FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

FOOD STANDARDS AUSTRALIA NEW ZEALAND

APPLICATION HANDBOOK

Contents

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PART 3

CONTENTS
OF AN APPLICATION

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

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

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

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SECTION 3.1

GENERAL REQUIREMENTS

3.1 GENERAL REQUIREMENTS

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

Note:

CONSULTATION WITH FSANZ

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

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

TYPES OF APPLICATIONS

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

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

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

MANDATORY INFORMATION REQUIREMENTS

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

NON-MANDATORY INFORMATION REQUIREMENTS

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

3.1.1 FORM OF THE APPLICATION

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

Applications sent by facsimile will not be accepted.

A. Language

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

B. Format

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

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

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

C. Copies

Applications must be lodged in both electronic and hard copy.

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

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

3.1.2 APPLICANT DETAILS

The application must contain the following contact details:

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

3.1.3 PURPOSE OF THE APPLICATION

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

Note:

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

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

3.1.4 JUSTIFICATION FOR THE APPLICATION

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

Note:

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

3.1.5 INFORMATION TO SUPPORT THE APPLICATION

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

Note:

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

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

Note:

QUALITY OF DATA

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

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

All types of data

(a) The source, author(s) and year the data was produced should be provided.

(b) The data provided should be obtained using validated or standardised methods, where these are available. Standardised methods should be validated for accuracy and reproducibility, and declare the sensitivity and specificity of the method where appropriate.

(c) The data provided should be analysed using appropriate statistical techniques.

Data from literature searches

(a) Literature searches should identify the databases searched (such as MEDLINE, EMBASE, TOXLINE, FSTA, Science Citation Index, BIOSIS, PsycINFO, or the Australian Medical Index etc).

(b) Literature searches should identify the criteria used to specify the search, such as the key words, the time period of the search, and any other limiting criteria.

(c) Literature searches should identify all of the papers identified in the search and provide an analysis according to the NHMRC *Guidelines for the review of scientific literature*. These Guidelines can be found at: http://www.nhmrc.gov.au/publications/synopses/cp65syn.htm

Data related to safety studies

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

(b) Studies designed to establish evidence for a diet-disease relationship in humans should be conducted in accordance with the NHMRC 2000 publication *How to use the evidence: assessment and application of scientific evidence*. This can be found at: http://www.nhmrc.gov.au/publications/synopses/cp69syn.htm.

(c) All studies conducted for a regulatory purpose should be accompanied by evidence of a quality control/assurance program or evidence of independent auditing of the conduct and reporting of the study.

(d) Safety studies should contain full details of the conduct of the study and its results, including raw data where appropriate. Summaries alone of study results are not adequate for safety assessment purposes.

Data related to surveys on chemicals in food

(a) The survey design and method should be clearly enunciated along with the findings and the conclusions. Where surveys are designed to be targeted or selective, the basis for doing so should be clearly stated

(b) The survey should maximise representation and avoid skewing results from unrepresentative (abnormal) samples by sampling a sufficient number of representative samples across different subjects/respondents, regions/locations, times/seasons, manufacturers/producers, conditions etc. The numbers of samples surveyed should be statistically significant. The sample size and the sample pool should be stated. All samples collected should be surveyed consistently in accordance with the pre determined survey plan. If samples are excluded from being considered in the survey the basis for excluding them should be defined and reported.

(c) Where surveys involve laboratory analysis, international (International Standards Organisation (ISO)) or national (Australian Standard (AS)) test method should be used, where possible. Where no standard method exists (e.g. vitamin analysis, emerging micro-organisms) credible test methods should be used.

(d) Laboratories must provide evidence of accreditation to the International Organisation for Standardization standard *ISO 17025 – General Requirements for the Competence of Calibration and Testing Laboratories.* In Australia, laboratories should be NATA accredited.

(e) Surveys should include evidence of quality control/assurance systems. Information on limits of reporting should also be included.

Data related to consumer research

(a) Consumer and/or market research should be consistent with the International Organization for Standardization standard ISO 20253:2006 *Market, opinion and social research – vocabulary and service requirements*.

(b) In Australia, such research should comply with the Australian Standard AS44752 – *Australian and Social Research Standard* or its equivalent.

3.1.6 ASSESSMENT PROCEDURE

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

3.1.7 CONFIDENTIAL COMMERCIAL INFORMATION (CCI)

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

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

Note:

See Section 2.1.5 for further information on CCI.

3.1.8 EXCLUSIVE CAPTURABLE COMMERCIAL BENEFIT (ECCB)

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

Note:

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

3.1.9 INTERNATIONAL AND OTHER NATIONAL STANDARDS

A. International Standards

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

Note:

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

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

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

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

B. Other National Standards or Regulations

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

3.1.10 STATUTORY DECLARATION

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

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

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

3.1.11 CHECKLIST

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

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

SECTION 3.2

STANDARDS RELATED TO LABELLING AND OTHER INFORMATION REQUIREMENTS

3.2.1 GENERAL FOOD LABELLING

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

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

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

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

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

A. General information on the application

The application must contain the following general information:

1. Purpose of the application

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

2. Justification for the application

This part includes general statements addressing:

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

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

B. General information to support the proposed labelling change

The application must contain the following information:

1. A description of the proposed labelling change

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

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

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

Note:

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

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

The application must contain the following information:

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

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

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

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

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

Note:

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

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

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

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

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

The application must contain the following information:

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

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

2. Impact on international trade

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

Note:

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

3.2.2 WARNING AND ADVISORY STATEMENTS

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

Note:

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

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

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

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

The application must contain the following information:

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

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

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

Note:

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

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

The application must contain the following information:

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

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

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

3.2.3 DECLARATION OF ALLERGENS

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

Note:

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

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

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

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

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

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

The application must contain the following information:

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

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

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

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

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

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

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

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

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

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

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

The application must contain the following information:

1. Information on the nature of the food derivative

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

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

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

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

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

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

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

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

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

Note:

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

3.2.4 LABELLING FOR CONSUMER INFORMATION AND CHOICE

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

Note:

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

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

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

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

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

The application must contain the following information:

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

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

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

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

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

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

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

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

Note:

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

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

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

3.2.5 NUTRITION INFORMATION LABELLING

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

Note:

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

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

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

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

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

The application must contain the following information:

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

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

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

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

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

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

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

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

Note:

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

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

> ***Energy factor*** *means the metabolisable energy (ME) of the food component calculated according to the following formula, expressed in kilojoules per gram of food component, rounded to the nearest whole number -*
>
> ***ME = GE – FE – UE – GaE – SE***
>
> *Where –*
>
> ***ME*** *means metabolisable energy*
> ***GE*** *means gross energy (as measured by bomb calorimetry)*
> ***FE*** *means energy lost in faeces*
> ***UE*** *means energy lost in urine*
> ***GaE*** *means the energy lost in gases produced by fermentation in the large intestine*
> ***SE*** *means the energy content of waste products lost from surface areas*

The application must contain the following information:

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

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

2. Measures or estimates of energy for the food ingredient

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

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

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

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

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

Note:

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

SECTION 3.3

STANDARDS RELATED TO SUBSTANCES ADDED TO FOOD

3.3.1 FOOD ADDITIVES

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

Note:

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

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

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

A. General information on the application

The application must contain the following information:

1. Purpose of the application

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

2. Justification for the application

This part includes general statements addressing:

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

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

3. Support for the application

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

B. Technical information on the food additive

The application must contain the following technical information:

1. Nature and technological function of the additive

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

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

2. Information to enable identification of the additive

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

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

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

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

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

4. Information on the impurity profile

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

5. Manufacturing process

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

6. Specification for identity and purity

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

7. Information for food labelling

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

8. Analytical method for detection

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

C. Information related to the safety of the food additive

Note:

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

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

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

(a) For an application for a new food additive, this part includes detailed reports of all studies conducted in animals or humans to examine the metabolic fate of the food additive and, if necessary, its degradation products or major metabolites.

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

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

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

Note:

The application should address the following categories of animal studies:

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

(g) Special studies, such as neurotoxicity or immunotoxicity

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

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

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

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

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

Note:

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

The application must contain the following information:

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

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

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

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

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

The application should contain the following information:

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

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

Note:

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

3.3.2 PROCESSING AIDS

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

Note:

Standard 1.3.3 defines a processing aid as follows:

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

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

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

A. General information on the application

The application must contain the following information:

1. Purpose of the application

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

2. Justification for the application

This part includes general statements addressing:

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

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

3. Support for the application

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

B. Technical information on the processing aid

The application must contain the following information:

1. Information on the type of processing aid

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

Note:

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

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

2. Information on the identity of the processing aid

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

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

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

4. Manufacturing process

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

5. Specification for identity and purity

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

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

The application must contain the following information:

1. General information on the industrial use of the chemical

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

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

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

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

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

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

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

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

Note:

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

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

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

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

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

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

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

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

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

The application must contain the following information:

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

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

2. Information on the toxicity of the enzyme processing aid

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

Note:

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

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

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

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

The application must contain the following additional information:

1. Information on the source micro-organism

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

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

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

3. Information on the genetic stability of the source organism

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

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

The application must contain the following additional information:

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

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

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

Note:

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

The application must contain the following information:

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

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

2. The levels of residues of the processing aid or its metabolites for each food or food group

3. The percentage of the food group in which the processing aid is likely to be found or the percentage of the market likely to use the processing aid

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

The application should contain the following information:

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

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

Note:

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

3.3.3 NUTRITIVE SUBSTANCES

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

Note:

Standard 1.1.1 defines a nutritive substance as follows:

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

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

For further information regarding both voluntary and mandatory addition of vitamins and minerals to food, see the *Fortification Implementation Framework* which was prepared by FSANZ in May 2005 (http://www.foodstandards.gov.au/_srcfiles/Fort_Imple_Frame_May05_2.pdf#search=%22fortification%20framework%22)

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

A. General information on the application

The application must contain the following information:

1. Purpose of the application

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

2. Justification for the application

This part includes general statements addressing:

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

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

Note:

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

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

3. Support for the application

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

B. Technical information on the nutritive substance

The application must contain the following technical information:

1. Information to enable identification of the nutritive substance

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

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

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

3. Information on the impurity profile

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

4. Manufacturing process

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

5. Specification for identity and purity

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

6. Analytical method for detection

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

7. Information on the proposed food label

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

C. Information related to the safety of the nutritive substance

Note:

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

The application must contain the following information**:**

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

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

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

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

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

Note:

The following categories of animal studies need to be considered:

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

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

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

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

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

D. Information on dietary exposure to the nutritive substance

Note:

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

The application must contain the following information:

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

2. The maximum proposed level of the nutritive substance for each food group or food, or the proposed changes to the currently permitted levels

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

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

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

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

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

Note:

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

The application should include the following information:

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

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

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

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

Note:

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

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

The application must contain the following information:

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

This part includes:

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

Note:

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

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

Refer to Section 3.1.8 for further information regarding data quality.

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

The application must contain the following information:

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

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

(a) data to demonstrate clinical or sub-clinical evidence of deficiency or data to demonstrate low levels of intake in one or more population groups; or
(b) data to demonstrate that deficiencies are likely to develop in one or more population groups because of changing food habits; or
(c) generally accepted scientific evidence that an increase in the intake of a vitamin and/or mineral can deliver a health benefit; or
(d) evidence that the reduced nutritional profile of a processed food can be substantially restored; or
(e) evidence that the nutritional profile of specified substitute food2 can be aligned with the primary food.

