FOOD STANDARDS
AUSTRALIA NEW ZEALAND

APPLICATION HANDBOOK

1 August 2011
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<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCC</td>
<td>Australian Competition and Consumer Commission</td>
</tr>
<tr>
<td>ADI</td>
<td>Acceptable daily intake</td>
</tr>
<tr>
<td>ALARA</td>
<td>As low as reasonably achievable</td>
</tr>
<tr>
<td>AS</td>
<td>Australian Standard</td>
</tr>
<tr>
<td>CA</td>
<td>Chemical Abstracts</td>
</tr>
<tr>
<td>CCI</td>
<td>Confidential commercial information</td>
</tr>
<tr>
<td>Codex</td>
<td>Codex Alimentarius Commission</td>
</tr>
<tr>
<td>DBPCFC</td>
<td>Double blind placebo controlled food challenge</td>
</tr>
<tr>
<td>DIAMOND</td>
<td>Dietary modelling of nutritional data</td>
</tr>
<tr>
<td>ECCB</td>
<td>Exclusive capturable commercial benefit</td>
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<tr>
<td>ERL</td>
<td>Extraneous residue limit</td>
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<tr>
<td>FAO</td>
<td>Food and Agricultural Organization</td>
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<tr>
<td>GM</td>
<td>Genetically modified</td>
</tr>
<tr>
<td>GMP</td>
<td>Good manufacturing practice</td>
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<tr>
<td>HACCP</td>
<td>Hazard assessment critical control point</td>
</tr>
<tr>
<td>IUPAC</td>
<td>International Union of Pure and Applied Chemists</td>
</tr>
<tr>
<td>ISO</td>
<td>International Standards Organization</td>
</tr>
<tr>
<td>JECFA</td>
<td>Joint (FAO/WHO) Expert Committee on Food Additives</td>
</tr>
<tr>
<td>ME</td>
<td>Metabolisable energy</td>
</tr>
<tr>
<td>ML</td>
<td>Maximum level</td>
</tr>
<tr>
<td>MRL</td>
<td>Maximum residue limit</td>
</tr>
<tr>
<td>NATA</td>
<td>National Association of Testing Authorities</td>
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<tr>
<td>NHMRC</td>
<td>National Health &amp; Medical Research Council</td>
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<tr>
<td>OBPR</td>
<td>Office of Best Practice Regulation</td>
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<tr>
<td>RIS</td>
<td>Regulatory impact statement</td>
</tr>
<tr>
<td>TPA</td>
<td>Trade Practices Act</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WTO</td>
<td>World Trade Organization</td>
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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 must 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 proposed application with FSANZ prior to submission in order to clarify the nature of the application and to identify the information required.

Additionally, when assessing an application to develop or amend food regulatory measures, FSANZ must have regard to any relevant formal policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council. Applicants should inform themselves of any policy guidelines which may have a bearing on their application and ensure these are considered in their application. Applicants should also seek advice from FSANZ on any pending policy guidelines or materials under development which may have a bearing on their Application. Current Policy Guidelines are on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/changingthecode/ministerialcouncilpolicyguidelines/.

Furthermore, potential applicants are strongly encouraged to seek their own independent legal advice on proposed amendments to the Code. In addition, when assessing applications or potential applications to amend the Code, the views of FSANZ on proposed amendments may not be the same as the views of food enforcement agencies or the Courts. Potential applicants should therefore seek their own independent advice about the need for any amendment to the Code and the effect of any proposed amendments.

Contact details for food enforcement agencies are available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/foodenforcementcontacts/.

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 and other commodities.

The Code can be viewed on the FSANZ website at [http://www.foodstandards.gov.au/foodstandards/foodstandardscode/](http://www.foodstandards.gov.au/foodstandards/foodstandardscode/). 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 the food laws of the Australian States and Territories. For the purpose of the *Imported Food Control Act 1992*, the amendments to the Code are also registered as legislative instruments in Australia. Food Standards in New Zealand take effect 28 days after a food standard has been issued by the Minister for Food Safety under the New Zealand *Food Act 1981*.

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.

Boxed text such as notes or examples in Part 3 of the Handbook provide additional information or clarification to requirements outlined in the guidelines only, and are not to be taken to be part of the guidelines.
Read Parts 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.

Does your application relate to Labelling? Go to section 3.2

Complete Section 3.2.1 General Labelling Requirements

For Warning and Advisory Statements, complete Section 3.2.2

For Declaration of Allergens, complete Section 3.2.3

For Labelling for Consumer Information & Choice, complete Section 3.2.4

For Nutrition Information Labelling, complete Section 3.2.5

Does your application relate to Substances Added to Foods? Go to section 3.3

For Food Additives, complete Section 3.3.1

For Processing Aids, complete Section 3.3.2

For Nutritive Substances, complete Section 3.3.3

Does your application relate to Contaminants or Natural Toxicants? Go to Section 3.4

For Chemical Contaminants and Natural Toxicants, complete Section 3.4.1

For Microbiological Limits, complete Section 3.4.2

For Prohibited and Restricted Plants and Fungi, complete Section 3.4.3

Does your application relate to New Foods? Go to Section 3.5

For Foods Produced Using Gene Technology, complete Section 3.5.1

For Novel Foods, complete Section 3.5.2

For Irradiated Foods, complete Section 3.5.3

Does your application relate to the Composition of Foods? Go to Section 3.6

For Standardised Foods, complete Section 3.6.1

For Special Purpose Foods, complete Section 3.6.2

For Prohibited and Restricted Plants and Fungi, complete Section 3.6.3

Does your application relate to Food Production? Go to Section 3.7

For Food Safety Programs, complete Section 3.7.1

For Food Processing & Primary Production, complete Section 3.7.2

For Food Safety Programs, complete Section 3.7.2

If you encounter any issues regarding the required information or have any other questions please contact FSANZ (Standards Management Officer) for further advice at standards.management@foodstandards.gov.au or +61 2 6271 2280.
PART 2

GENERAL
APPLICATION PROCEDURES
2.1 MAKING AN APPLICATION

2.1.1 Application inquiries

Application inquiries must be directed to the Standards Management Officer by email to standards.management@foodstandards.gov.au or telephone: +61 2 6271 2280.

It is the responsibility of applicants to prepare and finalise their own application for lodgement. However, prior to formally lodging their application, applicants are strongly advised that it is in their interests to consult with FSANZ to ensure that it contains all the required information. This can be done via a teleconference, a video link or at a face-to-face meeting in FSANZ’s offices in Canberra (Australia) or Wellington (New Zealand). 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.

FSANZ staff can provide valuable assistance to an applicant to ensure that their application complies with all mandatory requirements. Many of those applicants whose applications have been rejected after an Administrative Assessment for failing to meet the mandatory requirements, did not discuss their application with FSANZ prior to formal lodgement.

2.1.2 Lodging an application

Before any application is formally lodged, please ensure all electronic documents are able to be opened by checking on a different computer to the one which was used to create or burn them on CD. This will help ensure that documents that are corrupted or which have other problems which prevent FSANZ access are not provided.

If under 3 MB, or via a Zip file if larger than 3 MB, electronic versions of applications can be emailed to the Standards Management Officer at applications@foodstandards.gov.au. The two hard copies (and the electronic version on CD, floppy disc or other electronic device if not emailed) should be sent by post or courier to the Standards Management Officer at either of the following addresses:

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

Food Standards Australia New Zealand
Ground Floor
Boeing House
55 Blackall Street
BARTON ACT 2600

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

Applicants should note that the Australian Government’s new Information Publication Scheme commenced on 1 May 2011. The scheme aims to promote transparency and pro-disclosure and will mean that all applications to change the Code, as well as submissions on applications and proposals, will be published on our website.
We will not publish any material that is confidential commercial information. FSANZ has always summarised applications and submissions in assessment reports. Members of the public could also request access to these documents through our Public Register. Applications will be published when we publicly notify FSANZ’s decision on completion of the Administrative Assessment. Submissions will be published as soon as possible after the end of the public comment period.

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.

An applicant should submit all information relevant to the consideration of the safety of a substance, whether the information is an explicit requirement of the Handbook or not.

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. For example, an application for approval of a novel food that requests an exclusive permission be granted for that particular novel food is likely to be considered to confer an ECCB.

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 section 27 of the FSANZ Act.

For applications where an ECCB applies, payment of either the full cost-recovery charge or the 1st instalment (as indicated below) must be paid within 20 business days after the section 27 notification has been issued. The application is rejected if payment is not received by FSANZ within that time.

Where an applicant wishes to expedite consideration of the application, there is no deadline for payment of the fees (as indicated below) after the section 27 notification has been issued.

Applications being considered under the Minor Procedure or Level 1 or Level 2 of the General Procedure

FSANZ must receive the full cost recovery fees. Work will not commence on the application until the full cost-recovery charge is paid.

Applications being considered under Level 3 or Level 4 of the General Procedure

Fees may either be paid in full OR in two instalments of the full cost-recovery charge. Work will not commence on the application until either:

- the full cost-recovery charge is paid OR
- a 1st instalment (75% of the full charge) is paid. Payment of the 2nd instalment of the remaining 25% of the full charge is then due by the date submissions for the round of public comment close. FSANZ will then not continue work on the application until after the 2nd instalment is paid.

Applications being considered under the Major Procedure

Fees may either be paid in full OR in two instalments of the full cost-recovery charge. Work will not commence on the application until either:

- the full cost-recovery charge is paid OR
- a 1st instalment (25% of the full charge) is paid. Payment of the 2nd instalment of the remaining 75% of the full charge is then due by the date submissions for the first round of public comment close. FSANZ will then not continue work on the application until after the 2nd 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. For overseas applicants making deposits, Australian banks charge a fee on overseas EFT payments – please allow an additional $AUD20-25 for this charge, in addition to the FSANZ fees.

Refunds of the hourly charge and Administrative charge are partially or fully refundable, in accordance with the FSANZ Regulations. The fees are exempt from GST. Fees are indicated in the table below:
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Hours</th>
<th>Hourly Charge</th>
<th>Admin Charge</th>
<th>Total Fees $AUD</th>
<th>Indicative Total Fees $NZ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor Procedure</td>
<td>Maximum of 100 hours</td>
<td>11,500</td>
<td>10,000</td>
<td>21,500</td>
<td>26,875</td>
</tr>
<tr>
<td>General Procedure</td>
<td>Maximum of 350 hours</td>
<td>40,250</td>
<td>10,000</td>
<td>50,250</td>
<td>62,815</td>
</tr>
<tr>
<td></td>
<td>Maximum of 650 hours</td>
<td>74,750</td>
<td>10,000</td>
<td>84,750</td>
<td>105,940</td>
</tr>
<tr>
<td></td>
<td>Maximum of 1000 hours</td>
<td>115,000</td>
<td>10,000</td>
<td>125,000</td>
<td>156,250</td>
</tr>
<tr>
<td></td>
<td>More than 1000 hours</td>
<td>115,000+**</td>
<td>10,000</td>
<td>125,000+**</td>
<td>156,250+</td>
</tr>
<tr>
<td>Major Procedure</td>
<td>1200 hours or more</td>
<td>138,000***</td>
<td>10,000</td>
<td>148,000+***</td>
<td>185,000+</td>
</tr>
</tbody>
</table>

* The figures above are therefore only indicative, calculated on an exchange rate of $AUD1 = $NZ1.25.
** If FSANZ determines, under the FSANZ Regulations, that the application consideration process is likely to require more than 1000 hours, a surcharge of $AUD115 per hour will apply for each completed hour.
*** If FSANZ determines, under the FSANZ Regulations, that the application consideration process is likely to require more than 1200 hours, a surcharge of $AUD115 per hour will apply for each completed hour.

