

EXPLANATORY STATEMENT

AMENDMENTS TO FOOD STANDARDS AUSTRALIANEW ZEALAND *APPLICATION HANDBOOK*

**(known as Part 3 of the
FSANZ Application Handbook)**

Amendment No. 5 – 2011

1. PURPOSE

Applications must meet mandatory information and format requirements as determined by Food Standards Australia New Zealand (FSANZ) in writing and in advance. These mandatory requirements are contained in Part 3 of the *FSANZ Application Handbook*.

Parts 1 and 2 of the *Application Handbook* are for information only. Part 1 provides an overview of the food standards system. Part 2 provides general information on application procedures, fees, assessment procedures and food standard-setting processes.

Section 23 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) empowers FSANZ to make guidelines:

- (a) *specifying the form in which applications for the development of a food regulatory measure, or the variation of a food regulatory measure, are to be made; and*
- (b) *specifying the information, or the kinds of information, to be included with such applications; and*
- (c) *specifying any thing, or kind of thing, to be included with such applications.*

1.1 Application ‘Guidelines’

Under section 22 of the FSANZ Act, an application to amend the Code must:

- (a) be in writing; and
- (b) if the form in which the application is to be made is specified in the guidelines made under section 23—be in the form specified; and
- (c) include all of the information that, under the guidelines made under section 23 is to be included with the application; and
- (d) include each thing that, under the guidelines made under section 23, is to be included with the application; and
- (e) identify the procedure that, in the applicant’s view, applies to the consideration of the application.

If the information requirements are not met, then FSANZ has the power under section 26 of the FSANZ Act to reject the application after a 15-day Administrative Assessment.

The guidelines are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*, but are not subject to sunset or disallowance. For the purposes of section 23, Part 3 of the *FSANZ Application Handbook* (Handbook) fulfils these requirements.

1.2 Proposed Amendments to Part 3 (Mandatory Requirements)

FSANZ has approved a number of amendments to Part 3 of the Handbook for the following reasons:

- Assessments of applications should be able to proceed without delays where FSANZ seeks further information or data from an applicant to enable assessment of the application to proceed. This will assist in ensuring that statutory timeframes are met.
- Part 3 fulfils the intention of the FSANZ Act amendment that there be clearly defined application requirements, including the requirement to provide supporting material with applications.

Many of the amendments are generally mechanical in nature and relate to the correction of typographical errors, reduction in duplication of text and the clarification of the meaning of the text to further assist applicants in understanding what information is required.

More detailed amendments relate to clarification of information and data requirements, including to requirements for general applications, as well as those relating to nutritive substances, nutrition information labelling, special purpose foods, food irradiation and processing aids. The amendments, in many cases, do not add any additional requirements to potential applicants. In addition, a number of references have been updated to assist applicants e.g. references to the latest nutrition surveys for Australia and New Zealand have been included.

The amendments are set out in Attachment 1.

1.2.1 Substances other than Vitamins and Minerals

In 2008, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) developed the Policy Guideline on the *Addition to Food of Substances other than Vitamins and Minerals*. As this Policy Guideline has implications for FSANZ's regulatory processes, a range of amendments to the Handbook have been approved.

The amendments include additional information requirements to assess the stated purpose, efficacy, any potential significant negative public health impacts of substances intentionally added to food/s for other than technological reasons, and clarification of the type of consumer information required. It should be noted that such information has been requested by FSANZ in the past, although the proposed changes will enhance administrative certainty. The Policy Guideline specifically excludes Special Purpose Foods, hence Part 3.6.2 is not affected.

1.2.2 Special Purpose Foods

In 2009, the Ministerial Council developed the Policy Guideline on the *Intent of Part 2.9 – Special Purpose Foods*. As this Policy Guideline has implications for FSANZ's regulatory processes for Special Purpose Foods, amendments to Part 3.6.2 of the Handbook are proposed.

The amendments to Section 3.6.2 include clarification of the types of products that may be considered to be special purpose foods. They also include information requirements on the physical and physiological need of the target population, information requirements to assess the impact of compositional and labelling changes, and information where relevant demonstrating consistency with internationally recognised codes of practices.

1.2.3 Irradiation

Several requirements have been deleted as they are not mandatory requirements for assessment of an application. These include information on:

- packaging
- irradiation facilities
- the verification of the use of irradiation, the irradiation process and dosimetry
- information on record keeping.

The labelling provisions in Standard 1.5.3 are generic provisions and do not need to be assessed for each application. Therefore specific requests for information on labelling are no longer required.

It should be noted that under Application A1038—Irradiation of Persimmons, FSANZ is proposing to remove specific provisions for packaging of irradiated foods.

1.2.4 GM

FSANZ has clarified the information requirements concerning analytical detection of a GM food. This will enable testing for compliance of the GM food with the Standard, both in terms of approved GM lines and mandatory labelling provisions.

1.2.5 Enzyme Processing Aids

The safety data requirements for enzyme processing aids are being revised to decrease the emphasis on toxicity studies which are now largely unnecessary for assessing the safety of enzyme preparations but to require data to allow an assessment of potential allergenicity. Following the receipt of submissions following consultation FSANZ reconsidered the approach to toxicity and allergenicity and has revised the requirements such that a tiered approach is used to define data needs. Additional minor changes have also been introduced to correct errors in the previous version and to more clearly distinguish between the data requirements for enzyme processing aids and those for chemical processing aids.