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

This part includes:

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

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

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

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

Note:

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

The application must contain the following information:

1. Information to demonstrate consumer awareness and understanding of the nutritive substances in the food(s)

2. Information on the actual and/or potential behaviour of consumers in response to proposed food(s)

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

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

Note:

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

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

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

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

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

The application must contain the following information:

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

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

2. Impact on international trade

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

Note:

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

SECTION 3.4

STANDARDS RELATED TO CONTAMINANTS AND NATURAL TOXICANTS

3.4.1 CHEMICAL CONTAMINANT AND NATURAL TOXICANT MAXIMUM LEVELS

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

Note:

The purpose of Standard 1.4.1 is stated as follows:

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

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

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

Standard 1.4.1 contains the following definition:

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

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

A. General information on the application

The application must contain the following general information:

1. Purpose of the application

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

2. Justification for the application

This part includes general statements addressing:

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

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

B. General information on the contaminant or natural toxicant

The application must contain the following:

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

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

2. Analytical method for detection

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

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

The application must contain the following:

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

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

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

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

Note:

The following categories of animal studies need to be considered:

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

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

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

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

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

The application must contain the following information:

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

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

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

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

Note:

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

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

The application must contain the following information:

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

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

2. Impact on international trade

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

Note:

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

3.4.2 MICROBIOLOGICAL LIMITS

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

Note:

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

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

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

A. General information on the application

The application must contain the following general information:

1. Purpose of the application

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

2. Justification for the application

This part includes general statements addressing:

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

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

B. Technical information on food production methods

The application must contain the following information:

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

This part includes:

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

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

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

C. Information related to food safety

The application must contain the following information:

1. Nature of the microbiological hazard

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

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

This part includes:

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

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

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

D. Information on the nutritional impact

The application must contain the following information:

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

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

E. Information related to dietary exposure

The application must contain the following information:

1. Food consumption data, if applicable

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

Note:

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

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

The application must contain the following information:

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

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

2. Impact on international trade

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

Note:

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

3.4.3 PROHIBITED AND RESTRICTED PLANTS AND FUNGI

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

Note:

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

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

A. General information on the application

The application must contain the following general information:

1. Purpose of the application

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

2. Justification for the application

This part includes general statements addressing:

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

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

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

The application must contain the following:

1. Nature of the plant or fungi

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

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

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

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

The application must contain the following:

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

This part includes a literature survey of relevant toxicity literature.

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

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

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

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

SECTION 3.5

STANDARDS RELATED TO NEW FOODS

3.5.1 FOODS PRODUCED USING GENE TECHNOLOGY

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

Note:

In Standard 1.5.2, there are the following definitions:

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

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

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

A. General information on the application

The application must contain the following information:

1. Purpose of the application

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

2. Justification for the application

This part includes general statements addressing:

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

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

B. Technical information on the genetically modified food

The application must contain the following information:

1. Nature and identity of the genetically modified food

This part includes all of the following:

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

2. History of use of the host and donor organisms

This part includes all of the following:

(a) A description of all the donor organism(s) from which the genetic elements are derived, including:

    (i) common and scientific names and taxonomic classification;
    (ii) information about any known pathogenicity, toxicity or allergenicity of relevance to the food; and
    (iii) information about the history of use of the organism in the food supply or history of human exposure to the organism through other than intended food use (e.g. as a normal contaminant).

(b) A description of the host organism into which the genes were transferred and its history of safe use for food, including:

    (i) any relevant phenotypic information;
    (ii) how the organism is typically propagated for food use;
    (iii) what part of the organism is typically used as food;
    (iv) whether special processing is required to render food derived from the organism safe to eat; and
    (v) the significance to the diet in Australia and New Zealand of food derived from the host organism.

3. The nature of the genetic modification

This part includes all of the following:

(a) A description of the method used to transform the host organism.
(b) Information about the intermediate host organisms (e.g. bacteria) used for all laboratory manipulations prior to transformation of the host organism.
(c) A description of the gene construct and the transformation vectors used, including:

    (i) the size, source and function of all the genetic components including marker genes, regulatory and other elements; and
    (ii) a detailed map of the location and orientation of all the genetic components contained within the construct and vector, including the location of relevant restriction sites.

(d) A full molecular characterisation of the genetic modification in the new organism, including:

(i) identification of all transferred genetic material and whether it has undergone any rearrangements;
(ii) a determination of the number of insertion sites, and the number of copies at each insertion site;
(iii) full DNA sequence data of each insertion event, including junction regions with the host DNA, sufficient to identify any substances expressed as a consequence of the inserted material, or where more appropriate, other information such as analysis of transcripts or expression products to identify any new substances that may be present in the food;
(iv) a map depicting the organisation of the inserted genetic material at each insertion site; and
(v) the identification and characterisation of any unexpected open reading frames within the inserted DNA or created by insertion with contiguous genomic DNA, including those that could result in fusion proteins or unexpected protein expression products.

(e) A description of how the line or strain from which food is derived was obtained from the original transformant (i.e. provide a family tree or describe the breeding process).

(f) Evidence of the stability of the genetic changes, including:

(i) the pattern of inheritance of the transferred gene(s) and the number of generations over which this has been monitored; and
(ii) the pattern of inheritance and expression of the phenotype over several generations and, where appropriate, across different environments.

4. Information on the labelling of the GM food

This part includes both of the following:

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

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

The application must contain the following information:

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

This part includes all of the following:

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

2. The characterisation of novel proteins or other novel substances

This part includes all of the following:

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

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

This part includes all of the following:

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

Note:

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

4. The potential allergenicity of novel proteins

Note:

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

This part includes all of the following:

(a) Source of the introduced protein.

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

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

5. Compositional analyses of the GM food

This part includes all of the following:

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

Note:

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

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

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

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

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

Note:

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

2. Data from an animal feeding study, if available

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

Note:

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

Note:

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

3.5.2 NOVEL FOODS

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

Note:

Standard 1.5.1 contains the following definitions:

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

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

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

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

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

A. General information on the application

The application must contain the following general information:

1. Purpose of the application

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

2. Justification for the application

This part includes general statements addressing:

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

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

3. Support for the application

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

B. Technical information on the novel food

The application must contain the following information:

1. Information on the type of novel food

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

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

Note:

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

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

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

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

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

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

3. Information on the impurity profile for a typical preparation

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

4. Manufacturing process for a novel food ingredient

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

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

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

6. Analytical method for detection

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

C. Information on the safety of the novel food

Note:

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

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

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

(I) Plants or animals (or their components)

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

1. Information on the composition of the novel food

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

2. Information on the effects of food processing or preparation

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

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

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

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

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

(II) Plant or animal extracts

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

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

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

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

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

Note:

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

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

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

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

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

1. Information on the history of use of the herb

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

2. Information on the composition of the herb

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Note:

The application should address the following categories of animal studies:

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

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

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

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

(VI) Micro-organisms (including probiotics)

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

1. Information on potential pathogenicity

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

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

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

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

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

4. Information on human toleration studies

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

(VII) Food ingredients derived from a new source

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

1. Information on the safety of the source organism

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

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

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

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

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

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

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

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

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

1. Details of the process not previously applied to food

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

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

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

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

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

D. Information on dietary exposure to the novel food

Note:

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

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

The application must contain the following information:

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

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

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

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

4. Data to show whether the food, or the food in which the novel food ingredient is used, is likely to replace another food from the diet, if applicable

This part includes information on projected consumption levels for the novel food or food(s) containing the novel food ingredient, and frequency of consumption. This could include market research data or data from other international markets.

5. Details of target groups and at risk groups in the population

6. Information relating to the use of the novel food or novel food ingredient in other countries, if applicable

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

E. Information on the nutritional impact of the novel food

Note:

Some of the information derived from Section C – Information on the safety of the novel food, will be used also to assess the nutritional impact of the novel food. The information below is in addition to this information.

The application must contain the following information:

1. Information to demonstrate that the use of the novel food or novel food ingredient will not cause a nutritional imbalance in the diet

This part includes:

(a) information relating to the nutritional properties of the novel food or novel food ingredient, its effect on the bioavailability of other nutrients, and its impact on the overall diet (particularly dietary macro-components); and
(b) data on the macro- and micro-nutrient profile of the novel food or food(s) containing the novel food ingredient.

F. Information related to potential impact on consumer understanding and behaviour

Note:

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

The application must contain the following information:

1. Information to demonstrate consumer awareness and understanding of the novel food or novel food ingredient

2. Information on the actual and/or potential behaviour of consumers in response to the novel food or novel food ingredient

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

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

Note:

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

Novel foods or novel food ingredients can be used in food products for different purposes, not all of which may impact on consumer behaviour in relation to food products (e.g. cyclodextrins). The amount of information necessary to address the impact on consumer behaviour will depend on the nature of the novel food or ingredient, its extent of use, and the nature of the claims associated with the food.

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

The application must contain the following information:

1. Data on the projected impact on the food industry of the proposed novel food or novel food ingredient

This part includes information on the costs of foods containing the novel food or novel food ingredient, and, if applicable, the impact of the new foods on the sale of similar existing products.

2. Impact on international trade

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

Note:

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

3.5.3 IRRADIATED FOODS

An application to vary the Code is required to approve the irradiation of food. Approval for irradiation for foods is specified in Standard 1.5.3 – Irradiation of Food.

Note:

Standard 1.5.3 – Irradiation of Food contains the following definitions:

Irradiation *means the processing of food by subjecting it to the action of ionising radiation, but does not include ionising radiation imparted to food by measuring or inspection instruments, and 'irradiate' and 'irradiated' have corresponding meanings.*

Re-irradiate *does not include the irradiation of food –*

(a) prepared from materials that have been irradiated at low dose levels (not exceeding in any case 1 kGy) and are irradiated again; or
(b) which contains less than 50 g/kg of irradiated ingredients; or
(c) where the required full dose of ionising radiation is applied to the food in divided doses for a specific technological reason;

provided that the cumulative maximum radiation dose absorbed by the food does not exceed that specified in the Table to clause 4.

Technological need*, in relation to the irradiation of food, refers to the minimum dose of ionising irradiation required to ensure the safety or quality of the food, provided the process is performed in accordance with good manufacturing practice, and includes the extension of shelf life, the destruction of certain bacteriological contamination or pest disinfestations.*

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

A. General information on the application

The application must contain the following information:

1. Purpose of the application

This part includes information on the purpose of the proposed change to Standard 1.5.3.

2. Justification for the application

This part includes general statements addressing:

(a) the advantages of irradiating the food, referencing the technological need for each type of food;
(b) the safety of the irradiated food; and
(c) the costs and benefits for industry, consumers and government associated with use of the irradiated food.

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

3. Support for the application

This part includes evidence that the food industry has an interest in marketing the irradiated food in Australia and New Zealand as a result of the proposed change to the Code.

B. Technical information on the irradiated food

The application must contain the following information:

1. Information on the nature of the food or food ingredient to be irradiated

This part includes a description of the primary foods, food ingredients or mixed foods to be irradiated.

2. Information on the technological need to use irradiation compared to other available technologies

This part includes:

(a) information on the use of GMP in relation to foods proposed to be irradiated; and
(b) data on the microbiological load to demonstrate its effectiveness in each of the food in which it is proposed to be used.

3. The food products likely to contain the irradiated food or food ingredient

This part includes information on use of the irradiated food or food ingredient in food products.

4. Information on packaging used for irradiated food

This part includes the following:

(a) evidence that the packaging materials used to contain food during irradiation have been tested for their functionality for this purpose over the dose range used;
(b) evidence that the components of the packaging materials will not present any safety concerns in relation to the irradiation food; and
(c) evidence that irradiation will not affect the storage condition of food.

5. Information on the proposed labelling of the irradiated food

This part includes the proposed labelling for the irradiated food.

6. Verification of the use of irradiation

This part includes information on an appropriate detection method suitable for analytical purposes.

C. Information on the safety and nutritional impact of irradiation

The application must contain the following information:

1. Compositional analysis of the irradiated food

This part includes the following:

(a) The levels of key nutrients compared (using appropriate statistical analyses) to the levels in the non-irradiated food.
(b) The identity of any new components in the food formed as a result of the irradiation process.

2. Data on the dietary intake of the irradiated food

This part includes information on the anticipated dietary intake of the irradiated food.

3. Data to assess the nutritional impact of compositional changes in the food, if applicable

This part includes one or both of the following:

(a) Dietary modelling to examine the impact of the irradiated food on the nutrient content of the overall diet, if the compositional analysis indicates significant changes to the level and/or bioavailability of certain nutrients in the irradiated food.
(b) An animal feeding study with the irradiated food over the period of rapid growth of the animal, using an animal species that would normally consume the non-irradiated food, if the dietary modelling indicates a significant impact of the irradiated food on the nutrient content of the overall diet.