**How to pay fees**

Payment of fees in Australian Dollars 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)
SWIFT Code: CTBAAU2S

**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.

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 the Work Plan. Commencement of the formal assessment of unpaid applications depends on the allocation of resources within FSANZ.

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.

The Work Plan can be viewed on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/changingthecode/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 Manager 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.

2.1.8 Confidential and other information

Applicants may request that information, other than confidential commercial information, be treated confidentially. To ensure that the information is protected as confidential information applicants will need to satisfy the following:

1. the information claimed to be confidential must be specifically identified and marked ‘Confidential’;
2. at the time of providing the information the applicant must state that the information is being provided in-confidence;
3. provide reasons for why the information should be treated as confidential. For example, disclosure of the information would cause the applicant to suffer a detriment or the information is not publicly available and known only to a limited number persons; and

In addition to the above, Applicants who provide unpublished manuscripts will need to indicate whether or not the author is aware that the manuscript has been provided to FSANZ.

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;
- 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 four levels.

Level 1 (maximum of 350 hours)

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

(a) extending the use of a food or food additive that is permitted under a standard; or
(b) a new source organism for an enzyme; or
(c) a minor change to a labelling requirement; or
(d) a minor change to a compositional requirement for a food; or
(e) 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 less than average complexity; or
(b) have a limited, or no, social or economic impact; or
(c) require a toxicological, nutritional, food technology, dietary modelling or microbiological assessment of less than average complexity; or
(d) require an assessment of risk management measures of less than average complexity; or
(e) involve the development of a basic community communications strategy to address public concern.

**Level 2 (maximum of 650 hours)**

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

(a) extending the use of a substance to a specific food; or
(b) a pre-market approval similar to a previous approval; or
(c) a new microorganism; or
(d) changing a compositional requirement for a food; or
(e) inserting or increasing 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 a low social or economic impact; or
(c) require a toxicological, nutritional, food technology, dietary modelling or microbiological assessment of average complexity; or
(d) require an assessment of risk management measures of average complexity; or
(e) involve the development of a community communications strategy to address public concern.

**Level 3 (maximum of 1000 hours)**

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

(a) extending the use of a substance to a range of foods; or
(b) changing a labelling requirement for a food; or
(c) a pre-market approval; or
(d) establishing or increasing a maximum permitted concentration for an environmental contaminant or heavy metal.

This kind of application is likely to:

(a) involve an assessment of the risk to public health and safety of greater than average complexity; or
(b) have a broad social or economic impact; or
(c) require a toxicological, nutritional, food technology, dietary modelling or microbiological assessment of greater than average complexity; or
(d) require an assessment of risk management measures of greater than average complexity; or
(e) involve the development of a complex community communications strategy to address public concern; or
(f) require targeted consultation with key stakeholders or special interest groups; or
(g) require the provision of advice to advisory groups, peak organisations or other stakeholders.

**Level 4 (more than 1000 hours)**

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

(a) adding a new substance to a limited range of foods; or
(b) changing a labelling requirement for a limited range of foods; or
(c) a complex pre-market approval.

This kind of application is likely to:

(a) involve an extensive and complex assessment of the risk to public health and safety; or
(b) have a broad and significant social or economic impact; or
(c) require an extensive and complex toxicological, nutritional, food technology, dietary modelling or microbiological assessment; or
(d) require an extensive and complex assessment of risk management measures; or
(e) involve the development of an extensive and complex community communications strategy to address public concern; or
(f) require targeted consultation with key stakeholders or special interest groups; or
(g) require the development and distribution of community education material; or
(h) require the establishment of external working groups to discuss and interpret scientific evidence and social perceptions.

**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
STEP 1
Application received

ADMINISTRATIVE ASSESSMENT
Application meets requirements, ECCB (Application only)
Determination of procedure (Applications and proposals)
Note that, under the FSANZ Act, proposals do not have an Administrative Assessment, however, for internal purposes a similar approach will be taken.

STEP 2
ACCEPTANCE/ PROPOSAL PREPARED
Application accepted / rejected OR proposal prepared
If accepted/proposal prepared, placed on Work Plan at completion of this stage.

STEP 3
NOTIFICATION TO APPLICANT
Application accepted / rejected

‘EARLY BIRD’ PUBLIC NOTIFICATION
Application accepted / rejected OR proposal prepared. If accepted/prepared application/proposal to be assessed. How to obtain further information etc.

STEP 3 & STEP 4
ASSESSMENT
Assess application/proposal having regard to s.13 objectives, benefits vs. costs, alternatives, NZ standards, and other relevant matters

DRAFT REGULATORY MEASURE DEVELOPED
Either:
1. prepare a draft food regulatory measure OR
2. reject application / abandon proposal

STEP 5
NOTIFICATION TO APPLICANT
If the draft variation differs from that envisaged/not envisaged in the application, the applicant must be notified and given notice that FSANZ will call for submissions within 10 business days of the notice. Public notification cannot be made within this 10-day period.

PUBLIC NOTIFICATION
Call for submissions.

STEP 6
APPROVAL
Approve / approve with amendments / reject draft variation having regard to submissions.
Report prepared containing decision, reasons, submissions list, analysis of submissions, RIS, approved food regulatory measure etc

STEP 7
PUBLIC NOTIFICATION
Public notice + publish in newspapers

GENERAL PROCEDURE
(Subdivision D)
Default – Unpaid applications or proposals – cannot be used for a new food regulatory measure

15 business days

10 business days

9 months

START – date FSANZ begins assessment
NB. Clock can be stopped for: further information; OR awaiting policy guidelines or principles from the Ministerial Council.

FINISH – date of approval

NOTIFICATION TO MINISTERIAL COUNCIL
Public notice + publish in newspapers

Within 20 business days
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. An 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 & 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.
Application received

ADMINISTRATIVE ASSESSMENT
Application meets requirements. ECCB (Application only Determination of procedure (Applications and proposals)
Note that, under the FSANZ Act, proposals do not have an Administrative Assessment, however, for internal purposes a similar approach will be taken.

STEP 1

STEP 2

STEP 3

STEP 4

STEP 5

STEP 6

STEP 7

Application accepted / rejected OR proposal prepared

APPLICATION MEETS REQUIREMENTS

ACCEPTANCE/ PROPOSAL PREPARED
Application accepted / rejected OR proposal prepared

NOTIFICATION TO APPLICANT
Application accepted / rejected

‘EARLY BIRD’ PUBLIC NOTIFICATION
Application accepted / rejected OR proposal prepared. If accepted/prepared application/proposal to be assessed. How to obtain further information etc.

ASSESSMENT
Assess application having regard to s.13 objectives, benefits vs. costs – not necessary due to minor nature, alternatives, NZ standards, and other relevant matters

DRAFT REGULATORY MEASURE DEVELOPED
Either:
1. prepare a draft food regulatory measure OR
2. reject application / abandon proposal

NOTIFICATION TO APPLICANT & NOTIFICATION TO APPROPRIATE GOVT AGENCIES
Call for submissions.

APPROVAL
Approve / approve with amendments / reject draft variation having regard to submissions.
Report prepared containing decision, reasons, submissions list, analysis of submissions, approved food regulatory measure etc

PUBLIC NOTIFICATION
Public notice + publish in newspapers

15 business days

Within 20 business days

3 months

START – date FSANZ begins assessment

NB. Clock can be stopped for: further information; OR awaiting policy guidelines or principles from the Ministerial Council.

FINISH – date of approval

10 business days

NOTIFICATION TO MINISTERIAL COUNCIL

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.

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

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

(a) developing a new standard; or
(b) changing a labelling requirement affecting a wide range of foods; or
(c) changing a compositional requirement for a wide range of foods; or
(d) adding a new substance affecting a wide range of foods; or
(e) a pre-market approval, with no similar previous approvals.

This kind of application is likely to:

(a) involve a very extensive and complex assessment of the risk to public health and safety; or
(b) have a very broad and significant social or economic impact; or
(c) require a very extensive and complex toxicological, nutritional, food technology, dietary modelling or microbiological assessment; or
(d) require a very extensive and complex assessment of risk management measures; or
(e) involve the development of a very extensive and complex community communications strategy to address public concern; or
(f) require targeted consultation with key stakeholders or special interest groups; or
(g) require the development and distribution of community education material; or
(h) require extensive consultation with government agencies, industry, health professionals and consumer groups; or
(i) require the establishment of high-level advisory groups to discuss and interpret scientific evidence and social perceptions; or
(j) require community meetings including public hearings.

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
<table>
<thead>
<tr>
<th>Step 6</th>
<th>Approval of draft food regulatory measure</th>
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<tbody>
<tr>
<td>Step 7</td>
<td>Notification of approval of draft food regulatory measure to Ministerial Council</td>
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<tr>
<td>Step 8</td>
<td>Gazettal following advice from Ministerial Council to not review the approval decision</td>
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MAJOR PROCEDURE (Subdivision F)
Unpaid applications or proposals – Development of new food regulatory measures & major variations

ADMINISTRATIVE ASSESSMENT
Application meets requirements, ECCB (Application only
Determination of procedure (Applications and proposals)
Note that, under the FSANZ Act, proposals do not have an Administrative Assessment, however, for internal purposes a similar approach will be taken.

STEP 1
APPLICATION RECEIVED

STEP 2
ACCEPTANCE/ PROPOSAL PREPARED
Application accepted / rejected OR proposal prepared
If accepted/proposal prepared, placed on Work Plan at completion of this stage.

STEP 3A
NOTIFICATION TO APPLICANT
Application accepted / rejected

STEP 3B
‘EARLY BIRD’ PUBLIC NOTIFICATION
Application accepted / rejected OR proposal prepared. If accepted/prepared application/proposal to be assessed. How to obtain further information etc.

STEP 4
ASSESSMENT
Assess application having regard to s.13 objectives, benefits vs. costs, alternatives, NZ standards, and other relevant matters

STEP 5
PUBLIC NOTIFICATION
Call for submissions.

