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Office of the Chief Executive Officer

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

Food Standards Australia New Zealand Act 1991

Pursuant to subsection 23(1) of the *Food Standards Australia New Zealand Act 1991*, I make the attached amendments to the application guidelines.

STEVE McCUTCHEON
Chief Executive Officer
Delegate of the Board of Food Standards Australia New Zealand

1 July 2011

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

Food Standards Australia New Zealand Act 1991

Preamble

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

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

Citation

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

Commencement

These variations will commence on 1 August 2011.

SCHEDULE

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

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

substituting –

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

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

[3] ***Section 3.1*** *is varied by* –

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

MANDATORY INFORMATION REQUIREMENTS

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

substituting –

Federal Register of Legislative Instruments F2011L01439

MANDATORY INFORMATION REQUIREMENTS

The word '**must**' is used in Part 3 of the *Application Handbook* to identify information that is mandatory. Applicants should note that if this information is not provided, the application may be rejected at the Administrative Assessment stage. Rejection will not preclude an applicant from re-lodging the application at a later date.

[3.2] *omitting from 3.1.1 –*

Applications sent by facsimile will not be accepted.

[3.3] *omitting from 3.1.1.B. –*

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

substituting –

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

[3.4] *omitting from 3.1.2 –*

(d) Telephone and facsimile numbers

substituting –

(d) Telephone number

[3.5] *omitting* 3.1.3*, substituting –*

3.1.3 Purpose of the application

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

[3.6] *omitting 3.1.4, substituting –*

3.1.4 Justification for the application

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

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

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

A. Regulatory Impact Information

The application must include current information and data:

1. Costs and benefits

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

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

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

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

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

Note:

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

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

2. Impact on international trade

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

[3.7] *omitting* 3.1.5*, substituting –*

3.1.5 Information to support the application

The application must contain sufficient supporting information or data to enable the objectives specified in section 18 of the FSANZ Act to be addressed (*see Section 1.3.2*). Where the application relates to matters referred to in Sections 3.2-3.7, please refer to the relevant Section for specific information requirements. In some instances more than one of these Sections may apply.

The following general issues should be considered:

(a) any public health and safety issues related to the proposed change including details of target groups and population groups that may be adversely affected

(b) any consumer choice issues related to the proposed change
(c) any evidence that the food industry generally or other specific companies have an interest in, or support, the proposed change to the Code (this item is mandatory for applications relating to food additives, processing aids, nutritive substances, novel foods, irradiated foods).

A. Data requirements

Note:

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

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

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

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

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

If a literature search is undertaken, the applicant must:

(a) list the databases searched (such as MEDLINE, EMBASE, TOXLINE, FSTA, Science Citation Index, BIOSIS, PsycINFO, or the Australian Medical Index etc)

(b) provide the criteria used to specify the search, such as the key words, the time period of the search, and any other limiting criteria

(c) list all of the papers identified in the search

(d) list and provide in full all of the papers included as the basis of the evidence in the application. Summaries of study findings and papers are not adequate.

Note:

Useful guidelines on undertaking literature searches can be found at: http://www.nhmrc.gov.au/publications/synopses/cp65syn.htm.

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

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

1. Data related to safety studies

(a) Studies submitted for safety assessment purposes should be designed and conducted in accordance with the principles and intent of good laboratory practice (GLP). For safety assessments of chemicals, reference should be made to *OECD Principles on Good Laboratory Practice* (http://www.oecd.org/document/63/0,3746,en_2649_34381_2346175_1_1_1_1,00.html) and relevant OECD Guidelines for the Testing of Chemicals (http://www.oecd.org/department/0,2688,en_2649_34377_1_1_1_1_1,00.html) or other recognised test guidelines, such as the US Food and Drug Administration Redbook 2000 *Toxicological Principles for the Safety Assessment of Food Ingredients* (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/Redbook/default.htm).