D. Information on the irradiation process

The application must contain the following information:

1. Information on the irradiation facilities

This part includes the following:

(a) evidence that the irradiation facility to be used is licensed and conforms to current Australian or New Zealand licensing laws and Codes of Practice for irradiation facilities; and
(b) specific approval to irradiate foods has been sought from Australian or New Zealand regulatory bodies if the irradiation facility is used to irradiate goods other than foods.

2. Information on dosimetery and record keeping

This part includes the following:

(a) evidence that dosimetry will be carried out according to an internationally recognised method;

(b) evidence that the proposed maximum dose is justified according to technological need and, if possible, references international experience; and
(c) information on recording keeping in relation to:

(i) the nature and quantity of the food treated;
(ii) the minimum durable life of the food treated;
(iii) the irradiation process used; and
(iv) the minimum and maximum dose absorbed by the food.

SECTION 3.6

STANDARDS RELATED TO THE COMPOSITION OF FOOD PRODUCTS

3.6.1 STANDARDISED FOODS

An application to vary the Code is required to change the compositional requirements for standardised foods.

Note:

Chapter 2 of the Code contains compositional requirements for a variety of foods including cereals, meat, eggs, fish, fruit and vegetables, edible oils, dairy products, alcoholic beverages, non-alcoholic beverages, sugars and honey, vinegar, salt, and special purpose foods.

The following information is required to support an application related to the composition of standardised foods. This information is in addition to that specified in Section 3.1 – General Requirements.

If the compositional change involves a change to the current permissions for a food additive, processing aid, novel food or novel food ingredient, or a nutritive substance, the information requirements to change these permissions are provided elsewhere in this Application Handbook.

Additional information may be required if the application relates to a special purpose food. The additional information requirements relating to special purpose foods are presented in Subsection 3.6.2 – Special Purpose Foods.

A. General information on the application

The application must contain the following general information:

1. Purpose of the application

This part includes general information on the proposed food compositional change.

2. Justification for the application

This part includes general statements addressing:

(a) the need for the proposed compositional change;
(b) any nutrition issues related to the proposed compositional change;
(c) any consumer choice issues related to the proposed compositional change; and
(d) the costs and benefits for industry, consumers and government associated with the proposed compositional change.

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

B. General information to support the proposed compositional change

The application must contain the following information:

1. A description of the nature of the proposed compositional change

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

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

This part includes details of the foods affected by the proposed compositional change.

C. Information related to nutritional impact

The application must contain the following information:

1. Information on the nutritional content of the standardised food

This part includes details of any anticipated change in the overall nutrient content of the standardised food which may affect the overall diet for the affected population groups.

D. Information related to potential impact on consumer understanding and behaviour

The application must contain the following information:

1. Information to demonstrate consumer understanding of the proposed compositional change

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

Note:

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

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

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

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

The application must contain the following information:

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

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

2. Impact on international trade

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

Note:

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

3.6.2 SPECIAL PURPOSE FOODS

An application to vary the Code is required to change the compositional and/or labelling requirements for Special Purpose Foods contained in Part 2.9 of the Code. Currently, this includes Standard 2.9.1 – Infant Formula Products, Standard 2.9.2 – Food for Infants, Standard 2.9.3 – Formulated Meal Replacement and Formulated Supplementary Foods or Standard 2.9.4 – Formulated Supplementary Sports Foods

Note:

Part 2.9 – Special Purpose Foods contains Standards which set out specific compositional and labelling requirements for a number of special purpose foods, including infant formula products, infant foods, meal replacements, supplementary foods, and sports foods.

FSANZ has previously proposed the following working definition of a special purpose food:

Special purpose food is food that has been specially processed or formulated to satisfy particular dietary requirements that exist because of a particular physical or physiological need, and / or specific diseases and disorders.

In this definition, the phrase *particular dietary requirements* refer to nutritional requirements that cannot be met by consumption of a normal diet. *Physical or physiological need* includes reference to normal states in the life cycle such as pregnancy and lactation, as well as physical (including lifestyle) and physiological conditions that occasion the use of special purpose food.

The following additional information is required to change the compositional and/or labelling requirements of a special purpose food. This information is in addition to that specified in Section 3.1 – General Requirements. There may be information requirements in other Sections of this Application Handbook if the application relates to the addition of a food additive, processing aid, novel food, novel food ingredient or nutritive substance.

A. General information on the application

The application must contain the following general information:

1. Purpose of the application

This part includes general information on the proposed compositional or labelling change for the Special Purpose Food.

2. Justification for the application

This part includes general statements addressing:

(a) the need for the proposed compositional or labelling change;
(b) any nutrition issues related to the proposed compositional or labelling change;
(c) any consumer choice issues related to the proposed compositional or labelling change; and

(d) the costs and benefits for industry, consumers and government associated with the proposed compositional or labelling change.

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

B. Information related to general compositional requirements

The application must contain the following information if it relates to a change to the general compositional requirements:

1. Information related to the safety of the proposed compositional change

This part includes information as applicable to a food additive, processing aid, novel food or novel food ingredient, or nutritive substance (as indicated elsewhere in this *Application Handbook*) with a particular focus on the target population. It may also include safety information related to other composition changes.

2. Information related to the nutritional impact or performance impact of the proposed compositional change

This part may include clinical studies to examine the nutritional suitability of the food, particularly in the case of infant formula products and food for infants.

This part may also include information on the performance goals of sports people if it relates to the addition of a nutritive substance or novel food ingredient to foods regulated under Standard 2.9.4 – Formulated Supplementary Sports Foods.

Note:

A discussion paper on the clinical testing of infant formulas prepared by the US Academy of Pediatrics for the US Food and Drug Administration can be found at http://www.cfsan.fda.gov/~dms/inf-clin.html .

With regard to performance goals of sports people, this should include, as a minimum, a literature search on the potential for the nutritive substance or novel food ingredient to improve performance goals.

