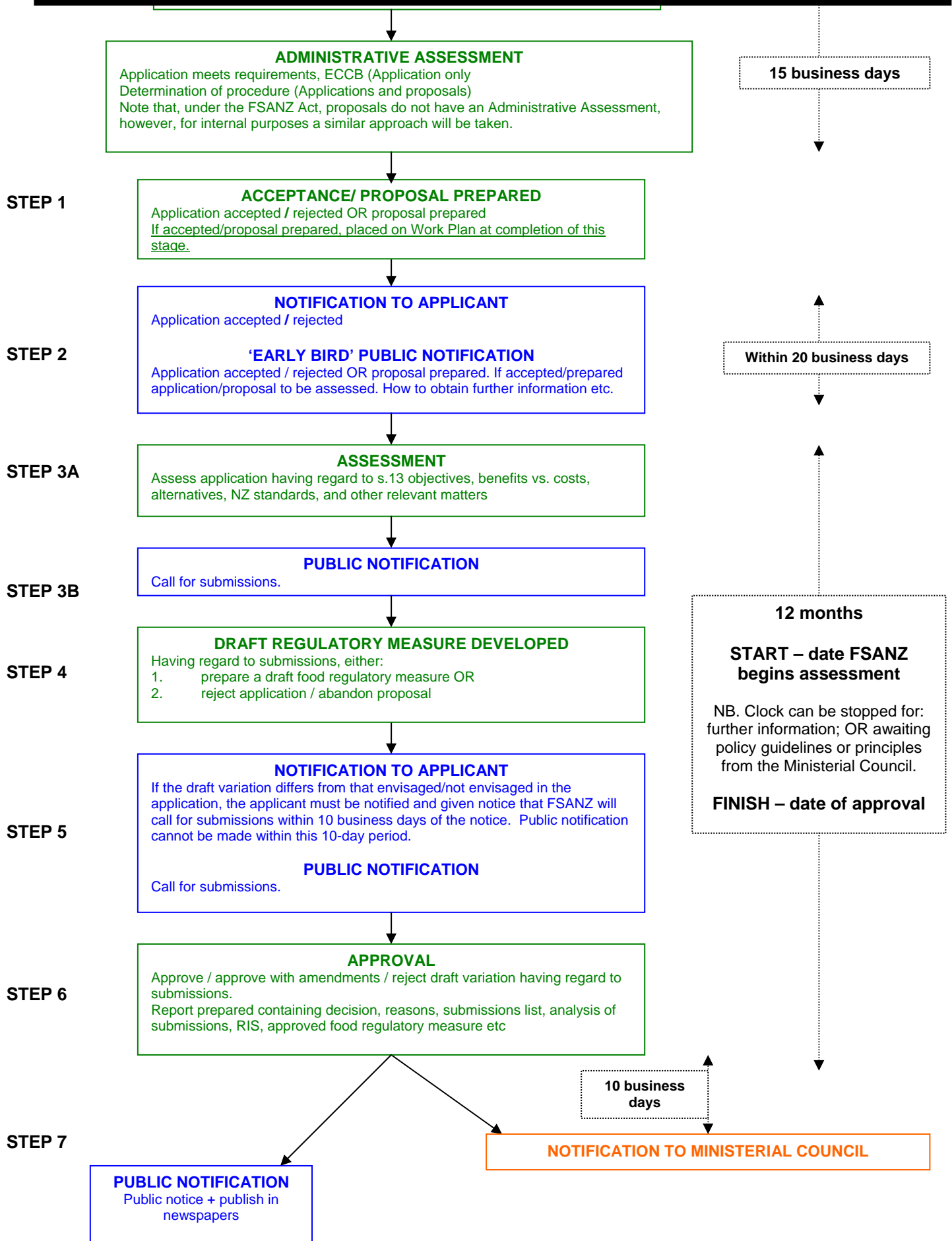
### ***Key Procedural Steps***

- |        |   |
|--------|---|
| Step 1 | Acceptance of application   |
| Step 2 | Notification to applicant & 'Early Bird' public notice                |
| Step 3 | Assessment, notification to applicant and call for public submissions |
| Step 4 | Draft food regulatory measure developed                               |
| Step 5 | Notification to applicant and call for public submissions             |

- Step 6 Approval of draft food regulatory measure
- Step 7 Notification of approval of draft food regulatory measure to Ministerial Council
- Step 8 Gazettal following advice from Ministerial Council to not review the approval decision

# MAJOR PROCEDURE (Subdivision F)

Unpaid applications or proposals – Development of new food regulatory measures & major variations



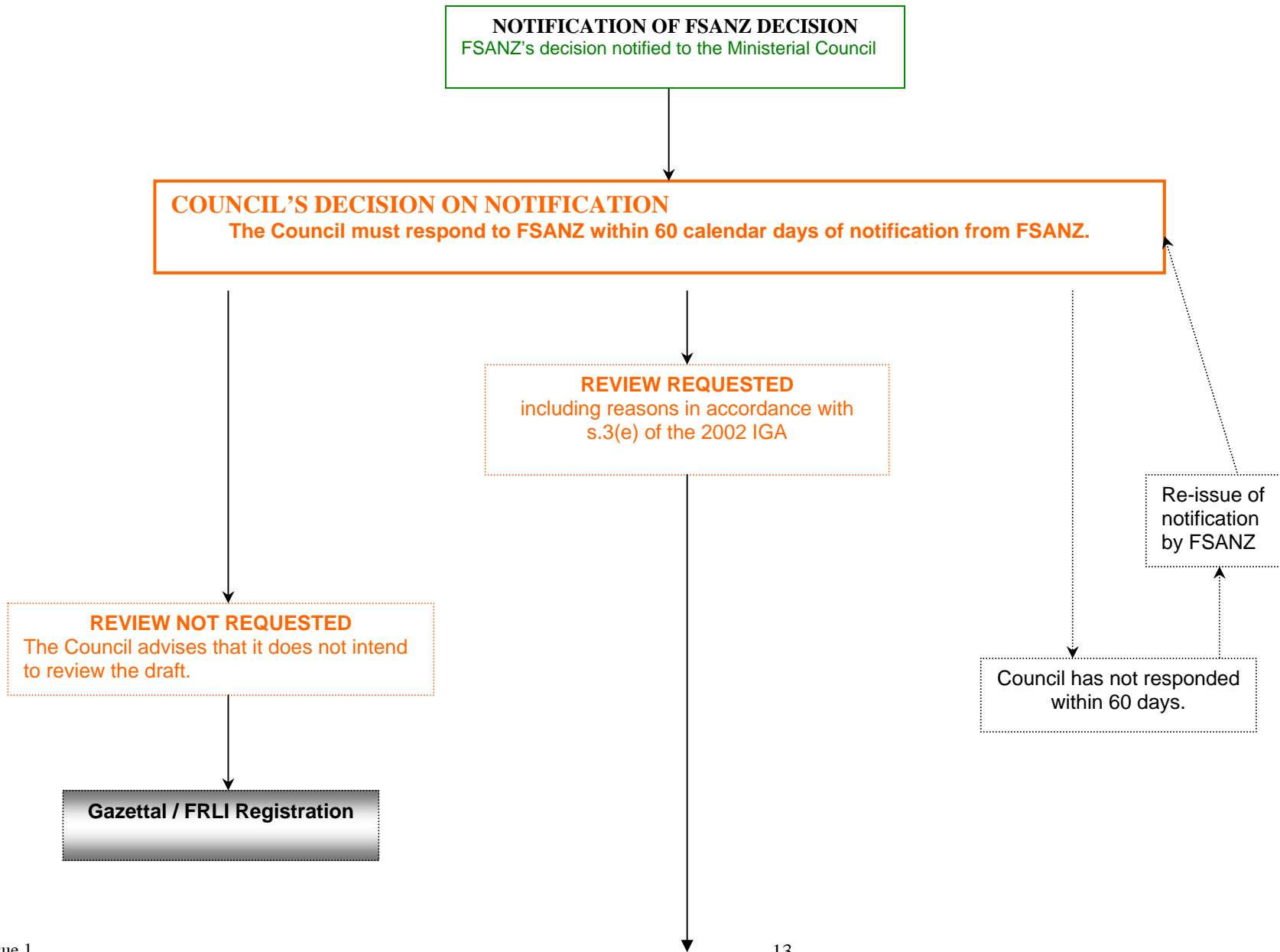
### **2.2.8 Ministerial Council Review**

After amendments to the Treaty with New Zealand are made, the Ministerial Council has one opportunity to request a review of a decision made by FSANZ. Following the Review, the Ministerial Council must make one of the decisions that was previously available after the Second Review, that is:

- inform FSANZ that it does not intend to amend or reject the draft; or
- amend the draft; or
- reject the draft.

Note that these amendments are pending, subject to the finalisation of the necessary corresponding change to the Treaty between Australia and New Zealand on the joint food standards system.

# MINISTERIAL COUNCIL PROCESS



# REVIEW

3 months for FSANZ Board to complete (Ministerial Council can allow more time) 3 month timeframe commences on the date of the Council's request for a Review.

**Review completed by FSANZ**

Either:

1. re-affirm approval OR
2. re-affirm approval, subject to amendment/s OR
3. withdraw approval

Decision notified to Ministerial Council

**COUNCIL'S DECISION ON OUTCOME OF REVIEW**  
 The Council must respond to FSANZ within 60 calendar days of notification from FSANZ\*.  
 If withdrawal of approval by Board, no further action by the Council required.

**WILL NOT AMEND or REJECT**  
 The Council advises it does not intend to amend or reject the draft Standard/variation

**AMENDS**  
 The Council amends the draft Standard/variation by written instrument

If the Council wishes to amend the standard/variation, FSANZ MUST have an opportunity to submit a draft of the text before Ministers consider the amendment.

**REJECTS**  
 The Council rejects the draft standard/variation

Re-issue of notification by FSANZ

The Council has not accepted, amended by written instrument or rejected within 60 days\*.

\*Note: Consideration being given to extending time limit if Council needs to amend.

**Gazettal / FRLI Registration**

**FSANZ ADVISED**  
 The Council informs FSANZ as soon as practicable, providing a copy of the amended draft standard/variation

**NOTICE PREPARED**  
 The Council (FR Secretariat) must prepare a notice outlining decision and reasons for decision, provide it to FSANZ and publish on the Internet and in a newspaper circulating in each S/T and in NZ. FSANZ to provide a link on its website.

### 2.2.9 Cost Benefit Analysis

As part of the assessment of an application, FSANZ is required to prepare a Regulatory Impact Statement (RIS), which includes an analysis of potential costs and benefits both economically and socially of the regulatory options available. The RIS, wherever possible, includes factual quantitative information. Potential effects of applications to amend the Code are assessed in relation to:

- Sectors of the food industry wishing to market the food products subject to the application. In particular, the effect on small business will be studied.
- Consumers – who will either benefit as a result of a new range of product becoming available or be subject to higher costs or savings.
- Government – usually there will be an impact on enforcing agencies or one State or Territory may be affected more than others or there may be a significant impact on New Zealand.
- Socio-economic issues in regional and rural areas.

To assist FSANZ in its assessment of the application in this area, Part 3 of the *Application Handbook* indicates what information on any social, economic and/or environmental impacts of the proposed amendment to the Code is required.

### 2.2.10 Withdrawal of an Application

Withdrawal of an application can occur in one of two ways:

1. an applicant can withdraw their application at any time after FSANZ has accepted the application, but before the approval of a food regulatory measure or notification that FSANZ has rejected an application. The notice to FSANZ of withdrawal must be in writing (to the Standards Management Officer); or
2. an application can be taken to have been withdrawn by FSANZ if an applicant fails or refuses to comply with FSANZ's request for further information under s.108 of the FSANZ Act without reasonable excuse.

If the application is a paid application, fees will be partially refundable, in accordance with the FSANZ Regulations.

### 2.2.11 Rejection of an Application

Rejection of an application can occur at a number of stages in the assessment process:

1. By FSANZ – at the conclusion of Administrative Assessment stage when a decision is taken to accept an application or not. The grounds for rejection are:
  - whether the application complies with the requirements of Part 3 of the *Application Handbook*;
  - whether the application relates to a matter that may be developed as a food regulatory measure, or that warrants the variation of a food regulatory measure;
  - whether the application is so similar to a previous application or proposal for the development or variation of a food regulatory measure that it ought to be rejected;

- any other relevant matter.

If the application is a paid application and is rejected, fees may be partially refundable, in accordance with the FSANZ Regulations.

2. By FSANZ – when fees due for an application with an ECCB have not been received. The grounds for rejection are:

- if the charge is not paid within 20 business days of the notification of the acceptance of an application.

Rejection in this case does not preclude the application from being re-submitted to FSANZ.

3. By FSANZ – at the completion of the Assessment or Approval stages. The grounds for rejection are:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure;
- whether other measures would be more cost-effective than a food regulatory measure developed or varied as a result of the application;
- any relevant New Zealand standards;
- submissions made to FSANZ;
- any other relevant matters, including the objectives of the FSANZ in developing food regulatory measures and variations of those measures (s.18 of the FSANZ Act).

If the application is a paid application and is rejected, fees may be partially refundable, in accordance with the FSANZ Regulations.

4. By the Ministerial Council – after a request to FSANZ for a review of a decision. The grounds for rejection of a draft variation or standard (from the Inter-Governmental Agreement and the Treaty between Australia and New Zealand on the joint food standards system) are:

- it is not consistent with existing Ministerial Council policy guidelines;
- it is not consistent with the objectives of the FSANZ Act;
- it does not protect public health and safety;
- it does not promote consistency between domestic and international standards where these are at variance;
- it does not provide adequate information to enable informed choice;
- it is difficult to enforce or comply with in both practical or resource terms;
- it places an unreasonable cost burden on industry or consumers.

# PART 3

## CONTENTS

## OF AN APPLICATION

The application requirements contained in this Part of the *Application Handbook* are made under sections 22 and 23 of the *Food Standards Australia New Zealand Act 1991*. These sections of the *Food Standards Australia New Zealand Act 1991* provides that an application to vary a standard in the *Australia New Zealand Food Standards Code* must –

- be in the form specified in any applicable application guidelines; and
- contain all the information specified in any applicable application guidelines.

Accordingly, applicants applying to vary the *Australia New Zealand Food Standards Code* must provide all the information specified in Part 3 of this *Application Handbook*.

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# **SECTION 3.1**

## **GENERAL REQUIREMENTS**

## 3.1 GENERAL REQUIREMENTS

An application can be made to vary any part of the *Australia New Zealand Food Standards Code* (the Code). The application must contain the information specified in this Section and as appropriate, the information indicated in Sections 3.2 to 3.7 of this *Application Handbook*.

### Note:

#### CONSULTATION WITH FSANZ

Applicants are strongly advised to consult with FSANZ prior to submitting an application to ensure that the application contains all the necessary information relevant to the proposed amendment to the Code. On-going consultation with FSANZ throughout the application process is also encouraged.

Industry and consumer groups are also encouraged to bring to the attention of FSANZ food standards issues which may require attention through means other than via an application.

#### TYPES OF APPLICATIONS

Applications will generally, but not exclusively, relate to one of the following groups of Standards:

1. Standards related to labelling and other information requirements
2. Standards related to substances added to food
3. Standards related to contaminants and natural toxins
4. Standards related to new foods
5. Standards related to composition of food products
6. Standards related to food production

Applications will need to address the information requirements of Section 3.1 and, in most cases, one or more of the Sub-sections in Sections 3.2-3.7.

#### MANDATORY INFORMATION REQUIREMENTS

The word '**must**' is used in Part 3 of the *Application Handbook* to identify information whose provision in an application is mandatory. Applicants should note that if this information is not provided, the application may be rejected at the administrative assessment stage and the applicant would then need to re-apply in a manner that meets the information requirements.

#### NON-MANDATORY INFORMATION REQUIREMENTS

The word '**should**' is used in Part 3 of the *Application Handbook* to identify information which would be useful in an application but its provision is not mandatory. Failure to provide this information will not result in rejection of an application at the administrative assessment stage. However, the information may be requested during assessment of the application.

### **3.1.1 FORM OF THE APPLICATION**

An application must be in the following form, otherwise it will not be considered as ‘given’ to FSANZ under the FSANZ Act.

Applications sent by facsimile will not be accepted.

#### **A. *Language***

The application and abstracts of supporting information must be presented in English. Supporting information written in another language should be accompanied by a full English translation if the information is of high relevance to the application.

#### **B. *Format***

The application must contain an ‘Executive Summary’ that provides a synopsis of all of the data supporting the application.

The application must clearly identify the relevant Section(s) of Part 3 *Contents of an Application* that is being addressed.

The application must be sequentially numbered on each page and hard copies of the application must be capable of being laid flat when opened.

#### **C. *Copies***

Applications must be lodged in both electronic and hard copy.

Electronic copies should be provided on floppy disc or CD or other device, or as an attachment to an email or through the FSANZ website.

At the same time, or as soon as practicable, two hard copies of the application must be provided.

### **3.1.2 APPLICANT DETAILS**

The application must contain the following contact details:

- (a) Applicant’s name/s
- (b) Company/organisation name
- (c) Address (street and postal)
- (d) Telephone and facsimile numbers
- (e) Email address
- (f) Nature of applicant’s business
- (g) Details of other individuals, companies or organisations associated with the application.

### 3.1.3 PURPOSE OF THE APPLICATION

The application must contain a statement regarding the purpose of the application and, to the extent possible, identify the Standard(s) that need to be amended to achieve the intended purpose of the application. For the majority of applications i.e. those which relate to a matter dealt with in Sections 3.2-3.7, the purpose of the application relevant to that Section must be provided.

**Note:**

Consultation with FSANZ prior to submission of an application will assist in identifying those Standard(s) which may need to be amended in order to achieve the intended purpose of the application. This consultation will enable the potential applicant to identify the relevant sections in Part 3 of the *Application Handbook* that need to be addressed and the information required to accompany the application.

The application must also contain details of the status of similar applications made in other countries by the applicant, if applicable.

### 3.1.4 JUSTIFICATION FOR THE APPLICATION

The application must contain a statement regarding the justification for the application. For the majority of applications i.e. those which relate to a matter dealt with in Sections 3.2-3.7, the justification needs to address the specific points relevant to that Section.