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

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

2. Data related to surveys on chemicals or other substances in food

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

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

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

3. Data related to epidemiological/intervention studies in humans

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

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

4. Data related to consumer research

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

[3.8] *omitting from 3.1.6 –*

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

substituting –

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

[3.9] *omitting from 3.1.7 –*

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

substituting –

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

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

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

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

substituting –

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

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

[3.11] *omitting from 3.1.11 –*

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

substituting –

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

Note:

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

[4] ***Section 3.2.1*** *is varied by –*

[4.1] *omitting from A. –*

The application must contain the following information:

substituting –

The application must contain the following information:

[4.2] *omitting* C.

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

The application must contain the following information:

substituting –

The application must contain the following information:

[6] ***Section 3.2.5*** *is varied by –*

[6.1] *omitting –*

Note:

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

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

A. Additional information to support a change to the nutrition information labelling of a food

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

The application must contain the following information:

1. A description of how the proposed labelling will change the nutrition information labelling of the food

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

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

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

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

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

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

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

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

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

2. Details on the calculation of the energy factor

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

Note:

The equation in clause 2 of Standard 1.2.8 is:

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

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

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

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

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

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

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

(i) a direct measurement of the percentage of the food ingredient that reaches the large intestine and is fermented; or
(ii) subtracting measured amounts of the food ingredient that are excreted unchanged in the faeces (uFE) from amounts that are *not* absorbed in the upper intestine (jejunum and duodenum).

(e) The use or otherwise of default values for one or more of **mFE, oFE, GaE or SE**. Default values are listed in the following table:

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

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

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

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

Note:

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

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

(I) Bomb calorimetry – GE

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

(II) Classical dietary energy balance – FE and UE

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

(III) Isotopic tracer methods – FE, UE, upper intestinal absorption, large intestinal fermentation

These methods involve the use of isotopically labelled substrates (e.g. ^{13}C or ^{14}C) and measure the percentage of the given dose that is recovered in metabolised form (e.g. in CO_2 in breath), in unmetabolised (urine) form, or undigested (faeces) form. It is acceptable to combine this method with other techniques to provide adjunct information on intestinal absorption (e.g. analysis of blood glucose fluctuations or other metabolites) and fermentation (breath hydrogen). It is also acceptable to use studies in germ free animals to provide comparative data that calculates the amount of the food ingredient fermented in the large intestine.

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

The breath hydrogen response is a reflection of the nutrients fermented in the large intestine, and is also suitable for use in estimating GaE. A common form of the test is to measure basal breath H_2 obtained after a dose of lactulose compared with the breath H_2 after a dose of the test food ingredient.

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

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

Combined with faecal excretion, ileal intubation is also able to provide an indirect measure of the proportion of the food ingredient that reaches the large intestine and is fermented.

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

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

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

[7] ***Section 3.3.1*** *is varied by –*

[7.1] *omitting from A.1. –*

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

substituting –

(b) the reason why the food additive is needed to fulfil these functions in each of the foods in which it is proposed to be used;
(c) evidence that the amounts proposed to be added are consistent with achieving the technological function; and
(d) if the food additive is a preservative, data to demonstrate its effectiveness in each of the foods in which it is proposed to be used.

[7.2] *omitting A.8., substituting –*

8. Analytical method for detection

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

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

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

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

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

Note:

The application should address the following categories of studies:

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

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

(b) For an application to extend the use of a currently permitted food additive, this part need only include the detailed reports of studies conducted since the last safety evaluation by FSANZ.

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

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

It is preferred that the food list be based on the food group classification system used in Standard 1.3.1 – Food Additives.

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

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

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

Note:

Information on likely consumption can be based on proposed levels of consumption (grams per day) or on consumption data for these foods from a similar market in another country. The most recent NNSs are the 1995 NNS (2 years and above), 1997 New Zealand NNS (15 years and above), the 2002 New Zealand Children's NNS (5-14 years) and the 2007 Australian Children's NNS (2-16 years).

The application should contain the following information:

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

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

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

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

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

This part includes any consumption information for foods where there has been a significant change in consumption since the most recent Australian and New Zealand NNSs which relate to this application. This can be based on market share data or sales data or on a similar market in another country.