C. Information related to the dietary exposure

The application must contain the following information if it relates to a change to the general compositional requirements:

1. Information on the identity of the target population

This part includes a description of the target population for the special purpose food.

2. Data on the dietary exposure of the target population

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

D. Information related to general labelling requirements

The application must contain the following information if it relates to a change to the general labelling requirements:

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

The part includes information to support the proposed labelling change, particularly if it relates to the inclusion of (or change to) a warning or advisory statement or directions for use.

2. Information to demonstrate that the proposed labelling change will be understood and will assist consumers, if applicable (see Note)

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

Note:

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

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

The application must contain the following information:

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

This part includes information on the market share of the affected foods, the costs of the compositional or labelling change, and the impact on the sale of existing products including any impacts on small business.

2. Impact on international trade

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

Note:

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

SECTION 3.7

STANDARDS RELATED TO FOOD PRODUCTION

3.7.1 FOOD SAFETY PROGRAMS

An application to vary the Code is required to change the requirements for food safety programs specified in Chapter 3, namely, Standard 3.2 1 – Food Safety Programs, Standard 3.2.2 – Food Safety Practices and General Requirements, Standard 3.2.3 – Food Premises and Equipment, Standard 3.3.1 – Food Safety Programs for Food Service to Vulnerable Persons. These Standards apply to Australia only.

Note:

The purpose of Chapter 3 – Food Safety Standards is:

To ensure that only safe and suitable food is sold in Australia.

(1) For the purposes of the Food Safety Standards, food is not safe if it would be likely to cause physical harm to a person who might later consume it, assuming it was –

- *(a) after that time and before being consumed by the person, properly subjected to all processes (if any) that are relevant to its reasonable intended use; and*
- *(b) consumed by the person according to its reasonable intended use.*

(2) However, food is not unsafe merely because its inherent nutritional or chemical properties cause, or its inherent nature causes, adverse reactions only in persons with allergies or sensitivities that are not common to the majority of persons.

(3) In subsection (1), processes include processes involving storage and preparation.

(4) For the purposes of the Food Safety Standards, food is not suitable if it –

- *(a) is damaged, deteriorated or perished to an extent that affects its reasonable intended use; or*
- *(b) contains any damaged, deteriorated or perished substance that affects its reasonable intended use; or*
- *(c) is the product of a diseased animal or an animal that has died otherwise than by slaughter, and has not been declared by or under another Act to be safe for human consumption; or*
- *(d) contains a biological or chemical agent, or other matter or substance, that is foreign to the nature of the food.*

The following information is required to support an application to amend these Standards. This information is in addition to that specified in Section 3.1 – *General Requirements*.

A. General information on the application

The application must contain the following general information:

1. Purpose of the application

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

2. Justification for the application

This part includes general statements addressing:

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

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

B. Information related to food safety

The application must contain the following information:

1. Data to show that the proposed change will protect public health and safety

The part includes:

(a) survey data, if applicable, to demonstrate that the proposed change will have result in protection of public health and safety equivalent to the current Standard; and
(b) information from other countries on current practices that relate to the proposed change.

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

The application must contain the following information:

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

This part includes information on the specific sector affected by the proposed amendment including market share of the affected foods, the potential costs of the change, the impact on the sale of existing products produced under the current Standards, and any potential impacts on other businesses.

Note:

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

3.7.2 FOOD PROCESSING AND PRIMARY PRODUCTION

An application to vary the Code is required to change the food processing requirements specified in Standard 1.6.2 – Processing Requirements or the primary production requirements for seafood, poultry meat, meat, dairy products, specific cheeses and wine specified in Chapter 4 – Primary Production Standards. These Standards apply to Australia only.

Note:

The purpose of Standard 1.6.2 – Processing Requirements is:

To set out the requirements for processing of foods regulated in Chapter 2 – Food Product Standards.

The purpose of Chapter 4 – Primary Production Standards is:

To set out food safety and suitability requirements for foods from pre-harvesting production up to manufacturing operations.

The following information is required to support an application to amend these Standards. This information is in addition to that specified in Section 3.1 – General Requirements.

A. General information on the application

The application must contain the following general information:

1. Purpose of the application

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

2. Justification for the application

This part includes general statements addressing:

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

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

B. Information related to food safety

The application must contain the following information:

1. Data to show that the proposed change will protect public health and safety

The part includes:

(a) data to demonstrate that the proposed change will have result in protection of public health and safety equivalent to the current Standard; and
(b) information from other countries on current practices that relate to the proposed change.

Note:

For further information on the use of equivalence, see the FSANZ Guidance Document *Guidelines for Determining the Equivalence of Food Safety Measures* on the FSANZ website.

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

The application must contain the following information:

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

This part includes information on the specific sector affected by the proposed amendment including market share of the affected foods, the potential costs of the change, the impact on the sale of existing products produced under the current Standards, and any potential impacts on other businesses.

2. Impact on international trade

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

Note:

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

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Appendix 1

Checklists

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CHECKLIST FOR STANDARDS RELATED TO LABELLING AND OTHER INFORMATION REQUIREMENTS

This checklist will assist you in determining if you have met the information requirements as detailed in the Application Handbook. Section 3.1 – General Requirements and section 3.2.1 – General Food Labelling are mandatory for all labelling applications. If your application is relation to sections 3.2.2-3.2.5, then the information required is in addition to sections 3.1 and 3.2.1.