**Note:**

In relation to the cost and benefits associated with the proposed change to the Code, the applicant should provide as much information relating to the impact on industry, consumers and government as is readily available. FSANZ will prepare a Regulatory Impact Statement (*see Section 2.2.9*) based on information sourced from the applicant and elsewhere.

### 3.1.5 INFORMATION TO SUPPORT THE APPLICATION

The application must contain sufficient supporting information or data to enable the objectives specified in section 18 of the FSANZ Act to be addressed (*see Section 1.3.2*). Where the application relates to matters referred to in Sections 3.2-3.7, refer to the relevant Section.

**Note:**

FSANZ will assess all the available data presented in support of an application.. The amount of data required for the assessment of an application will vary depending on the complexity of the issues, the levels of scientific assessment required, and the impact on consumers of the proposed change to the Code.

Good quality data are always preferable regardless of the nature of the application. In the absence of good quality data, data of lesser quality may still be useful in the assessment of an application. The better the quality of the data, however, the more likely an application will achieve a favourable and timely outcome.

**Note:**

**QUALITY OF DATA**

The following information relates to data quality for different types of data:

The term '**data**' in this document refers to units of information; facts; observations; or results of an experiment, study or survey.

**All types of data**

- (a) The source, author(s) and year the data was produced should be provided.
- (b) The data provided should be obtained using validated or standardised methods, where these are available. Standardised methods should be validated for accuracy and reproducibility, and declare the sensitivity and specificity of the method where appropriate.
- (c) The data provided should be analysed using appropriate statistical techniques.

**Data from literature searches**

- (a) Literature searches should identify the databases searched (such as MEDLINE, EMBASE, TOXLINE, FSTA, Science Citation Index, BIOSIS, PsycINFO, or the Australian Medical Index etc).
- (b) Literature searches should identify the criteria used to specify the search, such as the key words, the time period of the search, and any other limiting criteria.
- (c) Literature searches should identify all of the papers identified in the search and provide an analysis according to the NHMRC *Guidelines for the review of scientific literature*. These Guidelines can be found at:  
<http://www.nhmrc.gov.au/publications/synopses/cp65syn.htm>

**Data related to safety studies**

- (a) Studies designed for safety assessment purposes should be designed and conducted in accordance with good laboratory practice (Refer to *OECD Principles on Good Laboratory Practice*; see:  
[http://www.oecd.org/departement/0,2688,en\\_2649\\_34381\\_1\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/departement/0,2688,en_2649_34381_1_1_1_1_1,00.html)) and should reference the relevant sections of the *OECD Guidelines for the Testing of Chemicals* (see:  
[http://www.oecd.org/departement/0,2688,en\\_2649\\_34377\\_1\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/departement/0,2688,en_2649_34377_1_1_1_1_1,00.html)) or other recognised test guidelines, such as the US Food and Drug Administration Redbook 2000 *Toxicological Principles for the Safety Assessment of Food Ingredients* (see:  
<http://www.cfsan.fda.gov/~redbook/redtoc93.html> )

- (b) Studies designed to establish evidence for a diet-disease relationship in humans should be conducted in accordance with the NHMRC 2000 publication *How to use the evidence: assessment and application of scientific evidence*. This can be found at: <http://www.nhmrc.gov.au/publications/synopses/cp69syn.htm>.
- (c) All studies conducted for a regulatory purpose should be accompanied by evidence of a quality control/assurance program or evidence of independent auditing of the conduct and reporting of the study.
- (d) Safety studies should contain full details of the conduct of the study and its results, including raw data where appropriate. Summaries alone of study results are not adequate for safety assessment purposes.

#### **Data related to surveys on chemicals in food**

- (a) The survey design and method should be clearly enunciated along with the findings and the conclusions. Where surveys are designed to be targeted or selective, the basis for doing so should be clearly stated
- (b) The survey should maximise representation and avoid skewing results from unrepresentative (abnormal) samples by sampling a sufficient number of representative samples across different subjects/respondents, regions/locations, times/seasons, manufacturers/producers, conditions etc. The numbers of samples surveyed should be statistically significant. The sample size and the sample pool should be stated. All samples collected should be surveyed consistently in accordance with the pre determined survey plan. If samples are excluded from being considered in the survey the basis for excluding them should be defined and reported.
- (c) Where surveys involve laboratory analysis, international (International Standards Organisation (ISO)) or national (Australian Standard (AS)) test method should be used, where possible. Where no standard method exists (e.g. vitamin analysis, emerging micro-organisms) credible test methods should be used.
- (d) Laboratories must provide evidence of accreditation to the International Organisation for Standardization standard *ISO 17025 – General Requirements for the Competence of Calibration and Testing Laboratories*. In Australia, laboratories should be NATA accredited.
- (e) Surveys should include evidence of quality control/assurance systems. Information on limits of reporting should also be included.

#### **Data related to consumer research**

- (a) Consumer and/or market research should be consistent with the International Organization for Standardization standard *ISO 20253:2006 Market, opinion and social research – vocabulary and service requirements*.
- (b) In Australia, such research should comply with the Australian Standard *AS44752 – Australian and Social Research Standard* or its equivalent.

### 3.1.6 ASSESSMENT PROCEDURE

The Applicant must indicate what the applicant considers is the appropriate procedure to be adopted in assessing the application.

### 3.1.7 CONFIDENTIAL COMMERCIAL INFORMATION (CCI)

The applicant must identify any information he or she considers to be confidential commercial information. This information must be separated from the other parts of the application (both electronically and in hard copy).

The applicant must submit a formal request, including reasons that satisfy the definition of commercial confidential information in section 4 of the FSANZ Act, that the identified information be considered as confidential commercial information by FSANZ.

**Note:**

*See Section 2.1.5 for further information on CCI.*

### 3.1.8 EXCLUSIVE CAPTURABLE COMMERCIAL BENEFIT (ECCB)

The applicant must sign a declaration in relation to whether the application is expected to confer an Exclusive Capturable Commercial Benefit.

**Note:**

*See Section 2.1.4 for further information on Exclusive Capturable Commercial Benefit.*

### 3.1.9 INTERNATIONAL AND OTHER NATIONAL STANDARDS

#### A. *International Standards*

The application must contain details of any Codex Alimentarius Commission (Codex) Standards relevant to this application, where available.

**Note:**

This information is required since one of the five additional objectives to which FSANZ must have regard is: *The promotion of consistency between domestic and international standards.* (Refer to Section 1.3.2.).

Codex standards are regarded as the international standards related to food by the World Trade Organization (WTO). Information on Codex Alimentarius can be found at:  
<http://www.fao.org/docrep/w9114e/w9114e00.htm>

A list of current official Codex standards can be found at  
[http://www.codexalimentarius.net/web/standard\\_list.do?lang=en](http://www.codexalimentarius.net/web/standard_list.do?lang=en)

Both Australia and New Zealand, as members of the WTO, must comply with the Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary (SPS) agreements of the WTO.

### ***B. Other National Standards or Regulations***

The application should contain details of relevant standards or regulations in other countries with comparable regulatory processes, where available.

#### **3.1.10 STATUTORY DECLARATION**

The application must contain a signed Statutory Declaration that includes the following statements:

- 1. The information provided in this application fully sets out the matters required.*
- 2. The information provided in this application is true to the best of my knowledge and belief.*
- 3. No information has been withheld that might prejudice this application, to the best of my knowledge and belief.*

Templates for Australian and New Zealand Statutory Declarations are provided on the FSANZ website.

#### **3.1.11 CHECKLIST**

The Application must contain a completed checklist with regard to information requirement relevant to the application (*see Appendix 1*).

Where the information requirement is qualified with a ‘where applicable’ or ‘if available’ statement, the applicant should provide an explanation if the information is not provided.

# **SECTION 3.2**

## **STANDARDS RELATED TO LABELLING AND OTHER INFORMATION REQUIREMENTS**

### **3.2.1 GENERAL FOOD LABELLING**

An application to vary the Code is required to change the many aspects of food labelling that are detailed in Part 1.2 – Labelling and Other Information Requirements. This includes both the information contained on the label and the way in which this information is presented on the food product.

The following information is required to support an application related to food labelling. This information is in addition to that specified in Section 3.1 – General Requirements.

Additional information may be required if the application relates to one or more of the following:

- (a) warning and advisory statements
- (b) declaration of allergens
- (c) labelling for consumer information and choice
- (d) nutrition information labelling

The additional information requirements relating to the above matters are presented in sub-section 3.2.2 to sub-section 3.2.5.

#### **A. General information on the application**

The application must contain the following general information:

##### ***1. Purpose of the application***

This part includes a statement on the purpose of the proposed labelling change.

##### ***2. Justification for the application***

This part includes general statements addressing:

- (a) the need for the proposed labelling change;
- (b) any public health and safety issues related to the proposed labelling change;
- (b) any nutrition issues related to the proposed labelling change;
- (c) any consumer choice issues related to the proposed labelling change; and
- (d) the costs and benefits for industry, consumers and government associated with the proposed labelling change, if available.

Reference may be made to other sections of the application that contain detailed supporting information, where necessary.

#### **B. General information to support the proposed labelling change**

The application must contain the following information:

**1. A description of the proposed labelling change**

This part includes detailed information on the proposed labelling change, and should indicate the Standards which will be affected.

**2. A list of the foods and/or food groups likely to be affected by the proposed change**

This part includes details of the specific foods or food categories affected by the proposed labelling change.

**Note:**

Specific food categories include: packaged or unpackaged food, food intended for restaurants, food intended for catering purposes, food intended for retail sale and food not intended for retail sale. Additional information on likely foods to be exempted from proposed labelling would also be useful.

**C. Information related to the potential impact on consumer understanding and behaviour**

The application must contain the following information:

**1. Information to demonstrate consumer support of the proposed labelling change**

This part includes information (possibly consumer research data) to show that the issue(s) underlying the proposed labelling change are significant to consumers. This part also includes information on which consumer groups will be affected and the number of consumers affected.

**2. Information to demonstrate that the proposed labelling change will be understood and will assist consumers**

This part includes consumer research information to demonstrate the anticipated consumer response to the proposed change, or data obtained from an overseas market where the proposed labelling is in place.

**3. Information to demonstrate that the proposed labelling change will not have any adverse health or diet impacts on any population groups (e.g. age or cultural groups)**

**Note:**

The extent of the impact of a food labelling change on consumer understanding and behaviour will vary depending on:

- (a) the nature of the labelling change; and
- (b) the foods to which it will apply.

Thus the amount of information necessary to address the impact on consumer understanding and behaviour will depend on the level of impact. Consultation with FSANZ may be necessary to examine the expected level of impact.

Also, there may be situations where consumer support for the proposed labelling is not required e.g. where there is an identified public health benefit associated with the labelling change.

**D. Information related to the impact on the food industry (food industry applicants only)**

The application must contain the following information:

**1. *Data on the projected cost to the food industry of the proposed labelling change***

This part includes information on the market share of the affected foods, the costs of the labelling change, the impact on the sale of existing products, traceability costs and issues, and any impacts on small and medium enterprises.

**2. *Impact on international trade***

This part includes information, if available, on the impact of the proposed change on foods imported into Australia/New Zealand.

**Note:**

In relation to the impact on the food industry of the proposed labelling change, the applicant should provide as much information as is readily available. FSANZ will use this information together with information from other sources to prepare a Regulatory Impact Statement (*see Section 2.2.9*).

### 3.2.2 WARNING AND ADVISORY STATEMENTS

An application to vary the Code is required to include or change the mandatory warning and advisory statements that are listed in Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations.

**Note:**

Warning statements are generally reserved for well characterised, potentially life-threatening public health and safety risks where the target population is unaware of the potential risk and a prescribed labelling statement is needed to alert consumers. Advisory statements may be used to advise the general population or a specific target population of potential public health and safety risks associated with a food.

The following additional information is required to support an application to include or change a mandatory warning or advisory statement in relation to a food or food ingredient.

This information is in addition to that specified in Section 3.1 – General Requirements and in Section 3.2.1 – General Food Labelling. Declaration of allergens is considered under Section 3.2.3.

**A. Additional information related to the safety of the food or food ingredient**

The application must contain the following information:

**1. *Data to indicate that the food or food ingredient presents a potential health concern to one or more population groups***

This part includes one or more of the following types of information:

- (a) Epidemiology studies on the target population group(s)
- (b) Clinical studies on individuals from the target population group(s)
- (c) Case studies of affected individuals
- (d) Reports adverse food-medicine interactions in individuals
- (e) Reports of safety studies in experimental animals

**Note:**

The nature of the target population will vary with the particular potential health concern. Examples of mandatory advisory statements can be found in the Table to clause 2 in Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations. Examples of mandatory warning statements can be found in the Table to clause 3 in Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations.

**B. Additional information related to consumers' awareness of a potential public health and safety risk associated with the food**

The application must contain the following information:

**1. *Data to indicate that one or more consumer groups are unaware of the public health and safety risk***

This part includes one or more of the following types of information:

- (a) Currently available information regarding use and consumption of the food;
- (b) Reports of epidemiology studies or case studies of consumers being at risk through consumption of the food or food ingredient;
- (c) Data from consumer surveys indicating a potential risk associated with the use of the food or food ingredient.

### 3.2.3 DECLARATION OF ALLERGENS

An application is required to vary the Code to include or change the requirements for mandatory declaration of certain foods or food ingredients, which are listed in Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations.

**Note:**

Standard 1.2.3 requires the presence of the following foods and food ingredients (referred to in the Standard as ‘substances’) to be declared on the label on the package of a food, when present as an ingredient; or an ingredient of a compound ingredient; or a food additive or component of a food additive; or a processing aid or component of a processing aid.

- (a) Cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridised strains other than where these substances are present in beer and spirits standardised in Standards 2.7.2 and 2.7.5 respectively
- (b) Crustacea and their products
- (c) Egg and egg products
- (d) Fish and fish products
- (e) Milk and milk products
- (f) Peanuts and soybeans, and their products
- (g) Added sulphites in concentrations of 10 mg/kg or more
- (h) Tree nuts and sesame seeds and their products

Where food is not required to bear a label, this information must be declared on or in connection with the display of the food or provided to the purchaser upon request.

Currently, all of the ‘declared substances’ on the list are foods except for sulphites. Sulphite is generally not regarded as an allergen since the adverse reaction to sulphite operates through a different mechanism to an allergenic response (i.e. not IgE-mediated).

#### **A. Additional information to support addition of an allergen to the list of declared foods**

The following additional information is required to support an application to add an allergenic food on the list of foods in the Standard which are required to be declared on the label. This information is in addition to that specified in Section 3.1 – General Requirements and in Section 3.2.1 – General Food Labelling

The application must contain the following information:

##### **1. Information to demonstrate the food causes an IgE-mediated allergy**

This part includes clinical data associating IgE-mediated allergic reactions with the specific food including one or more of the following:

- (a) Patient history
- (b) Skin testing
- (c) Double blind placebo controlled food challenges (DBPCFC).

**2. *Information on the incidence in the population of allergic reactions to the food***

This part includes published data or data derived from allergy clinics on the incidence of allergic reactions to the food in the population.

**3. *Information on the severity of the allergic reaction to the food in relation to the amount of food consumed***

This part includes clinical reports on the range of symptoms associated with the allergic reaction and an estimate of the amount of food that may provoke these symptoms.

**4. *Information on the extent of use in the food supply and the range of food containing the allergen***

This part includes information on the quantity of the allergen in the food supply and an indication of the range of foods where it is used. As much as possible, projections for extended use in the immediate and near future should also be included.

**B. *Additional information to support removal of a food derivative from the list of declared foods***

The following additional information is required to support an application to exclude a derivative of an allergenic food from the list of foods in the Standard which are required to be declared on the label. This information is in addition to that specified in Section 3.1 – General Requirements and in Section 3.2.1 – General Food Labelling

The application must contain the following information:

**1. *Information on the nature of the food derivative***

This part includes a specification for identity and purity for the food derivative, including data on the level of protein in the derivative.

**2. *Information on the use of the food derivative and its presence in the final food***

This part includes information on how the food derivative is used in foods and the range of foods in which it is used.

**3. *Information on the level of dietary intake of the food derivative***

This part includes information on dietary intake for different population groups.

**4. *Information on the history of safe use of foods containing the food derivative***

This part must include information on the range of foods containing the food derivative and reports of any allergic reactions to these foods.

**5.        *Clinical information on the safety of the food derivative, if applicable (see Note)***

This part includes clinical challenge studies where the food derivative is tested in individuals who are sensitised to the source of the food derivative.

**Note:**

If the information derived from points 1-5 is insufficient to conclude that the food derivative should be exempted from declaration on the label e.g. if the food derivative is present in the final food and there is significant dietary exposure to the derivative, data from clinical challenge studies will be required.

### 3.2.4 LABELLING FOR CONSUMER INFORMATION AND CHOICE

An application is required to vary the Code to include or change the labelling requirements which are in place to provide adequate information and allow consumer choice.

**Note:**

Certain food labelling is directed towards (i) providing adequate information in order to allow consumers to make to an informed choice; or (ii) preventing misleading and deceptive conduct by food manufacturers. Such labelling could be in relation to a public health and safety matter or the need for additional information to give consumers confidence in the food regulatory system. This is sometimes referred to as a ‘market failure’.

In the case of deceptive conduct to mislead the consumer, this would be dealt with under trade practices legislation rather than through a variation to the Code.

The following additional information is required to support an application related to food labelling for consumer information and choice.

This information is in addition to that specified in Section 3.1 – General Requirements and in Section 3.2.1 – General Food Labelling.

**A. Additional information related to assisting consumers to make an informed choice**

The application must contain the following information:

**1. *Information to show that the current labelling, or lack of labelling, or information from alternative sources does not allow consumers to make an informed choice***

This part includes information to show that consumers have a limited ability to make an informed choice based on the information provided on the label and that consumers are unable to source the necessary information from alternative sources.