2. CONSULTATION

A list of over 500 people with an interest in the Handbook are on a stakeholder mailing list for consultation on amendments. This mailing list includes all previous applicants, industry representatives, consultants and consumers. The people on the mailing list were sent email alerts calling for submissions on 20 April 2011 and 13 May 2011. Email alerts were included as part of the publication of the Food Standards Notification Circular. Over 4000 people are on the mailing list for this alert. The closing date for comments was 26 May 2011.

Comments from seven submitters were received. FSANZ has responded to each of the issues raised by the submitters, and in some cases (as indicated in the Table in Attachment 2), has adjusted the amendments that were consulted on to address the concerns raised. Submitters generally supported the amendments, with the exception of those issues mentioned in Attachment 2.

3. IMPACT ANALYSIS

The impact analysis represents likely impacts based on available information. The impact analysis is designed to assist in the process of identifying the affected parties, any alternative options consistent with the objective of the proposed changes, and the potential impacts of any regulatory or non-regulatory provisions.

In accordance with the Best Practice Regulation Guidelines, completion of a preliminary assessment of the proposed amendments indicated that they were of a low or negligible impact. The Office of Best Practice Regulation agreed that the amendments were machinery in nature, notified approval of the preliminary assessment (RIS ID: 12531) and advised that a Regulatory Impact Statement (RIS) was not required.

Two options are identified in relation to the proposed amendments:

Option 1 – Not proceed with the amendments to Part 3 of the Handbook.

Option 2 – Proceed with the amendments to Part 3 of the Handbook.

3.1 Affected Parties

Parties affected by the amendments to Part 3 include:

- potential applicants who may be affected either positively or negatively
- FSANZ.

3.2 Benefit Cost Analysis

3.2.1 Option 1 – Not proceed with the amendments to Part 3 of the Handbook

3.2.1.1 Benefits

For applicants and FSANZ, this option would not result in any discernable benefits.

3.2.1.2 Costs

Applicants will be disadvantaged if their completion of the assessment of their applications is delayed due to insufficient information.

3.2.2 Option 2 – Proceed with the amendments to Part 3 of the Handbook

3.2.2.1 Benefits

FSANZ will not have to assess applications which are deficient in relevant data, thus freeing-up resources for other work.

Applicants will be able to release products into the market in a timely manner as their applications will be assessed by FSANZ without undue delays waiting for key information to be provided for the assessment to proceed.

3.2.2.2 Costs

For applicants and FSANZ, this option would not result in any discernable costs as the information is already required of applicants.

3.3 Comparison of Options

FSANZ considers the impact of various regulatory (and non-regulatory) options on all sectors of the community. FSANZ decided to proceed with the amendments.

4. COMMENCEMENT

The Part 3 variations will commence on 1 August 2011. Following registration, the amendments to Part 3 will be made to the *Application Handbook* and an updated version made available to the public on the Federal Register of Legislative Instruments. The amendments to Parts 1 and 2 will be included in an updated Handbook compilation and made available to the public on the FSANZ website on the same day as the registration of Part 3 as a legislative instrument.

5. PROPOSED AMENDMENTS TO PART 2 OF THE HANDBOOK (INFORMATION ONLY)

Parts 1 and 2 of the Handbook are for information only and are not included in the legislative instrument relating to the changes to Part 3. However, for the sake of completeness and transparency, reference has been made to them in this Explanatory Statement and attachments.

Most of the amendments are minor in nature and include correction of typographical errors and clarification of text.

The amendments to Parts 1 and 2 will be included in an updated Handbook compilation and made available to the public on the FSANZ website on the same day as the registration of Part 3 as a legislative instrument.

ATTACHMENTS

1. Amendments to Part 3 of the FSANZ *Application Handbook*
2. Submitters' and FSANZ comments
3. Amendments to Parts 1 and 2 of the FSANZ *Application Handbook*

AMENDMENTS TO PART 3 OF THEFSANZ *APPLICATION HANDBOOK*

SCHEDULE AMENDMENTS

Items [1], [4.1], [5], [7.3], [8.2], [8.9], [9.3], [10.1], [13.1], and [15.1]

These amendments correct typographical and grammatical errors or duplication of text.

Item [2]

This amendment changes the current spelling of micro-organism to be consistent with the spelling in the Code.

Items [3], [6], [7.2] part, [7.4], [8.3][8.8], [8.10]-[8.12], [9.1], [9.2], [10.2], [11.1], [12], [13.4]-[13.6] part, [14], [17]

These amendments include corrections of inconsistencies and minor points of clarification of data and information requirements.

Items[7.1], [7.2] part, [8.1], [9.4]-[9.6], [13.2], [13.6] part, [13.7]-[13.9]

These amendments reflect the Ministerial Council Policy guideline on the *Addition to Food of Substances other than Vitamins and Minerals* (the Policy Guideline).

Items [4.2], [9.7], [10.3], [11.2], [13.10], [15.2] and [18]

These amendments removed duplication of requirements that are already in Part 3.1. Item 4 adds some of this text into Part 3.1 to provide additional guidance.

Item [16]]

This amendment reflects the Ministerial Council Policy guideline on the *Intent of Part 2.9 – Special Purpose Foods*.

Item [19]

These amend the Checklist to assist applicants in ensuring they have met all mandatory format requirements and reflect changes made below.

FSANZ *Application Handbook* – Part 3 – Amendment No. 5 – 2011

Food Standards AustraliaNew Zealand Act 1991

Preamble

The amendments set forth in the Schedule below are variations to guidelines in Part 3 of the *FSANZ Application Handbook*, which was originally registered as a legislative instrument on 1 August 2007.

These amendments are published pursuant to section 23 of the *Food Standards AustraliaNew Zealand Act 1991*.

Citation

These amendments may be known collectively as the *FSANZ Application Handbook – Amendment No. 5 – 2011*.