General Requirements (3.1)

☐	Form of application	☐	Assessment procedure
☐	Applicant details	☐	Confidential Commercial Information
☐	Purpose of the application	☐	Exclusive Capturable Commercial Benefit
☐	Justification for the application	☐	International standards
☐	Information to support the application	☐	Statutory Declaration

General Food Labelling (3.2.1)

☐	Description of proposed labelling change	☐	Information that proposed labelling change will not have any adverse health impacts
☐	Foods potentially affected identified	☐	Data on potential costs of labelling change to industry
☐	Demonstrated consumer support for the labelling change	☐	Information on potential impacts to trade
☐	Information that proposed labelling will be understood and assist consumers	☐	

Warning and Advisory Statements (3.2.2)

☐	Data on potential health concern	☐	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)

☐	Demonstration that the food causes IgE-mediated allergy	☐	Information on severity of allergic reaction
☐	Information on incidence of allergic reaction	☐	Information on extent of use of allergen in foods

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

☐	Nature of food derivative	☐	Information on the history of safe use
☐	Use of food derivative in food	☐	Clinical information on safety of food derivative
☐	Dietary intake information		

Labelling for Consumer Information and Choice (3.2.4)

☐	Current labelling or alternative information inadequacies	☐	Information to show effectiveness of proposed labelling change
☐	Information on lack of suitable alternatives available to consumers	☐	Information to demonstrate labelling is the best method of providing this information

Nutrition Information Labelling (3.2.5)

Nutrient contents label change (3.2.5 A)

☐	Description of proposed labelling change	☐	Data to demonstrate labelling will assist consumers

Energy factors (3.2.5 B)

☐	Nature and composition of the food ingredient	☐	Documentation of other factors which might impact energy measures
☐	Measures or estimates of energy		

CHECKLIST FOR STANDARDS RELATED TO SUBSTANCES ADDED TO FOOD

This checklist will assist you in determining if you have met the information requirements as detailed in the Application Handbook. Section 3.1 – General Requirements is mandatory for all applications. Sections 3.3.1-3.3.3 are related to the specifics of your application and the information required is in addition to section 3.1.

General Requirements (3.1)

- ☐ Form of application
- ☐ Applicant details
- ☐ Purpose of the application
- ☐ Justification for the application
- ☐ Information to support the application
- ☐ Assessment procedure
- ☐ Confidential Commercial Information
- ☐ Exclusive Capturable Commercial Benefit
- ☐ International standards
- ☐ Statutory Declaration

Food Additives (3.3.1)

- ☐ Support for the application
- ☐ Nature and technological function information
- ☐ Identification information
- ☐ Chemical and physical properties
- ☐ Impurity profile
- ☐ Manufacturing process
- ☐ Specifications
- ☐ Food labelling
- ☐ Analytical detection method
- ☐ Toxicokinetics and metabolism information
- ☐ Toxicity information
- ☐ Safety assessments from international agencies
- ☐ List of foods likely to contain the food additive
- ☐ Proposed levels in foods
- ☐ Percentage of food group to contain the food additive
- ☐ Use in other countries (if applicable)

Processing Aids (3.3.2)

- ☐ Support for the application
- ☐ Type of processing aid
- ☐ Identification information
- ☐ Chemical and physical properties
- ☐ Manufacturing process
- ☐ Specification information
- ☐ Industrial use information (chemical only)
- ☐ Information on enzyme use on other countries (enzyme only)
- ☐ Toxicity information of enzyme (enzyme only)
- ☐ Information on source organism (enzyme from micro-organism only)
- ☐ Pathogenicity and toxicity of source micro-organism (enzyme from micro-organism only)
- ☐ Genetic stability of source organism (enzyme from micro-organism only)
- ☐ Nature of genetic modification (PA from GM micro-organism only)
- ☐ List of foods likely to contain the processing aid

☐ Information on use in other countries (chemical only)

☐ Toxicokinetics and metabolism information (chemical only)

☐ Toxicity information (chemical only)

☐ Safety assessments from international agencies (chemical only)

☐ Anticipated residue levels in foods

☐ Percentage of food group to use processing aid

☐ Information on residues in foods in other countries (if available)

Nutritive Substances (3.3.3)

☐ Support for the application

☐ Identification information

☐ Information on chemical and physical properties

☐ Impurity profile information

☐ Manufacturing process information

☐ Specification information

☐ Analytical detection method

☐ Proposed food label

☐ Toxicokinetics and metabolism information

☐ Animal or human toxicity studies

☐ Safety assessments from international agencies

☐ List of food groups or foods likely to contain the nutritive substance

☐ Proposed maximum levels in food groups or foods

☐ Percentage of food group anticipated to contain nutritive substance

☐ Food consumption data for new foods

☐ Information on use in other countries

☐ Food consumption data for foods with changed consumption patterns

☐ Nutritional purpose

☐ Need for nutritive substance in food

☐ Demonstrated potential deficit or health benefit

☐ Consumer awareness and understanding

☐ Actual or potential behaviour of consumers

☐ Demonstration of no adverse affects to any population groups

☐ Impact on food industry

☐ Impact on trade

CHECKLIST FOR STANDARDS RELATED TO CONTAMINANTS AND NATURAL TOXICANTS

This checklist will assist you in determining if you have met the information requirements as detailed in the Application Handbook. Section 3.1 – General Requirements is mandatory for all applications. Sections 3.4.1-3.4.3 are related to the specifics of your application and the information required is in addition to section 3.1.

General Requirements (3.1)

- ☐ Form of application
- ☐ Applicant details
- ☐ Purpose of the application
- ☐ Justification for the application
- ☐ Information to support the application
- ☐ Assessment procedure
- ☐ Confidential Commercial Information
- ☐ Exclusive Capturable Commercial Benefit
- ☐ International standards
- ☐ Statutory Declaration

Chemical Contaminant and Natural Toxicant Maximum Levels (3.4.1)

- ☐ Nature of contaminant or natural toxicant
- ☐ Analytical detection method
- ☐ Toxicokinetics & metabolism information
- ☐ Toxicity studies
- ☐ Human studies relevant to safety
- ☐ List of foods where maximum level is proposed
- ☐ Survey data on contaminant levels in foods
- ☐ Impact on food industry
- ☐ Impact on trade

Microbiological Limits (3.4.2)

- ☐ Raw inputs, production and manufacturing process
- ☐ Food technology
- ☐ Nature of the microbiological hazard
- ☐ Source & prevalence of contamination
- ☐ Consumer handling and use
- ☐ Evidence of nutritional benefit of change
- ☐ Food consumption data
- ☐ Impact on food industry
- ☐ Impact on trade

Prohibited and Restricted Plants and Fungi (3.4.3)

- ☐ Nature of plant or fungi
- ☐ Identity and levels of natural toxicants
- ☐ Toxicity studies
- ☐ Human toxicity case studies
- ☐ Use in other countries

CHECKLIST FOR STANDARDS RELATED TO NEW FOODS

This checklist will assist you in determining if you have met the information requirements as detailed in the Application Handbook. Section 3.1 – General Requirements is mandatory for all applications. Sections 3.5.1-3.5.3 are related to the specifics of your application and the information required is in addition to section 3.1.