**2. *Information to show that there are no, or a limited number of, suitable substitute products in all food categories currently available to consumers***

**3. *Information to show that the proposed specific labelling change will assist consumers to make an informed choice or will provide alternative labelling that will not hinder consumers from making an informed choice***

This part includes information on the proposed specific labelling change, and consumer research data to demonstrate the appropriate consumer response to the proposed change, or data from an overseas market where the proposed labelling is currently used.

**4. *Information to demonstrate that, in the absence of the proposed labelling, alternative measures to address the issue would not be effective***

This part includes information on one or more of the following alternative measures:

- (a) Voluntary labelling (e.g. endorsement or product approval programs)
- (b) Self-regulation (e.g. codes of practice)
- (c) Other legislative measures (e.g. trade practices)
- (d) National manufacturing standards (including those developed by Standards Australia)

**Note:**

The Code should be read in conjunction with other applicable laws, such as the Australian *Trade Practices Act 1974* (TPA) and the New Zealand and State and Territory Fair Trading Acts. The provisions in these Acts - particularly relating to conduct which is false, misleading or deceptive - apply to the supply of food in trade and commerce.

The prevention of misleading or deceptive conduct is one of the primary objectives that must be satisfied by FSANZ in developing or varying a food standard (*Food Standards Australia New Zealand Act 1991*).

The Australian Competition and Consumer Commission (ACCC) is responsible for ensuring compliance with the Australian TPA. The substantive provisions of the TPA are expressly limited to activities undertaken by corporations, subject to certain exceptions and qualifications. State and Territory fair trading laws are not subject to these constitutional limitations, and so fill the gaps left by the limited application of the TPA. The TPA is a Commonwealth law, and the Code is usually given legal force through State legislation. The Code is enforced by the States and Territories.

### 3.2.5 NUTRITION INFORMATION LABELLING

An application is required to vary the Code to change the labelling requirements which are in place to provide nutrition information.

**Note:**

Nutrition information labelling aims to provide consumers with adequate information to make informed choices about the nutritional value of food. This includes information about (A) the nutrient content of the food and (B) the energy content of the food.

The following additional information is required to support an application related to food labelling for nutrition information.

This information is in addition to that specified in Section 3.1 – General Requirements and in Section 3.2.1 – General Food Labelling.

**A. Additional information to support a change to the nutrient content label of a food**

The following additional information is required to support an application to include or remove information on the label regarding the nutrient content of the food, or change the way in which the label currently displays the nutrient content of the food.

The application must contain the following information:

**1. *A description of how the proposed labelling will change the information on nutrient content of the food***

This part includes detailed information on the nature and intent of the proposed labelling change, and should indicate the foods or food categories which will be affected.

If applicable, this part also includes information on how the proposed labelling of a specific nutrient will affect the declaration of related nutrients.

**2. *Data to demonstrate that the proposed labelling change will assist consumers to make an informed choice and will not mislead them***

This part includes consumer research data to demonstrate the anticipated response to the proposed change, or data obtained from an overseas market where the proposed labelling is in place.

This part also includes information to show that alternative measures to provide nutrient content information are not, or would not, be effective.

**B. Additional information to establish or vary an energy factor of a food**

The following additional information is required to support an application to establish an energy factor for a new food component or to vary an energy factor for an existing food component.

**Note:**

Energy factors are required for food ingredients in order to establish the overall energy content of a food product. This information is required to support the labelling statements on low or reduced energy food products.

Energy factors are specified in Standard 1.2.8 of the Code. In this Standard, energy factor is defined as follows:

***Energy factor** means the metabolisable energy (ME) of the food component calculated according to the following formula, expressed in kilojoules per gram of food component, rounded to the nearest whole number -*

$$ME = GE - FE - UE - GaE - SE$$

Where –

***ME** means metabolisable energy*

***GE** means gross energy (as measured by bomb calorimetry)*

***FE** means energy lost in faeces*

***UE** means energy lost in urine*

***GaE** means the energy lost in gases produced by fermentation in the large intestine*

***SE** means the energy content of waste products lost from surface areas*

The application must contain the following information:

**1. Information on the nature and composition of the food ingredient**

This part includes information related to the identity and purity of the food ingredient. If it is a mixture of ingredients, this part should identify the relative proportions of each, together with information related to the variability between commercial batches and the batch tested for the various energy measurements.

**2. Measures or estimates of energy for the food ingredient**

This part includes information on the value of the gross energy (GE), urinary energy (UE), faecal energy (FE), gaseous energy (GaE) and surface energy (SE) per gram of food ingredient, so that these be used to derive the energy factor using the equation for metabolisable energy prescribed in clause 2, Standard 1.2.8.

**3. Documentation of other factors that affect any of the above measures or estimates of energy within a reasonable range of background diets**

This part includes information on one or more of the following matters:

- (a) justification for and limitations of the methods used;
- (b) whether the GE of the food ingredient is constant or varies with different proportions of constituent compounds;

- (c) whether different constituents of the food ingredients are digested and/or absorbed differently;
- (d) effects of habituation/adaptation to consumption of the food ingredient;
- (e) dose dependency (i.e. variations with amount consumed, how consumed such as a single large dose or several small doses, or with solids or liquids);
- (g) the nature of background diet (e.g. high or low fat or fibre or protein); and
- (h) individual variability.

**Note:**

For further information on energy factors, see the FSANZ Guidance Document *Guidelines for Deriving the Energy Factors for Food Ingredients* on the FSANZ website.

# **SECTION 3.3**

# **STANDARDS RELATED TO SUBSTANCES ADDED TO FOOD**

### 3.3.1 FOOD ADDITIVES

An application to vary the Code is required to approve the use of a new food additive in the food supply or to change the permissions for a currently used food additive. Permissions for use of food additives are specified in Standard 1.3.1 – Food Additives.

**Note:**

Standard 1.3.1 – Food Additives, describes a food additive as follows:

*A food additive is any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5. It or its by-products may remain in the food. Food additives are distinguishable from processing aids and vitamins and minerals added to food for nutritional purposes.*

The following information is required to support an application for a new food additive or to change the permissions for a currently used food additive. This information is in addition to that specified in Section 3.1 – General Requirements.

#### **A. General information on the application**

The application must contain the following information:

##### **1. Purpose of the application**

This part includes information on the purpose of the proposed change(s) to Standard 1.3.1 – Food Additives.

##### **2. Justification for the application**

This part includes general statements addressing:

- (a) technological function for the food additive;
- (b) the safety of the food additive; and
- (c) the costs and benefits for industry, consumers and government associated with use of the food additive.

Reference may be made to other sections of the application that contain detailed supporting information, where necessary.

##### **3. Support for the application**

This part includes evidence that the food industry has an interest in using the food additive in foods in Australia and New Zealand as a result of the proposed change to the Code, or that food containing the food additive may be imported into Australia or New Zealand.

#### **B. Technical information on the food additive**

The application must contain the following technical information:

## **1. *Nature and technological function of the additive***

This part includes information related to the technological function of the food additive and includes the following specific information:

- (a) each of the technological functions listed in Schedule 5 of Standard 1.3.1 – Food Additives that the additive fulfils;
- (b) the reason why the food additive is needed to fulfil these functions in each of the foods in which it is proposed to be used; and
- (c) if the food additive is a preservative, data to demonstrate its effectiveness in each of the foods in which it is proposed to be used.

## **2. *Information to enable identification of the additive***

This part includes the chemical name (according to both Chemical Abstracts (CA) and the International Union of Pure and Applied Chemistry (IUPAC)); structural formula; common name and synonyms; manufacturers' code; marketing name; and Chemical Abstract Service (CAS) registry number.

For additives that are not single chemicals, the name should describe the additive as completely as possible.

For additives that are derived from animals, plants or micro-organisms, the source should be provided.

## **3. *Information on the chemical and physical properties of the additive***

This part includes sufficiently detailed information to enable the technological properties of the additive in a food matrix to be characterised, such as how it may interact with different foods, as well as providing general information on the likely metabolic fate of the additive following consumption.

## **4. *Information on the impurity profile***

This part includes details on the nature and amounts (by weight) of all impurities, including isomers and manufacturing by-products, present in the additive preparation. Where possible, impurities should be identified by their CA or IUPAC names.

## **5. *Manufacturing process***

This part includes a detailed description of the method of manufacture of the additive.

## **6. *Specification for identity and purity***

This part includes a specification from one of the published sources identified in Standard 1.3.4 – Identity and Purity. If there is no published specification in one of the identified sources, a detailed specification must be provided.

## **7. Information for food labelling**

This part includes information on the functional class of the food additive and, if available, the code number for the additive.

## **8. Analytical method for detection**

This part includes a method for detection of the additive, or its degradation products, in the foods in which it will be used, which will be suitable for analytical purposes.

## **C. Information related to the safety of the food additive**

### **Note:**

FSANZ will undertake a safety assessment, using the detailed study reports where possible, of all animal and human toxicity studies related to the food additive and, if applicable, establish an acceptable daily intake (ADI) for the food additive, if the studies are suitable for this purpose.

An application for a food additive must contain the following information:

### **1. Information on the toxicokinetics and metabolism of the food additive and, if necessary, its degradation products and/or major metabolites**

- (a) For an application for a new food additive, this part includes detailed reports of all studies conducted in animals or humans to examine the metabolic fate of the food additive and, if necessary, its degradation products or major metabolites.
- (b) For an application to extend the use of a currently permitted food additive, this part need only include reports of the studies conducted since the last safety evaluation by FSANZ. If no previous evaluation by FSANZ is available, this part should include published papers or a comprehensive review article on this matter.

### **2. Information on the toxicity of the food additive and, if necessary, its degradation products and major metabolites**

- (a) For an application for a new food additive, this part includes reports of all *in vitro* studies and all *in vivo* studies conducted in animals or humans to examine the toxicity of the food additive and, if necessary, its metabolites or degradation products.

### **Note:**

The application should address the following categories of animal studies:

- (a) Acute toxicity studies
- (b) Short-term toxicity studies
- (c) Long-term toxicity and carcinogenicity studies
- (d) Reproductive toxicity studies
- (e) Developmental toxicity studies
- (f) Genotoxicity studies

(g) Special studies, such as neurotoxicity or immunotoxicity

Where data are not available or is not considered relevant to the safety assessment of the additive, an explanatory statement must be provided.

(b) For an application to extend the use of a currently permitted food additive, this part need only include the detailed reports of studies conducted since the last safety evaluation by FSANZ. If no previous evaluation by FSANZ is available, this part should include reports of any evaluation by the Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) or equivalent expert group.

**3. *Safety assessment reports prepared by international agencies or other national government agencies, if available.***

This part includes safety assessment reports prepared by JECFA (unless provided under 2.) or by other national or supranational agencies responsible for food safety.

**D. Information related to the dietary exposure to the food additive**

**Note:**

FSANZ will undertake a dietary exposure assessment for all food additive applications requesting changes to permissions in Standard 1.3.1 using a custom-made computer program, DIAMOND, which combines food consumption data from the latest Australian and New Zealand National Nutrition Surveys together with food chemical concentration data derived from either the proposed levels of use, the current permissions for use specified in the Code, analytical data derived from surveys or data on use provided by the manufacturers. The information required to undertake this assessment will be derived from different sources, including the application.

The application must contain the following information:

**1. *A list of the food groups or foods proposed to contain the food additive, or changes to currently permitted foods***

This food list should be based on the food group classification system used in Standard 1.3.1 – Food Additives.

**2. *The maximum proposed level and/or the concentration range of the food additive for each food group or food, or the proposed changes to the currently permitted levels***

**3. *The percentage of the food group in which the food additive is proposed to be used or the percentage of the market likely to use the food additive***

This part includes information based on projected uptake or market share data for foods likely to contain the food additive. This can be based on a similar market in another country.

The application should contain the following information:

**4. Information relating to the use of the food additive in other countries, if applicable**

This part includes information on the foods and/or food groups in which it is used and the use levels.

**Note:**

For further information on estimating dietary exposure, see the FSANZ Guidance Document *Estimating Dietary Exposure to Food Chemicals for Food Regulatory Purposes* on the FSANZ website.

### 3.3.2 PROCESSING AIDS

An application to vary the Code is required to approve the use of a new processing aid or to change the permissions for a currently used processing aid. Permissions for use of processing aids are specified in Standard 1.3.3 – Processing Aids.

**Note:**

Standard 1.3.3 defines a processing aid as follows:

*Processing aid means a substance listed in clauses 3 to 18, where –*

- (a) *the substance is used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment or processing, but does not perform a technological function in the final food; and*
- (b) *the substance is used in the course of manufacture of a food at the lowest level necessary to achieve a function in the processing of that food, irrespective of any maximum permitted level specified.*

The following information is required to support an application for a new processing aid or to change the permissions for a currently used processing aid. This information is in addition to that specified in Section 3.1 – General Requirements.

#### **A. General information on the application**

The application must contain the following information:

##### **1. Purpose of the application**

This part includes information on the purpose of the proposed change(s) to Standard 1.3.3 – Processing Aids.

##### **2. Justification for the application**

This part includes general statements addressing:

- (a) technological need for the processing aid;
- (b) the safety of the processing aid; and
- (c) the costs and benefits for industry, consumers and government associated with use of the processing aid.

Reference may be made to other sections of the application that contain detailed supporting information, where necessary.

##### **3. Support for the application**

This part includes evidence that the food industry has an interest in using the processing aid in foods in Australia and New Zealand as a result of the proposed change to the Code, or that food containing the processing aid may be imported into Australia or New Zealand.

## **B. Technical information on the processing aid**

The application must contain the following information:

### **1. Information on the type of processing aid**

This part includes a brief description of the processing aid and the category (if any) in Standard 1.3.3 – Processing Aids into which it falls.

#### **Note:**

The categories of processing aids in Standard 1.3.3 are as follows:

- (a) Generally permitted processing aids
- (b) Antifoam agents
- (c) Catalysts
- (d) Decolourants, clarifying, filtration and adsorbent agents
- (e) Desiccating preparation
- (f) Ion exchange resins
- (g) Lubricants, release and anti-stick agents
- (h) Carriers, solvents and diluents
- (i) Processing aids used in packaged water and in water used as an ingredient in other foods
- (j) Bleaching agents, washing and peeling agents
- (k) Extraction solvents
- (l) Miscellaneous functions
- (m) Enzymes of animal origin
- (n) Enzymes of plant origin
- (o) Enzymes of microbial origin
- (p) Microbial nutrients and microbial nutrient adjuncts

### **2. Information on the identity of the processing aid**

This part includes the chemical name (according to both Chemical Abstracts (CA) and the International Union for Pure and Applied Chemistry (IUPAC)); structural formula; common name and synonyms; manufacturers' code; marketing name; and CAS registry number. For enzymes, this part includes the name and source of the enzyme together with the Enzyme Commission (EC) number. If the enzyme is from a genetically modified microbial source, this part includes both the host and donor organism, including alternative names for the microbial source, if applicable.

### **3. Information on the chemical and physical properties of the processing aid**

This part includes details of the chemical and physical properties that make it suitable as a food processing aid. This must include information on possible interactions of the processing aid with different foods. If the processing aid is an enzyme, this must include information on its enzymatic properties.

#### **4. *Manufacturing process***

This part includes a description of the method of manufacture of the processing aid.

#### **5. *Specification for identity and purity***

This part includes a specification from one of the published sources identified in Standard 1.3.4 – Identity and Purity will be available. If a published specification is not available, a detailed specification must be provided.

### **C. Information related to the safety of a chemical processing aid**

The application must contain the following information:

#### **1. *General information on the industrial use of the chemical***

This part includes any information on non-food industrial uses for the chemical, particularly where the information is relevant to human safety.

#### **2. *General information on the use of the chemical as a food processing aid in other countries***

This part includes any information on the use of the chemical as a processing aid in other countries, particularly where the information is relevant to human safety.

#### **3. *Data on the toxicokinetics and metabolism of the processing aid and, if necessary, its metabolites***

- (a) For an application for a new processing aid, this part includes detailed reports of all studies conducted in animals or humans to examine the metabolic fate of the processing aid and, if necessary, its major metabolites; particularly when a residue of the processing aid or its metabolites is expected in the final food.
- (b) For an application to extend the use of a currently permitted processing aid, this part includes only the reports of studies conducted since the last safety evaluation by FSANZ. If no previous evaluation by FSANZ is available, this part should include published papers and /or a comprehensive review article on this matter.

#### **4. *Information on the toxicity of the processing aid and, if necessary, its major metabolites***

- (a) For an application for a new processing aid, this part includes detailed reports of all *in vitro* studies and all *in vivo* studies conducted in animals or humans to examine the toxicity of the processing aid and, if necessary, its metabolites; particularly when a residue of the processing aid or its metabolite is expected in the final food.

**Note:**

The application should address, as a minimum, the following categories of animal studies:

- (a) Acute toxicity studies
- (b) Short-term toxicity studies

The application should also address the following categories of animal studies, if data are available:

- (a) Long-term toxicity and carcinogenicity studies
- (b) Reproductive toxicity studies
- (c) Developmental toxicity studies
- (d) Genotoxicity studies
- (e) Special studies such as neurotoxicity or immunotoxicity

Where data are not available or is not considered relevant to the safety assessment of the additive, an explanatory statement must be provided.

- (b) For an application to extend the use of a currently permitted processing aid, this part need only include the detailed reports of studies conducted since the last safety evaluation by FSANZ. If no previous evaluation by FSANZ is available, this part should include reports of any evaluation by the Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) or equivalent expert group.

**5. *Safety assessment reports prepared by international agencies or other national government agencies, if available.***

This part includes safety assessment reports prepared by JECFA (unless provided under 4.) or by other national or supranational agencies responsible for food safety.

**D. Information related to the safety of an enzyme processing aid**

The application must contain the following information:

**1. *General information on the use of the enzyme as a food processing aid in other countries***

This part includes any information on the use of the enzyme as a processing aid in other countries, particularly where the information is relevant to human safety.

**2. *Information on the toxicity of the enzyme processing aid***

This part includes detailed reports of all *in vitro* studies and all *in vivo* studies conducted in animals or humans to examine the toxicity of the enzyme processing aid.

**Note:**

The application should address, as a minimum, the following categories of studies:

- (a) a short-term (generally 90-day) toxicity study in a rodent species on the final purified enzyme from the specified source organism used in the fermentation process;
- (b) *in vitro* genotoxicity studies in (i) bacteria (a gene mutation assay) and (ii) mammalian cells (a chromosome aberration assay).