Commencement

These variations will commence 1 August 2011.

SCHEDULE

[1] *Part 3* Contents of an Application *is varied by omitting –*

These sections of the *Food Standards Australia New Zealand Act 1991* provides that an application to vary a standard in the *Australia New Zealand Food Standards Code* must –
substituting –

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 –

[2] *Part 3* *is varied by omitting* micro-organism *wherever occurring, substituting* microorganism

[3] *Section 3.1* *is varied by–*

[3.1] *omitting from the Note* preceding 3.1.1 –

MANDATORY INFORMATION REQUIREMENTS

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

substituting –

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.

[3.2] *omitting from 3.1.1 –*

Applications sent by facsimile will not be accepted.

[3.3] *omitting from 3.1.1.B. –*

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

substituting –

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

[3.4] *omitting from 3.1.2 –*

(d) Telephone and facsimile numbers

substituting –

(d) Telephone number

[3.5] *omitting 3.1.3, substituting –*

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.

[3.6] *omitting 3.1.4, substituting –*

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.

[3.7] *omitting 3.1.5, substituting –*

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:<http://www.nhmrc.gov.au/publications/synopses/cp65syn.htm>.

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_1,0_0.html) and relevant OECD Guidelines for the Testing of Chemicals (http://www.oecd.org/departement/0,2688,en_2649_34377_1_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*.

[3.8] *omitting from 3.1.6–*

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

substituting –

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.

[3.9] *omitting from 3.1.7 –*

The applicant must identify any information he or she considers to be confidential commercial information.

substituting –

The applicant must identify any information they consider to be confidential commercial information.

[3.10] *omitting from the Note following A –*

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

A list of current official Codex standards can be found at
http://www.codexalimentarius.net/web/standard_list.do?lang=en

substituting –

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

A list of current official Codex standards can be found at
http://www.codexalimentarius.net/web/standard_list.do?lang=en.

[3.11] *omitting from 3.1.11 –*

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

substituting –

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*).

Note:

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.

[4] Section 3.2.1 is varied by –

[4.1] *omitting from A.–*

The application must contain the following information:

substituting –

The application must contain the following information:

[4.2] *omitting C.*

[5] Section 3.2.4 is varied by omitting from A.–

The application must contain the following information:

substituting –

The application must contain the following information:

[6] Section 3.2.5 is varied by –

[6.1] *omitting–*

Note:

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

[6.2] *omitting A.and B., substituting –*

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

ME means **metabolisable energy**

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

FE means energy lost in **faeces**.

UE means energy lost in **urine**.

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

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

The application must 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 (**ME, GE, UE, FE, GaE 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 **FE**, **UE**, **GaE** 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 FE = 4.8 kJ/g (0.3 x 16 kJ/g).

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

uFE: the proportion of the food ingredient that is excreted unchanged in the faeces

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

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 **mFE**, **oFE** 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 (uFE) from amounts that are *not* absorbed in the upper intestine (jejunum and duodenum).

- (e) 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:

	For ingredients fermented or partly fermented in the large intestine	For ingredients not fermented in the large intestine
mFE (as a % of the ingested food ingredient that is fermented in the large intestine)	30	Not applicable
oFE (as a % of the ingested food ingredient that is fermented in the large intestine)	0	Not applicable
GaE (as a % of the ingested food ingredient that is fermented in the large intestine)	5	Not applicable
SE (as a % of the ingested food ingredient)	0	0

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.

[7] Section 3.3.1 is varied by –

[7.1] omitting from A.1. –

- (b) the reason why the food additive is needed to fulfil these functions in each of the foods in which it is proposed to be used; and
- (c) if the food additive is a preservative, data to demonstrate its effectiveness in each of the foods in which it is proposed to be used.

substituting –

- (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.

[7.2] omitting A.8., substituting –

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.

[7.3] omitting the Note following B.2.(a) and B.2.(b) substituting –

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.

[7.4] *omitting C.1. to C.4., substituting –*

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.

[8] Section 3.3.2 is varied by –

[8.1] omitting A.1., substituting –

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.

[8.2] omitting (e) from the Note following A.1., substituting –

(e) Desiccating preparations

[8.3] omitting from A.2. –

if applicable.

substituting –

if applicable, and a statement as to whether or not the enzyme has been protein-engineered.

[8.4] omitting from A.3. –

If the processing aid is an enzyme, this must include information on its enzymatic properties.

substituting –

If the processing aid is an enzyme, this must include information on its technological function, including enzymatic properties.

[8.5] omitting from A.5. –

Where residues from the processing aid are likely to be present in the final food, an analytical method should be provided to 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.

substituting –

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.

[8.6] *omitting from B. –*

The substance or preparation (including enzyme preparation) assessed should be representative of the commercial product on which approval is sought.

substituting –

The chemical substance or preparation assessed should be representative of the commercial product on which approval is sought.

[8.7] *omitting B.3. and B.4., substituting –*

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.

[8.8] *omitting C.2., substituting –*

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.

[8.9] *omitting* non-toxinogenic from D.2., *substituting* non-toxigenic

[8.10] *omitting* E., *substituting* –

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.

[8.11] *omitting from the Note preceding F.1. –*

derived from analytical data on the level of the processing in the final foods.

substituting –

derived from analytical data on the level of the processing aid or its metabolite in the final foods.

[8.12] *omitting F.1. to F.4., substituting –*

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.

[9] **Section 3.3.3** is varied by –

[9.1] omitting A.2., substituting –

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.

[9.2] omitting A.6., substituting –

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.

[9.3] omitting the Note following B.2(a), substituting –

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.

