**Part 3**

**Application guidelines**

Subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (Cth) (FSANZ Act) provides that an application for the development or variation of a food regulatory measure **must**, amongst other things:

* be in the form specified in the application guidelines; and
* include all the information specified by the Application guidelines.

The application guidelines set out at this Part 3 of the *Application Handbook* are guidelines made by legislative instrument in accordance with subsection 23(1) of the FSANZ Act.

For the purposes of these guidelines, an **application** includes all documents provided to FSANZ in support of the development or variation of a food regulatory measure.

The guidelines outline requirements related to each of the groups of standards in the following list. Applications to vary the Code will generally, but not exclusively, relate to one or more of the following groups of standards. In many cases, an application may seek a change that means the information requirements of several guidelines must be met:

* standards related to labelling and other information requirements
* standards related to substances added to food
* standards related to contaminants and natural toxins
* standards related to new foods
* standards related to special purpose foods or standardised foods
* standards related to food production

Each of these broad. groups of standards contains a number of individual food standards which relates to specific food matters. For each, there will be different information requirements. Applicants should identify the guidelines that are relevant to their particular application.

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 information requirements for Guidelines 3.1.1 –General requirements, 3.3.3 – Substances used for a nutritive purpose and 3.6.2 – Special purpose food – Infant formula products, would be relevant.

In the case of Chapter 3.2, Applicants should begin with the Guideline on general food labelling, which contains general requirements for an application related to labelling. The other guidelines relate to particular aspects of labelling, which may or may not be relevant to a particular application.

Boxed text such as notes or examples in these application guidelines provide additional information or clarification of requirements outlined in the guidelines only. They do not form part of the guidelines.

**Chapter 3.1**

**General requirements for applications**

## 3.1.1 General requirements

The application **must** contain the information specified in this Guideline (3.1.1) and as appropriate, the information indicated in Chapters. 3.2–3.7.

**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 food regulatory measure or variation to a food regulatory measure. 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.

***Mandatory information requirements***

The word ‘**must**’ is used in these guidelines to identify information must be included in an application. Applicants should note that if this information is not provided, the application may be rejected at the administrative assessment stage. Rejection will not preclude an applicant from re-lodging the application at a later date.

***Non-mandatory information requirements***

The word ‘**should**’ is used in these Application guidelines to identify information which, though not required to be included in an application, may assist FSANZ in its assessment. 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.

There may be occasions where the information required or recommended for inclusion in an application by these Application guidelines is not sufficient to allow FSANZ to properly assess an application. In such situations, pursuant to section 108 of the FSANZ Act, FSANZ may request additional information from an applicant.

***Drafting***

It is recommended that applicants not include proposed drafting in their application. It is FSANZ’s responsibility to determine what the appropriate drafting should be for the food regulatory measure in response to an application. To enable FSANZ to prepare appropriate drafting, applicants are expected to outline in general terms the change(s) to the Code that they consider are required to secure the outcomes they want. This can include mentioning the relevant sections of the Code and the matters. that any amended or new provisions need to cover or address. Providing explicit drafting in an application may limit that application’s scope and make its assessment more difficult. If proposed drafting is included in an application, in the absence of an express request in the application to include that drafting in the Code, FSANZ will proceed on the basis that that drafting is not being sought by the applicant, but is provided only as an example of how the Code might be amended.

**A Form of the application**

***A.1 Language***

The application **must** be in English.

**Note:**

FSANZ will accept supporting information of high relevance to the application in a language other than English that is accompanied by a full English translation.

***A.2 Format***

The application should contain a table of contents. The table of contents should use the heading titles for the guidelines that are relevant to the application.

The application **must** contain an executive summary of the application. The executive summary **must** be provided as an electronic file separate from other parts of the application.

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

The application **must** be numbered sequentially on each page.

***A.3 Copies***

The application **must** be submitted electronically. The application **must** not be sent by facsimile.

The application should be provided on a thumb drive, CD or other device, as an attachment to an email or through the FSANZ website.

Unless these Application guidelines state otherwise, the application **must** include full electronic copies of all references referred to in the application.

The application should be searchable by word and phrase.

**Note:**

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

If under 20 MB, or via a compressed file if larger than 20 MB, the application can be emailed to the Standards Management Officer at applications@foodstandards.gov.au or sent by post or courier to either of the following addresses:

Standards Management Officer

Food Standards Australia New Zealand

PO Box 5423
KINGSTON ACT 2604

AUSTRALIA

Standards Management Officer

Food Standards Australia New Zealand

Ground Floor

Boeing House

55 Blackall Street

BARTON ACT 2600

AUSTRALIA

**B Applicant details**

The application **must** contain the following contact details:

(a) applicant (individual or organisation’s) name

(b) name of contact person

(c) address (street and postal)

(d) telephone number

(e) email address

(f) nature of applicant’s business

(g) details of other individuals, companies or organisations associated with the application.

**C Purpose of the application**

The application **must** contain a statement regarding the purpose of the application. To the extent possible, the application should identify existing food regulatory measure(s) that need to be varied to achieve the intended purpose of the application. For applications that relate to a matter dealt with under Chapters. 3.2–3.7, the purpose of the application relevant to any particular guidelines **must** be provided.

**D Justification for the application**

The application **must** provide information to indicate why a food regulatory measure is proposed. Such information may, depending on the purpose of the application as outlined according to requirements in section C of this Guideline (3.1.1), include:

(a) the need for the proposed change

(b) the advantages of the proposed change over the status quo, taking into account any disadvantages.

**Note:**

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.

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

***D.1 Regulatory impact information***

The application **must** include current information and data on the following costs and benefits:

*D.1.1 Costs and benefits of the application*

This may include:

(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

(c) the costs and benefits to government e.g. increased regulatory costs.

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

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

**Note:**

If the OBPR makes a decision that a RIS is required, FSANZ must meet the OBPR’s information requirements. In such a case, FSANZ may need to request further information from an applicant before the assessment of the application can continue.

*D.1.2 Impact on international trade*

This may include information on the impact of the proposed change on international trade.

**E 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. This includes all information relevant to the consideration of the safety of a substance.

**Note:**

Where the application relates to matters. referred to in Chapters. 3.2–3.7, please refer to the relevant guideline for specific information requirements. In some instances more than one guideline may apply.

***E.1 Data requirements***

**Note:**

The term ‘**data**’ in this document refers, among other things, to units of information; facts; observations; or results of an experiment, study or survey.

FSANZ will assess all the available data presented in support of an application.

Wherever the data requirements are mandatory but cannot be met, a reason should be provided.

When a literature search is undertaken, the application **must**:

(a) list the databases and journals searched (such as MEDLINE, EMBASE, TOXLINE, FSTA, Science Citation Index, BIOSIS, PsycINFO, CINAHL, Cochrane Library, 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.

*E.1.1 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 the following:

(i) OECD Principles on Good Laboratory Practice

<http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm>

(ii) relevant OECD Guidelines for the Testing of Chemicals

<http://www.oecd.org/env/ehs/testing/>

(iii) other recognised test guidelines such as:

US Food and Drug Administration Redbook 2000 *Toxicological Principles for the Safety Assessment of Food Ingredients*

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm2006826.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.

*E.1.2 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.

*E.1.3 Data related to epidemiological/intervention studies in humans*

(a) Epidemiological/intervention studies should include comprehensive detail about:

(i) **the study design** e.g. randomised controlled trial, cohort study, nested case-control study

(ii) **the objectives or hypothesis**

(iii) **the sample size in the study groups** including the numbers. in each group that were recruited, randomised, completed the study, and included in the analyses, and any power calculations

(iv) **the participants’ characteristics** including age, sex, setting, health status

(v) **the methodology** including duration of intervention (or study) and period of follow-up, measurement of outcomes and confounders, statistical analysis

(vi) **the study results** including effect size and statistical significance, any adverse effects.

(b) The studies should have a sample size that provides sufficient power to detect an intended effect.

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| **Note:**Examples of the main types of intervention and epidemiological study designs include: Intervention (experimental) studies:* clinical trials
* field trials
* individual level
* aggregated level (community trials)

Observational (non-experimental) studies:* cohort studies
* case-control studies
* cross-sectional surveys
* routine data-based studies:
* individual level data
* aggregated level data (ecological studies)
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| **Note:**A number of resources exist which provide guidance on how to report research methods and findings. These resources specify a minimum set of items required for a clear and transparent account of what was done and what was found in a research study, reflecting in particular, issues that might introduce bias into the research. Most widely recognised guidelines are based on the available evidence and reflect consensus opinion of experts in a particular field, including research methodologists and journal editors. These resources are all available online. A list of links to useful resources is provided below:(i) [Equator Network](http://www.equator-network.org/index.aspx?o=1032): overview of reporting guidelines<http://www.equator-network.org/index.aspx?o=1032>(ii) [GRADE](http://www.jclinepi.com/content/jce-GRADE-Series): Grades of Recommendation, Assessment, Development, and Evaluation <http://www.jclinepi.com/content/jce-GRADE-Series>(iii) [CONSORT Statement](http://www.cochrane.org/about-us/evidence-based-health-care/webliography/books/reporting#consort): Consolidated Standards Of Reporting Trials <http://www.consort-statement.org/>(iv) [PRISMA Statement](http://www.cochrane.org/about-us/evidence-based-health-care/webliography/books/reporting#prisma) (formerly QUOROM): Preferred Reporting Items for Systematic Reviews and Meta-Analyses<http://www.prisma-statement.org/>(v) [STARD Statement](http://www.cochrane.org/about-us/evidence-based-health-care/webliography/books/reporting#stard): Standards for Reporting Studies of Diagnostic Accuracy<http://www.consort-statement.org/resources/downloads/other-instruments/> (vi) [MOOSE Statement](http://www.cochrane.org/about-us/evidence-based-health-care/webliography/books/reporting#moose): proposal for reporting meta analyses of observational studies in epidemiology<http://www.consort-statement.org/index.aspx?o=1347>(vii) [STARLITE Statement](http://www.cochrane.org/about-us/evidence-based-health-care/webliography/books/reporting#starlite): Standards for Reporting Literature searches <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1629442/pdf/i1536-5050-094-04->0421.pdf(viii) [STROBE Statement (& STREGA)](http://www.cochrane.org/about-us/evidence-based-health-care/webliography/books/reporting#strobe): STrengthening the Reporting of OBservational studies in [Epidemiology](http://www.cochrane.org/glossary/5#term226).<http://www.strobe-statement.org/>  |

**F Assessment procedure**

If related to a variation to the Code, the application **must** provide details as to what an applicant considers. is the appropriate procedure to be adopted in assessing the application i.e. general, minor, major or high level health claim variation. This is a requirement under paragraph 22(2)(e) of the FSANZ Act. As a matter of practice, FSANZ has regard to the applicant’s suggestion, but makes its own determination on the process to be adopted. The process to be adopted by FSANZ will be communicated to FSANZ in accordance with section 27(c) of the FSANZ Act.