[8] ***Section 3.3.2*** *is varied by –*

[8.1] *omitting A.1., substituting –*

1. Information on the type of processing aid

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

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

(e) Desiccating preparations

[8.3] *omitting from A.2. –*

if applicable.

substituting –

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

[8.4] *omitting from A.3. –*

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

substituting –

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

[8.5] *omitting from A.5. –*

Where residues from the processing aid are likely to be present in the final food, an analytical method should be provided to quantify the amount of the processing aid remaining in the final food. Such an analytical method should be robust and applicable for analytical laboratories to determine compliance of any limits prescribed in the Code.

substituting –

6. Analytical method for detection

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

[8.6] *omitting from B. –*

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

substituting –

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

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

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

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

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

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

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

Note:

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

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

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

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

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

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

[8.8] *omitting C.2., substituting –*

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

This part includes the following for all enzymatic processing aids:

(a) Information on the enzyme's prior history of human consumption and/or its similarity to proteins with a history of safe human consumption.
(b) Information on any significant similarity between the amino acid sequence of the enzyme and that of known protein toxins.

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

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

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

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

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

Note:

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

3. Information on the potential allergenicity of the enzyme processing aid

Note:

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

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

This part includes the following for all enzymatic processing aids:

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

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

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

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

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

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

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

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

[8.10] *omitting E., substituting –*

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

The application must contain the following additional information:

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

This part includes information on the nature of the genetic modification and the steps used to construct the final production strain.

Note:

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

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

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

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

substituting –

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

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

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

It is preferred if the food list is based on the food group classification system used in Standard 1.3.1 – Food Additives.

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

The chemical identity of the residue must be stated.

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

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

Note:

Information on likely consumption can be based on proposed levels of consumption (grams per day) or on consumption data for these foods from a similar market in another country. The most recent NNSs are the 1995 NNS (2 years and above), 1997 New Zealand NNS (15 years and above), the 2002 New Zealand Children's NNS (5-14 years) and the 2007 Australian Children's NNS (2-16 years).

The application should contain the following information:

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

This part includes information based on projected uptake or market share data for foods likely to contain the processing aid or its metabolites.

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

This part includes information on the food groups and/or foods in which the processing aid is used and any relevant concentration data for its metabolites.

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

This part includes any consumption information for foods where there has been a significant change in consumption since the most recent Australian and New Zealand NNSs which relate to this application. This can be based on market share data or sales data or on a similar market in another country.

[9] ***Section 3.3.3*** *is varied by –*

[9.1] *omitting A.2., substituting –*

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

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

[9.2] *omitting A.6., substituting –*

6. Analytical method for detection

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

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

Note:

The following categories of studies need to be considered:

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

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

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

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

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

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

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

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

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

Note:

Information on likely consumption can be based on proposed levels of consumption (grams per day) or on consumption data for these foods from a similar market in another country. The most recent NNSs are the 1995 NNS (2 years and above), 1997 New Zealand NNS (15 years and above), the 2002 New Zealand Children's NNS (5-14 years) and the 2007 Australian Children's NNS (2-16 years).

The application should include the following information:

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

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

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

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

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

This part includes any consumption information for foods where there has been a significant change in consumption since the most recent Australian and New Zealand NNSs which relate to this application. This can be based on market share data or sales data or on a similar market in another country.

[9.5] *omitting D.1., substituting –*

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

This part includes data to demonstrate the nutritive substance is consistent with its nutritional purpose as described in Part 3.1.4.(c) and:

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

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

Note:

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

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

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

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

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

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

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

[9.7] *omitting G.*

[10] ***Section 3.4.1*** *is varied by –*

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

Note:

The following categories of studies need to be considered:

(a) acute toxicity
(b) short-term toxicity
(c) long-term toxicity and carcinogenicity

(d) reproductive toxicity
(e) developmental toxicity
(f) genotoxicity
(g) special studies such as neurotoxicity or immunotoxicity.