STEP 6
DRAFT REGULATORY MEASURE DEVELOPED
Having regard to submissions, either:
1. prepare a draft food regulatory measure OR
2. reject application / abandon proposal

STEP 5
NOTIFICATION TO APPLICANT
If the draft variation differs from that envisaged/not envisaged in the application, the applicant must be notified and given notice that FSANZ will call for submissions within 10 business days of the notice. Public notification cannot be made within this 10-day period.

STEP 6
PUBLIC NOTIFICATION
Call for submissions.

STEP 7
APPROVAL
Approve / approve with amendments / reject draft variation having regard to submissions.
Report prepared containing decision, reasons, submissions list, analysis of submissions, RIS, approved food regulatory measure etc

PUBLIC NOTIFICATION
Public notice + publish in newspapers

15 business days

Within 20 business days

12 months

START – date FSANZ begins assessment
NB. Clock can be stopped for: further information; OR awaiting policy guidelines or principles from the Ministerial Council.

FINISH – date of approval

PUBLIC NOTIFICATION
Call for submissions.

10 business days

NOTIFICATION TO MINISTERIAL COUNCIL

1 August 2011  Part 2.2
2.2.8 Ministerial Council review

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 following decisions:

- inform FSANZ that it does not intend to amend or reject the draft; or
- amend the draft; or
- reject the draft.
COUNCIL’S DECISION ON NOTIFICATION
The Council must respond to FSANZ within 60 calendar days of notification from FSANZ.

REVIEW REQUESTED
including reasons in accordance with s.3(e) of the 2002 IGA

REVIEW NOT REQUESTED
The Council advises that it does not intend to review the draft.

Gazettal / FRLI Registration

NOTIFICATION OF FSANZ DECISION
FSANZ’s decision notified to the Ministerial Council

Council has not responded within 60 days.

Re-issue of notification by FSANZ
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.

Gazetted / FRLI Registration

FSANZ ADVISED

The Council informs FSANZ as soon as practicable, providing a copy of the amended 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

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.

Re-issue of notification by FSANZ

*Note: Consideration being given to extending time limit if Council needs to amend.
2.2.9 Cost benefit analysis

As part of the assessment of an application, FSANZ may be required to prepare a Regulatory Impact Statement (RIS) by the Office of Best Practice Regulation (OBPR). An assessment of costs and benefits is also required under the FSANZ Act in many instances.

Note:

An assessment of costs and benefits under the FSANZ Act is carried out on all applications and can be undertaken using readily available data supplemented by qualitative statements in relation to costs and benefits.

A Regulatory Impact Statement (RIS) needs to comply with the COAG guidelines and can involve complex economic analysis and will potentially trigger the need to undertake new economic research. Full details of the RIS process and likely informational requirements are available in the Best Practice Regulation: A Guide for Ministerial Councils and Standard Setting Bodies (COAG, October 2007).

Applicants must provide FSANZ with current information and data on all costs and benefits that will change should their application be successful. This information can be appropriately limited where an application seeks to extend permission under the Code or relax a prohibition where no costs or restrictions on others are likely.

Where an application is likely to place costs or regulatory restrictions on third parties (government, industry or consumers) full details of the costs and benefits to industry, government and consumers must be provided as a RIS may be required by the OBPR.

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 may benefit from the outcome of the application (e.g. new products becoming available, provision of more information etc) or be subject to higher costs or savings.
- Government – there may be an impact on enforcement agencies or one State or Territory may be affected more than others, or there may be a significant impact in New Zealand.

To assist FSANZ in its assessment of the application in this area, Part 3 of the Application Handbook indicates what information on any social and economic 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 provide 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.
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 that is mandatory. Applicants should note that if this information is not provided, the application may be rejected at the Administrative Assessment stage. Rejection will not preclude an applicant from re-lodging the application at a later date.

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.

An application must be in the form prescribed below.
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.

Information contained within the application must clearly identify all parts of the relevant Section(s) of Part 3 to which they relate.

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

The hard copy and electronic copy of the application must be identical.

C. **Copies**

Applications must be lodged in both electronic and paper copy at the same time or received within 24 hours of each other.

Two paper copies of the application must be provided.

An application must not be sent by facsimile.

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.

The application must include full electronic and hard copies of all references referred to in the application.

### 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 number  
(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.
3.1.4 Justification for the application

The application must be justified. The following general issues should be considered depending on the purpose of the application as outlined according to requirements in Section 3.1.3:

(a) the need for the proposed change; and
(b) the advantages of the proposed change over the status quo, taking into account any disadvantages.

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

A. Regulatory impact information

The application must include current information and data:

1. Costs and benefits

This part includes information on all costs and benefits that will change, should the application be successful. The following should be considered in the provision of this information:

(a) the cost and benefits to the consumer e.g. health benefits;
(b) the costs and benefits to industry and business in general, noting any specific effects on small businesses e.g. savings in production costs; and
(c) the costs and benefits to government e.g. increased regulatory costs.

Where an application is likely to place costs or regulatory restrictions on third parties (government, industry or consumers), full details of the costs and benefits to industry, government and consumers must be provided.

Costs and benefits should be quantified in monetary terms wherever possible. However, where this is not possible, other quantitative measures and qualitative evidence should be provided.

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

Note:

In many instances, this information can be appropriately limited where the application seeks to extend permission under the Code or relax a prohibition where no costs or restrictions on others are likely (see Part 2.2.9).

If the OBPR makes a decision that a RIS is required FSANZ must meet the OBPR’s information requirements and therefore may need to request further information from the applicant before an application can proceed.

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.
### 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, please refer to the relevant Section for specific information requirements. In some instances more than one of these Sections may apply.

The following general issues should be considered:

(a) any public health and safety issues related to the proposed change including details of target groups and population groups that may be adversely affected
(b) any consumer choice issues related to the proposed change
(c) any evidence that the food industry generally or other specific companies have an interest in, or support, the proposed change to the Code (this item is mandatory for applications relating to food additives, processing aids, nutritive substances, novel foods, irradiated foods).

A. **Data requirements**

**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.

Wherever the data requirements are mandatory but cannot be met, please indicate a reason.

During the assessment phase of an application, FSANZ may need to request further information from the applicant which must be provided before an assessment can proceed.

If the OBPR makes a decision that a RIS is required, FSANZ must meet the OBPR's information requirements and may need to request further information from the applicant which must be provided before the assessment of the application can commence or continue.

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

If a literature search is undertaken, the applicant must:

(a) list the databases searched (such as MEDLINE, EMBASE, TOXLINE, FSTA, Science Citation Index, BIOSIS, PsycINFO, or the Australian Medical Index etc)
(b) provide the criteria used to specify the search, such as the key words, the time period of the search, and any other limiting criteria
(c) list all of the papers identified in the search
(d) list and provide in full all of the papers included as the basis of the evidence in the application. Summaries of study findings and papers are not adequate.
Note:
Useful guidelines on undertaking literature searches can be found at:

The data underpinning the evidence to support the application should also:

(a) identify the source, author(s) and year the data was produced
(b) 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) be representative of the Australian and New Zealand populations
(d) be analysed using appropriate statistical techniques.

1. Data related to safety studies

(a) Studies submitted for safety assessment purposes should be designed and conducted in accordance with the principles and intent of good laboratory practice (GLP). For safety assessments of chemicals, reference should be made to OECD Principles on Good Laboratory Practice (http://www.oecd.org/document/63/0,3746,en_2649_34381_2346175_1_1_1_1,00.html) and relevant OECD Guidelines for the Testing of Chemicals (http://www.oecd.org/department/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 (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/Redbook/default.htm).

(b) 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.

(c) Studies should contain full details of the conduct of the study and its results, including raw data where appropriate.

2. Data related to surveys on chemicals or other substances 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 use a design that avoids biasing the results. The target population should be identified, and the sample frame described in terms of the target population. The survey should have a sample size that provides sufficient power to detect an effect. The sampling method used (e.g. simple random sampling, cluster sampling) should be described, and the reason for the method provided. Any deviations from the sampling method should be identified and the reasons for deviation provided. Data analysis and reporting should be consistent with the sampling method. If any observation/case is excluded from data analysis, the reason for exclusion should be defined and reported.

(c) Surveys should include evidence of quality control/assurance systems. Information on limits of reporting should also be included.
3. Data related to epidemiological/intervention studies in humans

(a) Epidemiological/intervention studies should include comprehensive detail about: study design, purpose, methods, statistical analysis and results.

(b) The checklist provided in the CONSORT Statement 2010 (http://www.consort-statement.org/) for the reporting of randomised controlled trials provides guidance on the preparation of information for these types of studies.

4. Data related to consumer research

Where consumer and market research data is provided, this should be collected in a manner consistent with the Australian Standard AS ISO 20252:2007 Market, opinion and social research – vocabulary and service requirements.

3.1.6 Assessment procedure

The applicant must indicate what they consider is the appropriate procedure to be adopted in assessing the application i.e. General, Minor or Major. The cost recovery level within those procedures is for FSANZ to determine during the Administrative Assessment.

3.1.7 Confidential commercial information (CCI)

The applicant must identify any information they consider 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 should indicate whether or not the application is expected to confer an Exclusive Capturable Commercial Benefit (see Part 2.1.4).

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.
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](http://www.fao.org/docrep/w9114e/w9114e00.htm).


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

More than one guideline may apply to an application. The application must contain completed checklists for all relevant guidelines with regard to format and information requirements relevant to the application (*see Appendix 1*).

An example of when more than one guideline might apply is where an application involves adding a nutritive substance to infant formula. In this case, the checklists for Part 3.1 (General Requirements), 3.3.3 (Nutritive Substances) and 3.6.2 (Special Purpose Foods) would be relevant.

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, including the conditions that govern such information.

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 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 and/or clauses 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.

B. 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 impact from the proposed labelling is not required e.g. where there is an identified public health benefit associated with the labelling change, or where the impact is on industry rather than consumers.
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-threatenning 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.

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 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.

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 nutrition information labelling of a food

The following additional information is required to support an application to include or remove nutrition information on a food label or to change the way in which the label currently displays the nutrition information.

The application must contain the following information:

1. A description of how the proposed labelling will change the nutrition information labelling 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 or energy 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 or data obtained from an overseas market where the proposed labelling is in place, to demonstrate the anticipated consumer response to the proposed change.

If applicable, this part also includes information to show that alternative measures to provide the nutrition information are not, or would not, be effective.

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

The application must contain the following information to support the establishment of an energy factor for a new food ingredient or to vary an energy factor for an existing food ingredient.

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. Details on the calculation of the energy factor

This part includes details on the calculation of the proposed energy factor for a food ingredient. This calculation must follow the equation prescribed in clause 2 of Standard 1.2.8 – Nutrition Information Requirements. Energy factors based on other calculation methods will not be considered.