**Note:**

FSANZ makes the final determination on the appropriate procedure and cost recovery level (based on the number of hours. estimated for the assessment) during the administrative assessment, taking account of the purpose and complexity of the application.

**G Confidential commercial information (CCI)**

Any information that the applicant considers. to be CCI **must** be identified as CCI. This information **must** be separated from the other parts of the application (both electronically and in hard copy).

The application **must** be accompanied by a written explanation of why and how that identified information is CCI. That is, how that information satisfies the definition of CCI in section 4 of the FSANZ Act.

The application **must** be accompanied by provide a non-confidential general summary of any information that they consider to CCI. That summary must be sufficiently detailed for it to be useful for assessment. This allows FSANZ to address the information in general terms as part of the assessment.

**Note:**

FSANZ may not accept an applicant’s claim that information is CCI. In such a case, if FSANZ is satisfied that the information is not CCI, FSANZ will advise the applicant that it does not consider that the material is protected by section 114 of the FSANZ Act.

FSANZ will deal with CCI in accordance with section 114 of the FSANZ Act. Applicants should note that section 114 allows CCI to be disclosed to third parties in certain circumstances.

FSANZ will provide CCI to advisory committees or groups established by FSANZ to provide it with expert advice and analysis on an as needs basis, for example, information relating to analytical methods. The members. of such advisory committees and groups are subject to the same confidentiality requirements of the FSANZ Act as FSANZ staff.

**H Other confidential information**

Applications **must** identify all non-CCI information that the applicant wishes to be treated as confidential.

That information **mus**t be separated from other material provided to FSANZ and be marked ‘Confidential’. It **must** be accompanied by a written statement detailing the reasons as to why the applicant wishes that information to be treated as confidential. For example, disclosure of the information would be detrimental to the applicant or the information is not publicly available and known only to a limited number of people.

Applicants who provide unpublished manuscripts **must** indicate whether or not the author is aware that the manuscript has been provided to FSANZ.

**Note:**

The fact that FSANZ agrees to accept information on a confidential basis does not mean that that information cannot be made public or disclosed to others. FSANZ can be required by law, Parliament and the courts to disclose information provided to it on a confidential basis.

If applicants have concerns about personal information contained in an application being published by FSANZ on its website, they may wish to provide a redacted version of the application, in addition to the required complete electronic version of that application. FSANZ will then decide whether to publish the redacted version instead. of the complete version.

**I Exclusive capturable commercial benefit (ECCB)**

The applicant should indicate whether or not the application is expected to confer an exclusive capturable commercial benefit. The applicant should provide a justification for their assertion to assist FSANZ in making a decision.

**Note:**

Consideration of the circumstances surrounding the application, including the following factors, may help in determining whether or not an ECCB is conferred:

* Why are you making this application? What are you hoping to get out its approval?
* How will you benefit from the approval of your application?
* Who besides you, will benefit from the approval of your application? How and why will they benefit?
* If your application is approved, whose permission will be required before anyone can derive a benefit from that approval?
* Who holds the intellectual property in the subject matter of your application?

**J International and other national standards**

***J.1 International Standards***

The application **must** contain details of any Codex Alimentarius Commission (Codex) Standards relevant to the application.

**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*.

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.

***J.2 Other national standards or regulations***

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

**K 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.*

A statutory declaration provided on behalf of a body corporate **must** be made by a senior officer of that body corporate who is authorised to make the declaration on its behalf. The senior officer **must** state their name and source of knowledge and authority in making the statutory declaration and include a sufficient explanation of who they are (name, address, organisation/employer, position).

Templates for Australian and New Zealand statutory declarations are provided on the FSANZ website at <http://www.foodstandards.gov.au/code/changes/applying/Pages/Statutory-declaration.aspx>.

**Note:**

For overseas applicants, FSANZ will accept signed equivalent documents from other countries (in English).

**L Checklist**

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

Page numbers. **must** be included with the checklist as indicated in the Appendix.

**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 Guidelines 3.1.1 – General requirements, 3.3.3 – Substances used for a nutritive purpose and 3.6.3 – Special purpose foods – Other foods, would be relevant.

**Chapter 3.2**

**Guidelines for applications** **for**

**labelling** **and other information requirements**

**3.2.1 General food labelling**

An application to vary the Code is required to change the many aspects of food labelling that are detailed in Part 1.2 – Labelling and other information requirements. This includes both the information contained on the label and the way in which this information is presented on the food product, including the conditions that govern such information.

The following information is required to support an application related to food labelling. This information is in addition to that specified in Guideline 3.1.1 – 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

(e) nutrition content and health claims.

The additional information requirements relating to the above matters. are outlined in Guidelines 3.2.2–3 2.6.

**A General information to support the proposed labelling change**

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

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

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

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

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

**Note:**

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

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

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

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

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

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

This 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.

***B.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

(b) the foods to which it will apply.

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

Also, there may be situations where consumer impact from the proposed labelling is not required e.g. where there is an identified public health benefit associated with the labelling change, or where the impact is on industry rather than consumers.

**3.2.2 Warning and advisory statements**

An application to vary the Code is required to include or change the mandatory warning and advisory requirements that are listed in Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations or Schedule 9 – Mandatory advisory statements.

**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 Guideline 3.1.1 – General requirements and 3.2.1 – General food labelling. Declaration of allergens is considered under Guideline 3.2.3.

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

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

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

This 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 Code in the table to section S9—2. Examples of mandatory warning statements and declarations can be found in sections 1.2.3—3, 4 and 5 in the Code.

**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:

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

This 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 – Information requirements – warning statements, advisory statements and declarations*.*

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

The following additional information is required to support an application to add an allergenic food on the list of foods in the Standard which are required to be declared on the label. This information is in addition to that specified in Guidelines 3.1.1 – General requirements and 3.2.1 – General food labelling.

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

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

This 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).

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

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

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

This 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.

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

This 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 Guidelines 3.1.1 – General requirements and 3.2.1 – General food labelling.

The application **must** contain the information in sections B.1–4 of this Guideline (3.2.3). Data **must** also be provided in accordance with subsection B.5 if the information derived from sections B.1–4 is insufficient to conclude that the food derivative should be exempted from declaration on the label.

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

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

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

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

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

This includes information on dietary intake for different population groups.

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

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

***B.5 Clinical information on the safety of the food derivative, if applicable***

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

**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 Australian Consumer Law, rather than through a variation to the Code.

**Note:**

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum.

For the labelling of GM, irradiated or novel foods, or other foods using new technologies, the relevant Policy Guideline is the Labelling of Foods produced or processed using New Technologies.

FSANZ will have regard to these policy principles during the assessment of applications involving foods produced or processed using new technologies. The Guideline is available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The information requirements outlined below take the Policy Guideline into consideration.

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 Guidelines 3.1.1 – General requirements and 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:

***A.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 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.

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

***A.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 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.

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

This 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 Consumer Law (Commonwealth legislation)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 subsection 18(1) objectives in the FSANZ Act that must be satisfied by FSANZ in developing or varying a food standard.

The ACCC is responsible for ensuring compliance with the Australian Consumer Law. The substantive provisions of the Australian Consumer Law 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 Australian Consumer Law. The Code is usually given legal force through State legislation and is enforced by the States and Territories and by the Australian Government at the border.

**3.2.5 Nutrition information labelling**

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

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

This information is in addition to that specified in Guidelines 3.1.1 – General requirements and 3.2.1 – General food labelling.

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

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

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

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

This 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 also includes information on how the proposed labelling of a specific nutrient or energy will affect the declaration of related nutrients.

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

This 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 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.

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

This includes information related to the identity and purity of the food ingredient. If it is a mixture of ingredients, this 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.

***B.2 Details on the calculation of the energy factor***

This includes details on the calculation of the proposed energy factor for a food ingredient. This calculation **must** follow the following equation. Energy factors. based on other calculation methods will not be considered.

**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)** expressedin 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.

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

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 of methods (not exhaustive) that are acceptable for estimating the individual components of ME:(a) **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.(b) **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).(c) **isotopic tracer methods – FE, UE, upper intestinal absorption, large intestinal fermentation**These methods involve the use of isotopically labelled substrates (e.g. 13C or 14C) and measure the percentage of the given dose that is recovered in metabolised form (e.g. in CO2 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. (d) **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 H2 obtained after a dose of lactulose compared with the breath H2 after a dose of the test food ingredient.(e) **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.  |

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

The application **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)

(g) individual variability.

**3.2.6 Nutrition content and health claims**

The following information is required to amend Standard 1.2.7 – Nutrition, health and related claims, Schedule 4 – Nutrition, health and related claims, or Schedule 6 –Required elements of a systematic review. This information is required in addition to that specified in Guidelines 3.1.1 – General requirements and 3.2.1 – General food labelling.

This Guideline (3.2.6) is divided into two parts. Section A addresses the application requirements for amendments to Standard 1.2.7. Section B is for applications to add a new food-health relationship to the table to section S4—4 (high level health claims) or to the table to section S4—5 (general level health claims) in the Code.

**Note:**

Applications to make a change in Schedule 4 to the list of high level health claims in section S4—4 and to add a general level health claim to section S4—5 are required to be considered using the high level health claim variation procedure. Other applications seeking to amend Standard 1.2.7 will be assessed using the general, minor or major procedure as applicable. If a single application seeks a high level or general level health claim variation as well another variation, then FSANZ will automatically progress the different variations under separate applications, each using the relevant procedure.

**A Amendments to Standard 1.2.7 or Schedule 4, other than adding new food-health relationships to the tables to sections S4—4 and 5**

***A.1 Information related to nutrition content claims in the table to section S4—3***

If the application relates to nutrition content claims in the table to section S4—3, the following information **must** be provided:

(a) consideration of the following in relation to any proposed changes to the claim conditions related to the property of food and each descriptor:

(i) the nutrient composition of foods likely to carry the nutrition content claim as described in response to subsection A.2 in Guideline 3.2.1

(ii) any relevant reference values pertaining to the property of food

(iii) whether the conditions are achievable in the Australian and New Zealand food supply.

If the application is for new claim conditions for a property of food not already mentioned in Schedule 4, the application must include a robust analytical method suitable for analytical laboratories to use for detecting and quantifying the property of food in a food.

***A.2 Information related to the amendment of an existing high level or general level health claim in the table to S4—4 or the table to S4—5***

If the application seeks to vary the food, property of food or the health effect of an existing high level or general level health claim, the application **must** meet the requirements in Section 2 of this Guideline. If the application seeks to delete an existing high level or general level health claim from the tables to S4—4 or S4—5, then it **must** contain sufficient detail to justify why the relationship should not be regarded as causal.