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

[10.2] *inserting after C.2. –*

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

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

Note:

Information on likely consumption can be based on proposed levels of consumption (grams per day) or on consumption data for these foods from a similar market in another country. The most recent NNSs are the 1995 NNS (2 years and above), 1997 New Zealand NNS (15 years and above), the 2002 New Zealand Children's NNS (5-14 years) and the 2007 Australian Children's NNS (2-16 years).

The application should include the following information:

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

This part includes any consumption information for foods where there has been a significant change in consumption since the most recent Australian and New Zealand NNSs which relate to the application. This can be based on market share data or sales data or on a similar market in another country.

[10.3] *omitting D.*

[11] ***Section 3.4.2*** *is varied by –*

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

1. Food consumption data, if applicable

This part includes data on food consumption levels for the foods affected by the proposed amendment, as either proposed serves per day (gram amount) or per capita. For new foods (foods not included in the most recent Australian and New Zealand National Nutrition Surveys, the application must include projected consumption data, which can include information from international markets.

Note:

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

[11.2] *omitting E.*

[12] ***Section 3.5.1*** *is varied by –*

[12.1] *omitting from A.3.(d) –*

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

substituting –

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

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

4. Analytical method for detection

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

Note:

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

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

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

The application must contain the following information:

1. Equivalence studies

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

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

This part includes all of the following:

(a) information on the clinical and veterinary importance, if any, in Australia and New Zealand of the antibiotic to which any transferred antibiotic resistance genes confer resistance
(b) information on whether the presence in food of the enzyme or protein encoded by the antibiotic resistance marker gene would compromise the therapeutic efficacy of the orally administered antibiotic

(c) information on the safety of the gene product

(d) if the new GM organism is a microorganism, information on whether it will remain viable in the final food.

3. The characterisation of novel proteins or other novel substances

This part includes all of the following:

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

4. The potential toxicity of novel proteins

This part includes all of the following:

(a) a bioinformatic comparison of the amino acid sequence of each of the novel proteins to known protein toxins and anti-nutrients (e.g. protease inhibitors, lectins)
(b) information on the protein stability to proteolysis in appropriate gastrointestinal model systems.

Note:

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

5. The potential allergenicity of novel proteins

Note:

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

(a) a newly expressed protein is one to which certain individuals may already be sensitive

(b)	a protein new to the food supply is likely to induce allergic reactions in some individuals.

This part includes all of the following:

(a) source of the introduced protein
(b) any significant similarity between the amino acid sequence of the protein and that of known allergens
(c) the novel protein's structural properties, including, but not limited to, its susceptibility to enzymatic degradation (e.g. proteolysis), heat and/or acid stability
(d) specific serum screening where a newly expressed protein is derived from a source known to be allergenic or has sequence homology with a known allergen.

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

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

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

Note:

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

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

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

7. Compositional analyses of the GM food

This part includes all of the following:

(a) The levels of key nutrients, toxicants and anti-nutrients in the GM food compared with the levels in an appropriate comparator (usually the non-GM counterpart). The statistical significance of any observed differences must be assessed in the context of the range of natural variations for that parameter to determine its biological significance.
(b) The levels of any other constituents that may potentially be influenced by the genetic modification, as a result, for example, of downstream metabolic effects, compared with the levels in an appropriate comparator.

Note:

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

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

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

This part includes all of the following:

(a) Data are required on the anticipated dietary intake of the GM food in relation to the overall diet, together with any information which may indicate a change to the bioavailability of the nutrients from the GM food.
(b) Where the GM food contains an intended nutritional change, information, such as clinical trial data, must be provided to determine the nutritional impact of the GM food.

2. Data from an animal feeding study, if available

There is no requirement for animal feeding studies to be conducted on the GM food. However, if available, such studies should be submitted.