Where data are not considered relevant to the safety assessment of the enzyme, an explanatory statement must be provided.

**E. Additional information related to the safety of an enzyme processing aid derived from a micro-organism**

The application must contain the following additional information:

**1. Information on the source micro-organism**

The part includes information to demonstrate that the source micro-organism is a discrete and stable strain or variant that has been taxonomically characterised.

**2. Information on the pathogenicity and toxicity of the source micro-organism**

This part includes information to demonstrate that the strain of the source micro-organism is non-pathogenic and non-toxinogenic. If the enzyme is from a fungal source, this must include information to demonstrate that the strain does not produce toxicologically significant amounts of mycotoxins.

**3. Information on the genetic stability of the source organism**

This part includes information to demonstrate that the strain of the source micro-organism does not undergo strain drift and that the culture conditions can be applied consistently between batches.

**F. Additional information related to the safety of a processing aid derived from a genetically-modified micro-organism**

The application must contain the following additional information:

**1. Information on the methods used in the genetic modification of the source organism**

This part includes information on the nature of the genetic change and the methods used to transform the host organism. A description of the gene construct, the source of the donor gene, and the transformation vectors used must be provided.

## **G. Information related to the dietary exposure to the processing aid**

### **Note:**

FSANZ may undertake a dietary exposure assessment for processing aid applications when a residue of the processing aid or its metabolites is expected in the final food. This assessment will be undertaken using a custom-made computer program, DIAMOND, which combines food consumption data from the latest Australian and New Zealand National Nutrition Surveys together with food chemical concentration data derived from analytical data on the level of the processing in the final foods. The information required to undertake this assessment will be derived from different sources, including the application.

The application must contain the following information:

- 1. A list of foods or food groups likely to contain the processing aid or its metabolites***

This part includes a food list based on the food group classification system used in Standard 1.3.1 – Food Additives.

- 2. The levels of residues of the processing aid or its metabolites for each food or food group***
- 3. The percentage of the food group in which the processing aid is likely to be found or the percentage of the market likely to use the processing aid***

This part includes information based on projected uptake or market share data for foods likely to contain the processing aid or its metabolites. This can be based on a similar mature market in another country.

The application should contain the following information:

- 4. Information relating to the levels of residues in foods in other countries***

This part includes information on the food groups and/or foods in which the processing aid is used.

### **Note:**

For further information on estimating dietary exposure, see the FSANZ Guidance Document *Estimating Dietary Exposure to Food Chemicals for Food Regulatory Purposes* on the FSANZ website.

### 3.3.3 NUTRITIVE SUBSTANCES

An application to vary the Code is required to approve the use of a new nutritive substance or to change the permissions for a currently used nutritive substance.

**Note:**

Standard 1.1.1 defines a nutritive substance as follows:

*Nutritive substance means a substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which, after extraction and/or refinement, or synthesis, is intentionally added to a food to achieve a nutritional purpose, and includes vitamins, minerals, amino acids, electrolytes and nucleotides.*

If the substance or ingredient intended to be added to food does not meet the above definition, i.e. it is not added to food to achieve a nutritional purpose, it may be regarded as a novel food ingredient and considered under Section 3.5.2 – Novel Foods.

For further information regarding both voluntary and mandatory addition of vitamins and minerals to food, see the *Fortification Implementation Framework* which was prepared by FSANZ in May 2005

([http://www.foodstandards.gov.au/srcfiles/Fort\\_Imple\\_Frame\\_May05\\_2.pdf#search=%22fortification%20framework%22](http://www.foodstandards.gov.au/srcfiles/Fort_Imple_Frame_May05_2.pdf#search=%22fortification%20framework%22))

The following information is required to support an application for a new nutritive substance or to change the permissions for a currently used nutritive substance. This information is in addition to that specified in Section 3.1 – General Requirements.

#### **A. General information on the application**

The application must contain the following information:

##### **1. Purpose of the application**

This part includes information on the purpose of the proposed change(s) to the Code.

##### **2. Justification for the application**

This part includes general statements addressing:

- (a) nutritional purpose of adding the nutritive substance to each type of food;
- (b) the safety of the nutritive substance; and
- (c) the costs and benefits for industry, consumers and government associated with use of the nutritive substance.

Reference may be made to other sections of the application that contain detailed supporting information, where necessary.

**Note:**

In the case of an application to add vitamins or minerals to food, either through voluntary or mandatory fortification, the Ministerial Council has developed a policy guidance document Policy Guideline: Fortification of Food with Vitamins and Minerals.

FSANZ is required under the FSANZ Act to have regard to Ministerial Council policy guidelines in considering an application to fortify foods with vitamins and minerals. The policy guideline can be found at <http://www.foodstandards.gov.au/standardsdevelopment/ministerialcouncilpo1603.cfm>.

### **3. *Support for the application***

This part includes evidence that the food industry has an interest in using the nutritive substance in foods in Australia and New Zealand as a result of the proposed change to the Code, or that food containing the nutritive substance may be imported into Australia or New Zealand.

#### **B. *Technical information on the nutritive substance***

The application must contain the following technical information:

##### **1. *Information to enable identification of the nutritive substance***

This part includes the chemical name (according to both Chemical Abstracts (CA) and the International Union for Pure and Applied Chemistry (IUPAC)); structural formula; common name and synonyms; manufacturers' code; marketing name; and CAS registry number. For biologically-derived nutritive substances, the source should be provided.

##### **2. *Information on the chemical and physical properties of the nutritive substance***

This part includes detailed information on the food technology aspects of using the nutritive substance in each of the foods or food categories proposed. It should contain sufficient detail to support the use of the nutritive substance in each food and provide a rationale for how the nutritional purpose will be achieved in each food. It should also provide information on the likely metabolic fate of the nutritive substance.

##### **3. *Information on the impurity profile***

This part includes details on the nature and amounts (by weight) of all impurities, including isomers and manufacturing by-products, present in the nutritive substance preparation. Where possible, impurities should be identified by their CA or IUPAC names.

##### **4. *Manufacturing process***

This part includes a description of the method of manufacture of the nutritive substance.

## **5. *Specification for identity and purity***

This part includes a specification from one of the published sources identified in Standard 1.3.4 – Identity and Purity. If a published specification is not available, a detailed specification should be provided.

## **6. *Analytical method for detection***

This part includes a method for detection of the nutritive substance or its degradation products in the foods in which it is proposed to be used.

## **7. *Information on the proposed food label***

This part includes details of the proposed labelling statements relating to the presence of the nutritive substance in the food.

## **C. Information related to the safety of the nutritive substance**

### **Note:**

FSANZ will undertake an assessment of all of available reports of animal and human toxicity studies related to the nutritive substance, where appropriate, and, if possible, establish a safe level of intake, or assess the safety of the nutritive substance at the levels proposed to be used in the food. Where an upper level of safety (UL) has been established, this will be used. The NHMRC publication *Nutrient Reference Values for Australia and New Zealand including Recommended Daily Intakes* can be found at <http://www.nhmrc.gov.au/publications/synopses/n35syn.htm>

The application must contain the following information:

### **1. *Information on the toxicokinetics and metabolism of the nutritive substance and, if necessary, its degradation products and major metabolites***

For an application for a new nutritive substance, this part includes published reviews or individual study reports on the metabolic fate of the nutritive substance and, if necessary, its degradation products and major metabolites.

For an application to extend the use of a currently permitted nutritive substance, this part need only include the studies conducted since the last safety evaluation by FSANZ. If no previous evaluation by FSANZ is available, this part should included published papers and/or a comprehensive review article on this matter.

### **2. *Information from studies in animals or humans that is relevant to the toxicity of the nutritive substance and, if necessary, its degradation products and major metabolites***

(a) For an application for a new nutritive substance, this part includes published reviews or detailed reports of all *in vitro* studies and all *in vivo* studies conducted in animals or humans to examine the toxicity of the nutritive substance and, where necessary, its metabolites or degradation products.

**Note:**

The following categories of animal studies need to be considered:

- (a) Acute toxicity studies
- (b) Short-term toxicity studies
- (c) Long-term toxicity and carcinogenicity studies
- (d) Reproductive toxicity studies
- (e) Developmental toxicity studies
- (f) Genotoxicity studies
- (g) Special studies such as neurotoxicity or immunotoxicity

Where data are not available or is not considered relevant to the safety assessment of the nutritive substance, an explanatory statement should be provided.

- (b) For an application to extend the use of a currently permitted nutritive substance, this part need only include only the original reports of studies conducted since the last safety evaluation by FSANZ. If no previous evaluation by FSANZ is available, this part needs to include a published papers and/or a comprehensive review article on this matter.

**3. *Safety assessment reports prepared by international agencies or other national government agencies, if available.***

This part includes safety assessment reports prepared by WHO or by other national or supranational agencies responsible for food safety or public health.

**D. Information on dietary exposure to the nutritive substance**

**Note:**

FSANZ will undertake a dietary exposure assessment for all nutritive substance applications using a custom-made computer program, DIAMOND, which combines food consumption data from the latest Australian and New Zealand National Nutrition Surveys together with food nutrient concentration data derived from naturally occurring concentrations, proposed levels of use, the current permissions for use specified in the Code, analytical data derived from surveys or data on use provided by the manufacturers. The information required to undertake this assessment will be derived from different sources, including the application.

The application must contain the following information:

- 1. *A list of the food groups or foods proposed to contain the nutritive substance, or changes to currently permitted foods***
- 2. *The maximum proposed level of the nutritive substance for each food group or food, or the proposed changes to the currently permitted levels***

This part includes information on the proposed levels of use in food as well as naturally-occurring levels in foods.

**3. *The percentage of the food group in which the nutritive substance is proposed to be used or the percentage of the market likely to use the nutritive substance***

This part includes information based on projected uptake of the nutritive substance in foods or market share data for foods likely to contain the nutritive substance. This could be based on a similar market in another country.

**4. *For foods or food groups that are new to the Australian or New Zealand markets, information on likely level of consumption***

This part includes any consumption information for food groups not included in the 1995 Australian National Nutrition Survey (NNS) or the 1997 New Zealand NNS which relate to this application.

**Note:**

Information on likely consumption of new foods or food groups can be based on proposed levels of consumption (grams per day) or on consumption data for these foods from a similar market in another country.

The application should include the following information:

**5. *Information relating to the use of the nutritive substance in other countries***

This part includes information on the foods and/or food groups in which the nutritive substance is used, the use levels and consumption amounts in other countries.

**6. *For foods where consumption has changed in recent years, information on likely current food consumption***

This part includes any consumption information for foods where there has been a significant change in consumption since the 1995 Australian NNS or the 1997 New Zealand NNS which relate to this application. This can be based on market share data or sales data.

**Note:**

For further information on estimating dietary exposure, see the FSANZ Guidance Document *Estimating Dietary Exposure to Food Chemicals for Food Regulatory Purposes* on the FSANZ website.

**E. *Information related to the nutritional impact of a nutritive substance other than vitamins and minerals (for vitamins and minerals see Section F)***

The application must contain the following information:

**1. *Information related to the nutritional purpose of adding the nutritive substance to each food***

This part includes:

- (a) data to demonstrate that the nutritive substance can deliver a health benefit; and
- (b) data to demonstrate that specific food(s) containing the nutritive substance will deliver the health benefit in the target group at the anticipated level of intake; or
- (c) data to demonstrate that the nutritional profile of the specified substitute food<sup>1</sup> can be aligned with the reference food.

**Note:**

The scientific evidence for a health benefit is assessed using the following criteria:

- (a) The evidence must be based on studies conducted on human subjects.
- (b) The evidence must be based on a food product or food product group containing the nutritive substance rather than the nutritive substance alone.
- (c) The evidence must relate to normal use by the target population and the food product must deliver a health benefit relevant to the target population.

Refer to Section 3.1.8 for further information regarding data quality.

**F. Information related to the nutritional impact of a vitamin or mineral**

The application must contain the following information:

**1. *Information to demonstrate a need to permit the addition of a vitamin or mineral to food***

This part includes information addressing at least one of the following:

- (a) data to demonstrate clinical or sub-clinical evidence of deficiency or data to demonstrate low levels of intake in one or more population groups; or
- (b) data to demonstrate that deficiencies are likely to develop in one or more population groups because of changing food habits; or
- (c) generally accepted scientific evidence that an increase in the intake of a vitamin and/or mineral can deliver a health benefit; or
- (d) evidence that the reduced nutritional profile of a processed food can be substantially restored; or
- (e) evidence that the nutritional profile of specified substitute food<sup>2</sup> can be aligned with the primary food.

**2. *Information to demonstrate the permitted addition of the vitamin or mineral has the potential to address the deficit or deliver a health benefit to the population or a population subgroup***

This part includes:

- (a) data on the level of absorption of the particular form of the vitamin or mineral from the specified food at normal levels of consumption;

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<sup>1</sup> Based on the definition of a substitute food in the Codex General Principles, FSANZ defines a substitute food as a food which is designed to resemble a common food in appearance and texture and is intended to be used as a complete or partial replacement for the food it resembles (i.e. reference food).

<sup>2</sup> See footnote 1

- (b) data on the metabolic fate of the vitamin or mineral under the conditions above; and
- (c) information on the food vehicle, including the presence of substances that will have an inhibitory or enhancing effect on absorption.

**G. Information related to potential impact on consumer understanding and behaviour**

**Note:**

Some of the information derived from Section D – Information on dietary exposure to the nutritive substance, will be used also to assess the impact on consumers of the nutritive substance. The information below is in addition to this information.

The application must contain the following information:

1. ***Information to demonstrate consumer awareness and understanding of the nutritive substances in the food(s)***
2. ***Information on the actual and/or potential behaviour of consumers in response to proposed food(s)***

This part includes information such as changes in consumption behaviour and changes in health and diet behaviour.

3. ***Information to demonstrate that the food(s) containing the nutritive substance will not adversely affect any population groups (e.g. particular age or cultural groups)***

**Note:**

Consumption behaviour changes include substitution, addition or avoidance. Health and diet behaviour changes relate to the potential impacts of the food in the context of not promoting patterns inconsistent with nutrition and physical activity policies and/or guidelines for Australia and New Zealand.

The extent of the impact of the addition of a nutritive substance to food on consumer behaviour will vary depending on:

- (a) the nature of the nutritive substance and the food(s) to which it will be added;
- (b) the projected consumption levels for the food(s) containing the nutritive substance including amount consumed and how often it will be consumed;
- (c) whether currently used foods may be substituted for food(s) containing the nutritive substance.

Thus, the amount of information necessary to address the impact on consumer behaviour will depend on the level of the impact. This will need to be considered in addressing the points above.

## **H. Information related to impact on the food industry (industry applicants only)**

The application must contain the following information:

### **1. *Data on the projected impact on the food industry of the proposed food(s) containing the nutritive substance***

This part includes information on the costs of foods containing the nutritive substance and, if applicable, the impact of the new foods on the sale of similar existing products.

### **2. *Impact on international trade***

This part includes information, if available, on the impact of the proposed change on foods imported into Australia/New Zealand.

#### **Note:**

In relation to the impact on the food industry of the proposed change to the permissions for use of a nutritive substance, the applicant should provide as much information as is readily available. FSANZ will use this information together with information from other sources to prepare a Regulatory Impact Statement (*see Section 2.2.9*).

**SECTION 3.4**

**STANDARDS  
RELATED TO  
CONTAMINANTS  
AND  
NATURAL TOXICANTS**

### 3.4.1 CHEMICAL CONTAMINANT AND NATURAL TOXICANT MAXIMUM LEVELS

An application to vary the Code is required to approve a new maximum level for a contaminant in food or to change the current maximum levels which are specified in Standard 1.4.1 – Contaminants and Natural Toxicants.

**Note:**

The purpose of Standard 1.4.1 is stated as follows:

*This Standard sets out the maximum levels (MLs) of specified metal and non-metal contaminants and natural toxicants in nominated foods. As a general principle, regardless of whether or not a ML exists, the levels of contaminants and natural toxicants in all foods should be kept As Low As Reasonably Achievable (the ALARA principle). The ALARA level, which may be viewed as the irreducible level for a contaminant, is defined as that concentration of a substance that cannot be eliminated from a food without involving the discarding of that food altogether or severely compromising the ultimate availability of major food supplies.*

*An ML has been established only where it serves an effective risk management function and only for those foods which provide a significant contribution to the total dietary exposure. The Standard does not prohibit the presence of low levels of contaminants or natural toxicants unless the contaminant or natural toxicant exceeds a level prescribed in the Standard. An ML has not been assigned where the contaminant or natural toxicant in a food represents a low public health risk. However, the general provisions of the Food legislation relating to the availability of safe foods apply to all foods, irrespective of whether an ML exists or not.*

*MLs have been set at levels that are consistent with public health and safety and which are reasonably achievable from sound production and natural resource management practices. Consideration has also been given to Australia's and New Zealand's international trade obligations under the World Trade Organization's Sanitary and Phytosanitary Agreement and Technical Barrier to Trade Agreement.*

Standard 1.4.1 contains the following definition:

**Maximum level (ML)** means the maximum level of a specified contaminant, or specified natural toxicant, which is permitted to be present in a nominated food expressed, unless otherwise specified, in milligrams of the contaminant or the natural toxicant per kilogram of the food (mg/kg).

The following information is required to support an application for a new maximum level for a contaminant or to change the current maximum level. This information is in addition to that specified in Section 3.1 – General Requirements.

#### **A. General information on the application**

The application must contain the following general information:

**1. Purpose of the application**

This part includes information on the purpose of the proposed change(s) to Standard 1.4.1.

**2. Justification for the application**

This part includes general statements addressing:

- (a) the need to add, amend or delete a maximum level including, if applicable, the history of compliance;
- (b) any public health and safety issues related to the proposed change to the maximum level; and
- (c) the costs and benefits for industry, consumers and the government associated with the proposed change to the maximum level.

Reference may be made to other sections of this application that contain detailed supporting information, where necessary.