If the application seeks to vary the conditions in Column 5 of the tables to sections S4—4 or S4—5 relating to the food or property of food that is the subject of the food-health relationship, then it **must** contain sufficient detail about the relationship to allow an effective amount of the food or property of food to be determined. Information about the likely dietary intake of the food or property of food by the target group (if there is one) or by the whole population **must** also be provided.

***A.3 Information related to the amendment of the nutrient profiling scoring criterion or method in Schedules 4 or 5 of Standard 1.2.7***

If the application seeks to vary the nutrient profiling scoring criterion or method in Schedules 4 or 5, the following information **must** be provided:

(a) a description of the variation(s) to Schedules 4 or 5, including any food category and other definitions that are to be introduced

(b) a detailed analysis of the impact of the proposed variation on the food eligibility that would occur if the proposed variation was implemented. The analysis **must** include a range of different types of foods illustrative of those in the market in Australia and New Zealand, not solely the foods of interest to the applicant. It **must** include:

(i) a description of how the applicant selected the range of foods examined, including how their nutrient and other relevant compositional characteristics were determined

(ii) a description of how the eligibility status of the range of foods tested was affected when evaluated under the current requirements and under the proposed variation.

FSANZ may request the applicant to supply the dataset containing the range of foods analysed in a form that enables FSANZ to review the data referred to in paragraph A.3(b) of this Guideline (3.2.6).

***A.4 Information related to variation of the required elements of a systematic review in Schedule 6***

If the application seeks to vary any of the required elements of a systematic review as described in Schedule 6, the application **must** provide sufficient information to support the proposed variation, including an indication about how the proposed variation will deliver an equivalent level of rigour in evaluating the scientific information.

**B Amendments to add food-health relationships to the tables to sectionsS4—4 or S4—5**

If the application seeks to add a new food-health-relationship to either the tables to sections S4—4 or S4—5, the application **must** include suitable data, as described below, to assess the nominated food-health relationship and to permit determination of appropriate conditions for a claim based on the relationship.

If the application seeks to vary a food-health relationship already listed in the Code (Columns 1 and 2 in the tables to sections S4—4 or S4—5), then this is equivalent to a new relationship and appropriately suitable data **must** be provided, as outlined below.

***B.1 The scope of the food-health relationship***

*B.1.1 A clear description of the food or property of food in the food-health relationship*

The application **must** clearly characterise the food group, the food (e.g. genus, species, variety) or property of food that is the subject of the proposed health effect.

**Note:**

The food or property of food (see for example, Column 1 in the tables to sections S4—4 or S4—5) may include:

* a food group (e.g. fruit)
* a single ingredient food (e.g. banana)
* a food with more than one ingredient (e.g. chewing gum, bread)
* a property of food that may either be added or inherent (e.g. a nutrient, ingredient, a component of an ingredient, such as dietary fibre, or other substance or feature of food).

If the food or property of food is a substance or a novel food, a permission to add the substance to food or introduce a novel food must be present in the Code. If there is no permission in the Code for the substance or novel food, a simultaneous application may be required because the processes to amend the relevant standards are different.

There can be concurrent, but separate, applications for both a new substance or novel food and a new food-health relationship.

If a property of food is the subject of the food-health relationship, the application **must** also include:

(a) a summary of the source and specifications of the property of food

(b) if permission to add the property of food to food is already in the Code, evidence to confirm that the property of food under consideration is the same as already in the Code

(c) a description of the relative bioequivalence of the property of food when consumed in different food matrices, or of a relevant aspect of bioequivalence such as bioavailability or bioconversion

(d) a robust analytical method suitable for analytical laboratories to use for detecting and quantifying the property of food in the foods in which it is present.

*B.1.2 A clear description of the health effect in the food-health relationship*

The application **must** detail the health effect of the food or property of food and how it is measured.

*B.1.3 A clear description of the proposed food-health relationship*

The application **must** contain a summary of the food-health relationship including the amount of food or property of food required to achieve the health effect, the nature and extent of the health effect, including its direction, and the target population group.

***B.2 Identifying and filtering literature for the proposed food-health relationship***

The application **must** contain the information in either subsections B.2.1 or B.2.2 of this Guideline (3.2.6), whichever applies. Only original literature involving humans can be used as a basis to establish a food-health relationship or update an existing systematic review.

*B.2.1 A clear description of the search strategy used for food-health relationships examined using original literature only*

If the proposed food-health relationship is being examined using the original literature, the application **must** contain a clear description of the search strategy used to capture the scientific evidence. This includes:

(a) identification of the electronic databases (e.g. Medline, CINAHL, Cochrane Library, Embase and PsycINFO etc.) used for the search

(b) the search parameters. including search terms, time period and languages

(c) justification for excluding the use of any closely related ant search terms

(d) reasons for choosing a specified time period

(e) other restrictions placed on the search (e.g. language and study design)

(f) a description of any manual (non-electronic) search techniques employed, including hand-searching, and the strategy used to identify any unpublished studies

(g) a list of inclusion and exclusion criteria used to filter the literature

(h) the number of studies identified from the search strategy, and number of studies excluded at each stage (Title filter, abstract filter and full-text filter) of filtering

(i) a list of the publications (includes author, reference and publication details) excluded at the full text screening stage, and for each excluded publication, the reason(s) why it was considered not relevant (e.g. the inclusion criteria that were not met).

**Note:**

If a completed literature search yields a very large number of articles (e.g. 500) it is suggested using the inclusion and exclusion criteria to filter studies by reading the titles, then read. the abstracts to screen those left, and then finally screen with full-text reading.

The following data sources are not suitable:

* articles published in newspapers, magazines, or newsletters.
* books or book chapters. for consumers. or the general public
* information intended for the general public on the internet, such as Wikipedia.

A relationship between a food or property of food and a health effect cannot be established from animal and *in vitro* studies alone. However, animal and *in vitro* studies may be provided in support of a relationship.

*B.2.2 Food-health relationships based on updating existing systematic reviews*

Where the proposed food-health relationship is based on an existing systematic review, the application **must**:

(a) demonstrate that the food-health relationship described in the existing systematic review is based on the same, or is within the scope of, the proposed food-health relationship

(b) demonstrate that the existing review includes all relevant data from human studies (i.e. evidence in favour, equivocal evidence and evidence that is not in favour of the food-health relationship) given the time period and search criteria that it used

(c) include a full copy of the existing systematic review

(d) describe how the existing systematic review was updated.

Note:

The comparability with the methods of the existing systematic review could be demonstrated by showing that the updating search was done using the same criteria (i.e. points in paragraphs B.2.1 (a)–(f) and B.2.2(a)–(b) above) that were described by the authors. of an existing review. It is important to include the time period covered by an existing review and show how the updated review complements the existing review.

***B.3 Summarising literature for the proposed food-health relationship***

The application **must** summarise the studies in humans for the proposed food-health relationship in tabular form, including objectives, sample size, participant characteristics, measurement methods, control for confounding, results and any adverse effects. If an existing systematic review is being updated, the tabulation **must** include studies from the existing systematic review as well as additional literature identified in the update. If the tabulation in the existing review covers. all the items, then it is acceptable to reproduce the table(s) from the existing review, or to expand them if one or more items are missing.

Each study **must** be assessed for quality. A description of the quality assessment method used **must** be provided.

**Note:**

***Presentation of data from human studies***

Relevant data from each of the included studies should be presented in tabulated form. Original studies (i.e. not reviews or pooled/meta-analyses) should be organised according to study design (e.g. intervention/experimental studies, observational studies) into one or more tables. Tables should include the following information for each study:

(a) the study reference: reference by author/date for each study

(b) the study design: e.g. randomised controlled trial, cohort study, nested case-control study

(c) the objectives or hypothesis

(d) the sample size in the study groups: including the numbers. in each group who were recruited, randomised, completed the study, and included in the analyses, and any power calculations. Include loss to follow up or non-response

(e) the participants characteristics: including age, sex, setting, health status, background diets (including use of supplements if relevant) and other relevant aspects of lifestyle

(f) the method used to measure the food or property of food including amount consumed: including additional dietary intake (including methodology for this), method and frequency of consumption, form of substance including the food matrix (where applicable), amount consumed per day, duration of intervention (or study) and period of follow-up

(g) confounders. measured and method used to control for confounding

(h) the method used to measure the health effect

(i) the study results, including effect size and statistical significance

(j) any adverse effects.

Where an application is based on an existing systematic review, data from the studies included in the existing review and the additional studies that update the review should be organised in one or more tables and provide the information listed under a-j above.

Updates of existing reviews should include commentary about how the update affects the conclusions drawn by the authors. of the existing reviews.

***Empirical analysis of the data***

A meta-analysis of the data can be undertaken. This may add to the weight of evidence in support of the food-health relationship.

***B.4 Assessment of the data from human studies***

The application **must** include a scientific assessment about how the studies reviewed demonstrate, with a high degree of certainty, that a causal relationship exists between the food or property of food and the health effect.

**Note:**

Whether a causal relationship is likely to be established depends on the totality and weight of evidence that supports the proposed food-health relationship under investigation. The evidence would include consideration of a consistent association across all high quality studies that are independent of other factors, inclusion of well-conducted trials temporality and biological plausibility. It may be useful to consider if the relationship could be reversed by at least one additional high quality study.

***B.5 Information for setting conditions***

The application **must** contain sufficient detail about the relationship to allow the amount of the food or property of food that is necessary to achieve the health effect, to be determined. Information about the likely dietary intake by the target population group (if there is one) or the whole population of the food or property of food **must** also be provided.

If the proposed food-health relationship covers. a wider target population group than the groups studied (for example, a wider age-sex range than covered by the included studies), the application **must** include justification of the validity of the extrapolation.”

**Chapter 3.3**

**Guidelines for applications** **for**

**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 Schedule 15 – Substances that may be used as food additives.

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

The following information is required to support an application for a new permissions to use a food additive or to change the permissions for a currently used food additive. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

**A Technical information on the food additive**

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

**Note:**

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum.

For food additives, the relevant Guideline is the Addition to Food of Substances other than Vitamins and Minerals. Since food additives perform a technological purpose in food the specific order policy principles relevant for food additives are the five listed under Technological Function within this Guideline.

FSANZ will have regard to these policy principles during the assessment of the application. The Guideline is available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The information requirements outlined below take the Policy Guideline into consideration.

***A.1 Nature and technological purpose of the additive***

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

(a) each of the technological purposes listed in Schedule 14 – Technological purposes performed by substances used as food additives that the additive fulfils

(b) the reason why the food additive is needed to fulfil these purposes 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 purpose

(d) if the food additive is a preservative, data to demonstrate its effectiveness in each of the food groups in which it is proposed to be used

(e) information is required on how the food additive is incorporated homogenously and stably into the different food matrices to which it is proposed to be added.