General Requirements (3.1)

- ☐ Form of application
- ☐ Applicant details
- ☐ Purpose of the application
- ☐ Justification for the application
- ☐ Information to support the application
- ☐ Form of application
- ☐ Assessment procedure
- ☐ Confidential Commercial Information
- ☐ Exclusive Capturable Commercial Benefit
- ☐ International standards
- ☐ Statutory Declaration
- ☐ Assessment procedure

Foods Produced using Gene Technology (3.5.1)

- ☐ Nature and identity of GM food
- ☐ History of use of host and donor organisms
- ☐ Nature of genetic modification
- ☐ Labelling information on GM food
- ☐ Antibiotic resistance marker genes (if used)
- ☐ Characterisation of novel protein(s)/substances
- ☐ Toxicity of novel protein(s)/substances
- ☐ Potential allergenicity of novel protein(s)
- ☐ Compositional analysis of GM food
- ☐ Nutritional impact of GM food
- ☐ Animal feeding studies (if available)

Novel Foods (3.5.2)

- ☐ Support for the application
- ☐ Type of novel food
- ☐ Chemical and physical properties
- ☐ Impurity profile
- ☐ Manufacturing process
- ☐ Specification and identity
- ☐ Analytical detection method
- ☐ Safety information for specified section I-XIII *(see below)
- ☐ List of foods likely to contain the novel food or novel food ingredient
- ☐ Percentage of food group anticipated to contain novel food or novel food ingredient
- ☐ Predicted consumption (replacement)
- ☐ Details of target or at risk population groups
- ☐ Use in other countries
- ☐ Nutritional impact information
- ☐ Demonstrated consumer awareness and understanding
- ☐ Potential behaviour in response to foods
- ☐ Demonstration of no adverse affects to any population groups
- ☐ Impact on food industry

☐ Proposed levels in foods

☐ Impact on trade

**Novel foods - safety information*

(I) Plants and animals (or their components)

☐ Composition

☐ *Current use*

☐ E*f*fects of food processing or preparation

☐ Potential adverse effects

(II) Plant and animal extracts

☐ Method or extraction and composition of extract

☐ Toxicity studies

☐ Use as a food in other countries

(III) Herbs (including extracts)

☐ History of use

☐ Potential allergenicity

☐ Composition

☐ Toxicity studies

☐ Method of extraction and composition of extract

☐ Overseas safety *reports*

☐ Use in other countries

(IV & V) Single chemical entities & dietary macrocomponents

☐ Toxicokinetics and metabolism

☐ Overseas safety reports

☐ Toxicity studies

(VI) Micro-organism

☐ Potential pathogenicity

☐ Use as a food in other countries

☐ Effects on gut microflora

☐ Human toleration studies

(VII) Food ingredients derived from a new source

☐ Safety of the source organism

☐ Toxicity studies

☐ Composition

☐ Overseas safety reports

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

☐ Details of the new process

☐ Overseas safety reports

☐ Toxicity studies

Irradiated Foods (3.5.3)

☐ Support for the application

☐ Analytical detection method

☐ Nature of the food or food ingredient to be irradiated

☐ Composition of irradiated food

☐ Technological need for irradiation

☐ Dietary intake

☐ Food products likely to contain irradiated food

☐ Data on potential nutritional impact

☐ Packaging for irradiated food

☐ Irradiation facilities information

☐ Food labelling information

☐ Dosimetry and record keeping

CHECKLIST FOR STANDARDS RELATED TO THE COMPOSITION OF FOOD PRODUCTS

This checklist will assist you in determining if you have met the information requirements as detailed in the Application Handbook. Section 3.1 – General Requirements is mandatory for all applications. Sections 3.6.1 and 3.6.2 are related to the specifics of your application and the information required is in addition to section 3.1.

General Requirements (3.1)

☐	Form of application	☐	Assessment procedure
☐	Applicant details	☐	Confidential Commercial Information
☐	Purpose of the application	☐	Exclusive Capturable Commercial Benefit
☐	Justification for the application	☐	International standards
☐	Information to support the application	☐	Statutory Declaration
☐	Form of application	☐	Assessment procedure

Standardised Foods (3.6.1)

☐	Proposed compositional change	☐	Potential adverse health or diet impacts
☐	List of foods likely to be affected	☐	Impact on the food industry
☐	Nutritional content of standardised food	☐	Impact on trade
☐	Demonstrated consumer understanding of proposed change		

Special Purpose Foods (3.6.2)

☐	Safety of proposed compositional change	☐	Safety and nutritional impact of labelling change
☐	Nutritional impact of compositional change	☐	Demonstrated understanding of labelling change
☐	Target population	☐	Impact on food industry
☐	Dietary exposure information	☐	Impact on trade

CHECKLIST FOR STANDARDS RELATED TO FOOD PRODUCTION

This checklist will assist you in determining if you have met the information requirements as detailed in the Application Handbook. Section 3.1 – General Requirements is mandatory for all applications. Sections 3.7.1 and 3.7.2 are related to the specifics of your application and the information required is in addition to section 3.1.

General Requirements (3.1)

☐	Form of application	☐	Assessment procedure
☐	Applicant details	☐	Confidential Commercial Information
☐	Purpose of the application	☐	Exclusive Capturable Commercial Benefit
☐	Justification for the application	☐	International standards
☐	Information to support the application	☐	Statutory Declaration
☐	Form of application	☐	Assessment procedure

Food Safety Programs (3.7.1)

☐	Public health and safety data	☐	Projected costs to food industry

Food Processing and Primary Production (3.7.2)

☐	Public health and safety data	☐	Impact on trade
☐	Projected costs to food industry		