**B. General information on the contaminant or natural toxicant**

The application must contain the following:

**1. Nature of the contaminant or natural toxicant, including chemical and physical properties**

This part includes information on the nature of the contaminant or natural toxicant, its chemical and physical properties, the source of the contaminant or natural toxicant, the factors that influence the level of contamination of food, the interaction of the contaminant or natural toxicant with the food, and current control measures.

**2. Analytical method for detection**

This includes a method for detection and quantitation of the contaminant or natural toxicant in the foods in which it is found.

**C. Information on the safety of the contaminant or natural toxicant**

The application must contain the following:

**1. Information on the toxicokinetics and metabolism of the contaminant or natural toxicant and, if necessary, its degradation products**

This part includes published reviews or individual study reports on the metabolic fate of the contaminant or natural toxicant and, if necessary, its degradation products.

**2. Information from studies in animals that is relevant to the toxicity of the contaminant or natural toxicant and, if necessary, its degradation products**

This part includes published reviews or detailed reports of all *in vitro* studies and all *in vivo* studies conducted in animals to examine the toxicity of the contaminant or natural toxicant.

**Note:**

The following categories of animal studies need to be considered:

- (a) Acute toxicity studies
- (b) Short-term toxicity studies
- (c) Long-term toxicity and carcinogenicity studies
- (d) Reproductive toxicity studies
- (e) Developmental toxicity studies
- (f) Genotoxicity studies
- (g) Special studies such as neurotoxicity or immunotoxicity.

Where data are not available or is not considered relevant to the safety assessment of the contaminant, an explanatory statement should be provided.

**3. Information from human studies that is relevant to the toxicity of the contaminant or natural toxicant and, if applicable, its degradation products**

The part includes reviews or reports on human epidemiology studies or individual case studies related to the contaminant or natural toxicant, particularly reports of potential adverse effects on population sub-groups at the levels found in food.

**D. Information on dietary exposure to the contaminant or natural toxicant**

The application must contain the following information:

**1. The foods or food groups) where a maximum level is proposed, or where a change to the maximum level is proposed**

This part includes information on the full range of foods likely to contain the contaminant or natural toxicant.

**2. Surveys on the levels of the contaminant or natural toxicant in foods**

This part includes the details of any surveys which have been conducted in Australia or New Zealand on the levels found in foods. If applicable, this part must also include details of any surveys conducted in other countries.

**Note:**

For further information on estimating dietary exposure, see the FSANZ Guidance Document *Estimating Dietary Exposure to Food Chemicals for Food Regulatory Purposes* on the FSANZ website.

**E Information related to the impact on the food industry (industry applicants only)**

The application must contain the following information:

**1. *Data on the projected cost to the food industry of the proposed change to the maximum level***

This part includes information on the market share of the affected foods, the costs associated with the change to the maximum level, the impact on the sale of existing products, and any impacts on small businesses.

**2. *Impact on international trade***

This part includes information, if available, on the impact of the proposed change to the maximum level on foods imported into and exported from Australia/New Zealand.

**Note:**

In relation to the impact of the proposed change to the contaminant maximum level on the food industry, the applicant should provide as much information as is readily available. FSANZ will use this information together with information from other sources to prepare a Regulatory Impact Statement (*see Section 2.2.9*).

### 3.4.2 MICROBIOLOGICAL LIMITS

An application to vary the Code is required to change the permissible limits for a micro-organism in food or to change the sampling provisions, including the sampling plans, the prescribed methods of analysis or other requirements which are specified in Standard 1.6.1 – Microbiological limits for foods.

**Note:**

The purpose of Standard 1.6.1 – Microbiological limits for foods is:

*To list the maximum permissible levels of food-borne micro-organisms that pose a risk to human health in nominated foods, or classes of foods. This Standard includes mandatory sampling plans, used to sample lots or consignments of nominated foods or classes of foods, and the criteria for determining when a lot or consignment of food poses a risk to human health and therefore should not be offered for sale, or further used in the preparation of food for sale. The microbiological standards included in the Schedule to this Standard are applicable to the foods listed in the Schedule.*

The following information is required to support an application for a new maximum permissible limit or to change the current maximum permissible limits, or to change other aspects of this standard. This information is in addition to that specified in Section 3.1 – General Requirements.

#### **A. General information on the application**

The application must contain the following general information:

##### **1. Purpose of the application**

This part includes information on the purpose of the proposed change(s) to Standard 1.6.1.

##### **2. Justification for the application**

This part includes general statements addressing:

- (a) the need to change the current microbiological limit;
- (b) any public health and safety issues related to the proposed change to the microbiological limit; and
- (c) the costs and benefits for industry, consumers and the government associated with the proposed change to the microbiological limit.

Reference may be made to other sections of this application that contain detailed supporting information, where necessary.

#### **B. Technical information on food production methods**

The application must contain the following information:

**1. *Information relating to raw inputs, production and manufacturing process for the food(s)***

This part includes:

- (a) details of the raw ingredients, production process and methods of manufacture, including key properties that may impact on microbial growth, survival and/or inactivation (e.g. pH, water properties etc); and
- (b) full details of the analytical controls and quality assurance procedures used during the various stages of these manufacturing, processing and packaging operations through to storage conditions of retailer (if applicable).

**2. *Information on the use of new or amended food technology, if applicable***

This part includes details of any new or amended food technology to be used to support the proposed changes to the microbiological limits.

**C. *Information related to food safety***

The application must contain the following information:

**1. *Nature of the microbiological hazard***

This part includes information on the nature of the microbiological hazard and any dose-response data or available epidemiological data.

**2. *Data on the source and prevalence of the microbiological contamination***

This part includes:

- (a) survey results on the prevalence and levels of the pathogen along the entire food production chain, including raw materials; and
- (b) microbiological validation studies and challenge test data (in either/or both laboratory and pilot-scale studies, if appropriate).

**3. *Information on consumer handling and use of foods, if applicable***

This part includes information on consumer use of the product including storage, product shelf life and handling instructions.

**D. *Information on the nutritional impact***

The application must contain the following information:

**1. *Evidence of the nutritional benefit of the proposed amendment, if applicable***

This part includes any information on the nutritional composition of food which indicates a nutritional benefit from the proposed amendment to the Standard.

## **E. Information related to dietary exposure**

The application must contain the following information:

### **1. Food consumption data, if applicable**

This part includes data on food consumption levels for the foods affected by the proposed amendment, as either proposed serves per day (gram amount) or per capita. For new foods (foods not included in the 1995 Australian National Nutrition Survey or the 1997 New Zealand National Nutrition Survey), this part must include projected consumption data, including information from international markets.

#### **Note:**

For further information on microbiological risk assessment, see the FSANZ Guidance Document *Guidelines for Undertaking Microbiological Risk Assessment* on the FSANZ website.

## **F. Information related to the impact on the food industry (industry applicants only)**

The application must contain the following information:

### **1. Data on the projected compliance cost to the food industry of the proposed change**

This part includes information on the market share of the affected foods, the costs of the change, the impact on the sale of existing products, and any impacts on small businesses.

### **2. Impact on international trade**

This part includes information, if available, on the impact of the proposed change on foods imported into Australia/New Zealand.

#### **Note:**

In relation to the impact of the proposed change to the microbiological level on the food industry, the applicant should provide as much information as is readily available. FSANZ will use this information together with information from other sources to prepare a Regulatory Impact Statement (*see Section 2.2.9*).

### 3.4.3 PROHIBITED AND RESTRICTED PLANTS AND FUNGI

An application to vary the Code is required to add, modify or delete an entry in relation to a plant or fungi in Standard 1.4.2 – Prohibited and Restricted Plants and Fungi.

**Note:**

Standard 1.4.1 regulates the use of toxic plants and fungi (or a part or derivative thereof) in food. It lists the species of plants and fungi that must not be added to food or offered for sale as food. It also lists the species of plants and fungi that may not be used in food except as a source of a flavouring substance.

The following information is required to support an application to add, modify or delete an entry in relation to a plant or fungi from Standard 1.4.2. This information is in addition to that specified in Section 3.1 – General Requirements.

#### **A. General information on the application**

The application must contain the following general information:

##### **1. Purpose of the application**

This part includes information on the purpose of the proposed change(s) to Standard 1.4.2.

##### **2. Justification for the application**

This part includes general statements addressing:

- (a) the need to add, modify or delete a plant or fungi from the Standard;
- (b) evidence that public health and safety will be protected following the proposed change; and
- (c) the costs and benefits for industry, consumers and the government associated with the proposed change.

Reference may be made to other sections of this application that contain detailed supporting information, where necessary.

#### **B. General information on the plant or fungi (or a part or derivative thereof)**

The application must contain the following:

##### **1. Nature of the plant or fungi**

This part includes information on the nature and identity of the plant or fungi, and its potential for use in food.

##### **2. Information on identity and levels of natural toxicants in the plant or fungi**

This part includes information on the natural toxicants in the food and the factors which influence the levels found in food.

**C. Information on the safety of the plant or fungi (or a part or derivative thereof)**

The application must contain the following:

**1. *Reviews or reports of toxicity studies on the plant or fungi***

This part includes a literature survey of relevant toxicity literature.

**2. *Reviews or reports of human cases of toxicity associated with the plant or fungi***

The part includes any reports of potential adverse effects on population sub-groups, particularly at the levels found in food.

**3. *Use of the plant or fungi in other countries, if applicable***

This part includes information on the use of the plant or fungi in food products in other countries.

# **SECTION 3.5**

## **STANDARDS RELATED TO NEW FOODS**

### 3.5.1 FOODS PRODUCED USING GENE TECHNOLOGY

Applications to vary the Code are required to approve the use of new foods produced using gene technology. Approved genetically modified (GM) foods are specified in Standard 1.5.2 – Food produced using Gene Technology.

**Note:**

In Standard 1.5.2, there are the following definitions:

*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.*

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

The following information is required to support an application for a new genetically modified food. This information is in addition to that specified in Section 3.1 – General Requirements.

#### **A. General information on the application**

The application must contain the following information:

##### **1. Purpose of the application**

This part includes information on the purpose of the proposed change(s) to Standard 1.5.2 – Food produced using Gene Technology.

##### **2. Justification for the application**

This part includes general statements addressing:

- (a) the advantages of the genetically modified food;
- (b) the safety of the genetically modified food;
- (c) the potential impact on trade; and
- (d) the costs and benefits for industry, consumers and government associated with use of the genetically modified food.

Reference may be made to other sections of the application that contain detailed supporting information, where necessary.

#### **B. Technical information on the genetically modified food**

The application must contain the following information:

##### **1. Nature and identity of the genetically modified food**

This part includes all of the following:

- (a) A description of the GM organism from which the new GM food is derived. The description must include the nature and purpose of the genetic modification.
- (b) The name, number or other identifier of each of the new lines or strains of GM organism from which the food is derived.
- (c) The name the food will be marketed under (if known).
- (d) The types of products likely to include the food or food ingredient.

## **2. *History of use of the host and donor organisms***

This part includes all of the following:

- (a) A description of all the donor organism(s) from which the genetic elements are derived, including:
  - (i) common and scientific names and taxonomic classification;
  - (ii) information about any known pathogenicity, toxicity or allergenicity of relevance to the food; and
  - (iii) information about the history of use of the organism in the food supply or history of human exposure to the organism through other than intended food use (e.g. as a normal contaminant).
- (b) A description of the host organism into which the genes were transferred and its history of safe use for food, including:
  - (i) any relevant phenotypic information;
  - (ii) how the organism is typically propagated for food use;
  - (iii) what part of the organism is typically used as food;
  - (iv) whether special processing is required to render food derived from the organism safe to eat; and
  - (v) the significance to the diet in Australia and New Zealand of food derived from the host organism.

## **3. *The nature of the genetic modification***

This part includes all of the following:

- (a) A description of the method used to transform the host organism.
- (b) Information about the intermediate host organisms (e.g. bacteria) used for all laboratory manipulations prior to transformation of the host organism.
- (c) A description of the gene construct and the transformation vectors used, including:
  - (i) the size, source and function of all the genetic components including marker genes, regulatory and other elements; and
  - (ii) a detailed map of the location and orientation of all the genetic components contained within the construct and vector, including the location of relevant restriction sites.
- (d) A full molecular characterisation of the genetic modification in the new organism, including:

- (i) identification of all transferred genetic material and whether it has undergone any rearrangements;
  - (ii) a determination of the number of insertion sites, and the number of copies at each insertion site;
  - (iii) full DNA sequence data of each insertion event, including junction regions with the host DNA, sufficient to identify any substances expressed as a consequence of the inserted material, or where more appropriate, other information such as analysis of transcripts or expression products to identify any new substances that may be present in the food;
  - (iv) a map depicting the organisation of the inserted genetic material at each insertion site; and
  - (v) the identification and characterisation of any unexpected open reading frames within the inserted DNA or created by insertion with contiguous genomic DNA, including those that could result in fusion proteins or unexpected protein expression products.
- (e) A description of how the line or strain from which food is derived was obtained from the original transformant (i.e. provide a family tree or describe the breeding process).
- (f) Evidence of the stability of the genetic changes, including:
- (i) the pattern of inheritance of the transferred gene(s) and the number of generations over which this has been monitored; and
  - (ii) the pattern of inheritance and expression of the phenotype over several generations and, where appropriate, across different environments.

#### **4. *Information on the labelling of the GM food***

This part includes both of the following:

- (a) Information on whether novel DNA or protein is likely to be present in final food.
- (b) Detection methodology for the GM food suitable for analytical purposes.

#### **C. *Information related to the safety of the genetically-modified food***

The application must contain the following information:

##### **1. *Information on antibiotic resistance marker genes (if used)***

This part includes all of the following:

- (a) Information on the clinical and veterinary importance, if any, in Australia and New Zealand of the antibiotic to which any transferred antibiotic resistance genes confer resistance.
- (b) Information on whether the presence in food of the enzyme or protein encoded by the antibiotic resistance marker gene would compromise the therapeutic efficacy of the orally administered antibiotic.
- (c) Information on the safety of the gene product.
- (d) If the new GM organism is a micro-organism, information on whether it will remain viable in the final food.

## **2. *The characterisation of novel proteins or other novel substances***

This part includes all of the following:

- (a) A full description of the biochemical function and phenotypic effects of all novel substances (e.g. a protein or an untranslated RNA) that could potentially be expressed in the new GM organism, including those resulting from the transfer of marker genes.
- (b) The identification of any other novel substances, (e.g., metabolites) that might accumulate on or in the GM organism as a result of the genetic modification, and their levels and site of accumulation.
- (c) Data on the site of expression of all novel substances, particularly whether they are likely to be present in the edible portions of the organism, and levels of expression.
- (d) Information on whether any newly expressed protein has undergone any unexpected post-translational modification in the new host.
- (e) Evidence of non-expression of a gene, in the case where a transferred gene is not expected to express any novel substances (e.g., because it has a 'silencing' role or is in a non-functional form).
- (f) Information about prior history of human consumption of the novel substances, if any, or their similarity to substances previously consumed in food.

## **3. *The potential toxicity of novel proteins or other novel substances***

This part includes all of the following:

- (a) A bioinformatic comparison of the amino acid sequence of each of the novel proteins to known protein toxins and anti-nutrients (e.g. protease inhibitors, lectins).
- (b) Information on the stability to heat or processing and/or to degradation in appropriate gastric and intestinal model systems.
- (c) Detailed reports of all available acute or short term oral toxicity studies in animals on the novel proteins or other novel substances.

### **Note:**

There is no requirement to conduct acute or short-term oral toxicity studies in animals on novel protein or other novel substances, however, if the bioinformatic comparison and biochemical studies indicate a concern, animal toxicity studies on the novel protein or other novel substances are recommended.

## **4. *The potential allergenicity of novel proteins***

### **Note:**

The information provided in this part must enable FSANZ to consider whether: (a) a newly expressed protein is one to which certain individuals may already be sensitive; and (b) a protein new to the food supply is likely to induce allergic reactions in some individuals.

This part includes all of the following:

- (a) Source of the introduced protein.

- (b) Any significant similarity between the amino acid sequence of the protein and that of known allergens.
- (c) Its structural properties, including but not limited to, its susceptibility to enzymatic degradation (e.g. digestion by pepsin), heat stability and/or, acid and enzymatic treatment.
- (d) Specific serum screening where a newly expressed protein is derived from a source known to be allergenic or has sequence homology with a known allergen.

If the introduced genetic material is obtained from wheat, rye, barley, oats, or related cereal grains, this part must also include information on whether the newly expressed protein(s) have a role in the elicitation of gluten-sensitive enteropathy.

### **5. *Compositional analyses of the GM food***

This part includes all of the following:

- (a) The levels of key nutrients, toxicants and anti-nutrients in the GM food compared with the levels in an appropriate comparator (usually the non-GM counterpart). The statistical significance of any observed differences must be assessed in the context of the range of natural variations for that parameter to determine its biological significance.
- (b) The levels of any other constituents that may potentially be influenced by the genetic modification, as a result, for example, of downstream metabolic effects, compared with the levels in an appropriate comparator.
- (c) The levels of any naturally occurring allergenic proteins in the GM food compared with the levels in an appropriate comparator. Particular attention must be paid to those foods that are required to be declared when present as an ingredient, and where significant alterations to protein content could be reasonably anticipated.

**Note:**

The comparator would normally be the near isogenic parental line or strain. Where this is not appropriate, the comparator should be as close as possible to the GM line or strain.

### **D. Information related to the nutritional impact of the genetically-modified food**

The application must contain the following information if the compositional analysis indicates biologically significant changes to the levels of certain nutrients in the GM food compared to the non-GM counterpart food:

#### **1. *Data to allow the nutritional impact of compositional changes in the food to be assessed***

This part includes data on the anticipated dietary intake of the GM food in relation to the overall diet, together with any information which may indicate a change to the bioavailability of the nutrients from the GM food.

**Note:**

If necessary, FSANZ will undertake a dietary exposure assessment for the nutrients in the GM food using a custom-made computer program, DIAMOND, which combines food consumption data from the latest Australian and New Zealand National Nutrition Surveys together with food nutrient composition data.

**2. *Data from an animal feeding study, if available***

This part includes an animal feeding study with the GM food using a species that consumes the non-GM counterpart food. Such studies are typically conducted over the period of rapid growth of the animal. Other studies in animals may be conducted to enable specific effects to be measured.