[9.4] omitting C.1. to C.6., substituting –

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.

[9.5] *omitting D.1., substituting –*

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.

[9.6] *omitting the Note following F.3., substituting –*

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.

[9.7] *omitting G.*

[10] *Section 3.4.1 is varied by –*

[10.1] *omitting the Note following B.2., substituting –*

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.

[10.2] *inserting after C.2. –*

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.

[10.3] *omitting D.*

[11] *Section 3.4.2 is varied by–*

[11.1] *omitting D.1., substituting –*

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).

[11.2] *omitting E.*

[12] **Section 3.5.1** is varied by–

[12.1] *omitting from A.3.(d) –*

- (v) the identification and characterisation of any unexpected open reading frames within the inserted DNA or created by insertion with contiguous genomic DNA, including those that could result in fusion proteins or unexpected protein expression products.

substituting –

- (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. .

[12.2] *omitting A.4., substituting –*

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.

[12.3] *omitting B. and the Note following B., substituting –*

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.

Note:

There is no requirement to conduct acute or short-term oral toxicity studies in animals on novel protein. However, if the bioinformatic comparison and biochemical studies indicate either a relationship with known protein toxins/anti-nutrients or resistance to proteolysis, animal toxicity studies on the novel protein are required. Similarly, if novel substances are identified then animal toxicity studies are required.

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.

[12.4] *omitting C.1. to C.2. and the related Notes, substituting –*

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.

[13] **Section 3.5.2 is varied by –**

[13.1] *omitting from A –*

If exclusive permission is sought, the application must include details of the following:

substituting –

If exclusive permission is sought, the application must include details of the following:

[13.2] *inserting after B.1. and renumbering the following parts –*

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.

[13.3] *omitting from B.6. –*

The application should contain the following information:

substituting –

The application must contain the following information:

[13.4] *omitting from the Note following C.(IV & V)2. –*

The application should address the following categories of animal studies:

substituting –

The application should address the following categories of studies:

[13.5] *omitting the Note preceding D.1., substituting –*

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.

[13.6] *omitting D.1. to D.5., substituting –*

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.

[13.7] *omitting E., substituting –*

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.

[13.8] *omitting from F., immediately before F.1. –*

The application should contain the following information:

substituting –

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:

[13.9] *omitting the Note following F.3., substituting –*

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.

[13.10] *omitting* G.

[14] **Section 3.5.3** is varied by –

[14.1] *omitting* –

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

substituting –

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.

[14.2] *omitting* A. to C., *substituting* –

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 food 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 disinfection.

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.

[15] Section 3.6.1 is varied by—

[15.1] omitting –

1. A list of the foods likely to be affected by the proposed compositional change substituting –

2. A list of the foods likely to be affected by the proposed compositional change

[15.2] omitting D.

[16] Section 3.6.2 is omitted, substituting –

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 Guideline is available at

<http://www.foodstandards.gov.au/foodstandards/changingthecode/ministerialcouncilpolicyguidelines/>.

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:

Examples of relevant 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 WHO International Code of Marketing of Breast-milk Substitutes at <http://www.who.int/nutrition/publications/infantfeeding/9241541601/en/index.html> 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.

[17] **Section 3.7.1 is varied by –**

[17.1] *omitting the title, substituting –*

3.7.1 FOOD SAFETY STANDARDS

[17.2] *omitting B.*

[18] **Section 3.7.2 is varied by omitting B.**

[19] **Appendix 1** is amended by omitting all Checklists, substituting –

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)

- | | |
|---|--|
| <input type="checkbox"/> 3.1.1 Form of application
<input type="checkbox"/> <i>Executive Summary</i>
<input type="checkbox"/> <i>Relevant sections of Part 3 identified</i>
<input type="checkbox"/> <i>Pages sequentially numbered</i>
<input type="checkbox"/> <i>Electronic + 2 hard copies</i>
<input type="checkbox"/> <i>Electronic and hard copies identical</i>
<input type="checkbox"/> <i>Hard copies capable of being laid flat</i>
<input type="checkbox"/> <i>All references provided</i> | <input type="checkbox"/> 3.1.7 Confidential Commercial Information
<input type="checkbox"/> <i>Confidential material separated in both electronic and hard copy</i>
<input type="checkbox"/> <i>Justification provided</i> |
| <input type="checkbox"/> 3.1.2 Applicant details | <input type="checkbox"/> 3.1.8 Exclusive Capturable Commercial Benefit |
| <input type="checkbox"/> 3.1.3 Purpose of the application | <input type="checkbox"/> 3.1.9 International and Other National standards |
| <input type="checkbox"/> 3.1.4 Justification for the application | <input type="checkbox"/> 3.1.10 Statutory Declaration |
| <input type="checkbox"/> 3.2.5 Information to support the application | <input type="checkbox"/> 3.1.11 Checklist/s provided with Application
<input type="checkbox"/> <i>3.1 Checklist</i>
<input type="checkbox"/> <i>Any other relevant checklists for Sections 3.2-3.7</i> |
| <input type="checkbox"/> 3.1.6 Assessment procedure
<input type="checkbox"/> <i>General</i>
<input type="checkbox"/> <i>Major</i>
<input type="checkbox"/> <i>Minor</i> | |

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)

- | | |
|---|---|
| <input type="checkbox"/> A.1 Proposed labelling change | <input type="checkbox"/> B.2 Will proposed labelling be understood and assist consumers |
| <input type="checkbox"/> A.2 Foods potentially affected | <input type="checkbox"/> B.3 Will proposed labelling change have any adverse health or diet impacts |
| <input type="checkbox"/> B.1 Demonstrated consumer support for the labelling change | |