[13] ***Section 3.5.2*** *is varied by –*

[13.1] *omitting from A –*

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

substituting –

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

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

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

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

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

[13.3] *omitting from B.6. –*

The application should contain the following information:

substituting –

The application must contain the following information:

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

The application should address the following categories of animal studies:

substituting –

The application should address the following categories of studies:

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

Note:

FSANZ will undertake a dietary exposure assessment for all novel foods applications. The type of dietary exposure assessment will vary depending on the nature of the novel food.

This may depend on whether the novel food is the final food, a major component of the final food or a minor component of the final food.

The dietary exposure assessment will use a custom-made computer program, DIAMOND, which combines food consumption data from the latest Australian and New Zealand National Nutrition Surveys together with food chemical concentration data derived from the proposed levels of use provided by the applicant or other concentration data where relevant, for example data from analytical surveys.

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

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

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

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

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

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

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

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

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

Note:

Information on likely consumption can be based on proposed levels of consumption (grams per day) or on consumption data for these foods from a similar market in another country. The most recent NNSs are the 1995 NNS (2 years and above), 1997 New Zealand NNS (15 years and above), the 2002 New Zealand Children's NNS (5-14 years) and the 2007 Australian Children's NNS (2-16 years).

The application should contain the following information:

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

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

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

This part includes any consumption information for foods where there has been a significant change in consumption since the most recent Australian and New Zealand NNSs which relate to this application. This can be based on market share data or sales data or on a similar market in another country.

Note:

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

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

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

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

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

[13.7] *omitting E., substituting –*

E. Information on the nutritional and health impact of the novel food

Note:

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

The application must contain the following information:

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

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

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

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

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

The application should contain the following information:

substituting –

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

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

Note:

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

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

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

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

Information to support F1-3 could include:

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

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

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

[13.10] *omitting G.*

[14] ***Section 3.5.3*** *is varied by –*

[14.1] *omitting –*

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

substituting –

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

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

A. Technical information on the irradiated food

The application must contain the following information:

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

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

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

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

(a) data on the reduction in microbiological load to demonstrate the effectiveness of the irradiation procedure in each of the foods on which it is proposed to be used.

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

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

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

B. Information on the safety of irradiation

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

C. Information on the nutritional impact of irradiation

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

[15] ***Section 3.6.1*** *is varied by –*

[15.1] *omitting –*

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

substituting –

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

[15.2] *omitting D.*

[16] ***Section 3.6.2*** *is omitted, substituting –*

3.6.2 SPECIAL PURPOSE FOODS

An application to vary the Code is required to change the compositional and/or labelling requirements for Special Purpose Foods contained in Part 2.9 of the Code. Currently, this includes:

- Standard 2.9.1 – Infant Formula Products
- Standard 2.9.2 – Foods for Infants
- Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods
- Standard 2.9.4 – Formulated Supplementary Sports Foods.

Note:

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

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

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

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

that occasion the use of special purpose food.

The Guideline is available at http://www.foodstandards.gov.au/foodstandards/changingthecode/ministerialcouncilpolicyguidelines/.

The following additional information is required to change the compositional and/or labelling requirements of a special purpose food. This information is in addition to that specified in Section 3.1 – General Requirements. There may also be additional information requirements in other parts of this Handbook if an application relates to the addition of a food additive, processing aid, novel food, novel food ingredient or nutritive substance, or to the labelling requirements in Part 1.2 of the Code.

A. Information related to general compositional requirements

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

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

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

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

This part demonstrates how the compositional change is consistent with the intended purpose of the special purpose food. This part may include clinical studies to examine the nutritional suitability of the food, particularly in the case of infant formula products and food for infants.

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

Note:

A discussion paper on the clinical testing of infant formulas prepared by the US Academy of Pediatrics for the US Food and Drug Administration can be found at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/InfantFormula/ucm170649.htm.