Note:

The equation in clause 2 of Standard 1.2.8 is:

\[
\text{ME} = \text{GE} - \text{FE} - \text{UE} - \text{GaE} - \text{SE}
\]

where

- \( \text{ME} \) means metabolisable energy
- \( \text{GE} \) means gross energy (as measured by bomb calorimetry).
- \( \text{FE} \) means energy lost in faeces.
- \( \text{UE} \) means energy lost in urine.
- \( \text{GaE} \) means the energy lost in gases produced by fermentation in the large intestine.
- \( \text{SE} \) means the energy content of waste products lost from surface areas.

The application must include the following information set out in (a)–(e) relating to the calculation of the food ingredient’s energy factor.

(a) The components and result of the equation \((\text{ME}, \text{GE}, \text{UE}, \text{FE}, \text{GaE} \text{ and SE})\) expressed in kilojoules per gram of food ingredient.

(b) The proportion (as a percentage) of gross energy per gram of original food ingredient lost through each of \(\text{FE}, \text{UE}, \text{GaE} \text{ and SE}\).

For example: 30\% of the food ingredient is lost in faeces, and the GE of the food ingredient is 16 kJ/g, therefore \(\text{FE} = 4.8 \text{ kJ/g} \ (0.3 \times 16 \text{ kJ/g})\).

(c) A calculation of either the total \(\text{FE}\) or a sum of its individual components such that \(\text{FE} = \text{uFE} + \text{mFE} + \text{oFE}\). The individual \(\text{FE}\) components are the energy lost from:

- \(\text{uFE}\): the proportion of the food ingredient that is excreted unchanged in the faeces
- \(\text{mFE}\): the excretion of microbial mass in faeces that is produced from the proportion of the food ingredient that reaches the large intestine and is fermented
- \(\text{oFE}\): the excretion into the faeces of other produced substances from the proportion of the food ingredient that escapes absorption, such as short chain fatty acids or other metabolites.

(d) The proportion of the food ingredient that reaches the large intestine and is fermented, for use in calculations of \(\text{mFE}, \text{oFE} \text{ or GaE}\). This amount should be calculated either by:

(i) a direct measurement of the percentage of the food ingredient that reaches the large intestine and is fermented; or

(ii) subtracting measured amounts of the food ingredient that are excreted unchanged in the faeces \(\text{uFE}\) from amounts that are not absorbed in the upper intestine (jejunum and duodenum).
The use or otherwise of default values for one or more of mFE, oFE, GaE or SE. Default values are listed in the following table:

<table>
<thead>
<tr>
<th></th>
<th>For ingredients fermented or partly fermented in the large intestine</th>
<th>For ingredients not fermented in the large intestine</th>
</tr>
</thead>
<tbody>
<tr>
<td>mFE (as a % of the ingested food ingredient that is fermented in the large intestine)</td>
<td>30</td>
<td>Not applicable</td>
</tr>
<tr>
<td>oFE (as a % of the ingested food ingredient that is fermented in the large intestine)</td>
<td>0</td>
<td>Not applicable</td>
</tr>
<tr>
<td>GaE (as a % of the ingested food ingredient that is fermented in the large intestine)</td>
<td>5</td>
<td>Not applicable</td>
</tr>
<tr>
<td>SE (as a % of the ingested food ingredient)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

If default values are not used for mFE, oFE, GaE of fermented food ingredients, or for SE, then the value for that respective component of the energy factor equation must be substantiated.

3. **Substantiation of the proposed energy factor of the food ingredient**

In this part, the application must include specific details on how each of the individual components (GE, UE, FE, GaE, and SE) of ME has been determined, and the scientific evidence and methods used to substantiate these individual values.

**Note:**

It is acceptable to use multiple scientific methods to substantiate the individual components of the energy factor calculation.

The following is a list (not exhaustive) of methods that are acceptable for estimating the individual components of ME.

**(I) **Bomb calorimetry – GE**

The GE of food ingredients, metabolites and excreta is determined as the heat of combustion, as measured by adiabatic bomb calorimetry. This is the only acceptable method for determining GE.

**(II) Classical dietary energy balance – FE and UE**

This method measures the energy excreted in faeces (FE) and urine (UE) following the ingestion of a known amount (and GE) of the food ingredient. The method involves careful measurement and control of intake for at least several days, preceded by a period of habituation, together with collection of urine and faeces for the equivalent period. It is acceptable for this method to use animal or human subjects, although coprophagy must have been eliminated during rat studies. This method is best suited to measurements of food ingredients that are not fermented in the large intestine and which do not produce gas. However, it is acceptable to use this method for food ingredients that are fermented in the large intestine if it is combined with other methods that measure the percentage of the food ingredient that is fermented (or gas production directly).
(III) **Isotopic tracer methods – FE, UE, upper intestinal absorption, large intestinal fermentation**

These methods involve the use of isotopically labelled substrates (e.g. $^{13}$C or $^{14}$C) and measure the percentage of the given dose that is recovered in metabolised form (e.g. in CO$_2$ in breath), in unmetabolised (urine) form, or undigested (faeces) form. It is acceptable to combine this method with other techniques to provide adjunct information on intestinal absorption (e.g. analysis of blood glucose fluctuations or other metabolites) and fermentation (breath hydrogen). It is also acceptable to use studies in germ free animals to provide comparative data that calculates the amount of the food ingredient fermented in the large intestine.

(IV) **Breath hydrogen test – GaE, large intestinal fermentation**

The breath hydrogen response is a reflection of the nutrients fermented in the large intestine, and is also suitable for use in estimating GaE. A common form of the test is to measure basal breath H$_2$ obtained after a dose of lactulose compared with the breath H$_2$ after a dose of the test food ingredient.

(V) **Ileal intubation and ileostomy effluent – small intestinal absorption, large intestinal fermentation**

Ileal intubation involves the insertion of a nasogastric tube and sampling the digestive matter in the terminal ileum. Ileostomy studies involve subjects who have had their large bowel surgically removed and in whom digestive excreta (from the end of the small bowel) is collected in a plastic bag. The results of these studies may not be quantitatively representative of normal physiologic status, but they are able to provide a direct estimate of upper intestine absorption by measuring small bowel content at the terminal end of the ileum. Combined with faecal excretion, ileal intubation is also able to provide an indirect measure of the proportion of the food ingredient that reaches the large intestine and is fermented.

4. **Information on other factors that affect the calculation of the energy factor**

An applicant must include information on the following matters where relevant:

(a) justification for and limitations of the evidence and methods used to substantiate the individual components of the energy factor equation;
(b) whether the GE of the food ingredient is constant or varies with different proportions of constituent compounds;
(c) any variation in the digestion and absorption related to the variation in the composition of the food ingredient;
(d) effects of habituation/adaptation to consumption of the food ingredient;
(e) dose dependency;
(f) the nature of the background diet (e.g. high or low in one or more of fat, fibre or protein); and
(g) individual variability.
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.

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. 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;
   (c) evidence that the amounts proposed to be added are consistent with achieving the technological function; and
   (d) 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 new food additives, a common name should be proposed.

   For additives that are not single chemicals, the name should describe the additive as completely as possible. The sources of the additive should be provided, together with either sufficient compositional data to accurately identify the additive, or reference to its common name in other publications used by regulatory agencies.

   For additives that are derived from animals, plants or microorganisms, 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. In cases where particle size is important to achieving the technological function or may relate to a difference in toxicity, the applicant must provide information on particle size, size distribution, and morphology, as well as any size-dependent properties.
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 description of the method of manufacture of the food additive.

Information is required to address whether the manufacture of the food additive results in carry-over of allergens or gives rise to any food safety issues. This part should cover both the food additive and, if relevant, other substances that are inherently part of the commercial product (for example, antioxidants in additive preparations).

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. Specifications should include information on the name of the food additive, its chemical and physical properties, its purity, acceptable levels of impurities, the method of preparation, and analytical methods of determining purity.

Where the substance, in the form in which it will be present in food, is particulate in nature, the applicant must provide information on particle size, size distribution and morphology in cases where the referenced specification does not include this information.

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**

An analytical method must be provided for detecting and quantifying the additive, or its degradation products, in the foods in which it will be used.

This part includes information on available methodology for detecting and quantifying the additive, or its degradation products, in the foods in which it will be used. The applicant must provide a robust analytical method suitable for analytical laboratories to determine compliance of any limits prescribed in the Code.

9. **Potential additional functions of the food additive when added to food**

This part includes a brief description about any additional functions, such as a nutritive or health-related function, of the food additive at the levels proposed to be added.

B. **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.
The substance or preparation assessed should be representative of the commercial product on which approval is sought. A statement to that effect must be made in the Application. If this situation is not the case for any of the relevant studies then a justification and explanation is required.

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 studies:

   (a) acute toxicity  
   (b) short-term toxicity  
   (c) long-term toxicity and carcinogenicity  
   (d) reproductive toxicity  
   (e) developmental toxicity  
   (f) genotoxicity  
   (g) special studies, such as neurotoxicity or immunotoxicity

   Where data are not available or are 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.

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.
C. 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

It is preferred that the food list 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. For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption

This part includes any consumption information for food groups not included in the most recent Australian or New Zealand National Nutrition Surveys (NNSs) which relate to this application. Data distinguishing likely consumption levels among target and non-target groups are preferred.

Note:
Information on likely consumption 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 most recent NNSs are the 1995 NNS (2 years and above), 1997 New Zealand NNS (15 years and above), the 2002 New Zealand Children’s NNS (5-14 years) and the 2007 Australian Children’s NNS (2-16 years).

The application should contain the following information:

4. 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.

5. 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.
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 most recent Australian and New Zealand NNSs which relate to this application. This can be based on market share data or sales data or on a similar market in another country.
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.

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. 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, the category (if any) in Standard 1.3.3 – Processing Aids into which it falls and evidence that the form and the amount of the processing aid performs the intended function.

<table>
<thead>
<tr>
<th>Note:</th>
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<tbody>
<tr>
<td>The categories of processing aids in Standard 1.3.3 are as follows:</td>
</tr>
<tr>
<td>(a) Generally permitted processing aids</td>
</tr>
<tr>
<td>(b) Antifoam agents</td>
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<tr>
<td>(c) Catalysts</td>
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<tr>
<td>(d) Decolourants, clarifying, filtration and adsorbent agents</td>
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<tr>
<td>(e) Desiccating preparations</td>
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<td>(f) Ion exchange resins</td>
</tr>
<tr>
<td>(g) Lubricants, release and anti-stick agents</td>
</tr>
<tr>
<td>(h) Carriers, solvents and diluents</td>
</tr>
<tr>
<td>(i) Processing aids used in packaged water and in water used as an ingredient in other foods</td>
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<tr>
<td>(j) Bleaching agents, washing and peeling agents</td>
</tr>
<tr>
<td>(k) Extraction solvents</td>
</tr>
<tr>
<td>(l) Miscellaneous functions</td>
</tr>
<tr>
<td>(m) Enzymes of animal origin</td>
</tr>
<tr>
<td>(n) Enzymes of plant origin</td>
</tr>
<tr>
<td>(o) Enzymes of microbial origin</td>
</tr>
<tr>
<td>(p) Microbial nutrients and microbial nutrient adjuncts</td>
</tr>
</tbody>
</table>

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, and a statement as to whether or not the enzyme has been protein-engineered.
For new processing aids, a common name should be proposed. Where relevant, this information should support the evidence that the amounts proposed to be added are consistent with achieving the technological function.