Warning and Advisory Statements (3.2.2)

- | | |
|---|--|
| <input type="checkbox"/> A.1 Data on potential health concern | <input type="checkbox"/> 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)

- | | |
|--|---|
| <input type="checkbox"/> A.1 Demonstration that the food causes IgE-mediated allergy | <input type="checkbox"/> A.3 Severity of allergic reaction |
| <input type="checkbox"/> A.2 Incidence of allergic reaction | <input type="checkbox"/> A.4 Extent of use of allergen in foods |

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

- | | |
|---|--|
| <input type="checkbox"/> B.1 Nature of food derivative | <input type="checkbox"/> B.4 History of safe use |
| <input type="checkbox"/> B.2 Use of food derivative | <input type="checkbox"/> B.5 Clinical information on safety of food derivative |
| <input type="checkbox"/> B.3 Dietary intake information | |

Labelling for Consumer Information and Choice (3.2.4)

- | | |
|--|---|
| <input type="checkbox"/> A.1 Current labelling or alternative information inadequacies | <input type="checkbox"/> A.3 How will proposed labelling change assist consumers |
| <input type="checkbox"/> A.2 Information on lack of suitable alternatives available to consumers | <input type="checkbox"/> A.4 Information to demonstrate absence of labelling would not be effective |

Nutrition Information Labelling (3.2.5)

- | | |
|--|--|
| <input type="checkbox"/> A.1 Description of proposed change and how it will change nutrition information labelling | <input type="checkbox"/> B.3.(II) Substantiation of energy factor – Classical dietary energy balance |
| <input type="checkbox"/> A.2 Data to demonstrate labelling will assist consumers | <input type="checkbox"/> B.3.(III) Substantiation of energy factor – Isometric tracer methods |
| <input type="checkbox"/> B.1. Nature and composition of the ingredient | <input type="checkbox"/> B.3.(IV) Substantiation of energy factor – Breath hydrogen test |
| <input type="checkbox"/> B.2. Calculation of energy factor | <input type="checkbox"/> B.3.(V) Substantiation of energy factor – Ileal intubation and ileostomy effluent |
| <input type="checkbox"/> B.3.(I) Substantiation of energy factor – Bomb calorimetry | <input type="checkbox"/> 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)

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

Processing Aids (3.3.2)

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

- | | |
|---|---|
| <input type="checkbox"/> B.3 Toxicokinetics and metabolism information (chemical only) | <input type="checkbox"/> F.3 Information on likely level of consumption |
| <input type="checkbox"/> B.4 Toxicity information (chemical only) | <input type="checkbox"/> F.4 Percentage of food group to use processing aid |
| <input type="checkbox"/> B.5 Safety assessments from international agencies (chemical only) | <input type="checkbox"/> F.5 Information on residues in foods in other countries (if available) |
| <input type="checkbox"/> C.1 Information on enzyme use on other countries (enzyme only) | <input type="checkbox"/> F.6 Where consumption has changed, information on likely consumption |
| <input type="checkbox"/> C.2 Toxicity information of enzyme (enzyme only) | |

Nutritive Substances (3.3.3)

- | | |
|---|---|
| <input type="checkbox"/> A.1 Identification information | <input type="checkbox"/> C.2 Proposed maximum levels in food groups or foods |
| <input type="checkbox"/> A.2 Chemical and physical properties | <input type="checkbox"/> C.3 Likely level of consumption |
| <input type="checkbox"/> A.3 Impurity profile information | <input type="checkbox"/> C.4 Percentage of food group to use nutritive substance |
| <input type="checkbox"/> A.4 Manufacturing process | <input type="checkbox"/> C.5 Use in other countries (if available) |
| <input type="checkbox"/> A.5 Specification information | <input type="checkbox"/> C.6 Where consumption has changed, information on likely consumption |
| <input type="checkbox"/> A.6 Analytical detection method | <input type="checkbox"/> D.1 Nutritional purpose |
| <input type="checkbox"/> A.7 Proposed food label | <input type="checkbox"/> E.1 Need for nutritive substance |
| <input type="checkbox"/> B.1 Toxicokinetics and metabolism information | <input type="checkbox"/> E.2 Demonstrated potential deficit or health benefit |
| <input type="checkbox"/> B.2 Animal or human toxicity studies | <input type="checkbox"/> F.1 Consumer awareness and understanding |
| <input type="checkbox"/> B.3 Safety assessments from international agencies | <input type="checkbox"/> F.2 Actual or potential behaviour of consumers |
| <input type="checkbox"/> C.1 List of food groups or foods likely to contain the nutritive substance | <input type="checkbox"/> F.3 Demonstration of no adverse effects on any population groups |

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)

- | | |
|--|--|
| <input type="checkbox"/> A.1 Nature of contaminant or natural toxicant | <input type="checkbox"/> C.1 List of foods where maximum level is proposed |
|--|--|

- | | |
|--|---|
| <input type="checkbox"/> A.2 Analytical detection method | <input type="checkbox"/> C.2 Survey data on contaminant or toxicant levels in foods |
| <input type="checkbox"/> B.1 Toxicokinetics & metabolism information | <input type="checkbox"/> C.3 Information on levels of consumption |
| <input type="checkbox"/> B.2 Toxicity studies | <input type="checkbox"/> C.4 Where consumption has changed, information on likely consumption |
| <input type="checkbox"/> B.3 Human studies relevant to safety | |

Microbiological Limits (3.4.2)