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

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

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

Note:

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

B. Information related to the dietary intake or dietary exposure

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

1. Information on the identity and physical and physiological need of the target population

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

2. Data to enable the dietary exposure of the target population to be estimated

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

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

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

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

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

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

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

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

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

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

Note:

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

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

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

Note:

Examples of relevant recommendations/guidelines are the WHO Infant and Young Child Nutrition Global Strategy on Infant and Young Children Feeding at http://apps.who.int/gb/archive/pdf_files/WHA55/ea5515.pdf and the WHO International Code of Marketing of Breast-milk Substitutes at http://www.who.int/nutrition/publications/infantfeeding/9241541601/en/index.html and the Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children at http://www.codexalimentarius.net/web/more_info.jsp?id_sta=11026.

[17] ***Section 3.7.1*** *is varied by –*

[17.1] *omitting the title, substituting –*

3.7.1 FOOD SAFETY STANDARDS

[17.2] *omitting B.*

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

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

CHECKLIST FOR GENERAL REQUIREMENTS

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

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

CHECKLIST FOR STANDARDS RELATED TO LABELLING AND OTHER INFORMATION REQUIREMENTS

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

General Food Labelling (3.2.1)	
☐ A.1 Proposed labelling change	☐ B.2 Will proposed labelling be understood and assist consumers
☐ A.2 Foods potentially affected	☐ B.3 Will proposed labelling change have any adverse health or diet impacts
☐ B.1 Demonstrated consumer support for the labelling change	

Warning and Advisory Statements (3.2.2)

☐ A.1 Data on potential health concern	☐ A.2 Data on lack of consumer awareness of health risk

Declaration of Allergens (3.2.3)

Addition of allergen to list of declared foods (3.2.3 A)

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

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

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

Labelling for Consumer Information and Choice (3.2.4)

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

Nutrition Information Labelling (3.2.5)

☐ A.1 Description of proposed change and how it will change nutrition information labelling	☐ B.3.(II) Substantiation of energy factor – Classical dietary energy balance
☐ A.2 Data to demonstrate labelling will assist consumers	☐ B.3.(III) Substantiation of energy factor – Isometric tracer methods
☐ B.1. Nature and composition of the ingredient	☐ B.3.(IV) Substantiation of energy factor – Breath hydrogen test
☐ B.2. Calculation of energy factor	☐ B.3.(V) Substantiation of energy factor – Ileal intubation and ileostomy effluent
☐ B.3.(I) Substantiation of energy factor – Bomb calorimetry	☐ B.4. Other factors

CHECKLIST FOR STANDARDS RELATED TO SUBSTANCES ADDED TO FOOD

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

Food Additives (3.3.1)

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

Processing Aids (3.3.2)

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

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

Nutritive Substances (3.3.3)

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

CHECKLIST FOR STANDARDS RELATED TO CONTAMINANTS AND NATURAL TOXICANTS

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

Chemical Contaminant and Natural Toxicant Maximum Levels (3.4.1)

☐	A.1 Nature of contaminant or natural toxicant	☐	C.1 List of foods where maximum level is proposed
☐	A.2 Analytical detection method	☐	C.2 Survey data on contaminant or toxicant levels in foods

☐ B.1 Toxicokinetics & metabolism information

☐ B.2 Toxicity studies

☐ B.3 Human studies relevant to safety

☐ C.3 Information on levels of consumption

☐ C.4 Where consumption has changed, information on likely consumption

Microbiological Limits (3.4.2)

☐ A.1 Raw inputs, production and manufacturing process

☐ A.2 Food technology

☐ B.1 Nature of the microbiological hazard

☐ B.2 Source & prevalence of contamination

☐ B.3 Consumer handling and use

☐ C.1 Nutritional impact

☐ D.1 Dietary exposure

Prohibited and Restricted Plants and Fungi (3.4.3)

☐ A.1 Nature of plant or fungi

☐ A.2 Identity and levels of natural toxicants

☐ B.1 Toxicity studies

☐ B.2 Human toxicity case studies

☐ B.3 Use in other countries

CHECKLIST FOR STANDARDS RELATED TO NEW FOODS

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

Foods Produced using Gene Technology (3.5.1)