Data should also be provided to address losses of the substance from the foods during normal shelf life conditions.

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

This includes the chemical name (according to both Chemical Abstracts (CA) and the International Union of Pure and Applied Chemistry (IUPAC)); structural formula; common name and synonyms; manufacturers’ code; marketing name; and Chemical Abstract Service (CAS) registry number. For new food additives, a common name should be proposed.

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

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

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

In cases where particle size is important to achieving the technological purpose or may relate to a difference in toxicity, the application **must** include information on particle size, size distribution, and morphology, as well as any size-dependent properties.

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

This 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.

***A.5 Manufacturing process***

This includes a description of the method of manufacture of the food additive.

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

This includes a specification from one of the published sources identified in Schedule 3 – Identity and purity. If there is no published specification in one of the identified sources, a detailed specification **must** be provided. Specifications should include information on the name of the food additive, its chemical and physical properties, its purity, acceptable levels of impurities, the method of preparation, and analytical methods of determining purity.

Information is also required for the presence of known allergens (see section 1.2.3—4 in the Code) in the commercial product.

***A.7 Information for food labelling***

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

***A.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 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 application **must** include a robust analytical method suitable for analytical laboratories to determine compliance of any limits prescribed in the Code.

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

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

**B Information related to the safety of the food additive**

**Note:**

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

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

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

(a) For an application for a new food additive, this 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, reports of the studies conducted since the last safety evaluation by FSANZ should be included. If no previous evaluation by FSANZ is available, published papers. or a comprehensive review article on this matter should be included.

***B.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 includes reports of all *in vitro* and *in vivo* studies conducted in animals or humans to examine the toxicity of the food additive and, if necessary, its metabolites or degradation products.

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 need only include the detailed reports of studies conducted since the last safety evaluation by FSANZ.

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

This includes safety assessment reports prepared by JECFA (unless provided under subsection B.2 of this Guideline (3.3.1)) or by other national or supranational agencies responsible for food safety.

**C Information related to the dietary exposure to the food additive**

**Note:**

FSANZ may undertake a dietary exposure assessment for all food additive applications requesting changes to permissions in Schedule 15 using a custom-made computer program, HARVEST, 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:

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

The food list should be based on the food group descriptions in the table to S15—5.

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

***C3 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 includes any consumption information for food groups not included in the most recent Australian or New Zealand 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 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey  (2 years. and above), the 2008–09 New Zealand NNS (15 years. and above) and the 2002 New Zealand Children’s NNS (5–14 years).

The application should contain the following information:

***C.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 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.

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

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

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

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

**3.3.2 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 Schedule 18 – Processing aids*.*

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

The 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 Guideline 3.1.1 – General requirements.

**Note:**

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum.

For processing aids, the relevant Guideline is the Addition to Food of Substances other than Vitamins and Minerals. Since processing aids perform a technological function during the manufacture of food the specific order policy principles relevant for processing aids are the five listed under Technological Function within this Guideline.

FSANZ will have regard to these policy principles during the assessment of the application. The Policy Guideline is available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The information requirements outlined in this section take the Policy Guideline into consideration.

**A Technical information on the processing aid**

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

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

This includes a brief description of the processing aid, the category (if any) in Schedule 18 into which it falls and evidence that the form and the amount of the processing aid performs the intended purpose.

The various functions performed by processing aids are listed in the relevant sections in Schedule 18.

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

This 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 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 includes both the host and donor organism, including alternative names for the microbial source, if applicable, and a statement as to whether or not the enzyme has been protein-engineered.

For new processing aids, a common name should be proposed. Where relevant, this information should support the evidence that the amounts proposed to be added are consistent with achieving the technological purpose.

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

This includes details of the chemical and physical properties that make it suitable as a food processing aid.

Information on how the food additive is incorporated homogenously and stably into the different food matrices to which it is proposed to be added should be provided. Data should also be provided to address losses of the substance from the foods during normal shelf life conditions.

The application **must** include information on possible interactions of the processing aid with different foods. If the processing aid is an enzyme, the application **must** include information on its technological purpose, including enzymatic properties.

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

***A.4 Manufacturing process***

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

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

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

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

This includes a specification from one of the published sources identified in Schedule 3 – Identity and purity. If a published specification is not available, a detailed specification **must** be provided. Specifications should include information on the name of the processing aid, its chemical and physical properties, its purity, acceptable levels of impurities, the method of preparation, and analytical methods for determining purity.

The presence of known allergens (see section 1.2.3—4 in the Code) in processing aid preparations **must** be identified

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

Where a processing aid or breakdown or by-products of a processing aid are likely to be present in the final food, an analytical method **must** be provided to detect and quantify the amount(s). Such an analytical method should be robust and applicable for analytical laboratories to determine compliance of any limits prescribed in the Code. This information is not required in the case of an enzymatic processing aid.

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

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

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

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

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

This 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.

***B.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 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 includes only the reports of studies conducted since the last safety evaluation by FSANZ. If no previous evaluation by FSANZ is available, published papers. and /or a comprehensive review article on this matter should be included.

***B.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 includes detailed reports of all *in vitro* and *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.

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 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 should include reports of any evaluation by the Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) or equivalent expert group.

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

This includes safety assessment reports prepared by JECFA (unless provided under subsection B.4 of this Guideline (3.3.2)) or by other national or supranational agencies responsible for food safety.

**C Information related to the safety of an enzyme processing aid**

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

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

This 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.

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

This includes the following for all enzymatic processing aids:

(a) information on the enzyme’s prior history of human consumption and 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 **must** be provided:

(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 **must** be provided:

(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.

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.

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

**Note:**

The information provided in this subsection 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 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 **must** be provided:

(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 **must** be provided:

(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.

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

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

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

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

***D.1 Information on the source microorganism***

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

The information provided should also contain the production method used.

***D.2 Information on the pathogenicity and toxicity of the source microorganism***

This includes information to demonstrate that the strain of the source microorganism is non-pathogenic and non-toxigenic. If the enzyme is from a fungal source, the application **must** include information to demonstrate that the strain does not produce toxicologically significant amounts of mycotoxins.

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

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

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

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

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

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

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

(d) information on the stability of the inserted gene.

**F Information related to the dietary exposure to the processing aid**

**Note:**

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

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

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

The food list should be based on the food group descriptions in the table to S15—5.

***F.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.

***F.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 includes any consumption information for food groups not included in the most recent Australian or New Zealand NNSs which relate to the 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 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey  (2 years. and above), the 2008–09 New Zealand NNS (15 years. and above) and the 2002 New Zealand Children’s NNS (5–14 years).

The application should contain the following information:

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

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

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

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

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

**3.3.3 Substances used for a nutritive purpose**

An application to vary the Code is required to approve the use of a new nutritive substance or to change the permissions for use of a nutritive substance. The use of a nutritive substance in food is achieved by the addition of that substance to food.

**Note:**

If the substance or ingredient intended to be added to food is not to be used as a nutritive substance, it may be regarded as a novel food substance and considered under Guideline 3.5.2 – Novel foods. A nutritive substance may also be regarded as a novel food, in which case both guidelines will apply.

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written Policy Guidelines formulated by the Forum.

In the case of an application to add vitamins or minerals to food, either through voluntary or mandatory fortification, the relevant Policy Guideline is the Fortification of Food with Vitamins and Minerals.

For applications relating to substances other than vitamins or minerals, the relevant Policy Guideline is the Addition to Food of Substances other than Vitamins and Minerals*.*

The Policy Guidelines are available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The information requirements outlined in this section take each Policy Guideline into consideration.

The following information is required to support an application for use of a new nutritive substance or to change the permissions for a use of a nutritive substance. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

**A Information on the use of the nutritive substance**

***A.1 Information on the purpose of the use of a nutritive substance in food***

The application **must** state all of the purpose(s) of the use of the nutritive substance in food. If such a substance has multiple purposes or functions then these must all be briefly described.

When the purpose for using a nutritive substance in food (including special purpose foods) relates to a nutritional purpose to deliver a potential beneficial physiological or health-related outcome, the application **must**:

(a) include a brief description of all of the physiological or health-related function(s) of the substance at the proposed level

(b) be stated in a way that can be measured i.e. as an outcome in clinical studies

***A.2 General data requirements for supporting evidence***

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

Studies provided as evidence to support an application **must** contain sufficient detail to enable an independent assessment of the methods and results to confirm the study conclusions. The scientific evidence for a potential beneficial physiological or health-relatedoutcome **must**:

(a) be based on studies conducted on human subjects

(b) be based on foods or food groups which contain the nutritive substance rather than the use of the substance alone

(c) relate to normal use by the target population group and the foods must contribute to the demonstrated nutritional role relevant to that target population.

**Note:**

Refer to section E in Guideline 3.1.1 for further information regarding data quality.

**B Technical information on the use of the nutritive substance**

For an application to extend the use of a nutritive substance, this **must** indicate that the technical information required in subsections B.1–B.7 in this Guideline (3.3.3) meets the current identity and purity specifications.

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

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

This 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.

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

This includes detailed chemical and physical properties of the nutritive substance that are important for understanding how the substance is incorporated into the requested food matrices. Specifically, information and data **must** be provided on how the substance is incorporated in a uniform manner into the food matrices. Studies on the stability of the incorporated substance in particular detailing losses during food processing and storage to the end of shelf life **must** be provided for the different food matrices.

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.

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

This 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.

***B.4 Manufacturing process***

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

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

This includes a specification from one of the published sources identified in Schedule 3 – Identity and purity. If a published specification is not available, a detailed specification should be provided.

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

This 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 application **must** include a robust analytical method suitable for analytical laboratories to determine compliance of any limits prescribed in the Code.

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

This 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 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 use of the nutritive substance at the levels proposed in the food. Where an upper level of safety (UL) has been established, this will be considered. The NHMRC publication *Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes* contains ULs for a range of vitamins and minerals. This publication can be found at <http://www.nhmrc.gov.au/publications/synopses/n35syn.htm>.

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

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

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

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

***C.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 the use of a new nutritive substance, this includes published reviews or detailed reports of all *in vitro* and *in vivo* studies conducted in animals or humans to examine the toxicity of the nutritive substance and, where necessary, its metabolites or degradation products.

The following categories of studies need to be considered:

(a) acute toxicity

(b) short-term toxicity

(c) long-term toxicity and carcinogenicity

(d) reproductive toxicity

(e) developmental toxicity

(f) genotoxicity

(g) special studies such as neurotoxicity or immunotoxicity.

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

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

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

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

**D Information on dietary intake of the nutritive substance**

**Note:**

FSANZ may undertake a dietary exposure assessment for all nutritive substance applications using a custom-made computer program, HARVEST, 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:

***D.1 A detailed list of the food groups or foods in which the use of a nutritive substance is proposed, or changes to currently permitted foods in which a nutritive substance is used***

This includes information about the nutrient content of foods to which the use of the nutritive substance is proposed such as total fat and saturated fat, total sugars, sodium, and energy content.