- | | |
|---|--|
| <input type="checkbox"/> A.1 Raw inputs, production and manufacturing process | <input type="checkbox"/> B.3 Consumer handling and use |
| <input type="checkbox"/> A.2 Food technology | <input type="checkbox"/> C.1 Nutritional impact |
| <input type="checkbox"/> B.1 Nature of the microbiological hazard | <input type="checkbox"/> D.1 Dietary exposure |
| <input type="checkbox"/> B.2 Source & prevalence of contamination | |

Prohibited and Restricted Plants and Fungi (3.4.3)

- | | |
|---|--|
| <input type="checkbox"/> A.1 Nature of plant or fungi | <input type="checkbox"/> B.2 Human toxicity case studies |
| <input type="checkbox"/> A.2 Identity and levels of natural toxicants | <input type="checkbox"/> B.3 Use in other countries |
| <input type="checkbox"/> B.1 Toxicity studies | |

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)

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

Novel Foods (3.5.2)

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

C–Information on the safety of the novel food

(I) Plant or animal extracts

- | | |
|---|---|
| <input type="checkbox"/> 1. Extraction and composition | <input type="checkbox"/> 3. Current use |
| <input type="checkbox"/> 2. Effects of food processing or preparation | <input type="checkbox"/> 4. Potential adverse effects |

(II) Plant and animal extracts

- | | |
|---|--|
| <input type="checkbox"/> 1. Method or extraction and composition of extract | <input type="checkbox"/> 3. Toxicity studies |
| <input type="checkbox"/> 2. Use as a food in other countries | <input type="checkbox"/> 4. Safety assessments from other agencies |

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

- | | |
|---|--|
| <input type="checkbox"/> 1. History of use | <input type="checkbox"/> 5. Potential allergenicity |
| <input type="checkbox"/> 2. Composition | <input type="checkbox"/> 6. Toxicity studies |
| <input type="checkbox"/> 3. Method of extraction and composition of extract | <input type="checkbox"/> 7. Safety assessments from other agencies |
| <input type="checkbox"/> 4. Use in other countries | |

(IV & V) Single chemical entities & Dietary macrocomponents

- | | |
|---|--|
| <input type="checkbox"/> 1. Toxicokinetics and metabolism | <input type="checkbox"/> 3. Safety assessments from other agencies |
| <input type="checkbox"/> 2. Toxicity studies | |

(VI) Microorganisms (including probiotics)

- | | |
|---|--|
| <input type="checkbox"/> 1. Potential pathogenicity | <input type="checkbox"/> 3. Use as a food in other countries |
| <input type="checkbox"/> 2. Effects on gut microflora | <input type="checkbox"/> 4. Human toleration studies |

(VII) Food ingredients derived from a new source

- | | |
|---|---|
| <input type="checkbox"/> 1. Safety of the source organism, including allergen statement | <input type="checkbox"/> 3. Toxicity studies |
| <input type="checkbox"/> 2. Composition | <input type="checkbox"/> 4. Overseas safety reports |

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

- | | |
|--|---|
| <input type="checkbox"/> 1. Details of the new process | <input type="checkbox"/> 3. Overseas safety reports |
| <input type="checkbox"/> 2. Toxicity studies | |

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

Irradiated Foods (3.5.3)

- | | |
|---|--|
| <input type="checkbox"/> A.1 Nature of the food or food ingredient to be irradiated | <input type="checkbox"/> B. Safety Information |
| <input type="checkbox"/> A.2 Technological need | <input type="checkbox"/> c. Nutritional impact |
| <input type="checkbox"/> A.3 Food products likely to contain irradiated food | |

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)

- | | |
|--|---|
| <input type="checkbox"/> A.1 Proposed compositional change | <input type="checkbox"/> C.1 Demonstrated consumer understanding of proposed change |
| <input type="checkbox"/> A.2 List of foods likely to be affected | <input type="checkbox"/> C.2 Potential adverse health or diet impacts |
| <input type="checkbox"/> B.1 Nutritional content | <input type="checkbox"/> |

Special Purpose Foods (3.6.2)

- | | |
|--|--|
| <input type="checkbox"/> A.1 Safety of proposed compositional change | <input type="checkbox"/> B.3 Level of consumption |
| <input type="checkbox"/> A.2 Nutritional impact of compositional change | <input type="checkbox"/> C.1 Safety and nutritional impact of labelling change |
| <input type="checkbox"/> A.3 Internationally recognised codes of Practice and guidelines | <input type="checkbox"/> C.2 Demonstrated understanding of labelling change |
| <input type="checkbox"/> B.1 Target population | <input type="checkbox"/> C.3 Internationally recognised codes of Practice and guidelines |
| <input type="checkbox"/> B.2 Dietary exposure information | |

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)

- | | |
|--|---|
| <input type="checkbox"/> A.1 Public health and safety data | <input type="checkbox"/> B.1 Projected costs to food industry |
|--|---|
-

Food Processing and Primary Production (3.7.2)

- | | |
|--|--------------------------|
| <input type="checkbox"/> A.1 Public health and safety data | <input type="checkbox"/> |
|--|--------------------------|
-

ATTACHMENT 2

SUBMITTERS' AND FSANZ'S COMMENTS

Submitters:

Food Technology Association of Australia (Paul Habojan) (supported all suggested amendments)

SA Department of Health [SA Health] (Joanne Cammans)

Vic Department of Health (John Ward)

Qld Health (Gary Bielby)

New Zealand Ministry of Agriculture and Forestry [MAF] (Jenny Reid)

European Association of Manufacturers and Formulators of Enzyme Products [AMFEP] (Youri Skaskevitch)

US Enzyme Technical Association [ETA] (John Carroll)

The following tables include only those issues where submitters did not agree with the proposed amendments or suggested additional amendments.