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 technological function, including enzymatic properties. Where the substance, in the form in which it will be present in food, is particulate in nature, the applicant must provide information on particle size, size distribution and morphology in cases where the referenced specification does not include this information.

4. **Manufacturing process**

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

Information is required to address whether the manufacture of the processing aid results in carry-over of allergens or gives rise to any food safety issues. This part should cover both the processing aid and, if relevant, other substances that are inherently part of the commercial product (for example, preservatives in a processing aid preparation).

For enzymes, detailed information on the manufacturing process must be provided, including any recombinant DNA techniques used to prepare genetically modified organisms used as an enzyme source.

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. Specifications should include information on the name of the processing aid, its chemical and physical properties, its purity, acceptable levels of impurities, the method of preparation, and analytical methods for determining purity.

Where the substance, in the form in which it will be present in food, is particulate in nature, the applicant must provide information on particle size, size distribution and morphology in cases where the referenced specification does not include this information.

This part must include details on the presence of known allergens (See clause 4 of Standard 1.2.3) present in the processing aid preparation.

6. **Analytical method for detection**

Where residues from a chemical processing aid are likely to be present in the final food, an analytical method must be provided to detect and quantify the amount of the processing aid remaining in the final food. Such an analytical method should be robust and applicable for analytical laboratories to determine compliance of any limits prescribed in the Code. This information is not required in the case of an enzymatic processing aid.

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

The chemical substance or preparation assessed should be representative of the commercial product on which approval is sought. A statement to that effect must be made in the Application.
If this situation is not the case for any of the relevant studies then a justification and explanation is required.

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 chemical processing aid and, if necessary, its metabolites**

(a) For an application for a new chemical 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 chemical 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 chemical processing aid and, if necessary, its major metabolites**

(a) For an application for a new chemical 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 chemical processing aid and, if necessary, its metabolites; particularly when a residue of the chemical processing aid or its metabolite is expected in the final food.

**Note:**

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

(a) acute toxicity
(b) short-term toxicity.

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

(a) long-term toxicity and carcinogenicity
(b) reproductive toxicity
(c) developmental toxicity
(d) genotoxicity
(e) special studies such as neurotoxicity or immunotoxicity.

Where data are not available or are 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 chemical 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.

C. **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 potential toxicity of the enzyme processing aid**

This part includes the following for all enzymatic processing aids:

(a) Information on the enzyme’s prior history of human consumption and/or its similarity to proteins with a history of safe human consumption.

(b) Information on any significant similarity between the amino acid sequence of the enzyme and that of known protein toxins.

In the case of an enzyme which does not have a history of safe human consumption, or where there is significant similarity between the amino acid sequence of the enzyme and that of a known protein toxin, the following additional information is needed:

(c) Information on the stability of the enzyme to degradation in appropriate gastric and, if applicable, intestinal model digestion systems.

In the case that the enzyme is tested for stability and found to be stable, the following data will also be needed:

(d) Acute or short term oral toxicity studies in a rodent species.

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

**Note:**

There is no requirement to routinely conduct acute or short term oral toxicity studies or genotoxicity studies on enzyme processing aids. However, if such data already exists it should also be provided.
3. Information on the potential allergenicity of the enzyme processing aid

Note:

The information provided in this part will enable FSANZ to consider whether:

(a) the enzyme is one to which certain individuals may already be sensitive; and
(b) an enzyme new to the food supply is likely to elicit allergic reactions in some individuals.

This part includes the following for all enzymatic processing aids:

(a) the source of the enzyme processing aid;
(b) an analysis of similarity between the amino acid sequence of the enzyme and that of known allergens.

In the case of an enzyme derived from an allergenic source, or where there is significant similarity between the amino acid sequence of the enzyme and that of a known allergen, the following additional information is needed:

(c) information on the stability of the enzyme to degradation in appropriate gastric and, if applicable, intestinal model digestion systems. In the case that the enzyme is tested for stability and found to be stable, the following data will also be needed:
(d) specific serum screening.

Information on whether the enzyme has a role in the elicitation of gluten-sensitive enteropathy must also be provided if the enzyme has been obtained from wheat, rye, barley, oats, or related cereal grains.

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

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

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

D. Additional information related to the safety of an enzyme processing aid derived from a microorganism

The application must contain the following additional information:

1. Information on the source microorganism

The information provided should include the production strain and the strains from which it was originally derived. Information should also be provided on where the wild-type strain is normally found. Any other information on the taxonomy of this strain which would help its characterisation should be provided. It should be stated if the production strain is currently used in food enzyme production.

The information provided should also contain the production method used.
2. **Information on the pathogenicity and toxicity of the source microorganism**

This part includes information to demonstrate that the strain of the source microorganism is non-pathogenic and non-toxigenic. 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 microorganism does not undergo strain drift and that the culture conditions can be applied consistently between batches. The steps which are taken to ensure strain stability should be provided, such as tests for morphological, growth and production characteristics of the strain.

E. **Additional information related to the safety of an enzyme processing aid derived from a genetically-modified microorganism**

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 modification and the steps used to construct the final production strain.

**Note:**

The application should provide, as a minimum, the following information:

(a) a full description of the gene construct, including information on the size, source and function of all genetic components, including marker genes;
(b) full details of any modifications to the DNA or amino acid sequence of the enzyme;
(c) a full description of the final production strain, including the steps and methods used to construct it, the integration site (plasmid or chromosome) of the introduced gene and organisation of all inserted genetic material; and
(d) information on the stability of the inserted gene.

F. **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 derived from analytical data on the level of the processing aid or its metabolite 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**

   It is preferred if the food list is 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**

   The chemical identity of the residue must be stated.

3. **For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption**

   This part includes any consumption information for food groups not included in the most recent Australian or New Zealand National Nutrition Surveys (NNSs) which relate to this application. Data distinguishing likely consumption levels among target and non-target groups are preferred.

   **Note:**

   Information on likely consumption 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 most recent NNSs are the 1995 NNS (2 years and above), 1997 New Zealand NNS (15 years and above), the 2002 New Zealand Children’s NNS (5-14 years) and the 2007 Australian Children’s NNS (2-16 years).

   The application should contain the following information:

4. **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.

5. **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 and any relevant concentration data for its metabolites.

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 most recent Australian and New Zealand NNSs which relate to this application. This can be based on market share data or sales data or on a similar market in another country.
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:

If the substance or ingredient intended to be added to food is not a nutritive substance, it may be regarded as a novel food ingredient and considered under Section 3.5.2 – Novel Foods.

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. 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 the nutritive substance, specifically its stability and homogeneity in each of the foods or food categories proposed. In cases where particle size is important to achieving the nutritive purpose or may relate to a difference in nutritional status or toxicity, the application must include information on particle size, size distribution, and morphology, as well as any size-dependent properties.

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. Where the substance, in the form in which it will be present in food, is particulate in nature, the applicant must provide information on particle size, size distribution and morphology in cases where the referenced specification does not include this information.
6. **Analytical method for detection**

This part includes a method for detection and quantification of the nutritive substance or its degradation products in the foods in which it is proposed to be used. The applicant must provide a robust analytical method suitable for analytical laboratories to determine compliance of any limits prescribed in the Code.

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.

B. **Information related to the safety of the nutritive substance**

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<th>Note:</th>
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<tr>
<td>FSANZ will undertake an assessment of all 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 considered. The NHMRC publication <em>Nutrient Reference Values for Australia and New Zealand including Recommended Daily Intakes</em> contains ULs for a range of vitamins and minerals. This publication can be found at <a href="http://www.nhmrc.gov.au/publications/synopses/n35syn.htm">http://www.nhmrc.gov.au/publications/synopses/n35syn.htm</a>.</td>
</tr>
</tbody>
</table>

The substance or preparation assessed should be representative of the commercial product on which approval is sought. A statement to that effect must be made in the Application. If this situation is not the case for any of the relevant studies then a justification and explanation is required.

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 form of a 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 include 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 studies need to be considered:

(a) acute toxicity  
(b) short-term toxicity  
(c) long-term toxicity and carcinogenicity  
(d) reproductive toxicity  
(e) developmental toxicity  
(f) genotoxicity  
(g) special studies such as neurotoxicity or immunotoxicity.

Where data are not available or are 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 form of a nutritive substance, this part need only include 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 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.

C. Information on dietary intake of the nutritive substance

Note:

FSANZ will undertake a dietary intake 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 detailed list of the food groups or foods proposed to contain the nutritive substance, or changes to currently permitted foods

This part includes information about the characterising nature of the food vehicle/s in terms of their composition such as total fat and saturated fat, total sugars, sodium, and energy content.

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. **For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption**

This part includes any consumption information for food groups not included in the most recent Australian or New Zealand National Nutrition Surveys (NNSs) which relate to this application. Data distinguishing likely consumption levels among target and non-target groups are preferred.

**Note:**

Information on likely consumption 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 most recent NNSs are the 1995 NNS (2 years and above), 1997 New Zealand NNS (15 years and above), the 2002 New Zealand Children’s NNS (5-14 years) and the 2007 Australian Children’s NNS (2-16 years).

The application should include the following information:

4. **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.

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 most recent Australian and New Zealand NNSs which relate to this application. This can be based on market share data or sales data or on a similar market in another country.

D. **Information related to the nutritional impact of a nutritive substance other than vitamins and minerals (for vitamins and minerals see Part 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 data to demonstrate the nutritive substance is consistent with its nutritional purpose as described in Part 3.1.4.(c) and:

(a) data to demonstrate that specific food(s) containing the form and amount of the nutritive substance can contribute to the nutritional purpose in the target population group at the anticipated level of intake; or
(b) data to demonstrate that the nutritional composition of the specified substitute food can be aligned with the reference food.

**Note:**

The scientific evidence for a nutritional purpose must:

(a) be based on studies conducted on human subjects;
(b) be based on foods or food groups containing the nutritive substance rather than the nutritive substance alone; and
(c) relate to normal use by the target population group and the foods must contribute to the demonstrated nutritional role relevant to that target population.

Refer to Part 3.1.5 for further information regarding data quality.

E. **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 the specified substitute food 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;
(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.

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 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 the level of 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 consumption of 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
(d) whether there is a claim.

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.