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

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

***D.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 includes any consumption information for food groups not included in the most recent Australian or New Zealand NNSs which relate to the 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 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey  (2 years. and above), the 2008–09 New Zealand NNS (15 years. and above) and the 2002 New Zealand Children’s NNS (5–14 years).

The application should include the following information:

***D.4 The percentage of the food group to which the use of the nutritive substance is proposed or the percentage of the market likely to use the nutritive substance***

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

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

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

This information provides an indication of the range of foods in Australia and New Zealand that might contain the used nutritive substance.

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

This 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.

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

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

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

This 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

(b) data to demonstrate that deficiencies are likely to develop in one or more population groups because of changing food habits

(c) generally accepted scientific evidence that an increase in the intake of a vitamin or mineral can deliver a health benefit

(d) evidence that the reduced nutritional profile of a processed food can be substantially restored

(e) evidence that the nutritional profile of the specified substitute food can be aligned with the primary food.

***E.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 includes:

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

(b) data on the metabolic fate of the vitamin or mineral under the conditions above

(c) information on the food vehicle, including the presence of substances that will have an inhibitory or enhancing effect on absorption.

**F Information related to the nutritional impact of a nutritive substance other than vitamins and minerals**

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

***F.1 Information related to the nutritional purpose of the use of the substance in each food***

This includes data to demonstrate the nutritive substance is consistent with its proposed purpose as described in subsection A.1 in this Guideline (3.3.3) and **must** include:

(a) the target population(s) be clearly stated

(b) 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(s) at the anticipated level of intake. The total amount should include naturally-occurring and added amounts.

(c) data to demonstrate that the nutritional composition of the specified substitute food can be aligned with the reference food.

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

**Note:**

In addition to the information specified in this section, some of the information derived from section D in this Guideline (3.3.3) will be used also to assess the impact on consumers. of the nutritive substance.

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

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

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

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

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

**Note:**

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

The extent of the impact of the use 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 subsections G.1–3 in this Guideline (3.3.3) 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 Section F in this Guideline (3.3.3), FSANZ may request the applicant to conduct empirical research to address these points. FSANZ can provide guidance here.

**Chapter 3.4**

**Guidelines for applications** **for**

**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 Schedule 19 – Maximum levels of contaminants and natural toxicants.

The following information is required to support an application for a new maximum level for a contaminant or to change the current maximum level. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

**A General information on the contaminant or natural toxicant**

The application **must** contain the following:

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

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

 In cases where particle characteristics may relate to the toxicity of the food contaminant, the application **must** include information on particle size and morphology.

***A.2 Analytical method for detection***

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

**B Information on the safety of the contaminant or natural toxicant**

The application **must** contain the following:

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

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

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

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.

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

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

**C Information on dietary exposure to the contaminant or natural toxicant**

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

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

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

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

This includes the details of any surveys which have been conducted in Australia or New Zealand on the levels found in foods.

If data derived from an analytical survey are used, details of how the survey was conducted and the analytical methods used **must** be provided. These details should include the sampling plan, the number of samples, where the samples were collected, whether the analysis was conducted on composite or individual samples, the method of analysis, the limits of detection/quantification/reporting (LOD, LOQ, LOR) for the analytical method used, whether the foods were prepared/cooked before analysis, whether the samples were from the edible portion only, and whether the sampling was targeted or randomly sampled.

If applicable, details of any surveys conducted in other countries **must** be included.

***C.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 includes any consumption information for food groups not included in the most recent Australian or New Zealand NNSs which relate to the 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 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey  (2 years. and above), the 2008–09 New Zealand NNS (15 years. and above) and the 2002 New Zealand Children’s NNS (5–14 years).

The application should include the following information:

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

This 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 may be based on market share data or sales data or on a similar market in another country.

**3.4.2 Microbiological limits**

An Application to vary the Code is required to change the permissible limits for a microorganism in food or to change the sampling provisions, including the sampling plans, the prescribed methods of analysis or other requirements which are specified in Standard 1.6.1 – Microbiological limits in food or Schedule 27 – Microbiological limits in food.

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 Guideline 3.1.1 – General requirements.

**A Technical information on food production methods**

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

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

This includes:

(a) details of the raw ingredients, production process and methods of manufacture, including key properties that may impact on microbial growth, survival or inactivation (e.g. pH, water properties etc)

(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).

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

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

**B Information related to food safety**

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

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

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

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

This includes:

(a) survey results on the prevalence and levels of the pathogen along the entire food production chain, including raw materials

(b) microbiological validation studies and challenge test data (in either/or both laboratory and pilot-scale studies, if appropriate).

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

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

**C Information on the nutritional impact**

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

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

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

**D Information related to dietary exposure**

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

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

This 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 NNSs, the application **must** include projected consumption data, which can include information from international markets.

**Note:**

The most recent NNSs are the 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey  (2 years. and above), the 2008–09 New Zealand NNS (15 years. and above) and the 2002 New Zealand Children’s NNS (5–14 years).

**3.4.3 Prohibited and restricted plants and fungi**

An application to vary the Code is required to add, modify or delete an entry in relation to a plant or fungi in Schedule 23 – Prohibited plants and fungi or Schedule 24 – Restricted plants and fungi.

The following information is required to support an application to add, modify or delete an entry in relation to a plant or fungi in Schedules 23 or 24. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

**A General information on the plant or fungi (or a part or derivative thereof)**

The application **must** contain the following:

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

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

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

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

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

The application **must** contain the following:

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

This includes a literature survey of relevant toxicity literature.

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

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

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

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

**Chapter 3.5**

**Guidelines for** **applications for** **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 Schedule 26 – Food produced using gene technology.

The following information is required to support an application for a new genetically modified food. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

**Note:**

Further explanatory information regarding some of the data requirements for this Guideline (3.5.1) is available in Part 2.3 of this Handbook (GM applications – additional information).

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum.

For the labelling of GM foods, the relevant Guideline is the Labelling of Foods produced or processed using New Technologies.

FSANZ will have regard to these policy principles during the assessment of applications involving foods produced or processed using new technologies. The Guideline is available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The information requirements outlined below take this Policy Guideline into consideration.

**A Technical information on the food produced using gene technology**

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

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

This **must** include 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, line number and OECD Unique 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).

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

The common and scientific names of host and donor organisms **must** be stated. Where information relating to an organism has been included in previous safety assessments prepared by FSANZ, it is not necessary to provide any further information. Where an organism has not been considered previously by FSANZ, the following information **must** be provided.

(a) For the donor organism(s) from which the genetic elements are derived:

(i) any known pathogenicity, toxicity or allergenicity of relevance to the food;

(ii) 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) For the host organism into which the genes were transferred:

(i) its history of safe use for food

(ii) the part of the organism typically used as food

(iii) the types of products likely to include the food or food ingredient

(iv) whether special processing is required to render food derived from the organism safe to eat.

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

This **must** include all of the following:

(a) a description of the method used to transform the host organism

(b) a description of the 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

(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.

(c) 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 of each insertion site, including junction regions with the host DNA

(iv) a map depicting the organisation of the inserted genetic material at each insertion site

(v) details of an analysis of the insert and junction regions for the occurrence of any open reading frames (ORFs).

(d) 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) including which generations have been used for each study.

(e) 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

(ii) the pattern of inheritance and expression of the phenotype over several generations and, where appropriate, across different environments.

(g) an analysis of the expressed RNA transcripts, where RNA interference has been used.

**B Characterisation and safety assessment of new substances**

The application **must** address the following sections:

***B.1 Characterisation and safety assessment of new substances***

This **must** include all of the following:

(a) a full description of the biochemical function and phenotypic effects of all new substances (e.g. a protein or an untranslated RNA) that are expressed in the new GM organism, including their levels and site of accumulation, particularly in edible portions

(b) information about prior history of human consumption of the new substances, if any, or their similarity to substances previously consumed in food.

(c) information on whether any new protein has undergone any unexpected post-translational modification in the new host

(d) where any ORFs have been identified (in subparagraph A.3(c)(v) of this Guideline (3.5.1)), bioinformatics analyses to indicate the potential for allergenicity and toxicity of the ORFs.

***B.2 New proteins***

If it can be shown the new protein(s) is identical to one previously assessed by FSANZ, the only other safety information that must be provided is an updated bioinformatics comparison of the amino acid sequence to known protein toxins, anti-nutrients and allergens.

Where the new protein is not identical to one previously assessed by FSANZ, the following **must** be provided:

(a) information on the potential toxicity of any new proteins, including:

(i) a bioinformatic comparison of the amino acid sequence of each of the new proteins to known protein toxins and anti-nutrients (e.g. protease inhibitors, lectins)

(ii) information on the stability of the protein to proteolysis in appropriate gastrointestinal model systems

(iii) an animal toxicity study if the bioinformatic comparison and biochemical studies indicate either a relationship with known protein toxins/anti-nutrients or resistance to proteolysis.

(b) information on the potential allergenicity of any new proteins, including:

(i) source of the new protein

(ii) a bioinformatics comparison of the amino acid sequence of the novel protein to known allergens

(iii) the new protein’s structural properties, including, but not limited to, its susceptibility to enzymatic degradation (e.g. proteolysis), heat and/or acid stability

(iv) specific serum screening where a new protein is derived from a source known to be allergenic or has sequence homology with a known allergen

(v) information on whether the new protein(s) have a role in the elicitation of gluten-sensitive enteropathy, in cases where the introduced genetic material is obtained from wheat, rye, barley, oats, or related cereal grains.

Where the new protein has been produced from an alternative source (e.g. microbial expression system) in order to obtain sufficient quantities for analysis, information **must** be provided to demonstrate that the protein tested is biochemically, structurally and functionally equivalent to that expressed in the food produced using gene technology.

Information on the potential toxicity and potential allergenicity of a newly expressed protein is also not required if:

(a) the protein is expressed from a transferred gene that is derived from the same species as the host or a species that is cross-compatible with the host, provided evidence is provided to demonstrate the following:

(i) the gene donor belongs to a species that is commonly used as food and has a history of safe use

(ii) the protein is expressed at levels in the new food produced using gene technology that are consistent with the levels in the gene donor.

(b) evidence is provided to demonstrate the absence of the newly expressed protein from the parts of the host organism consumed as food.

***B.3. Other (non-protein) new substances***

If other (non-protein) substances are produced as a result of the introduced DNA, information must be provided on the following:

(a) the identity and biological function of the substance

(b) whether the substance has previously been safely consumed in food

(c) potential dietary exposure to the substance

(d) where RNA interference has been used:

(i) the role of any endogenous target gene and any changes to the food as a result of silencing that gene

(ii) the expression levels of the RNA transcript

(iii) the specificity of the RNA interference

***B.4 Novel herbicide metabolites in GM herbicide-tolerant plants***

**Note:**

Novel metabolites are those not normally found in non-GM crops sprayed with the same herbicide.