[Item] Issue	Submitter	FSANZ Comment / Action
MANDATORY REQUIREMENTS IN PART 3 [Item No.]		
[3.5] Unclear as to why the amendment was proposed as useful information was provided for applicants.	MAF	<i>Noted – these changes were proposed to clarify the difference between the 'purpose' of an application and the 'justification' for the proposed changes. The information is still there in 1.1.</i>
[3.6] Additional guidance may be required about what details need to be provided if similar applications made in other countries: 1. Any additional information requested? 2. If so, provide that information to FSANZ. 3. Outcome? 4. Was application rejected?	Qld Health	<i>Noted– FSANZ believes 3. and 4. are covered by the existing reference to 'status'.</i>
[3.6] Health costs and benefits – difficult to quantify – long term studies may be required.	Qld Health	<i>Noted – FSANZ believes we cannot be too prescriptive and this is why we strongly recommend a pre-lodgement meeting to determine adequacy.</i>
[3.6] Why was 3.1.4.(c) duplicated in 3.1.5 (c) Typographical error in 3.1.4(b)	MAF	<i>Noted – this was a text error. The duplication has been removed from 3.1.4 and the typographical error corrected. See comment above for [3.5] to explain reason for amendment.</i>

[Item] Issue	Submitter	FSANZ Comment / Action
[3.6] Regulatory costs – guidance may need to be provided to applications on level of detail required e.g. costs for testing.	Qld Health	<i>Noted – FSANZ believes we cannot be too prescriptive and this is why we strongly recommend a pre-lodgement meeting to determine adequacy.</i>
[3.7] Several minor corrections to text suggested.	MAF	<i>Noted – amendments to text made. Heading 2 amended.</i>
[3.10] Clarification of the status of note boxes	MAF	<i>Noted – in line with the status of boxed text in Australian legislation, information in the note boxes is advisory only, providing additional information to assist applicants in meeting the information requirements. FSANZ has reviewed all text boxes and no information remains that would be considered mandatory. FSANZ has included a reference under Part 1.4 on navigating the Handbook to explain their purpose.</i>
[3.10] Note may be missing text	MAF	<i>Noted – Text amended.</i>
[6] Existing Ed note prior to new A. needs to be amended	MAF	<i>Noted – text amended</i>
[6] Numbering system for A. and B. differs.	MAF	<i>Noted – no further action. The numbering is different to the number of heading levels. B. is consistent with the numbering of 3.5.2.</i>

[Item] Issue	Submitter	FSANZ Comment / Action
<p>[6] Comments and suggested amendments in relation to the calculation of the energy factor:</p> <p>(a) a request to include colonic thermogenesis as part of calculations on large intestinal fermentation</p> <p>(b) a request to acknowledge the limitations of the studies provided</p>	MAF	<p><i>Noted – The equation for calculating an energy factor (Clause 2 of Standard 1.2.8) is an equation for metabolisable energy (ME). ME is an energy value that specifically excludes the energy losses associated with the thermogenesis of food. Therefore, FSANZ does not agree with the inclusion of thermogenesis within the calculation of large intestinal fermentation, as this would be inconsistent with the definition of ME</i></p> <p><i>The Handbook details the information that an application needs to include. It is not a document explaining how FSANZ will interpret this information, or use this information in its assessments. Therefore FSANZ does not agree with the need to provide further discussion on the limitations of the studies used to substantiate an energy factor calculation. An assessment of the quality of the studies that are provided can occur once an application is received.</i></p>
<p>[7.2] Title and text of paragraph 9 need to be clearer.</p>	MAF	<p><i>Noted – Text amended</i></p>
<p>[8.3] Is 'or not' required?</p>	MAF	<p><i>Noted – Text amended.</i></p>
<p>[8.5] Does not support the requirement for analytical methodology to detect and quantify residues from enzyme processing aids.</p>	AMFEP ETA	<p><i>Noted– FSANZ agrees that there is very limited benefit in requiring analytical methodology for enzymatic processing aids. This is due to enzyme processing aids being absent or present at very low levels in the final food, and if present are likely to be in an inactivated form. Therefore the text has been modified.</i></p>
<p>[8.8] Agrees in-principle with proposed elements, but instead suggests a tiered approach based on Codex Commission (details provided in submission).</p>	AMFEP ETA	<p><i>Noted – FSANZ has considered the evidence and modified the requirements such that digestibility and serum testing are only required when the enzyme is derived from an allergenic source and has significant compositional similarity to an allergenic protein</i></p>

[Item] Issue	Submitter	FSANZ Comment / Action
[9.1] Rationale for amendment not clear.	MAF	<i>Noted – The references to metabolic fate and nutritive purpose were removed because they are adequately covered in B1 and D1 respectively.</i>
[9.5] Incorrect paragraph numbering.	MAF	<i>Noted – amendment made.</i>
[9.5] Query re change from 'demonstrated' to 'intended'	MAF	<i>Noted – text amended.</i>
[9.5] Is the existing Note following D retained	MAF	<i>Yes – if the Note was to be removed, it would specifically be mentioned.</i>
[11.1] A note is mentioned in the instruction – there is no note in the 1 July 2010 version of the Handbook.	MAF	<i>Noted – reference removed</i>
[12.4] If feeding studies are submitted, they should meet the data requirements in 3.1.5. Noted that where previously provided, feeding studies provided by applicants have been limited. Independent data should be provided. FSANZ should not rely solely on applicant data.	Qld Health	<i>Noted – FSANZ has clarified the requirements to provide methodology.</i> <i>FSANZ has quality controls in place regarding the acceptability of all data submitted for evaluation, regardless of its source. Since feeding studies are optional, FSANZ will not stipulate data requirements.</i>
[12.2] and 1.2.4 in Explanatory Statement Concern with proposed deletion of requirement for provision of methodology to detect and quantify GM DNA.	Vic Health SA Health	<i>Noted – FSANZ has clarified the requirements to provide methodology.</i>
[12.2] Supports the proposed amendment, but seeks improvement to wording and questions its placement under Part A, Section 4, which concerns labelling of the GM food.	MAF	<i>Agreed – Text amended to improve clarity of information requirements. Reference to labelling is not appropriate and will be replaced with text relating to compliance.</i>
[12.2] and [12.3] Text from [12.2] located in [12.3] text.	MAF	<i>Noted – text corrected.</i>
[13.1] Typographical error in drafting.	MAF	<i>Noted – text corrected.</i>
[14.2] Reference to Biosecurity New Zealand to be replaced with New Zealand MAF.	MAF	<i>Noted – text corrected.</i>