**Note:**

There is no requirement for an animal feeding study to be conducted on the GM food, however, such a study may provide additional re-assurance that the GM food is at least nutritionally equivalent to the non-GM counterpart food. This will be particularly important when the GM food is a staple food.

**Note:**

For further information on the safety assessment of GM foods, see the FSANZ Guidance Document *Guidelines for the Safety Assessment of Genetically-Modified Foods* on the FSANZ website.

### 3.5.2 NOVEL FOODS

An application to vary the Code is required to approve the use of a new novel food or novel food ingredient. Permissions for use of novel foods or novel food ingredients are specified in Standard 1.5.1 – Novel Foods.

**Note:**

Standard 1.5.1 contains the following definitions:

*Novel food means a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account –*

- (a) the composition or structure of the product; or*
- (b) levels of undesirable substances in the product; or*
- (c) known potential for adverse effects in humans; or*
- (d) traditional preparation and cooking methods; or*
- (e) patterns and levels of consumption of the product.*

*Non-traditional food means a food which does not have a history of significant human consumption by the broad community in Australia or New Zealand.*

For further information relating to the operation of the Novel Food Standard, particular in relation to whether a particular food would be regarded as novel, refer to the *Guidelines for amending the Food Standards Code: Novel Foods* at <http://www.foodstandards.gov.au/srcfiles/Novel%20Food%20Guidelines%20-%20October%202005.doc>.

The following information is required to support an application for a novel food. This information is in addition to that specified in Section 3.1 – General Requirements.

#### **A. General information on the application**

The application must contain the following general information:

##### **1. Purpose of the application**

This part includes information on the purpose of the proposed change(s) to Standard 1.5.1 – Novel Foods.

##### **2. Justification for the application**

This part includes general statements addressing:

- (a) the purpose of using the novel food or novel food ingredient;
- (b) the safety of the novel food or food ingredient; and
- (c) the cost and benefits for industry, consumers and government associated with use of the novel food or novel food ingredient.

Reference may be made to other sections of the application that contain detailed supporting information, where necessary.

### **3. *Support for the application***

This part includes evidence that the food industry has an interest in marketing the novel food or novel food ingredient in Australia and New Zealand as a result of the proposed change to the Code, or that food containing the novel food or novel food ingredient may be imported into Australia or New Zealand.

#### **B. Technical information on the novel food**

The application must contain the following information:

##### **1. *Information on the type of novel food***

This part includes a brief description of the novel food, including the name the food will be marketed under (if known), and whether it falls within one of the following major identified categories:

- (I) Plants or animals and their components
- (II) Plant or animal extracts
- (III) Herbs (both non-culinary and culinary) including extracts
- (IV) Single chemical entities
- (V) Dietary macro-components
- (VI) Micro-organisms (including probiotics)
- (VII) Food ingredients derived from new sources
- (VIII) Foods produced by a process not previously applied to food.

#### **Note:**

Whether a food which falls into one of these categories will be regarded as novel will depend on how it relates to the definition of a novel food (*see above*). When a food is assessed in relation to its 'novelty', it will be listed under the novel food section of the FSANZ website at <http://www.foodstandards.gov.au/foodmatters/novelfoods/regulationofnovelfoo3024.cfm>.

The term **dietary macro-component** generally refers to those dietary components which constitute a significant proportion of the food, such as fats, sugars, proteins and polysaccharides. Novel macro-components are used to replace the naturally-occurring components, either for a functional purpose or to reduce the energy value of the food. Examples include olestra, tagatose, cyclodextrin, salatrim, diacylglycerol oil, trehalose, resistant starches.

The term single chemical entity generally refers to a substance, however derived, that is added to food but not consumed as food in its own right. It is intended for addition to food at levels consistent with use as a food ingredient. For the purposes of the Novel Food Standard, a single chemical entity does not include a nutritive substance or a substance used for a technological purpose.

The term **novel food** includes both whole foods and food ingredients – these terms are used both together or separately in this document, depending on the circumstances. When the novel food is clearly a food ingredient, only this term is used.

**2. *Information on the physical and chemical properties of the novel food or novel food ingredient***

This part includes detailed information on the physical and chemical properties of the novel food or novel food ingredient including, where relevant, chemical name, CAS registry number, empirical and structural formula, molecular weight, chemical stability, thermal stability, solubility in water and melting point.

**3. *Information on the impurity profile for a typical preparation***

This part includes details on the nature and amounts (by weight) of all impurities, including isomers and manufacturing by-products, present in the novel food ingredient preparation. Impurities should be identified by their Chemical Abstract (CA) or International Union of Pure and Applied Chemists (IUPAC) names.

**4. *Manufacturing process for a novel food ingredient***

This part includes a comprehensive outline of the method of manufacture of the novel food ingredient.

**5. *Specification for identity and purity for a novel food ingredient***

This part includes a specification from one of the published sources identified in Standard 1.3.4 – Identity and Purity. If a published specification is not available, a detailed specification must be provided.

**6. *Analytical method for detection***

This part includes a method for detection of the novel food ingredient or its degradation products in the foods in which it will be used.

**C. *Information on the safety of the novel food***

**Note:**

FSANZ will undertake an assessment of all available reports of animal and human studies which provide information related to the toxicity of the novel food or novel food ingredient. The safety of the novel food will be assessed at the proposed levels of use, using both the technical information provided in section A and the information specified in this section. For a novel food ingredient, a safe level of intake will be established, if possible, from the available studies.

Because there are a number of categories of novel foods, the data required for a safety assessment will vary depending on the nature of the novel foods. Factors to consider in a safety assessment will include:

- |  |
|--|
| <ul style="list-style-type: none"><li>(a) the history of use as a food in other countries</li><li>(b) the composition of the novel food, particularly the levels of anti-nutrients and naturally-occurring toxins</li><li>(c) the method of preparation and specifications of a novel food ingredient</li><li>(d) potential for allergenicity of the novel food</li><li>(e) metabolism/toxicokinetic studies on the novel food ingredient</li><li>(f) animal toxicity studies on the novel food ingredient</li><li>(g) human toleration studies on the novel food ingredient</li></ul> |
|--|

**(I) *Plants or animals (or their components)***

An application for a novel food which is a plant or animal (or their components) must contain the following information:

1. Information on the composition of the novel food

This part includes information on the levels of anti-nutrients and naturally-occurring toxins in the plant or animal (or their components).

2. Information on the effects of food processing or preparation

This part includes information on methods of reducing the levels of anti-nutrients or naturally-occurring toxins during food processing or food preparation.

3. Information on the current use of this food or food component in population sub-groups or in other countries

This part includes information on the extent and history of use of the food in other countries; any particular preparation, processing or cooking practices normally used; and the level and purpose of consumption (e.g. staple food, ceremonial use).

4. Information regarding the potential adverse effects associated with the food or its ingredients

This part includes published or unpublished reports of allergenicity or other adverse effects in humans associated with the food. If available, this part also includes any reports of toxicity studies conducted in animals or toleration studies conducted in humans.

**(II) *Plant or animal extracts***

An application for a novel food which is a plant or animal extract must contain all of the information in I. Plants or Animals (or their Components) above as well the following additional information:

1. Information on the method of extraction and the composition of the concentrated extract

This part includes the methodology used to prepare the extract and the composition of the extract. This must include information on the levels of potential contaminants from the extraction process.

2. Information on the use of this plant or animal extract as a food in other countries

This part includes information on the extent and history of use of the extract in other countries, together with reports of any adverse health effects.

**Note:**

Use of the plant or animal extract as a dietary supplement, natural medicine or complementary medicine in other countries should be provided. In some countries, this is regarded as food use rather than medicinal use. If adverse effects are reported, the nature of the adverse event reporting scheme should be provided, if known.

3. Information on the toxicity of the extract obtained from studies conducted in animals or humans

This part includes any reports of toxicity studies conducted in animals. It must also include any reports of toleration studies conducted in humans.

**(III) Herbs (both non-culinary and culinary) including extracts**

An application for a novel food which is a herb (both non-culinary and culinary) including extracts must contain the following information:

1. Information on the history of use of the herb

This part includes information on the use of the herb as a complementary medicine in Australia or as a dietary supplement in New Zealand, or as a food or medicine in other countries. The plant part(s) used must also be specified, if applicable.

2. Information on the composition of the herb

This part includes information on the levels of biologically active substances in the herbs or herbal extracts, and information on their potential adverse effects.

3. For a herbal extract, information on the method of extraction and the composition of the concentrated extract

This part includes detailed information on the plant part(s) used to prepare the extract, the method used to prepare the extract and the composition of the extract. This must include information on the levels of potential contaminants from the extraction process.

4. Information on the use of this herb or herbal extract as a food in other countries

This part includes information on the extent and history of use of the herb or herbal extract in other countries, together with reports of any adverse health effects. The nature of the adverse event reporting scheme in that country should be detailed, if available.

5. Information regarding the potential allergenicity of the herb or herbal extract

This part includes reports of allergenicity associated with the herb or herbal extract.

6. Information on the toxicity of the herb, herbal extract, or any key constituents obtained from studies conducted in animals or humans

This part includes any reports of toxicity studies conducted in animals. It must also include any reports of toleration studies conducted in humans.

7. Safety assessment reports prepared by international agencies or other national government agencies

This part includes published safety assessment reports prepared by other agencies.

***(IV & V) Single chemical entities and Dietary macro-components***

An application for a novel food which is a single chemical entity or a dietary macro-component must contain the following information:

1. Information on the toxicokinetics and metabolism of the single chemical entity and, where appropriate, its degradation products and major metabolites

This part includes reports of all studies conducted in animals or humans to examine the metabolic fate of the single chemical entity or dietary macrocomponent and, where necessary, its degradation products and major metabolites.

2. Information from studies in animals or humans that is relevant to the toxicity of the single chemical entity and, where appropriate, its degradation products and major metabolites

This part includes detailed reports of all in vitro and in vivo toxicity studies conducted in animals or humans to examine the toxicity of the single chemical entity or dietary macro-component and, where necessary, its metabolites or degradation products.

**Note:**

The application should address the following categories of animal studies:

- (a) Acute toxicity studies
- (b) Short-term toxicity
- (c) Long-term toxicity studies and carcinogenicity studies
- (d) Reproductive toxicity studies
- (e) Developmental toxicity studies
- (f) Genotoxicity studies
- (g) Special studies such as neurotoxicity or immunotoxicity

Where data are not available or is not considered relevant to the safety assessment of the single chemical entity, an explanatory statement should be provided.

3. Safety assessment reports prepared by international agencies or other national government agencies

This part includes safety assessment reports prepared by WHO or by other national or supranational agencies responsible for food safety or public health.

**(VI) *Micro-organisms (including probiotics)***

An application for a novel food which is a micro-organism (including probiotics) must contain the following information:

1. Information on potential pathogenicity

This part includes information related to the potential pathogenicity of the micro-organism and related micro-organisms

2. Information on the effects of the micro-organism on gut microflora

This part includes studies to demonstrate that the micro-organism does not have adverse effects on the gut microflora.

3. Information on the use of this micro-organism as a food in other countries

This part includes information on the extent and history of use of this micro-organism or related micro-organisms in other countries, together with reports of any adverse health effects. The nature of any adverse event reporting system in that country should be detailed, if available.

4. Information on human toleration studies

This part includes any published or unpublished reports of toleration studies conducted in humans.

**(VII) *Food ingredients derived from a new source***

An application for a novel food which is a food ingredient derived from a new source must contain the following information:

1. Information on the safety of the source organism

This part includes information on whether the source organism of the novel ingredient has a history of safe use as a food. If the source organism is microbial, this part must include information on any potential pathogenicity. This part must also include information on potential naturally-occurring toxins, if applicable.

2. Information on the composition of the novel food ingredient derived from a new source

This part includes information on the levels of major components and nutrients in the processed food.

3. Information on the toxicity of the novel food ingredient derived from the new source

This part includes any published or unpublished reports of toxicity studies conducted in animals. It must also include any reports of toleration studies conducted in humans.

4. Safety assessment reports prepared by international agencies or other national government agencies

This part includes safety assessment reports prepared by WHO or by other national or supranational agencies responsible for food safety or public health.

***(VIII) Foods produced or by a process not previously applied to food***

An application for a novel food which is produced by a process not previously applied to food must contain the following information:

1. Details of the process not previously applied to food

This part includes details of the new food processing technology and its impact on the composition of the food.

2. Information on the toxicity of the novel food produced by a process not previously applied to food

This part includes any published or unpublished reports of toxicity studies conducted in animals. It must also include any reports of toleration studies conducted in humans.

3. Safety assessment reports prepared by international agencies or other national government agencies

This part includes safety assessment reports prepared by WHO or by other national or supranational agencies responsible for food safety or public health.

**D. Information on dietary exposure to the novel food**

**Note:**

FSANZ will undertake a dietary exposure assessment for all novel foods applications. The type of dietary exposure assessment will vary depending on the nature of the novel food. For novel foods which are either the final food or a major component of the final food, the dietary exposure assessment may be based on the projected market share data, or data from markets in other countries.

For novel foods which are minor components of the final food, the dietary exposure assessment will use a custom-made computer program, DIAMOND, which combines food consumption data from the latest Australian and New Zealand National Nutrition Surveys together with food chemical concentration data derived from the proposed levels of use provided by the applicant.

The application must contain the following information:

- 1. *A list of the foods or food groups proposed to contain the novel food ingredient***
- 2. *The proposed level of the novel food ingredient for each food or food group***
- 3. *The percentage of the food group in which the novel food ingredient is proposed to be used or the percentage of the market likely to use the novel food ingredient***

This part includes information based on projected uptake or market share data for foods likely to contain the novel food or novel food ingredient. This could be based on a similar market in another country.

- 4. *Data to show whether the food, or the food in which the novel food ingredient is used, is likely to replace another food from the diet, if applicable***

This part includes information on projected consumption levels for the novel food or food(s) containing the novel food ingredient, and frequency of consumption. This could include market research data or data from other international markets.

- 5. *Details of target groups and at risk groups in the population***
- 6. *Information relating to the use of the novel food or novel food ingredient in other countries, if applicable***

This part includes information on the food groups and/or foods in which it is used and the use levels.

#### **E. Information on the nutritional impact of the novel food**

**Note:**

Some of the information derived from Section C – Information on the safety of the novel food, will be used also to assess the nutritional impact of the novel food. The information below is in addition to this information.

The application must contain the following information:

- 1. *Information to demonstrate that the use of the novel food or novel food ingredient will not cause a nutritional imbalance in the diet***

This part includes:

- (a) information relating to the nutritional properties of the novel food or novel food ingredient, its effect on the bioavailability of other nutrients, and its impact on the overall diet (particularly dietary macro-components); and
- (b) data on the macro- and micro-nutrient profile of the novel food or food(s) containing the novel food ingredient.

**F. Information related to potential impact on consumer understanding and behaviour**

**Note:**

Some of the information derived from Section D – Information on dietary exposure to the novel food, will be used also to assess the impact on consumers of the novel food. The information below is in addition to this information.

The application must contain the following information:

- 1. Information to demonstrate consumer awareness and understanding of the novel food or novel food ingredient***
- 2. Information on the actual and/or potential behaviour of consumers in response to the novel food or novel food ingredient***

This part includes information such as changes in consumption behaviour and changes in health and diet behaviour.

- 3. Information to demonstrate that the food(s) containing the novel food ingredient will not adversely affect any population groups (e.g. particular age or cultural groups)***

**Note:**

Consumption behaviour changes include substitution, addition or avoidance. Health and diet behaviour changes relate to the potential impacts of the food in the context of not promoting patterns inconsistent with nutrition and physical activity policies and/or guidelines for Australia and New Zealand.

Novel foods or novel food ingredients can be used in food products for different purposes, not all of which may impact on consumer behaviour in relation to food products (e.g. cyclodextrins). The amount of information necessary to address the impact on consumer behaviour will depend on the nature of the novel food or ingredient, its extent of use, and the nature of the claims associated with the food.

**G. Information related to impact on the food industry (industry applicants only)**

The application must contain the following information:

- 1. Data on the projected impact on the food industry of the proposed novel food or novel food ingredient***

This part includes information on the costs of foods containing the novel food or novel food ingredient, and, if applicable, the impact of the new foods on the sale of similar existing products.

## **2. *Impact on international trade***

This part includes information, if available, on the impact of the proposed change on foods imported into Australia/New Zealand.

**Note:**

In relation to the impact on the food industry of the proposed use of a novel food or novel food ingredient, the applicant should provide as much information as is readily available. FSANZ will use this information together with information from other sources to prepare a Regulatory Impact Statement (*see Section 2.2.9*).

### 3.5.3 IRRADIATED FOODS

An application to vary the Code is required to approve the irradiation of food. Approval for irradiation for foods is specified in Standard 1.5.3 – Irradiation of Food.

**Note:**

Standard 1.5.3 – Irradiation of Food contains the following definitions:

**Irradiation** means the processing of food by subjecting it to the action of ionising radiation, but does not include ionising radiation imparted to food by measuring or inspection instruments, and ‘irradiate’ and ‘irradiated’ have corresponding meanings.

**Re-irradiate** does not include the irradiation of food –

- (a) prepared from materials that have been irradiated at low dose levels (not exceeding in any case 1 kGy) and are irradiated again; or
- (b) which contains less than 50 g/kg of irradiated ingredients; or
- (c) where the required full dose of ionising radiation is applied to the food in divided doses for a specific technological reason;

provided that the cumulative maximum radiation dose absorbed by the food does not exceed that specified in the Table to clause 4.

**Technological need**, in relation to the irradiation of food, refers to the minimum dose of ionising irradiation required to ensure the safety or quality of the food, provided the process is performed in accordance with good manufacturing practice, and includes the extension of shelf life, the destruction of certain bacteriological contamination or pest disinfestations.

The following information is required to support an application to irradiate a new food. This information is in addition to that specified in Section 3.1 – General Requirements.

#### A. General information on the application

The application must contain the following information:

##### 1. Purpose of the application

This part includes information on the purpose of the proposed change to Standard 1.5.3.