Data **must** be provided on the identity and levels of herbicide and any novel metabolites that may be present in the food produced using gene technology.

If novel metabolites are present then the application should address the following, where appropriate:

(a) toxicokinetics and metabolism

(b) acute toxicity

(c) short-term toxicity

(d) long-term toxicity and carcinogenicity

(e) reproductive and developmental toxicity

(f) genotoxicity.

***B.5 Compositional analyses of the food produced using gene technology***

This **must** include all of the following:

(a) the levels of relevant key nutrients, toxicants and anti-nutrients in the food produced using gene technology compared with the levels in an appropriate comparator (usually the non-GM counterpart). A statistical analysis of the data must be provided.

(b) information on the range of natural variation for each constituent measured to allow for assessment of biological significance should any statistically significant differences be identified

(c) 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 as well as the range of natural variation.

In the case of herbicide-tolerant plants, the levels of each constituent in the food produced using gene technology **must** be determined using plants sprayed with the herbicide.

**C Information related to the nutritional impact of the food produced using gene technology**

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

(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.

**D Other information**

There is no requirement to conduct animal feeding or whole food toxicity studies on the food produced using gene technology. However, if a 90-day (or longer) whole food toxicity study in rodents has been provided to satisfy the data and information requirements of another jurisdiction, this should also be provided to FSANZ as additional supporting information.

**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 Schedule 25 – Permitted novel foods.

**Note:**

For further information relating to the operation of Standard 1.5.1 – Novel foods, particularly in relation to whether a particular food would be regarded as novel, refer to the FSANZ website at <http://www.foodstandards.gov.au/industry/novel/Pages/default.aspx>.

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

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum.

In the case of an application seeking approval of a novel food or ingredient, the relevant Guidelines are Novel Foods, the Addition to Food of Substances other than Vitamins and Minerals and the Labelling of Foods produced or processed using New Technologies.

The Guidelines are available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The information requirements outlined below take each Policy Guideline into consideration.

The following information is required to support an application for a novel food. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

**A Exclusive use of novel foods**

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

(a) the specific class of food

(b) the brand of the food, including the name the food will be marketed under (if known).

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

**B Technical information on the novel food**

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

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

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

This 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:

* plants or animals and their components
* plant or animal extracts
* herbs (both non-culinary and culinary) including extracts
* single chemical entities
* dietary macro-components
* microorganisms (including probiotics)
* food ingredients derived from new sources
* foods produced by a process not previously applied to food.

**Note:**

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

The term **dietary macro-component** generally refers. to those dietary components which constitute a significant proportion of the food, such as fats, sugars, proteins and polysaccharides. Novel macro-components are used to replace the naturally-occurring components, either for a functional purpose or to reduce the energy value of the food. Examples include tagatose, cyclodextrin, 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 Standard 1.5.1, a single chemical entity does not include a substance used for a technological purpose.

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

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

The application must state the purpose(s) of the addition of the novel food ingredient to food. If an added substance has multiple purposes or functions then these **must** all be specified.

If the purpose for adding a novel food ingredient to food (including special purpose foods) relates to a potential beneficial physiological or health-related outcome, the purpose **must**:

(a) include a brief description of any physiological or health-related function(s) of the substance at the proposed level

(b) be stated in a way that can be measured i.e. as an outcome in clinical studies

(c) provide supporting 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. The target population **must** be clearly stated.

***B.3 Information on the physical and chemical properties of the novel food or novel food ingredient***

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

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

***B.4 Information on the impurity profile for a typical preparation***

This 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.

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

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

***B.6 Specification for identity and purity for a novel food ingredient***

This includes a specification from one of the published sources identified in Schedule 3 – Identity and purity. If a published specification is not available, a detailed specification **must** be provided. Where the substance, in the form in which it will be present in food, is particulate in nature, the application **must** include information on particle size, size distribution and morphology in cases where the referenced specification does not include this information.

***B.7 Analytical method for detection of a novel food ingredient***

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

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

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

**Note:**

FSANZ will undertake an assessment of all available reports of animal and human studies which provide information related to the toxicity of the novel food or novel food ingredient. The safety of the novel food will be assessed at the proposed levels of use, using both the technical information provided in section A of this Guideline (3.5.2) and the information specified in this section.

For a novel food ingredient, a safe level of intake will be established, if possible, from the available studies.

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

(a) the history of use as a food in other countries

(b) the composition of the novel food, particularly the levels of anti-nutrients and naturally-occurring toxins

(c) the method of preparation and specifications of a novel food ingredient

(d) potential for allergenicity of the novel food

(e) metabolism/toxicokinetic studies on the novel food ingredient

(f) animal toxicity studies on the novel food ingredient

(g) human toleration studies on the novel food ingredient

The nature of the information on the safety of the novel food to be submitted will depend on the category of the novel food as identified in subsection B.1 of this Guideline (3.5.3).

***C.1 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:

*C.1.1 Information on the composition of the novel food*

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

*C.1.2 Information on the effects of food processing or preparation*

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

*C.1.3 Information on the current use of this food or food component in population sub-groups or in other countries*

This includes information on the extent and history of use of the food in other countries; any particular preparation, processing or cooking practices normally used; and the level and purpose of consumption (e.g. staple food, ceremonial use). This evidence of safe use should include the frequency of consumption, the extent of the population using the food, and the period of use.

*C.1.4 Information regarding the potential adverse effects associated with the food or its ingredients*

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

***C.2 Plant or animal extracts***

An application for a novel food which is a plant or animal extract **must** contain all of the information in subsection C.1 Plants or animals (or their components) above, as well the following additional information:

*C.2.1 Information on the method of extraction and the composition of the concentrated extract*

This 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.

*C.2.2 Information on the use of this plant or animal extract as a food in other countries*

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

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

*C.2.3 Information on the toxicity of the extract obtained from studies conducted in animals or humans*

This includes reports of toxicity studies conducted in animals. The application **must** also include any reports of toleration studies conducted in humans.

*C.2.4 Safety assessment reports prepared by international agencies or other national government agencies*

This includes published safety assessment reports prepared by other agencies.

***C.3 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:

*C.3.1.1 Information on the history of use of the herb*

This 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.

*C.3.2 Information on the composition of the herb*

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

*C.3.3 For a herbal extract, information on the method of extraction and the composition of the concentrated extract*

This 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. The application **must** include information on the levels of potential contaminants from the extraction process.

*C.3.4 Information on the use of this herbal extract as a food in other countries*

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

*C.3.5 Information regarding the potential allergenicity of the herb or herbal extract*

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

*C.3.6 Information on the toxicity of the herb, or herbal extract, or any key constituents obtained from studies conducted in animals or humans*

This includes reports of toxicity studies conducted in animals. The application **must** also include any reports of toleration studies conducted in humans.

*C.3.7 Safety assessment reports prepared by international agencies or other national government agencies*

This includes published safety assessment reports prepared by other agencies.

***C.4 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:

*C.4.1 Information on the toxicokinetics and metabolism of the single chemical entity and, where appropriate, its degradation products and major metabolites*

This 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.

*C.4.2 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 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.

The application should address the following categories of studies:

(a) acute toxicity studies

(b) short-term toxicity

(c) long-term toxicity studies and carcinogenicity studies

(d) reproductive toxicity studies

(e) developmental toxicity studies

(f) genotoxicity studies

(g) special studies such as neurotoxicity or immunotoxicity

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

*C.4.3 Safety assessment reports prepared by international agencies or other national government agencies*

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

***C.5 Microorganisms (including probiotics)***

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

*C.5.1 Information on potential pathogenicity*

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

*C.5.2 Information on the effects of the microorganism on gut microflora*

This includes studies to demonstrate that the microorganism does not have adverse effects on the gut microflora.

*C.5.3. Information on the use of this microorganism in food or as a food in other countries*

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

*C.5.4 Information on human toleration studies*

This includes any published or unpublished reports of toleration studies conducted in humans. Clinical evaluation of potential probiotics **must** use double-blind, placebo-controlled human trials, with detailed reporting of adverse side effects, which can be used to confirm the results observed in animal tests or *in vitro* studies.

***C.6 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:

*C.6.1 Information on the safety of the source organism*

This 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, the application **must** include information on any potential pathogenicity and toxicity. The application **must** also include information on potential naturally-occurring toxins, if applicable.

The application **must** include details on the presence of known allergens (see section 1.2.3—4 in the Code).

*C.6.2 Information on the composition of the novel food ingredient derived from a new source*

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

*C.6.3 Information on the toxicity of the novel food ingredient derived from the new source*

This includes any published or unpublished reports of toxicity studies conducted in animals. The application **must** also include any reports of toleration studies conducted in humans.

*C.6.4 Safety assessment reports prepared by international agencies or other national government agencies*

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

***C.7 Foods produced by a process not previously applied to food***

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

*C.7.1 Details of the process not previously applied to food*

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

*C.7.2 Information on the toxicity of the novel food produced by a process not previously applied to food*

This includes any published or unpublished reports of toxicity studies conducted in animals. The application **must** also include any reports of toleration studies conducted in humans. The nature of the toxicity or toleration studies to be submitted will depend on the category of the novel food as set out in B.1.

The application **must** include details on the presence of known allergens (see section 1.2.3—4 in the Code).

*C.7.3 Safety assessment reports prepared by international agencies or other national government agencies*

This includes safety assessment reports prepared by the 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 may 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, HARVEST, 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 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey  (2 years. and above), the 2008–09 New Zealand NNS (15 years. and above) and the 2002 New Zealand Children’s NNS (5–14 years).

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

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

***D.1 A list of the foods or food groups proposed to or which might contain the novel food ingredient or substance***

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

Data **must** be provided about the proposed concentration (or levels of addition) of the novel food ingredient in each of the foods or food groups identified in subsection D.1 of this Guideline (3.5.2) (i.e. proposed to contain the substance). Any information on naturally-occurring levels of the substance **must** also be provided. The application should indicate whether these are maximum or actual use levels.

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

This includes any consumption information for food groups not included in the most recent Australian or New Zealand NNSs which relate to the 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 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey  (2 years. and above), the 2008–09 New Zealand NNS (15 years. and above) and the 2002 New Zealand Children’s NNS (5–14 years).

The application should contain the following information:

***D.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 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.

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

This 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.

**Note:**

The most recent NNSs are the 2011–12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011–13 Australian Health Survey  (2 years. and above), the 2008–09 New Zealand NNS (15 years. and above) and the 2002 New Zealand Children’s NNS (5–14 years).