[Item] Issue	Submitter	FSANZ Comment / Action
<p>[16] Under B, it should be clearer that this refers to 'current' dietary exposure. It could be interpreted that data on potential dietary exposure of the substance to target populations is sought. If this is the case, then that should be clear in the Application Handbook.</p> <p>In addition, if the information sought also relates to food categories or food types, this should be explicit.</p>	MAF	<p><i>Noted – Text amended.</i> <i>This text does not refer to 'current' dietary exposure, but the 'expected' intake/exposure of the substance when added to food.</i></p>
<p>[16] Under B.1, 'altered energy intake' is too narrow – perhaps reference to other nutrients.</p>	MAF	<p><i>Noted – Text amended.</i></p>
<p>[16] Under C, it might be possible that a change to the general labelling requirements might be sought. Perhaps broaden information requirement.</p>	MAF	<p><i>Noted – Text added to paragraph prior to part A to make it clear that the requirements in Part 3.6.2 are in addition to the general requirements in Part.3.2.</i></p>

[Item] Issue	Submitter	FSANZ Comment / Action
OTHER [Item No.]		
Include OBPR acronym in abbreviations section	Qld Health	Text amended
Definition of 'application guideline' required.	MAF	<p><i>Noted – No further action.</i> <i>Information on what constitutes an application guideline' i.e. part 3 of the handbook, is included on the Part 3 introductory page.</i></p>
Use of and/or Removal of references in line with Code audit.	MAF	<p><i>Noted – a number of these references were removed in this update. Other occurrences will be dealt with in next amendment.</i></p>
[12.3] Removal of 7(c)	FSANZ	<p><i>FSANZ has removed this text which was included in error.</i></p>
Additional minor corrections to formatting, punctuation and correction of text in Parts 1, 2 and 3 for which no further public comment was required due to their machinery nature.	FSANZ	<p><i>Text amended</i></p>

AMENDMENTS TO PARTS 1 AND 2 OF THE FSANZ APPLICATION HANDBOOK

SCHEDULE AMENDMENTS

Item [1]

This amendment amends the Abbreviations and Acronyms section to include a reference to the OBPR and amend a reference to the NHMRC.

Item [2]

This amendment changes the current spelling of micro-organism to be consistent with the spelling in the Code.

Items [3], [6], [7], [8] [9], [10.1] and [12]

These amendments clarify the information provided to assist potential applicants.

Item [5] and [11]

This amendment clarifies how changes to the Code take effect after the Ministerial Council process has been finalised.

Item [10.2]

This amendment corrects a typographical error.

SCHEDULE

[1] Acronyms and Abbreviations *are varied by –*

[1.1] *omitting* National Health Medical Research Council, *and inserting* National Health & Medical Research Council

[1.2] *inserting –*

OBPR Office of Best Practice Regulation

[2] **Parts 1 and 2** *are varied by omitting* micro-organism *wherever occurring, substituting* microorganism

[3] **Section 1.1** *is varied by omitting –*

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

Potential applicants are encouraged to discuss their application with FSANZ prior to submission in order to clarify the nature of the application and to identify the information required in the application. Potential applicants are also strongly encouraged to discuss their potential application and possible amendments to the Code with relevant food enforcement agencies prior to making an application or any discussion with FSANZ.

Furthermore, potential applicants are strongly encouraged to seek their own independent legal advice on proposed amendments to the Code. FSANZ cannot provide an interpretation of the Code.

substituting –

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.

[4] **Section 1.3.1** is varied by omitting –

Once the Ministerial Council process is finalised, the variations to the Standards are gazetted and then automatically adopted by reference under food legislation of the Commonwealth of Australia, the Australian States and Territories and New Zealand.

substituting –

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*.

[5] **Section 1.4** is varied by inserting after 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.

[6] **Section 2.1.1** is varied by inserting after 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.

[7] ***Section 2.1.2 is varied by omitting –***

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 the following address:

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

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.

substituting –

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 commences on 1 May 2011. The scheme aims to promote transparency and pro-disclosure and will mean that all applications to change the *Australia New Zealand Food Standards 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.

[8] **Section 2.1.4** *is varied by omitting –*

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

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

substituting –

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 (AXXX)
SWIFT Code: CTBAU2S

[9] **Section 2.1.5** *is varied by omitting or the Public Register*

[10] **Section 2.1.6** *is varied by –*

[10.1] *omitting –*

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

substituting –

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

[10.2] *omitting the second occurrence of–*

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

[11] **Section 2.2.8** *is omitted, substituting–*

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.

[12] **Section 2.2.9** is omitted, substituting—

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.