##### 2. Justification for the application

This part includes general statements addressing:

- (a) the advantages of irradiating the food, referencing the technological need for each type of food;
- (b) the safety of the irradiated food; and
- (c) the costs and benefits for industry, consumers and government associated with use of the irradiated food.

Reference may be made to other sections of the application that contain detailed supporting information, where necessary.

### ***3. Support for the application***

This part includes evidence that the food industry has an interest in marketing the irradiated food in Australia and New Zealand as a result of the proposed change to the Code.

#### **B. Technical information on the irradiated food**

The application must contain the following information:

##### ***1. Information on the nature of the food or food ingredient to be irradiated***

This part includes a description of the primary foods, food ingredients or mixed foods to be irradiated.

##### ***2. Information on the technological need to use irradiation compared to other available technologies***

This part includes:

- (a) information on the use of GMP in relation to foods proposed to be irradiated; and
- (b) data on the microbiological load to demonstrate its effectiveness in each of the food in which it is proposed to be used.

##### ***3. The food products likely to contain the irradiated food or food ingredient***

This part includes information on use of the irradiated food or food ingredient in food products.

##### ***4. Information on packaging used for irradiated food***

This part includes the following:

- (a) evidence that the packaging materials used to contain food during irradiation have been tested for their functionality for this purpose over the dose range used;
- (b) evidence that the components of the packaging materials will not present any safety concerns in relation to the irradiation food; and
- (c) evidence that irradiation will not affect the storage condition of food.

##### ***5. Information on the proposed labelling of the irradiated food***

This part includes the proposed labelling for the irradiated food.

##### ***6. Verification of the use of irradiation***

This part includes information on an appropriate detection method suitable for analytical purposes.

## **C. Information on the safety and nutritional impact of irradiation**

The application must contain the following information:

### **1. *Compositional analysis of the irradiated food***

This part includes the following:

- (a) The levels of key nutrients compared (using appropriate statistical analyses) to the levels in the non-irradiated food.
- (b) The identity of any new components in the food formed as a result of the irradiation process.

### **2. *Data on the dietary intake of the irradiated food***

This part includes information on the anticipated dietary intake of the irradiated food.

### **3. *Data to assess the nutritional impact of compositional changes in the food, if applicable***

This part includes one or both of the following:

- (a) Dietary modelling to examine the impact of the irradiated food on the nutrient content of the overall diet, if the compositional analysis indicates significant changes to the level and/or bioavailability of certain nutrients in the irradiated food.
- (b) An animal feeding study with the irradiated food over the period of rapid growth of the animal, using an animal species that would normally consume the non-irradiated food, if the dietary modelling indicates a significant impact of the irradiated food on the nutrient content of the overall diet.

## **D. Information on the irradiation process**

The application must contain the following information:

### **1. *Information on the irradiation facilities***

This part includes the following:

- (a) evidence that the irradiation facility to be used is licensed and conforms to current Australian or New Zealand licensing laws and Codes of Practice for irradiation facilities; and
- (b) specific approval to irradiate foods has been sought from Australian or New Zealand regulatory bodies if the irradiation facility is used to irradiate goods other than foods.

### **2. *Information on dosimetry and record keeping***

This part includes the following:

- (a) evidence that dosimetry will be carried out according to an internationally recognised method;

- (b) evidence that the proposed maximum dose is justified according to technological need and, if possible, references international experience; and
- (c) information on recording keeping in relation to:
  - (i) the nature and quantity of the food treated;
  - (ii) the minimum durable life of the food treated;
  - (iii) the irradiation process used; and
  - (iv) the minimum and maximum dose absorbed by the food.

# **SECTION 3.6**

## **STANDARDS RELATED TO THE COMPOSITION OF FOOD PRODUCTS**

### 3.6.1 STANDARDISED FOODS

An application to vary the Code is required to change the compositional requirements for standardised foods.

**Note:**

Chapter 2 of the Code contains compositional requirements for a variety of foods including cereals, meat, eggs, fish, fruit and vegetables, edible oils, dairy products, alcoholic beverages, non-alcoholic beverages, sugars and honey, vinegar, salt, and special purpose foods.

The following information is required to support an application related to the composition of standardised foods. This information is in addition to that specified in Section 3.1 – General Requirements.

If the compositional change involves a change to the current permissions for a food additive, processing aid, novel food or novel food ingredient, or a nutritive substance, the information requirements to change these permissions are provided elsewhere in this Application Handbook.

Additional information may be required if the application relates to a special purpose food. The additional information requirements relating to special purpose foods are presented in Subsection 3.6.2 – Special Purpose Foods.

#### **A. General information on the application**

The application must contain the following general information:

##### **1. Purpose of the application**

This part includes general information on the proposed food compositional change.

##### **2. Justification for the application**

This part includes general statements addressing:

- (a) the need for the proposed compositional change;
- (b) any nutrition issues related to the proposed compositional change;
- (c) any consumer choice issues related to the proposed compositional change; and
- (d) the costs and benefits for industry, consumers and government associated with the proposed compositional change.

Reference may be made to other sections of the application that contain detailed supporting information, where necessary.

#### **B. General information to support the proposed compositional change**

The application must contain the following information:

**1. A description of the nature of the proposed compositional change**

This part includes detailed information on the proposed compositional change, and should indicate the Standards which will be affected.

**1. A list of the foods likely to be affected by the proposed compositional change**

This part includes details of the foods affected by the proposed compositional change.

**C. Information related to nutritional impact**

The application must contain the following information:

**1. Information on the nutritional content of the standardised food**

This part includes details of any anticipated change in the overall nutrient content of the standardised food which may affect the overall diet for the affected population groups.

**D. Information related to potential impact on consumer understanding and behaviour**

The application must contain the following information:

**1. Information to demonstrate consumer understanding of the proposed compositional change**

**2. Information to demonstrate that the proposed compositional change will not have any adverse health or diet impacts on any population groups (e.g. age or cultural groups).**

**Note:**

The extent of the impact of a food compositional change on consumer understanding and behaviour will vary depending on:

- (a) the nature of the compositional change; and
- (b) the foods to which it will apply.

Thus the amount of information necessary to address the impact on consumer understanding and behaviour will depend on the level of impact. Consultation with FSANZ may be necessary to examine the expected level of impact.

**E. Information related to impact on the food industry (industry applicants only)**

The application must contain the following information:

**1. *Data on the projected cost to the food industry of the proposed compositional change***

This part includes information on the market share of the affected foods, the costs of the compositional change, and the impact on the sale of existing products including any impacts on small business.

**2. *Impact on international trade***

This part includes information, if applicable, on the impact of the proposed compositional change on foods imported into Australia/New Zealand.

**Note:**

In relation to the impact of the proposed change to the composition of a standardised food on the food industry, the applicant should provide as much information as is readily available. FSANZ will use this information together with information from other sources to prepare a Regulatory Impact Statement (*see Section 2.2.9*).

## 3.6.2 SPECIAL PURPOSE FOODS

An application to vary the Code is required to change the compositional and/or labelling requirements for Special Purpose Foods contained in Part 2.9 of the Code. Currently, this includes Standard 2.9.1 – Infant Formula Products, Standard 2.9.2 – Food for Infants, Standard 2.9.3 – Formulated Meal Replacement and Formulated Supplementary Foods or Standard 2.9.4 – Formulated Supplementary Sports Foods

### **Note:**

Part 2.9 – Special Purpose Foods contains Standards which set out specific compositional and labelling requirements for a number of special purpose foods, including infant formula products, infant foods, meal replacements, supplementary foods, and sports foods.

FSANZ has previously proposed the following working definition of a special purpose food:

*Special purpose food is food that has been specially processed or formulated to satisfy particular dietary requirements that exist because of a particular physical or physiological need, and / or specific diseases and disorders.*

In this definition, the phrase *particular dietary requirements* refer to nutritional requirements that cannot be met by consumption of a normal diet. *Physical or physiological need* includes reference to normal states in the life cycle such as pregnancy and lactation, as well as physical (including lifestyle) and physiological conditions that occasion the use of special purpose food.

The following additional information is required to change the compositional and/or labelling requirements of a special purpose food. This information is in addition to that specified in Section 3.1 – General Requirements. There may be information requirements in other Sections of this Application Handbook if the application relates to the addition of a food additive, processing aid, novel food, novel food ingredient or nutritive substance.

### **A. General information on the application**

The application must contain the following general information:

#### **1. Purpose of the application**

This part includes general information on the proposed compositional or labelling change for the Special Purpose Food.

#### **2. Justification for the application**

This part includes general statements addressing:

- (a) the need for the proposed compositional or labelling change;
  - (b) any nutrition issues related to the proposed compositional or labelling change;
  - (c) any consumer choice issues related to the proposed compositional or labelling change;
- and

- (d) the costs and benefits for industry, consumers and government associated with the proposed compositional or labelling change.

Reference may be made to other sections of the application that contain detailed supporting information, where necessary.

## **B. Information related to general compositional requirements**

The application must contain the following information if it relates to a change to the general compositional requirements:

### ***1. Information related to the safety of the proposed compositional change***

This part includes information as applicable to a food additive, processing aid, novel food or novel food ingredient, or nutritive substance (as indicated elsewhere in this *Application Handbook*) with a particular focus on the target population. It may also include safety information related to other composition changes.

### ***2. Information related to the nutritional impact or performance impact of the proposed compositional change***

This part may include clinical studies to examine the nutritional suitability of the food, particularly in the case of infant formula products and food for infants.

This part may also include information on the performance goals of sports people if it relates to the addition of a nutritive substance or novel food ingredient to foods regulated under Standard 2.9.4 – Formulated Supplementary Sports Foods.

#### **Note:**

A discussion paper on the clinical testing of infant formulas prepared by the US Academy of Pediatrics for the US Food and Drug Administration can be found at <http://www.cfsan.fda.gov/~dms/inf-clin.html> .

With regard to performance goals of sports people, this should include, as a minimum, a literature search on the potential for the nutritive substance or novel food ingredient to improve performance goals.

## **C. Information related to the dietary exposure**

The application must contain the following information if it relates to a change to the general compositional requirements:

### ***1. Information on the identity of the target population***

This part includes a description of the target population for the special purpose food.

## **2. *Data on the dietary exposure of the target population***

This part includes information as applicable to a food additive, processing aid, novel food or novel food ingredient, or nutritive substance (as indicated elsewhere in this Handbook) with a particular focus on the target population.

### **D. Information related to general labelling requirements**

The application must contain the following information if it relates to a change to the general labelling requirements:

#### **1. *Information related to safety or nutritional impact of the proposed labelling change***

The part includes information to support the proposed labelling change, particularly if it relates to the inclusion of (or change to) a warning or advisory statement or directions for use.

#### **2. *Information to demonstrate that the proposed labelling change will be understood and will assist consumers, if applicable (see Note)***

This part includes consumer research information to demonstrate the anticipated consumer response to the proposed change, or data obtained from an overseas market where the proposed labelling is in place.

#### **Note:**

A proposed labelling change will only be relevant to consumers for those special purpose foods which are available for retail sale.

### **E. Information related to impact on the food industry (industry applicants only)**

The application must contain the following information:

#### **1. *Data on the projected cost to the food industry of the proposed compositional or labelling change***

This part includes information on the market share of the affected foods, the costs of the compositional or labelling change, and the impact on the sale of existing products including any impacts on small business.

#### **2. *Impact on international trade***

This part includes information, if applicable, on the impact of the proposed compositional or labelling change on foods imported into Australia/New Zealand.

**Note:**

In relation to the impact of the proposed change to the composition or labelling of a special purpose food on the food industry, the applicant should provide as much information as is readily available. FSANZ will use this information together with information from other sources to prepare a Regulatory Impact Statement (*see Section 2.2.9*).

# **SECTION 3.7**

# **STANDARDS RELATED TO FOOD PRODUCTION**

### 3.7.1 FOOD SAFETY PROGRAMS

An application to vary the Code is required to change the requirements for food safety programs specified in Chapter 3, namely, Standard 3.2.1 – Food Safety Programs, Standard 3.2.2 – Food Safety Practices and General Requirements, Standard 3.2.3 – Food Premises and Equipment, Standard 3.3.1 – Food Safety Programs for Food Service to Vulnerable Persons. These Standards apply to Australia only.

**Note:**

The purpose of Chapter 3 – Food Safety Standards is:

*To ensure that only safe and suitable food is sold in Australia.*

- (1) *For the purposes of the Food Safety Standards, food is not safe if it would be likely to cause physical harm to a person who might later consume it, assuming it was –*
- (a) *after that time and before being consumed by the person, properly subjected to all processes (if any) that are relevant to its reasonable intended use; and*
  - (b) *consumed by the person according to its reasonable intended use.*
- (2) *However, food is not unsafe merely because its inherent nutritional or chemical properties cause, or its inherent nature causes, adverse reactions only in persons with allergies or sensitivities that are not common to the majority of persons.*
- (3) *In subsection (1), processes include processes involving storage and preparation.*
- (4) *For the purposes of the Food Safety Standards, food is not suitable if it –*
- (a) *is damaged, deteriorated or perished to an extent that affects its reasonable intended use; or*
  - (b) *contains any damaged, deteriorated or perished substance that affects its reasonable intended use; or*
  - (c) *is the product of a diseased animal or an animal that has died otherwise than by slaughter, and has not been declared by or under another Act to be safe for human consumption; or*
  - (d) *contains a biological or chemical agent, or other matter or substance, that is foreign to the nature of the food.*

The following information is required to support an application to amend these Standards. This information is in addition to that specified in Section 3.1 – *General Requirements*.

#### **A. General information on the application**

The application must contain the following general information:

##### **1. Purpose of the application**

This part includes information on the proposed change(s) to the Standard(s).

## **2. *Justification for the application***

This part includes general statements addressing:

- (a) the need to change the current Standard;
- (b) any public health and safety issues related to the proposed change(s); and
- (c) the costs and benefits for industry, consumers and government associated with proposed change(s).

Reference may be made to other sections of the application that contain detailed supporting information, where necessary.

### **B. Information related to food safety**

The application must contain the following information:

#### **1. *Data to show that the proposed change will protect public health and safety***

The part includes:

- (a) survey data, if applicable, to demonstrate that the proposed change will have result in protection of public health and safety equivalent to the current Standard; and
- (b) information from other countries on current practices that relate to the proposed change.

### **C. Information related to the impact on the food industry (industry applicants only)**

The application must contain the following information:

#### **1. *Data on the projected compliance cost to the food industry of the proposed change***

This part includes information on the specific sector affected by the proposed amendment including market share of the affected foods, the potential costs of the change, the impact on the sale of existing products produced under the current Standards, and any potential impacts on other businesses.

#### **Note:**

In relation to the impact of the proposed change to requirement for food safety programs on the food industry, the applicant should provide as much information as is readily available. FSANZ will use this information together with information from other sources to prepare a Regulatory Impact Statement (*see Section 2.2.9*).

### 3.7.2 FOOD PROCESSING AND PRIMARY PRODUCTION

An application to vary the Code is required to change the food processing requirements specified in Standard 1.6.2 – Processing Requirements or the primary production requirements for seafood, poultry meat, meat, dairy products, specific cheeses and wine specified in Chapter 4 – Primary Production Standards. These Standards apply to Australia only.

**Note:**

The purpose of Standard 1.6.2 – Processing Requirements is:

*To set out the requirements for processing of foods regulated in Chapter 2 – Food Product Standards.*

The purpose of Chapter 4 – Primary Production Standards is:

*To set out food safety and suitability requirements for foods from pre-harvesting production up to manufacturing operations.*

The following information is required to support an application to amend these Standards. This information is in addition to that specified in Section 3.1 – General Requirements.

#### **A. General information on the application**

The application must contain the following general information:

##### **1. Purpose of the application**

This part includes information on the proposed change(s) to the Standard(s).

##### **2. Justification for the application**

This part includes general statements addressing:

- (a) the need to change the current Standard;
- (b) any public health and safety issues related to the proposed change(s); and
- (c) the costs and benefits for industry, consumers and government associated with proposed change(s).

Reference may be made to other sections of the application that contain detailed supporting information, where necessary.

#### **B. Information related to food safety**

The application must contain the following information:

##### **1. Data to show that the proposed change will protect public health and safety**

The part includes:

- (a) data to demonstrate that the proposed change will have result in protection of public health and safety equivalent to the current Standard; and
- (b) information from other countries on current practices that relate to the proposed change.

**Note:**

For further information on the use of equivalence, see the FSANZ Guidance Document *Guidelines for Determining the Equivalence of Food Safety Measures* on the FSANZ website.

**C. Information related to the impact on the food industry (industry applicants only)**

The application must contain the following information:

**1. Data on the projected compliance cost to the food industry of the proposed change**

This part includes information on the specific sector affected by the proposed amendment including market share of the affected foods, the potential costs of the change, the impact on the sale of existing products produced under the current Standards, and any potential impacts on other businesses.

**2. Impact on international trade**

This part includes information, if available, on the impact of the proposed change on foods imported into Australia.

**Note:**

In relation to the impact of the proposed change to the food processing requirements or to the primary production standards on the food industry, the applicant should provide as much information as is readily available. FSANZ will use this information together with information from other sources to prepare a Regulatory Impact Statement (*see Section 2.2.9*).

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# **Appendix 1**

## **Checklists**

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## **CHECKLIST FOR STANDARDS RELATED TO LABELLING AND OTHER INFORMATION REQUIREMENTS**

This checklist will assist you in determining if you have met the information requirements as detailed in the Application Handbook. Section 3.1 – General Requirements and section 3.2.1 – General Food Labelling are mandatory for all labelling applications. If your application is relation to sections 3.2.2-3.2.5, then the information required is in addition to sections 3.1 and 3.2.1.