Information to support F.1-3 above could include:

(a) a literature review of the available evidence from Australia and New Zealand, or internationally (where appropriate)
(b) robust quantitative or qualitative empirical research (where appropriate) assessing consumer responses to the proposed change, e.g. studies assessing the Australian and New Zealand general population; findings broken down by population subgroups, including target and non-target population groups.

Where there is insufficient information on Australian and New Zealand consumer responses (or potential responses), as specified in Section F, FSANZ may request the applicant to conduct empirical research to address these points. FSANZ can provide guidance here.
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.

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 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 and their effectiveness. In cases where particle characteristics may relate to the toxicity of the food contaminant, the applicant must provide information on particle size and morphology.

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.

B. 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 studies need to be considered:

(a) acute toxicity
(b) short-term toxicity
(c) long-term toxicity and carcinogenicity
(d) reproductive toxicity
(e) developmental toxicity
(f) genotoxicity
(g) special studies such as neurotoxicity or immunotoxicity.

Where data are not available or are 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.

C. **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 data derived from an analytical survey are used, details of how the survey was conducted and the analytical methods used must be provided.

These details should include the sampling plan, the number of samples, where the samples were collected, whether the analysis was conducted on composite or individual samples, the method of analysis, the limits of detection/quantification/reporting (LOD, LOQ, LOR) for the analytical method used, whether the foods were prepared/cooked before analysis, whether the samples were from the edible portion only, and whether the sampling was targeted or randomly sampled. If applicable, this part must also include details of any surveys conducted in other countries.

3. **For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption**

This part includes any consumption information for food groups not included in the most recent Australian or New Zealand National Nutrition Surveys (NNSs) which relate to this application. Data distinguishing likely consumption levels among target and non-target groups are preferred.

**Note:**

Information on likely consumption 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 most recent NNSs are the 1995 NNS (2 years and above), 1997 New Zealand NNS (15 years and above), the 2002 New Zealand Children’s NNS (5-14 years) and the 2007 Australian Children’s NNS (2-16 years).
The application should include the following information:

4. *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 most recent Australian and New Zealand NNSs which relate to the application. This can be based on market share data or sales data or on a similar market in another country.
3.4.2 MICROBIOLOGICAL LIMITS

An application to vary the Code is required to change the permissible limits for a microorganism 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.

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. 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.

B. 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.
C. 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.

D. 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 most recent Australian and New Zealand National Nutrition Surveys, the application must include projected consumption data, which can include information from international markets.

Note:

The most recent NNSs are the 1995 NNS (2 years and above), 1997 New Zealand NNS (15 years and above), the 2002 New Zealand Children’s NNS (5-14 years) and the 2007 Australian Children’s NNS (2-16 years).
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 1.4.1 – Prohibited and Restricted Plants and Fungi.

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 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.

B. 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.

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. **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 unintended open reading frames created at the junctions of inserted DNA with contiguous genomic DNA, including those that could result in fusion proteins or unexpected protein expression products, or created within the inserted DNA as a result of the transformation.

(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. **Analytical method for detection**

Information suitable for the detection of novel DNA or novel protein in the GM food, or where appropriate reference to an analytical method suitable for the detection of a novel substance produced as a result of the genetic modification.

**Note:**

The full nucleotide sequence of each insertion event, which must be provided at A.3(d)(iii), is considered sufficient for the detection of novel DNA characteristic of the GM food.

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

The application must contain the following information:
1. **Equivalence studies**

Where it is difficult to isolate sufficient quantities of the novel protein from the GM food for biochemical or toxicological analysis, an equivalent protein produced from an alternative source (e.g. a microbial expression system) can be used in toxicity and protein characterisation studies. In this circumstance, biochemical, physicochemical or other relevant information must be provided to demonstrate that the protein tested is biochemically and functionally equivalent to that expressed in the GM food.

2. **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 microorganism, information on whether it will remain viable in the final food.

3. **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.

4. **The potential toxicity of novel proteins**

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 protein stability to proteolysis in appropriate gastrointestinal model systems.
5. **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
(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) the novel protein’s structural properties, including, but not limited to, its susceptibility to enzymatic degradation (e.g. proteolysis), heat and/or acid stability
(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, the application must also include information on whether the newly-expressed protein(s) have a role in the elicitation of gluten-sensitive enteropathy.

6. **Toxicity of novel herbicide metabolites in GM herbicide-tolerant plants**

Data must be provided on the identity and levels of herbicide and any metabolites that may be present in the GM food.

**Note:**

The information provided in this part will enable FSANZ to consider whether, as a result of the genetic modification, novel herbicide metabolites are present in the food. If novel metabolites (i.e. those not normally found in non-GM crops) are present then the application should include appropriate studies on:

(a) toxicokinetics and metabolism
(b) acute toxicity
(c) short-term toxicity
(d) long-term toxicity and carcinogenicity
(e) reproductive and developmental toxicity
(f) genotoxicity.

Where data are not available or are not considered relevant to the safety assessment of the novel metabolite/s, a scientific rationale must be provided.
7. **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.

**Note:**

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

C. **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 all of the following:

(a) Data are required 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.

(b) Where the GM food contains an intended nutritional change, information, such as clinical trial data, must be provided to determine the nutritional impact of the GM food.

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

There is no requirement for animal feeding studies to be conducted on the GM food. However, if available, such studies should be submitted.
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:
For further information relating to the operation of the Novel Food Standard, particularly in relation to whether a particular food would be regarded as novel, refer to the FSANZ website at http://www.foodstandards.gov.au/consumerinformation/novelfoods/.

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

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. **Exclusive use of novel foods**

This part includes a statement as to whether the application is seeking exclusive permission for the novel food. If exclusive permission is sought, the application **must** include details of the following:

(a) the specific class of food; and
(b) the brand of the food.

Exclusive permission can only be sought if requested by the applicant at the time the application is received by FSANZ.

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) Microorganisms (including probiotics)
(VII) Food ingredients derived from new sources
(VIII) Foods produced by a process not previously applied to food.
Note:

These categories are provided as a guide based on previous experience and knowledge of the nature of products from enquiries received by FSANZ. It is anticipated that most novel foods will fall under one of these categories, however, this may not always be the case and the categories listed are not intended to be exhaustive.

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 substance used for a technological purpose.

A novel food may fit under more than one category above. In this case, all applicable requirements for each category should be addressed.

2. **Information on the purpose of adding a novel food ingredient to food**

If the purpose for adding a novel food ingredient to food relates to a potential beneficial physiological or health-related outcome, the purpose must be stated in a way that can be measured i.e. as an outcome in clinical studies.

If the purpose for adding a novel food ingredient to food relates to a potential beneficial physiological or health-related outcome, this will include evidence that the form and total amount of the novel food ingredient added to the food vehicle(s) delivers the stated purpose in the target population group. The total amount should include naturally-occurring amounts.

3. **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. In cases where particle size is important to achieving the functionality or may relate to a difference in nutritional status or toxicity, the applicant must provide information on particle size, size distribution, and morphology, as well as any size-dependent properties.

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

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

6. **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. Where the substance, in the form in which it will be present in food, is particulate in nature, the applicant must provide information on particle size, size distribution and morphology in cases where the referenced specification does not include this information.

7. **Analytical method for detection**

The application must contain the following information:

This part includes a method for detection and quantification of the novel food ingredient or its degradation products (where relevant) in the foods in which it will be used. Such analytical methods need to be robust and applicable for analytical laboratories to determine compliance of any limits prescribed in the Code.

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.

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

(a) the history of use as a food in other countries  
(b) the composition of the novel food, particularly the levels of anti-nutrients and naturally-occurring toxins  
(c) the method of preparation and specifications of a novel food ingredient  
(d) potential for allergenicity of the novel food  
(e) metabolism/toxicokinetic studies on the novel food ingredient  
(f) animal toxicity studies on the novel food ingredient  
(g) human toleration studies on the novel food ingredient

The substance or preparation assessed should be representative of the commercial product on which approval is sought. A statement to that effect must be made in the Application. If this situation is not the case for any of the relevant studies then a justification and explanation is required.

The nature of the information on the safety of the novel food to be submitted will depend on the category of the novel food as identified in Part B1.
(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, if relevant.

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). This evidence of safe use should include the frequency of consumption, the extent of the population using the food, and the period of 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 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 published safety assessment reports prepared by other agencies.

**(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.

2. **Information on the composition of the herb**

   This part includes information on the levels of active constituents 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 herbal extract as a food in other countries**

   This part includes information on the extent and history of use of the 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, or herbal extract, or any key constituents obtained from studies conducted in animals or humans**

   This part includes 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 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) Microorganisms (including probiotics)

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

1. *Information on potential pathogenicity*

This part includes information related to the potential pathogenicity of the microorganism and related microorganisms.

2. *Information on the effects of the microorganism on gut microflora*

This part includes studies to demonstrate that the microorganism does not have adverse effects on the gut microflora.
3. **Information on the use of this microorganism as a food in other countries**

This part includes information on the extent and history of use of this microorganism or related microorganisms 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. Clinical evaluation of potential probiotics must use double blind, placebo-controlled human trials, with detailed reporting of adverse side effects, which can be used to confirm the results observed in animal tests or in vitro studies.

(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 and toxicity. This part must also include information on potential naturally-occurring toxins, if applicable.

This part must include details on the presence of known allergens (see clause 4 of Standard 1.2.3).

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 final 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 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. The nature of the toxicity or toleration studies to be submitted will depend on the category of the novel food as set out in Part B1.

This part must include details on the presence of known allergens (see clause 4 of Standard 1.2.3).

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.

This may depend on whether the novel food is the final food, a major component of the final food or a minor component 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 or other concentration data where relevant, for example data from analytical surveys.

The most recent NNSs are the 1995 NNS (2 years and above), 1997 New Zealand NNS (15 years and above), the 2002 New Zealand Children’s NNS (5-14 years) and the 2007 Australian Children’s NNS (2-16 years).

The dietary exposure assessment may be based on the projected market share data, or data from markets in other countries.

The application must contain the following information:

1. A list of the foods or food groups proposed to contain the novel food ingredient

If the purpose for adding a novel food ingredient to food relates to a potential beneficial physiological or health-related outcome, this will include information about the characterising nature of the food vehicle(s) in terms of their composition such as total fat and saturated fat, total sugars and sodium, and energy content.

2. The proposed level of the novel food ingredient for each food or food group

Data that must be provided are the proposed levels of use (or concentration) of the novel food ingredient, for each of the foods or food groups identified as well as any naturally occurring levels.
The application should indicate whether these use levels are the maximum levels that will be used or are the likely actual use level.

3. **For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption**

This part includes any consumption information for food groups not included in the most recent Australian or New Zealand National Nutrition Surveys (NNSs) which relate to this application. Data distinguishing likely consumption levels among target and non-target groups are preferred.