***D.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 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.

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

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

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

**Note:**

Some of the information derived from section C in this Guideline (3.5.2) will be used also to assess the nutritional impact of the novel food. The information in this section E is in addition to the information set out in section C of this Guideline (3.5.2). Information in relation to the safety, dietary exposure and nutritional impact will be considered by FSANZ in characterising the risk of the novel food or novel food ingredient.

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

***E.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 includes information relating to the effect of the novel food, ingredient or substance on the bioavailability of other nutrients.

This also includes consideration of the effect on the intake of other components of the overall diet (particularly macronutrients) which may arise from the novel food, ingredient or substance.

***E.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 section F of this Guideline (3.5.2).

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

**Note:**

Some of the information derived from section D in this Guideline (3.5.2) will be used also to assess the impact on consumers. of the novel food. The information below is in addition to this information.

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

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

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

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

***F.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 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 subsections F.1–3 of this Guideline (3.5.2) 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 an applicant to conduct empirical research to address these points. FSANZ can provide guidance here.

**3.5.3 Irradiated foods**

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

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

**Note:**

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum.

For the labelling of irradiated foods, the relevant Policy Guideline is the Labelling of Foods produced or processed using New Technologies.

FSANZ will have regard to these policy principles during the assessment of applications involving foods produced or processed using new technologies. The Guideline is available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The information requirements outlined below take this Policy Guideline into consideration.

**A Technical information on the irradiated food**

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

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

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

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

This includes the following data 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 or support from an appropriate quarantine agency (e.g. the Australian Government Department of Agriculture and Water Resources or the New Zealand Ministry for Primary Industries) 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.

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

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

**B Information on the safety of irradiation**

The application **must** include 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.

**Chapter 3.6**

**Guidelines for applications for**

**special purpose foods and standardised foods**

**3.6.1 Standardised foods**

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

The following information is required to support an application related to the composition of standardised foods. This information is in addition to that specified in Guideline 3.1.1 – 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 in other guidelines in Part 3.

Additional information may be required if the application relates to a special purpose food. Additional information requirements relating to special purpose foods are in Guidelines 3.6.2 – Special purpose foods – Infant formula products and 3.6.3 – Special purpose foods – Other foods.

**A General information to support the proposed compositional change**

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

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

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

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

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

**B Information related to nutritional impact**

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

***B.1 Information on the nutritional content of the standardised food***

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

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

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

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

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

**Note:**

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

(a) the nature of the compositional change; and

(b) the foods to which it will apply.

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

**3.6.2 Special purpose food – Infant formula products**

Infant formula products comprise infant formula (0–12 months), follow-on formula (6–12 months) and infant formula for special dietary use (for infants aged 0–12 months).

An application to vary the Code is required to change the compositional or labelling requirements for infant formula products.

Compositional changes include: addition of a new substance not currently approved for use in infant formula products; an increase or decrease in the amount of a substance required for, or voluntarily added to, infant formula products. For the purposes of the Handbook, an increase or decrease in energy content or a macronutrient amount is considered to be a change to a nutritive substance.

The information requirements outlined below are in addition to those specified in Guideline 3.1.1 – General requirements and in other relevant guidelines in Part 3. The relevance of other guidelines is dependent on the proposed variation to the Code. Possible Guidelines include:

* 3.3.1 for a food additive
* 3.3.2 for a processing aid
* 3.3.3 for a nutritive substance
* 3.5.2. for a novel food or novel food ingredient
* 3.2.1 for general food labelling
* 3.2.3 for food allergens
* 3.2.4 for labelling for consumer information and choice
* 3.2.5 for nutrition information labelling

**Note:**

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum. The relevant Policy Guidelines for infant formula products are: the Regulation of Infant Formula Products, and Intent of Part 2.9 – Special Purpose Foods. These Policy Guidelines provide guidance on the composition, labelling, advertising and promotion of infant formula products.

Part 3 sets out the information requirements to enable FSANZ to have regard to these Policy Guidelines during the assessment of an application.

The Policy Guidelines are available on the FSANZ website at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

**A Information related to composition**

***A.1 Purpose of the compositional change***

The application **must** state the purpose of the compositional change to infant formula products.

This includes a brief description of all of the technological, nutritive or health-related function(s) of the substance at the proposed level in the relevant infant formula product(s). Where an added substance or compositional change has multiple purposes or functions, then these **must** be specified. This includes information on the target infant population(s) e.g. healthy term infants aged 0–12 months, or infants older than 6 months.

***A.2 General data requirements for supporting evidence***

This includes the general evidential requirements whereas A.3 includes the specific information required for the assessment of nutritional safety and efficacy.

Studies provided as evidence to support an application **must** contain sufficient detail to enable an independent assessment of the methods and results to confirm the study conclusions.

An application **must** include human studies as supporting evidence for nutritional safety, tolerance and the efficacy of the proposed compositional change. This can include published studies, detailed reports of unpublished studies and systematic reviews (with underlying studies also provided). It may be acceptable in certain cases not to include human studies. In this situation, safety and efficacy must be demonstrated by relevant data (as specified elsewhere in this Handbook); and the application **must** include an explanation of why human studies are not applicable.

**Note:**

Further information on design and reporting of data and data quality is found in subsection E of Guideline 3.1.1.

Discussion and guidance on data requirements for changes to infant formula products is available from the following:

(a) The US Institute of Medicine, Food and Nutrition Board guidelines that clarify the types and extent of safety testing necessary for new formula ingredients, particularly unconventional substances derived from novel sources or technologies. <http://www.iom.edu/Reports/2004/Infant-Formula-Evaluating-the-Safety-of-New-Ingredients.aspx>*.*

(b) The US Food and Drug Administration discussion paper prepared by the US Academy of Pediatrics on the clinical testing of infant formulas which can be found at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/ucm170649.htm>*.*

***A.3 Specific information requirements for the nutritional safety, tolerance and efficacy of the proposed compositional change***

This describes evidential requirements that **must** be addressed for a proposed change to the composition of infant formula products and it is divided into two components depending on the category of compositional change.

An application that relates to addition or changing the level of a nutritive substance (including energy or macronutrient), novel food or novel food ingredient **must** address the requirements listed in subsection A.3.1 of this Guideline (3.6.2).

An application that relates to a food additive or processing aid **must** address the requirements listed in component in subsection A.3.2 of this Guideline (3.6.2).

*A.3.1 Nutritive substance (including energy or macronutrient), novel food, or novel food ingredient*

(a) Characterisation of proposed substance or the comparable substances in breast milk

An application **must** include information about the presence of the proposed or comparable substance in breast milk. This supporting evidence includes:

(i) The mean amount and range of the proposed or comparable substance in breast milk. Where possible, include reference to breast milk composition from Australian or New Zealand mothers, or if not available, from mothers. in countries with similar dietary patterns to Australia and New Zealand. The breast milk reference values must be relevant to the type of infant formula product under consideration, for example levels found in colostrum may not be a relevant basis for levels in follow-on formula.

(ii) The variability of the levels of the proposed or comparable substance and consideration of the influence of maternal diet or other physiological factors. e.g. hormones, biochemical processes.

(iii) Comparison of relevant biochemical, physiological and functional endpoints between breastfed infants and infants fed the infant formula product containing the proposed composition change.

Where a proposed or comparable substance is not present in breast milk or no information is available on the presence or function of this substance in breast milk, the application **must** include an explanation of the reason(s) why the information is not provided.

(b) Nutritional safety and tolerance of the proposed compositional change

A composition change involving a nutritive substance (including energy or macronutrient) or a novel food or novel food ingredient **must** meet the respective safety requirements of Guidelines 3.3.3 and 3.5.2.

**Note:**

The requirement for human studies is primarily intended to establish infant tolerance of the formula and to ensure that the formula is able to support normal infant growth and development (see (i) below) and, in certain circumstances, to ensure no adverse effects on the absorption of essential nutrients.

The application **must** include evidence to support the nutritional safety and tolerance of the proposed composition change. This evidence includes:

(i) Human infant studies demonstrating that the infant formula products containing the substance at the proposed level, will support normal infant growth and development over a minimum interval of 3–4 months, beginning no later than 1 month of age. Reported growth measures **must** include at least infant length and weight. If studies for infant formula products demonstrating normal growth and development have been conducted for 3–4 months for infants aged from 1 month, additional studies for the same substance at the same level in follow-on formula are not required.

(ii) The exception to (b)(i) is an application for follow-on formula only (intended for use from 6 months). Studies **must** monitor and report growth measures for a minimum period of 2 months within the relevant age range.

(iii) Human infant studies **must** include a control group (i.e. an infant formula-fed group that is not exposed to the proposed compositional change), an exposure group (i.e. a formula-fed group that is exposed to the proposed compositional change, plus a breastfed reference group. If a breastfed reference group is not included, a rationale for its omission is required.

(iv) Information on the quality and strength of the evidence **must** include descriptions of the study design, methodology and characteristics of the study population and study limitations (refer to subsection 3.1.5.A of Guideline 3.1.1) for guidance).

(v) Evidence to demonstrate there is no risk of nutrient imbalances as a result of infants fed the infant formula product containing the proposed compositional change **must** be provided. If this evidence is not applicable, a rationale for its omission is required.

(c) Efficacy of the proposed compositional change

Any nutritive substance (including energy or macronutrient), novel food or novel food ingredient **must** meet the respective requirements of Guideline 3.3.3 (sections D or E) or Guideline 3.5.2 (section E). In addition, for a compositional change to infant formula products, efficacy and potential beneficial effect(s) of consumption of the substance at the proposed level **must** be described and supported by evidence as outlined below:

(i) Description and measures of the physiological, biochemical or functional effect(s) of the substance.

(ii) Description and measures of a health outcome. If no health outcome is specified, a rationale **must** be provided for its omission.

(iii) Study designs **must** align with the requirements for nutritional safety and tolerance outlined in paragraph A.3.1(b) of this Guideline (3.6.2).

**Note:**

The beneficial role of substances in infant formula products may be determined by the measurement of physiological, biochemical or functional effects and health outcome. Examples of these effects include enzyme pathways, blood levels, microbiological composition and counts, liver, kidney, gastrointestinal or other organ functions. An example of a possible health outcome may be reduced incidence of diarrhoea or ear infection.

Evidence from non-human studies will add weight to the determination of a substance’s role, particularly in understanding the mode of action.

*A.3.2 For a food additive or processing aid*

Compositional changes involving a food additive or processing aid **must** meet the respective safety requirements of Guidelines 3.3.1 and 3.3.2. In addition, the following **must** be provided:

(a) Tolerance of the proposed compositional change

Evidence to support tolerance **must** include appropriate human studies. This includes an explanation of the way in which this evidence relates to infants.