### **General Requirements (3.1)**

- |   |  |
|---|--|
| <input type="checkbox"/> Form of application                    | <input type="checkbox"/> Assessment procedure                    |
| <input type="checkbox"/> Applicant details                      | <input type="checkbox"/> Confidential Commercial Information     |
| <input type="checkbox"/> Purpose of the application             | <input type="checkbox"/> Exclusive Capturable Commercial Benefit |
| <input type="checkbox"/> Justification for the application      | <input type="checkbox"/> International standards                 |
| <input type="checkbox"/> Information to support the application | <input type="checkbox"/> Statutory Declaration                   |

### **General Food Labelling (3.2.1)**

- |  |  |
|--|--|
| <input type="checkbox"/> Description of proposed labelling change                                    | <input type="checkbox"/> Information that proposed labelling change will not have any adverse health impacts |
| <input type="checkbox"/> Foods potentially affected identified                                       | <input type="checkbox"/> Data on potential costs of labelling change to industry                             |
| <input type="checkbox"/> Demonstrated consumer support for the labelling change                      | <input type="checkbox"/> Information on potential impacts to trade   |
| <input type="checkbox"/> Information that proposed labelling will be understood and assist consumers | <input type="checkbox"/>   |

### **Warning and Advisory Statements (3.2.2)**

- |   |  |
|---|--|
| <input type="checkbox"/> Data on potential health concern | <input type="checkbox"/> Data on lack of consumer awareness of health risk |
|---|--|

### **Declaration of Allergens (3.2.3)**

#### **Addition of allergen to list of declared foods (3.2.3 A)**

- |  |  |
|--|--|
| <input type="checkbox"/> Demonstration that the food causes IgE-mediated allergy | <input type="checkbox"/> Information on severity of allergic reaction      |
| <input type="checkbox"/> Information on incidence of allergic reaction           | <input type="checkbox"/> Information on extent of use of allergen in foods |

#### **Removal of food derivative from the list of declared foods (3.2.3 B)**

- |   |  |
|---|--|
| <input type="checkbox"/> Nature of food derivative      | <input type="checkbox"/> Information on the history of safe use            |
| <input type="checkbox"/> Use of food derivative in food | <input type="checkbox"/> Clinical information on safety of food derivative |
| <input type="checkbox"/> Dietary intake information     |  |

---

**Labelling for Consumer Information and Choice (3.2.4)**

---

- |  |  |
|--|--|
| <input type="checkbox"/> Current labelling or alternative information inadequacies           | <input type="checkbox"/> Information to show effectiveness of proposed labelling change                        |
| <input type="checkbox"/> Information on lack of suitable alternatives available to consumers | <input type="checkbox"/> Information to demonstrate labelling is the best method of providing this information |

---

**Nutrition Information Labelling (3.2.5)**

---

**Nutrient contents label change (3.2.5 A)**

- |   |  |
|---|--|
| <input type="checkbox"/> Description of proposed labelling change | <input type="checkbox"/> Data to demonstrate labelling will assist consumers |
|---|--|

**Energy factors (3.2.5 B)**

- |  |  |
|--|--|
| <input type="checkbox"/> Nature and composition of the food ingredient | <input type="checkbox"/> Documentation of other factors which might impact energy measures |
| <input type="checkbox"/> Measures or estimates of energy               |  |
-

# CHECKLIST FOR STANDARDS RELATED TO SUBSTANCES ADDED TO FOOD

This checklist will assist you in determining if you have met the information requirements as detailed in the Application Handbook. Section 3.1 – General Requirements is mandatory for all applications. Sections 3.3.1-3.3.3 are related to the specifics of your application and the information required is in addition to section 3.1.

## General Requirements (3.1)

- |  |   |
|--|---|
| <input type="checkbox"/> Form of application<br><input type="checkbox"/> Applicant details<br><input type="checkbox"/> Purpose of the application<br><input type="checkbox"/> Justification for the application<br><input type="checkbox"/> Information to support the application | <input type="checkbox"/> Assessment procedure<br><input type="checkbox"/> Confidential Commercial Information<br><input type="checkbox"/> Exclusive Capturable Commercial Benefit<br><input type="checkbox"/> International standards<br><input type="checkbox"/> Statutory Declaration |
|--|---|

## Food Additives (3.3.1)

- |   |  |
|---|--|
| <input type="checkbox"/> Support for the application<br><input type="checkbox"/> Nature and technological function information<br><input type="checkbox"/> Identification information<br><input type="checkbox"/> Chemical and physical properties<br><input type="checkbox"/> Impurity profile<br><input type="checkbox"/> Manufacturing process<br><input type="checkbox"/> Specifications<br><input type="checkbox"/> Food labelling | <input type="checkbox"/> Analytical detection method<br><input type="checkbox"/> Toxicokinetics and metabolism information<br><input type="checkbox"/> Toxicity information<br><input type="checkbox"/> Safety assessments from international agencies<br><input type="checkbox"/> List of foods likely to contain the food additive<br><input type="checkbox"/> Proposed levels in foods<br><input type="checkbox"/> Percentage of food group to contain the food additive<br><input type="checkbox"/> Use in other countries (if applicable) |
|---|--|

## Processing Aids (3.3.2)

- |  |   |
|--|---|
| <input type="checkbox"/> Support for the application<br><input type="checkbox"/> Type of processing aid<br><input type="checkbox"/> Identification information<br><input type="checkbox"/> Chemical and physical properties<br><input type="checkbox"/> Manufacturing process<br><input type="checkbox"/> Specification information<br><input type="checkbox"/> Industrial use information (chemical only) | <input type="checkbox"/> Information on enzyme use on other countries (enzyme only)<br><input type="checkbox"/> Toxicity information of enzyme (enzyme only)<br><input type="checkbox"/> Information on source organism (enzyme from micro-organism only)<br><input type="checkbox"/> Pathogenicity and toxicity of source micro-organism (enzyme from micro-organism only)<br><input type="checkbox"/> Genetic stability of source organism (enzyme from micro-organism only)<br><input type="checkbox"/> Nature of genetic modification (PA from GM micro-organism only)<br><input type="checkbox"/> List of foods likely to contain the processing aid |
|--|---|

- |   |   |
|---|---|
| <input type="checkbox"/> Information on use in other countries (chemical only)          | <input type="checkbox"/> Anticipated residue levels in foods                                |
| <input type="checkbox"/> Toxicokinetics and metabolism information (chemical only)      | <input type="checkbox"/> Percentage of food group to use processing aid                     |
| <input type="checkbox"/> Toxicity information (chemical only)                           | <input type="checkbox"/> Information on residues in foods in other countries (if available) |
| <input type="checkbox"/> Safety assessments from international agencies (chemical only) |   |

### **Nutritive Substances (3.3.3)**

- |   |  |
|---|--|
| <input type="checkbox"/> Support for the application  | <input type="checkbox"/> Percentage of food group anticipated to contain nutritive substance |
| <input type="checkbox"/> Identification information   | <input type="checkbox"/> Food consumption data for new foods                                 |
| <input type="checkbox"/> Information on chemical and physical properties                        | <input type="checkbox"/> Information on use in other countries                               |
| <input type="checkbox"/> Impurity profile information   | <input type="checkbox"/> Food consumption data for foods with changed consumption patterns   |
| <input type="checkbox"/> Manufacturing process information                                      | <input type="checkbox"/> Nutritional purpose   |
| <input type="checkbox"/> Specification information  |  |
| <input type="checkbox"/> Analytical detection method  | <input type="checkbox"/> Need for nutritive substance in food                                |
| <input type="checkbox"/> Proposed food label  | <input type="checkbox"/> Demonstrated potential deficit or health benefit                    |
| <input type="checkbox"/> Toxicokinetics and metabolism information                              | <input type="checkbox"/> Consumer awareness and understanding                                |
| <input type="checkbox"/> Animal or human toxicity studies                                       | <input type="checkbox"/> Actual or potential behaviour of consumers                          |
| <input type="checkbox"/> Safety assessments from international agencies                         | <input type="checkbox"/> Demonstration of no adverse affects to any population groups        |
| <input type="checkbox"/> List of food groups or foods likely to contain the nutritive substance | <input type="checkbox"/> Impact on food industry   |
| <input type="checkbox"/> Proposed maximum levels in food groups or foods                        | <input type="checkbox"/> Impact on trade   |

# CHECKLIST FOR STANDARDS RELATED TO CONTAMINANTS AND NATURAL TOXICANTS

This checklist will assist you in determining if you have met the information requirements as detailed in the Application Handbook. Section 3.1 – General Requirements is mandatory for all applications. Sections 3.4.1-3.4.3 are related to the specifics of your application and the information required is in addition to section 3.1.

## General Requirements (3.1)

- |   |  |
|---|--|
| <input type="checkbox"/> Form of application                    | <input type="checkbox"/> Assessment procedure                    |
| <input type="checkbox"/> Applicant details                      | <input type="checkbox"/> Confidential Commercial Information     |
| <input type="checkbox"/> Purpose of the application             | <input type="checkbox"/> Exclusive Capturable Commercial Benefit |
| <input type="checkbox"/> Justification for the application      | <input type="checkbox"/> International standards                 |
| <input type="checkbox"/> Information to support the application | <input type="checkbox"/> Statutory Declaration                   |

## Chemical Contaminant and Natural Toxicant Maximum Levels (3.4.1)

- |  |  |
|--|--|
| <input type="checkbox"/> Nature of contaminant or natural toxicant | <input type="checkbox"/> List of foods where maximum level is proposed |
| <input type="checkbox"/> Analytical detection method               | <input type="checkbox"/> Survey data on contaminant levels in foods    |
| <input type="checkbox"/> Toxicokinetics & metabolism information   | <input type="checkbox"/> Impact on food industry                       |
| <input type="checkbox"/> Toxicity studies                          | <input type="checkbox"/> Impact on trade                               |
| <input type="checkbox"/> Human studies relevant to safety          |  |

## Microbiological Limits (3.4.2)

- |   |  |
|---|--|
| <input type="checkbox"/> Raw inputs, production and manufacturing process | <input type="checkbox"/> Evidence of nutritional benefit of change |
| <input type="checkbox"/> Food technology                                  | <input type="checkbox"/> Food consumption data                     |
| <input type="checkbox"/> Nature of the microbiological hazard             | <input type="checkbox"/> Impact on food industry                   |
| <input type="checkbox"/> Source & prevalence of contamination             | <input type="checkbox"/> Impact on trade                           |
| <input type="checkbox"/> Consumer handling and use                        |  |

## Prohibited and Restricted Plants and Fungi (3.4.3)

- |   |  |
|---|--|
| <input type="checkbox"/> Nature of plant or fungi                 | <input type="checkbox"/> Human toxicity case studies |
| <input type="checkbox"/> Identity and levels of natural toxicants | <input type="checkbox"/> Use in other countries      |
| <input type="checkbox"/> Toxicity studies                         |  |

## CHECKLIST FOR STANDARDS RELATED TO NEW FOODS

This checklist will assist you in determining if you have met the information requirements as detailed in the Application Handbook. Section 3.1 – General Requirements is mandatory for all applications. Sections 3.5.1-3.5.3 are related to the specifics of your application and the information required is in addition to section 3.1.

### General Requirements (3.1)

- |   |  |
|---|--|
| <input type="checkbox"/> Form of application                    | <input type="checkbox"/> Assessment procedure                    |
| <input type="checkbox"/> Applicant details                      | <input type="checkbox"/> Confidential Commercial Information     |
| <input type="checkbox"/> Purpose of the application             | <input type="checkbox"/> Exclusive Capturable Commercial Benefit |
| <input type="checkbox"/> Justification for the application      | <input type="checkbox"/> International standards                 |
| <input type="checkbox"/> Information to support the application | <input type="checkbox"/> Statutory Declaration                   |
| <input type="checkbox"/> Form of application                    | <input type="checkbox"/> Assessment procedure                    |

### Foods Produced using Gene Technology (3.5.1)

- |  |  |
|--|--|
| <input type="checkbox"/> Nature and identity of GM food                  | <input type="checkbox"/> Toxicity of novel protein(s)/substances     |
| <input type="checkbox"/> History of use of host and donor organisms      | <input type="checkbox"/> Potential allergenicity of novel protein(s) |
| <input type="checkbox"/> Nature of genetic modification                  | <input type="checkbox"/> Compositional analysis of GM food           |
| <input type="checkbox"/> Labelling information on GM food                | <input type="checkbox"/> Nutritional impact of GM food               |
| <input type="checkbox"/> Antibiotic resistance marker genes (if used)    | <input type="checkbox"/> Animal feeding studies (if available)       |
| <input type="checkbox"/> Characterisation of novel protein(s)/substances |  |

### Novel Foods (3.5.2)

- |  |  |
|--|--|
| <input type="checkbox"/> Support for the application   | <input type="checkbox"/> Percentage of food group anticipated to contain novel food or novel food ingredient |
| <input type="checkbox"/> Type of novel food  | <input type="checkbox"/> Predicted consumption (replacement)   |
| <input type="checkbox"/> Chemical and physical properties  | <input type="checkbox"/> Details of target or at risk population groups                                      |
| <input type="checkbox"/> Impurity profile  | <input type="checkbox"/> Use in other countries  |
| <input type="checkbox"/> Manufacturing process   | <input type="checkbox"/> Nutritional impact information  |
| <input type="checkbox"/> Specification and identity  | <input type="checkbox"/> Demonstrated consumer awareness and understanding                                   |
| <input type="checkbox"/> Analytical detection method   | <input type="checkbox"/> Potential behaviour in response to foods  |
| <input type="checkbox"/> Safety information for specified section I-XIII *(see below)            | <input type="checkbox"/> Demonstration of no adverse affects to any population groups                        |
| <input type="checkbox"/> List of foods likely to contain the novel food or novel food ingredient | <input type="checkbox"/> Impact on food industry   |

- Proposed levels in foods  Impact on trade

---

**\*Novel foods - safety information**

---

**(I) Plants and animals (or their components)**

- Composition  Current use
- Effects of food processing or preparation  Potential adverse effects

**(II) Plant and animal extracts**

- Method or extraction and composition of extract  Toxicity studies
- Use as a food in other countries

**(III) Herbs (including extracts)**

- History of use  Potential allergenicity
- Composition  Toxicity studies
- Method of extraction and composition of extract  Overseas safety reports
- Use in other countries

**(IV & V) Single chemical entities & dietary macrocomponents**

- Toxicokinetics and metabolism  Overseas safety reports
- Toxicity studies

**(VI) Micro-organism**

- Potential pathogenicity  Use as a food in other countries
- Effects on gut microflora  Human toleration studies

**(VII) Food ingredients derived from a new source**

- Safety of the source organism  Toxicity studies
- Composition  Overseas safety reports

**(VIII) Foods produced by a process not previously applied to foods**

- Details of the new process  Overseas safety reports
- Toxicity studies

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**Irradiated Foods (3.5.3)**

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- Support for the application  Analytical detection method
- Nature of the food or food ingredient to be irradiated  Composition of irradiated food
- Technological need for irradiation  Dietary intake
- Food products likely to contain irradiated food  Data on potential nutritional impact
- Packaging for irradiated food  Irradiation facilities information
- Food labelling information  Dosimetry and record keeping
-

## **CHECKLIST FOR STANDARDS RELATED TO THE COMPOSITION OF FOOD PRODUCTS**

This checklist will assist you in determining if you have met the information requirements as detailed in the Application Handbook. Section 3.1 – General Requirements is mandatory for all applications. Sections 3.6.1 and 3.6.2 are related to the specifics of your application and the information required is in addition to section 3.1.

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### **General Requirements (3.1)**

- |  |  |
|--|--|
| <input type="checkbox"/> Form of application<br><input type="checkbox"/> Applicant details<br><input type="checkbox"/> Purpose of the application<br><input type="checkbox"/> Justification for the application<br><input type="checkbox"/> Information to support the application<br><input type="checkbox"/> Form of application | <input type="checkbox"/> Assessment procedure<br><input type="checkbox"/> Confidential Commercial Information<br><input type="checkbox"/> Exclusive Capturable Commercial Benefit<br><input type="checkbox"/> International standards<br><input type="checkbox"/> Statutory Declaration<br><input type="checkbox"/> Assessment procedure |
|--|--|

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### **Standardised Foods (3.6.1)**

- |  |   |
|--|---|
| <input type="checkbox"/> Proposed compositional change<br><input type="checkbox"/> List of foods likely to be affected<br><input type="checkbox"/> Nutritional content of standardised food<br><input type="checkbox"/> Demonstrated consumer understanding of proposed change | <input type="checkbox"/> Potential adverse health or diet impacts<br><input type="checkbox"/> Impact on the food industry<br><input type="checkbox"/> Impact on trade |
|--|---|

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### **Special Purpose Foods (3.6.2)**

- |  |   |
|--|---|
| <input type="checkbox"/> Safety of proposed compositional change<br><input type="checkbox"/> Nutritional impact of compositional change<br><input type="checkbox"/> Target population<br><input type="checkbox"/> Dietary exposure information | <input type="checkbox"/> Safety and nutritional impact of labelling change<br><input type="checkbox"/> Demonstrated understanding of labelling change<br><input type="checkbox"/> Impact on food industry<br><input type="checkbox"/> Impact on trade |
|--|---|
-

## CHECKLIST FOR STANDARDS RELATED TO FOOD PRODUCTION

This checklist will assist you in determining if you have met the information requirements as detailed in the Application Handbook. Section 3.1 – General Requirements is mandatory for all applications. Sections 3.7.1 and 3.7.2 are related to the specifics of your application and the information required is in addition to section 3.1.

### General Requirements (3.1)

- |   |  |
|---|--|
| <input type="checkbox"/> Form of application                    | <input type="checkbox"/> Assessment procedure                    |
| <input type="checkbox"/> Applicant details                      | <input type="checkbox"/> Confidential Commercial Information     |
| <input type="checkbox"/> Purpose of the application             | <input type="checkbox"/> Exclusive Capturable Commercial Benefit |
| <input type="checkbox"/> Justification for the application      | <input type="checkbox"/> International standards                 |
| <input type="checkbox"/> Information to support the application | <input type="checkbox"/> Statutory Declaration                   |
| <input type="checkbox"/> Form of application                    | <input type="checkbox"/> Assessment procedure                    |

### Food Safety Programs (3.7.1)

- |  |   |
|--|---|
| <input type="checkbox"/> Public health and safety data | <input type="checkbox"/> Projected costs to food industry |
|--|---|

### Food Processing and Primary Production (3.7.2)

- |   |  |
|---|--|
| <input type="checkbox"/> Public health and safety data    | <input type="checkbox"/> Impact on trade |
| <input type="checkbox"/> Projected costs to food industry |  |