**Note:**

Information on likely consumption 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 most recent NNSs are the 1995 NNS (2 years and above), 1997 New Zealand NNS (15 years and above), the 2002 New Zealand Children’s NNS (5-14 years) and the 2007 Australian Children’s NNS (2-16 years).

The application should contain the following information:

4. **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 can be based on a similar market in another country.

5. **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 most recent Australian and New Zealand NNSs which relate to this application. This can be based on market share data or sales data or on a similar market in another country.

**Note:**

The most recent NNSs are the 1995 NNS (2 years and above), 1997 New Zealand NNS (15 years and above), the 2002 New Zealand Children’s NNS (5-14 years) and the 2007 Australian Children’s NNS (2-16 years).

6. **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.
7. **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 and health impact of the novel food**

**Note:**

Some of the information derived from Part C, will be used also to assess the nutritional impact of the novel food. The information below is in addition to this information. Information in relation to the safety, dietary exposure and nutritional impact will be considered in characterising the risk of the novel food or novel food ingredient.

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 information relating to the bioavailability of other nutrients, and its impact on the intake of other components of the overall diet (particularly macronutrients) which may arise from the novel food or novel food ingredient.

2. **Information to demonstrate that the addition of the novel food ingredient will not create a significant negative public health impact**

   If the purpose for adding a novel food ingredient to food relates to a potential beneficial physiological or health-related outcome, this will include information from scientific studies on any potential adverse effect(s) on the physiological status of the target or non-target population, including long term impact on health. This information is in addition to that outlined in Part F.

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.

If the purpose for adding a novel food ingredient to food relates to a potential beneficial physiological or health-related outcome, the application **must** contain the following information:

1. **Information to demonstrate the level of 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.

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

(a) the nature of the novel food ingredient and the food(s) to which it will be added
(b) the projected consumption levels for the food(s) containing the novel food ingredient including amount consumed and how often it will be consumed
(c) whether currently used foods may be substituted for food(s) containing the novel food ingredient
(d) whether there is a claim.

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.

Information to support F1-3 could include:

(a) a literature review of the available evidence from Australia and New Zealand, or internationally (where appropriate)

(b) robust quantitative or qualitative empirical research (where appropriate) assessing consumer responses to the proposed change, e.g. studies assessing the Australian and New Zealand general population; findings broken down by population subgroups, including target and non-target population groups.

Where there is insufficient information on Australian and New Zealand consumer responses (or potential responses), as specified in Part F, FSANZ may request the applicant to conduct empirical research to address these points. FSANZ can provide guidance here.
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.

In support of an application for irradiation of a particular food and to demonstrate that there is a technological need to irradiate a food, the following information must be provided to support an application to irradiate a new food.

A. 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 the following data and/or information to support that irradiation if used appropriately and at the correct doses can reduce bacterial contamination or increase shelf-life or reduce/eliminate pest infestation:

   (a) data on the reduction in microbiological load to demonstrate the effectiveness of the irradiation procedure in each of the foods on which it is proposed to be used.
   
   (b) data on the expected increase in shelf-life of a food post-irradiation, compared to its pre-irradiated shelf-life.
   
   (c) data and/or support from an appropriate quarantine agency (e.g. Biosecurity Australia or New Zealand Ministry of Agriculture and Forestry) that the use of irradiation is justified at the dose range requested (including a minimum and maximum value) to achieve the technological function of pest disinfestation.

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.

B. Information on the safety of irradiation

The applicant must submit to FSANZ studies that demonstrate the toxicological safety of the food that is the subject of the application or of closely related foods. Any studies performed to demonstrate the toxicological safety of the food following irradiation must be submitted. In particular, this should include the identity of any new components in the food formed as a result of the irradiation process.

C. Information on the nutritional impact of irradiation

You must contact FSANZ regarding information required to determine the nutritional impact of irradiation.
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.

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 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.

2. 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.

B. 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.

C. 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.
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 – Foods for Infants
- Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods
- Standard 2.9.4 – Formulated Supplementary Sports Foods.

Note:

The Ministerial Policy Guideline on the intent of Part 2.9 – Special Purpose Foods (endorsed in 2009) sets out a description of the scope for special purpose foods:

Part 2.9 – Special Purpose Foods, of the Code is intended to contain food standards that prescribe specific requirements for foods processed or manufactured for use by physiologically vulnerable individuals and population sub-groups. Requirements within food standards in Part 2.9 are prescribed relative to the particular intended dietary use of the food.

For the purposes of Part 2.9, physiological vulnerability relates only to situations where there is risk of dietary inadequacy to support:

- physical and physiological need arising from specific life stages (e.g. infancy), physical disease, disorder and disability; or
- physical and physiological conditions that require altered energy intake;

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 also be additional information requirements in other parts of this Handbook if an application relates to the addition of a food additive, processing aid, novel food, novel food ingredient or nutritive substance, or to the labelling requirements in Part 1.2 of the Code.

A. 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 related to the safety of a food additive, processing aid, novel food or novel food ingredient, or nutritive substance (as indicated elsewhere in the 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 demonstrates how the compositional change is consistent with the intended purpose of the special purpose food.

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.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/InfantFormula/ucm170649.htm.

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.

3. Information related to internationally recognised codes of practice and recommendations/guidelines

This part includes, where relevant, information demonstrating consistency with internationally recognised codes of practices, such as Codex and the WHO recommendations/guidelines, relating to the manufacture of special purpose foods. This information may be included in applications for other standards in the Code for provisions for special purpose foods such as Standard 1.6.1 – Microbiological Limits for Food.

Note:

Examples of relevant codes of practice and recommendations/guidelines are the WHO Infant and Young Child Nutrition Global Strategy on Infant and Young Children Feeding at http://apps.who.int/gb/archive/pdf_files/WHA55/ea5515.pdf and the Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children at http://www.codexalimentarius.net/web/more_info.jsp?id_sta=11026.

B. Information related to the dietary intake or 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 and physical and physiological need of the target population

This part includes a description of the target population for the special purpose food. It also includes a description of the physical and physiological need arising from specific life stages e.g. infancy, physical disease, disorder and disability of the target population; or physical and physiological conditions of the target population that require altered energy or nutrient intake.
2. *Data to enable the dietary exposure of the target population to be estimated*

This part includes information on the dietary exposure of a food additive, processing aid, novel food or novel food ingredient, or dietary intake of a nutritive substance (as indicated elsewhere in the Handbook) with a particular focus on the target population.

3. *Data on the recommended level of consumption of the special purpose food for the target population*

Information relating to the recommended number of serves per day and the size of each recommended serve should be provided for relevant special purpose foods with a particular focus on the target population.

C. *Information related to labelling requirements under Part 2.9 of the Code*

The application must contain the following information if it relates to a change to labelling requirements under Part 2.9 of the Code:

1. *Information related to safety or nutritional impact of the proposed labelling change*

This part includes information to support the proposed labelling change. For example, the inclusion of (or change to) a warning or advisory statement, directions for use, or claim conditions.

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

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.

For example, this part may include information to demonstrate how the proposed label change will assist consumer understanding of the specific nature of the food, the intended population group and/or the intended special purpose of the food;

**Note:**

A proposed labelling change will only be relevant to consumers for those special purpose foods which are available for retail sale.

3. *Information related to internationally recognised codes of practice and guidelines*

This part includes, where relevant, information demonstrating consistency with internationally recognised codes of practices, such as Codex and the WHO recommendations/guidelines, relating to the labelling of special purpose foods.
Note:

SECTION 3.7

STANDARDS RELATED TO FOOD PRODUCTION
3.7.1 FOOD SAFETY STANDARDS

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.

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. 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.
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.

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. 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.
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APPENDIX 1

CHECKLISTS
# CHECKLIST FOR GENERAL REQUIREMENTS

This Checklist will assist you in determining if you have met the information requirements as detailed in Section 3.1 – General Requirements. All applications must include this Checklist.

## General Requirements (3.1)

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**CHECKLIST FOR STANDARDS RELATED TO LABELLING AND OTHER INFORMATION REQUIREMENTS**

This Checklist is in addition to the Checklist for Section 3.1 and will assist you in determining if you have met the information requirements as specified in Section 3.2.1 – General Food Labelling which is mandatory for all labelling applications. If your application relates to Sections 3.2.2-3.2.5, then the information required is in addition to 3.2.1.

### General Food Labelling (3.2.1)

- **☐ A.1 Proposed labelling change**
- **☐ A.2 Foods potentially affected**
- **☐ B.1 Demonstrated consumer support for the labelling change**
- **☐ B.2 Will proposed labelling be understood and assist consumers**
- **☐ B.3 Will proposed labelling change have any adverse health or diet impacts**

### Warning and Advisory Statements (3.2.2)

- **☐ A.1 Data on potential health concern**
- **☐ A.2 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)**

- **☐ A.1 Demonstration that the food causes IgE-mediated allergy**
- **☐ A.2 Incidence of allergic reaction**
- **☐ A.3 Severity of allergic reaction**
- **☐ A.4 Extent of use of allergen in foods**

**Removal of food derivative from the list of declared foods (3.2.3 B)**

- **☐ B.1 Nature of food derivative**
- **☐ B.2 Use of food derivative**
- **☐ B.3 Dietary intake information**
- **☐ B.4 History of safe use**
- **☐ B.5 Clinical information on safety of food derivative**

### Labelling for Consumer Information and Choice (3.2.4)

- **☐ A.1 Current labelling or alternative information inadequacies**
- **☐ A.2 Information on lack of suitable alternatives available to consumers**
- **☐ A.3 How will proposed labelling change assist consumers**
- **☐ A.4 Information to demonstrate absence of labelling would not be effective**

### Nutrition Information Labelling (3.2.5)

- **☐ A.1 Description of proposed change and how it will change nutrition information labelling**
- **☐ A.2 Data to demonstrate labelling will assist consumers**
- **☐ B.3.(II) Substantiation of energy factor – Classical dietary energy balance**
- **☐ B.3.(III) Substantiation of energy factor – Isometric tracer methods**
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| ☐ B.3.(I) Substantiation of energy factor – Bomb calorimetry | ☐ B.4. Other factors |
## CHECKLIST FOR STANDARDS RELATED TO SUBSTANCES ADDED TO FOOD

This Checklist is in addition to the Checklist for Section 3.1 and will assist you in determining if you have met the information requirements as specified in Sections 3.3.1-3.3.3.