☐ A.1 Nature and identity of GM food

☐ A.2 History of use of host and donor organisms

☐ A.3 Nature of genetic modification

☐ A.4 Labelling information on GM food

☐ B.1 Equivalence studies

☐ B.2 Antibiotic resistance marker genes (if used)

☐ B.3 Characterisation of novel protein(s)/substances

☐ B.4 Toxicity of novel protein(s)/substances

☐ B.5 Potential allergenicity of novel protein(s)

☐ B.6 Toxicity of novel herbicide metabolites

☐ B.7 Compositional Analyses

☐ C.1 Nutritional impact of GM food

☐ C.2 Animal feeding studies (if available)

Novel Foods (3.5.2)

☐ A. Exclusive use

☐ B.4 Impurity profile

☐ B.1 Type of novel food

☐ B.2 Information on potential beneficial outcomes

☐ B.3 Chemical and physical properties

☐ B.5 Manufacturing process

☐ B.6 Specification for identity and purity

☐ B.7 Analytical detection method

C – Information on the safety of the novel food

(I) Plant or animal extracts

☐ 1. Extraction and composition

☐ 2. Effects of food processing or preparation

☐ 3. Current use

☐ 4. Potential adverse effects

(II) Plant and animal extracts

☐ 1. Method or extraction and composition of extract

☐ 2. Use as a food in other countries

☐ 3. Toxicity studies

☐ 4. Safety assessments from other agencies

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

☐ 1. History of use

☐ 2. Composition

☐ 3. Method of extraction and composition of extract

☐ 4. Use in other countries

☐ 5. Potential allergenicity

☐ 6. Toxicity studies

☐ 7. Safety assessments from other agencies

(IV & V) Single chemical entities & Dietary macrocomponents

☐ 1. Toxicokinetics and metabolism

☐ 2. Toxicity studies

☐ 3. Safety assessments from other agencies

(VI) Microorganisms (including probiotics)

☐ 1. Potential pathogenicity

☐ 2. Effects on gut microflora

☐ 3. Use as a food in other countries

☐ 4. Human toleration studies

(VII) Food ingredients derived from a new source

☐ 1. Safety of the source organism, including allergen statement

☐ 2. Composition

☐ 3. Toxicity studies

☐ 4. Overseas safety reports

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

☐ 1. Details of the new process

☐ 2. Toxicity studies

☐ 3. Overseas safety reports

☐ D.1 List of foods likely to contain the novel food or novel food ingredient

☐ D.2 Proposed levels in foods

☐ D.7 Use in other countries

☐ E.1 Nutritional impact information

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

Irradiated Foods (3.5.3)

☐	A.1 Nature of the food or food ingredient to be irradiated	☐	B. Safety Information
☐	A.2 Technological need	☐	c. Nutritional impact
☐	A.3 Food products likely to contain irradiated food		

CHECKLIST FOR STANDARDS RELATED TO THE COMPOSITION OF FOOD PRODUCTS

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

Standardised Foods (3.6.1)

☐	A.1 Proposed compositional change	☐	C.1 Demonstrated consumer understanding of proposed change
☐	A.2 List of foods likely to be affected	☐	C.2 Potential adverse health or diet impacts
☐	B.1 Nutritional content	☐	

Special Purpose Foods (3.6.2)

☐	A.1 Safety of proposed compositional change	☐	B.3 Level of consumption
☐	A.2 Nutritional impact of compositional change	☐	C.1 Safety and nutritional impact of labelling change
☐	A.3 Internationally recognised codes of Practice and guidelines	☐	C.2 Demonstrated understanding of labelling change
☐	B.1 Target population	☐	C.3 Internationally recognised codes of Practice and guidelines
☐	B.2 Dietary exposure information		

CHECKLIST FOR STANDARDS RELATED TO FOOD PRODUCTION

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

Food Safety Standards (3.7.1)	
☐ A.1 Public health and safety data	☐ B.1 Projected costs to food industry
Food Processing and Primary Production (3.7.2)	
☐ A.1 Public health and safety data	☐