### Food Additives (3.3.1)

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<th>A.1 Nature and technological function information</th>
<th>B.1 Toxicokinetics and metabolism information</th>
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<td></td>
<td>A.2 Identification information</td>
<td>B.2 Toxicity information</td>
</tr>
<tr>
<td></td>
<td>A.3 Chemical and physical properties</td>
<td>B.3 Safety assessments from international agencies</td>
</tr>
<tr>
<td></td>
<td>A.4 Impurity profile</td>
<td>C.1 List of foods likely to contain the food additive</td>
</tr>
<tr>
<td></td>
<td>A.5 Manufacturing process</td>
<td>C.2 Proposed levels in foods</td>
</tr>
<tr>
<td></td>
<td>A.6 Specifications</td>
<td>C.3 Likely level of consumption</td>
</tr>
<tr>
<td></td>
<td>A.7 Food labelling</td>
<td>C.4 Percentage of food group to contain the food additive</td>
</tr>
<tr>
<td></td>
<td>A.8 Analytical detection method</td>
<td>C.5 Use in other countries (if applicable)</td>
</tr>
<tr>
<td></td>
<td>A.9 Additional functions</td>
<td>C.6 Where consumption has changed, information on likely consumption</td>
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### Processing Aids (3.3.2)

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<thead>
<tr>
<th></th>
<th>A.1 Type of processing aid</th>
<th>C.3. Allergenicity information of enzyme (enzyme only)</th>
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</thead>
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<tr>
<td></td>
<td>A.2 Identification information</td>
<td>C.4. Overseas safety Assessment Reports</td>
</tr>
<tr>
<td></td>
<td>A.3 Chemical and physical properties</td>
<td>D.1 Information on source organism (enzyme from microorganism only)</td>
</tr>
<tr>
<td></td>
<td>A.4 Manufacturing process</td>
<td>D.2 Pathogenicity and toxicity of source microorganism (enzyme from microorganism only)</td>
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<tr>
<td></td>
<td>A.5 Specification information</td>
<td>D.3 Genetic stability of source organism (enzyme from microorganism only)</td>
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<tr>
<td></td>
<td>A.6 Analytical method for detection</td>
<td>E.1 Nature of genetic modification of source organism (enzyme from GM source microorganism)</td>
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<td>B.1 Industrial use information (chemical only)</td>
<td>F.1 List of foods likely to contain the processing aid</td>
</tr>
<tr>
<td></td>
<td>B.2 Information on use in other countries (chemical only)</td>
<td>F.2 Anticipated residue levels in foods</td>
</tr>
</tbody>
</table>
Nutritive Substances (3.3.3)

- A.1 Identification information
- A.2 Chemical and physical properties
- A.3 Impurity profile information
- A.4 Manufacturing process
- A.5 Specification information
- A.6 Analytical detection method
- A.7 Proposed food label
- B.1 Toxicokinetics and metabolism information
- B.2 Animal or human toxicity studies
- B.3 Safety assessments from international agencies
- C.1 List of food groups or foods likely to contain the nutritive substance
- C.2 Toxicity information of enzyme (enzyme only)
- C.3 Likely level of consumption
- C.4 Percentage of food group to use nutritive substance
- C.5 Use in other countries (if available)
- C.6 Where consumption has changed, information on likely consumption
- D.1 Nutritional purpose
- E.1 Need for nutritive substance
- E.2 Demonstrated potential deficit or health benefit
- F.1 Consumer awareness and understanding
- F.2 Actual or potential behaviour of consumers
- F.3 Demonstration of no adverse effects on any population groups
- F.4 Percentage of food group to use processing aid
- F.5 Information on residues in foods in other countries (if available)
- F.6 Where consumption has changed, information on likely consumption
- F.3 Information on likely level of consumption
# Checklist for Standards Related to Contaminants and Natural Toxicants

This Checklist is in addition to the Checklist for Section 3.1 and will assist you in determining if you have met the information requirements as specified in Sections 3.4.1-3.4.3.

## Chemical Contaminant and Natural Toxicant Maximum Levels (3.4.1)

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<tr>
<td>A.2</td>
<td>Analytical detection method</td>
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<tr>
<td>B.1</td>
<td>Toxicokinetics &amp; metabolism information</td>
</tr>
<tr>
<td>B.2</td>
<td>Toxicity studies</td>
</tr>
<tr>
<td>B.3</td>
<td>Human studies relevant to safety</td>
</tr>
<tr>
<td>C.1</td>
<td>List of foods where maximum level is proposed</td>
</tr>
<tr>
<td>C.2</td>
<td>Survey data on contaminant or toxicant levels in foods</td>
</tr>
<tr>
<td>C.3</td>
<td>Information on levels of consumption</td>
</tr>
<tr>
<td>C.4</td>
<td>Where consumption has changed, information on likely consumption</td>
</tr>
</tbody>
</table>

## Microbiological Limits (3.4.2)

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<td>Raw inputs, production and manufacturing process</td>
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<td>A.2</td>
<td>Food technology</td>
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<td>B.1</td>
<td>Nature of the microbiological hazard</td>
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<td>Source &amp; prevalence of contamination</td>
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<td>B.3</td>
<td>Consumer handling and use</td>
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<td>C.1</td>
<td>Nutritional impact</td>
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<td>D.1</td>
<td>Dietary exposure</td>
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## Prohibited and Restricted Plants and Fungi (3.4.3)

<table>
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<td>A.2</td>
<td>Identity and levels of natural toxicants</td>
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<td>B.1</td>
<td>Toxicity studies</td>
</tr>
<tr>
<td>B.2</td>
<td>Human toxicity case studies</td>
</tr>
<tr>
<td>B.3</td>
<td>Use in other countries</td>
</tr>
</tbody>
</table>
## CHECKLIST FOR STANDARDS RELATED TO NEW FOODS

This Checklist is in addition to the Checklist for Section 3.1 and will assist you in determining if you have met the information requirements as specified in Sections 3.5.1-3.5.3.

### Foods Produced using Gene Technology (3.5.1)

| A.1 Nature and identity of GM food | B.4 Toxicity of novel protein(s)/substances |
| A.2 History of use of host and donor organisms | B.5 Potential allergenicity of novel protein(s) |
| A.3 Nature of genetic modification | B.6 Toxicity of novel herbicide metabolites |
| A.4 Labelling information on GM food | B.7 Compositional Analyses |
| B.1 Equivalence studies | C.1 Nutritional impact of GM food |
| B.2 Antibiotic resistance marker genes (if used) | C.2 Animal feeding studies (if available) |
| B.3 Characterisation of novel protein(s)/substances |

### Novel Foods (3.5.2)

| A. Exclusive use | B.4 Impurity profile |
| B.1 Type of novel food | B.5 Manufacturing process |
| B.2 Information on potential beneficial outcomes | B.6 Specification for identity and purity |
| B.3 Chemical and physical properties | B.7 Analytical detection method |

### C – Information on the safety of the novel food

#### (I) Plant or animal extracts

| 1. Extraction and composition | 3. Current use |
| 2. Effects of food processing or preparation | 4. Potential adverse effects |

#### (II) Plant and animal extracts

| 1. Method or extraction and composition of extract | 3. Toxicity studies |
| 2. Use as a food in other countries | 4. Safety assessments from other agencies |

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

| 1. History of use | 5. Potential allergenicity |
| 2. Composition | 6. Toxicity studies |
| 3. Method of extraction and composition of extract | 7. Safety assessments from other agencies |
4. Use in other countries

(IV & V) **Single chemical entities & Dietary macrocomponents**
- 1. Toxicokinetics and metabolism
- 2. Toxicity studies
- 3. Safety assessments from other agencies

(VI) **Microorganisms (including probiotics)**
- 1. Potential pathogenicity
- 2. Effects on gut microflora
- 3. Use as a food in other countries
- 4. Human toleration studies

(VII) **Food ingredients derived from a new source**
- 1. Safety of the source organism, including allergen statement
- 2. Composition
- 3. Toxicity studies
- 4. Overseas safety reports

(VIII) **Foods produced by a process not previously applied to food**
- 1. Details of the new process
- 2. Toxicity studies
- 3. Overseas safety reports
- 4. Overseas safety reports

- D.1 List of foods likely to contain the novel food or novel food ingredient
- D.2 Proposed levels in foods
- D.3 Information on levels of consumption
- D.4 Percentage of food group or market
- D.5 Where consumption has changed, information on likely consumption
- D.6 Information to show whether the food or ingredient will replace another food
- D.7 Use in other countries
- E.1 Nutritional impact information
- E.2 Public health impact
- F.1 Demonstrated consumer awareness and understanding
- F.2 Potential behaviour in response to foods
- F.3 Demonstration of no adverse effects on any population groups

<table>
<thead>
<tr>
<th>Irradiated Foods (3.5.3)</th>
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<tbody>
<tr>
<td>A.1 Nature of the food or food ingredient to be irradiated</td>
</tr>
<tr>
<td>B. Safety information</td>
</tr>
<tr>
<td>A.2 Technological need</td>
</tr>
<tr>
<td>c. Nutritional impact</td>
</tr>
<tr>
<td>A.3 Food products likely to contain irradiated food</td>
</tr>
<tr>
<td>F.3 Demonstration of no adverse effects on any population groups</td>
</tr>
</tbody>
</table>
# Checklist for Standards Related to the Composition of Food Products

This Checklist is in addition to the Checklist for Section 3.1 and will assist you in determining if you have met the information requirements as specified in Sections 3.6.1-3.6.2.

## Standardised Foods (3.6.1)

<table>
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<th>A.1 Proposed compositional change</th>
<th>C.1 Demonstrated consumer understanding of proposed change</th>
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<tr>
<td></td>
<td>A.2 List of foods likely to be affected</td>
<td>C.2 Potential adverse health or diet impacts</td>
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<tr>
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<td>B.1 Nutritional content</td>
<td>C.2 Demonstrated understanding of labelling change</td>
</tr>
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</table>

## Special Purpose Foods (3.6.2)

<table>
<thead>
<tr>
<th></th>
<th>A.1 Safety of proposed compositional change</th>
<th>B.3 Level of consumption</th>
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<tbody>
<tr>
<td></td>
<td>A.2 Nutritional impact of compositional change</td>
<td>C.1 Safety and nutritional impact of labelling change</td>
</tr>
<tr>
<td></td>
<td>A.3 Internationally recognised codes of Practice and guidelines</td>
<td>C.2 Demonstrated understanding of labelling change</td>
</tr>
<tr>
<td></td>
<td>B.1 Target population</td>
<td>C.3 Internationally recognised codes of Practice and guidelines</td>
</tr>
<tr>
<td></td>
<td>B.2 Dietary exposure information</td>
<td></td>
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</table>
# Checklist for Standards Related to Food Production

This Checklist is in addition to the Checklist for Section 3.1 and will assist you in determining if you have met the information requirements as specified in Sections 3.6.1-3.6.2.

## Food Safety Standards (3.7.1)

- A.1 Public health and safety data
- B.1 Projected costs to food industry

## Food Processing and Primary Production (3.7.2)

- A.1 Public health and safety data
AMENDMENT HISTORY

Note 1
Part 3 of the FSANZ Application Handbook (in force under section 23 of the Food Standards Australia New Zealand Act 1991) as shown in this compilation is amended as indicated in the Tables below.

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