(b) Efficacy of the proposed compositional change

If the food additive also provides a nutritive or health-related function, the information requirements listed in component (I) for efficacy of proposed change **must** be met. If the function is purely technological, there are no further requirements in this section.

**B Information related to the dietary intake or dietary exposure**

***B.1 Data to enable the dietary intake or exposure of the target population to be estimated***

The application **must** meet the information requirements for the dietary exposure of a food additive, processing aid, novel food or novel food ingredient, or dietary intake of a nutritive substance (including energy or macronutrient), as outlined in these application guidelines. The information provided must have a focus on infants.

***B.2 Data on the recommended level of formula consumption for the target population***

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

(i) the capacity of the product scoop (in grams of product)

(ii) the number of scoops required per feed

(iii) the volume of water required per feed

(iv) total volume of the made-up feed

(v) recommended number of feeds per day relevant to each age group in the relevant target population.

***B.3 Information relating to the substance***

The application should also contain information or references on the levels (naturally occurring or naturally occurring and added) of the proposed substance in other foods that infants are likely to consume.

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

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

The application **must** include information to support the proposed labelling change. For example, the inclusion of (or change to) a warning or advisory statement, directions for use, or conditions.

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

This should include 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 already in place.

**Note:**

The extent of the impact of a 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.

**D Information related to internationally recognised standards, codes of practice, recommendations AND guidelines**

The application **must** include information demonstrating the level of consistency with internationally recognised standards, codes of practices, recommendations or guidelines such as Codex and the WHO, relating to the manufacture and labelling of infant formula products.

**Note:**

Examples of relevant standards, codes of practice, recommendations and guidelines are:

(a) Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants at <http://www.codexalimentarius.org/download/standards/288/CXS_072e.pdf>.

(b) Codex Standard for Follow-up Formula at <http://www.codexalimentarius.org/download/standards/293/CXS_156e.pdf>.

(c) Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children at <http://www.codexalimentarius.org/download/standards/11026/CXP_066e.pdf>.

(d) Marketing in Australia of Infant Formulas: Manufacturers. and Importers. Agreement 1992 at <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-publicat-document-brfeed-maif_agreement.htm>.

(e) The Infant Nutrition Council Code of Practice for the Marketing of Infant Formula in New Zealand at <http://www.infantnutritioncouncil.com/marketing-codes/code-in-new-zealand/>.

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

**3.6.3 Special purpose foods – Other foods**

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

* 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.
* Standard 2.9.5 – Food for special medical purposes.
* Standard 2.9.6 –Transitional Standard for special purpose foods (including amino acid modified foods)
* Schedule 29 – Special purpose foods (sections S29—11 to S29—21 and parts of section S29—7 (as determined by Standard 2.9.2

**Note:**

FSANZ is required by paragraph 18(2)(e) of the FSANZ Act to have regard to any written policy guidelines formulated by the Forum. The relevant Policy Guideline for special purpose foods is the Intent of Part 2.9 – Special Purpose Foods (approved in 2009).

The Policy Guideline is available at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>.

The following information is required to change the compositional or labelling requirements of a special purpose food under Part 2.9 of the Code. The information requirements outlined below are in addition to that specified in Guideline 3.1.1 – General requirements and in other relevant Guidelines in this Handbook.

The relevance of other guidelines is dependent on the proposed variation to the Code; possible Guidelines include:

* 3.3.1.1 for a food additive
* 3.3.2 for a processing aid
* 3.3.3 for a nutritive substance (including an increase or decrease in energy content or macronutrient amount)
* 3.4.2 microbiological limits
* 3.5.2. for a novel food or novel food ingredient
* 3.2.1 for general food labelling
* 3.2.3 for food allergens
* 3.2.4 for labelling for consumer information and choice
* 3.2.5 for nutrition information labelling.

**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:

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

The application **must** include a description of the target population for the special purpose food. It **must** also include a description of the physical and physiological need of specific life stages e.g. infancy, physical disease, disorder and disability of the target population; or physical and physiological need of the target population that require altered energy or nutrient intake.

***A.2 Purpose of the compositional change***

The application **must** include a brief description of all of the nutritive or health-related function(s) of the substance at the proposed level in the relevant food product(s). Where an added substance or compositional change has multiple purposes or functions, then these **must** be specified.

***A.3 Information related to the safety of the proposed compositional change***

The application **must** include information related to the safety of a food additive, processing aid, novel food or novel food ingredient, or nutritive substance for the target population (Information to demonstrate safety is also requested elsewhere in Part 3).

***A.4 Information related to the nutritional impact or performance impact of the proposed compositional change***

This demonstrates how the compositional change would contribute to achieving the intended purpose of the special purpose food.

The application **must** include clinical studies that examine the nutritional suitability of the food, for the target population.

This also includes 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 and Schedule 29 (sections S29—16 to S29—19)*.*

**Note:**

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

**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:

***B.1 Data to enable the dietary exposure of the target population to be estimated***

This 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 these Applications guidelines for the target population.

***B.2 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 for 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:

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

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

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

This 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, information to demonstrate how the proposed label change will assist consumer understanding of the specific nature of the food, the intended population group 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.

**D Information related to internationally recognised codes of practice and guidelines**

The application **must** contain information demonstrating the extent to which the application is consistent with internationally recognised standards and codes of practices. These include Codex and the WHO recommendations and guidelines, relating to the composition and labelling of special purpose foods.

**Note:**

Examples of relevant standards, codes of practice, recommendations and guidelines are:

Codex Guidelines for Formulated Supplementary Foods for Older Infants and Young Children at <http://www.codexalimentarius.org/download/standards/298/CXG_008e.pdf>.

Codex Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children

<http://www.codexalimentarius.org/download/standards/300/CXG_010e.pdf>.

Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children

<http://www.codexalimentarius.org/download/standards/11026/CXP_066e.pdf>.

Codex Standard for Processed Cereal-Based Foods for Infants and Young Children

<http://www.codexalimentarius.org/download/standards/290/cxs_074e.pdf>.

Codex Standard for Formula Foods for Use in Weight Control Diets

<http://www.codexalimentarius.org/download/standards/295/CXS_181e.pdf>.

Codex Standard for Labelling of and Claims for Foods for Special Medical Purposes at <http://www.codexalimentarius.org/download/standards/294/CXS_180e.pdf>.

Codex Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses

<http://www.codexalimentarius.org/download/standards/292/CXS_146e.pdf>.

**Chapter 3.7**

**Guidelines for applications for food production**

**3.7.1 Food safety standards**

An application to vary the Code is required to change the requirements for standards in Chapter 3 of the Code. The Chapter 3 standards apply in Australia only. Currently, these are:

* Standard 3.1.1 – Interpretation and Application
* 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.

The following information is required to support an application to amend these Standards. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

**A Information related to food safety**

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

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

This 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

(b) information from other countries on current practices that relate to the proposed change.

**3.7.2 Food processing and primary production**

An application to vary the Code is required to change the food processing requirements specified in Standard 1.6.2 – Processing requirements for meat, or the primary production requirements specified in Chapter 4 – Primary Production Standards. These Standards apply in Australiaonly.

The following information is required to support an application to amend these Standards. This information is in addition to that specified in Guideline 3.1.1 – General requirements.

**A Information related to food safety**

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

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

This includes:

(a) data to demonstrate that the proposed change will have result in protection of public health and safety equivalent to the current Standard

(b) information from other countries on current practices that relate to the proposed change.

**Appendix 1**

**Checklists**

**Checklist for General requirements**

This Checklist will assist you in determining if you have met the mandatory format and information requirements as detailed in Guideline 3.1.1 – General requirements. All applications **must** include this Checklist.

|  |
| --- |
| **General requirements (3.1.1)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A Form of application*□ Application in English**□ Executive Summary (separated from main application electronically)**□ Relevant sections of Part 3 clearly identified**□ Pages sequentially numbered**□ Electronic copy (searchable)**□ All references provided* |
| □ |  | B Applicant details |
| □ |  | C Purpose of the application  |
| □ |  | D Justification for the application*□ Regulatory impact information**□ Impact on international trade* |
| □ |  | E Information to support the application*□ Data requirements* |
| □ |  | F Assessment procedure*□ General**□ Major**□ Minor**□ High level health claim variation* |
| □ |  | G Confidential commercial information *□ CCI material separated from other application material**□ Formal request including reasons* *□ Non-confidential summary provided*  |
| □ |  | H Other confidential information*□ Confidential material separated from other application material**□ Formal request including reasons*  |
| □ |  | I Exclusive Capturable Commercial Benefit*□ Justification provided*  |
| □ |  | J International and other national standards*□ International standards* *□ Other national standards*  |
| □ |  | K Statutory Declaration |
| □ |  | L Checklist/s provided with application*□ 3.1.1 Checklist* *□ All page number references from application included**□ Any other relevant checklists for Chapters. 3.2–3.7* |

**Checklist for applications for labelling and** **other information requirements**

This Checklist is in addition to the Checklist for Guideline 3.1.1 and will assist you in determining if you have met the information requirements as specified in Guideline 3.2.1 – General food labelling which is mandatory for all labelling applications. If your application relates to Guidelines 3.2.2–3.2.6, then the information required is in addition to 3.2.1.

|  |
| --- |
| **General food labelling (3.2.1)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Proposed labelling change |
| □ |  | A.2 Foods or food groups potentially affected |
| □ |  | B.1 Demonstrated consumer support for change |
| □ |  | B.2 Proposed labelling to be understood and assist consumers |
| □ |  | B.3 Any adverse health or diet impacts |
| **Warning and advisory statements (3.2.2)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Data on potential health concern |
| □ |  | B.1 Data on lack of consumer awareness of health and safety risk |
| **Declaration of allergens (3.2.3)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| **A Addition of allergen to list of declared foods** |
| □ |  | A.1 Demonstration that the food causes IgE-mediated allergy |
| □ |  | A.2 Incidence of allergic reaction |
| □ |  | A.3 Severity of allergic reaction |
| □ |  | A.4 Extent of use of allergen in foods |
| **B Removal of food derivative from the list of declared foods** |
| □ |  | B.1 Nature of food derivative |
| □ |  | B.2 Use of food derivative and presence in final food |
| □ |  | B.3 Dietary intake information  |
| □ |  | B.4 History of safe use |
| □ |  | B.5 Clinical information on safety of food derivative |
| **Labelling for consumer information and choice (3.2.4)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Current labelling or alternative information inadequacies |
| □ |  | A.2 Information on lack of suitable alternatives available to consumers.  |
| □ |  | A.3 How proposed labelling change will assist consumers |
| □ |  | A.4 Information to demonstrate alternate measures in absence of labelling would not be effective |
| **Nutrition information labelling (3.2.5)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Proposed change and how it will change nutrition information labelling |
| □ |  | A.2 Data to demonstrate labelling will assist consumers |
| □ |  | B.1 Nature and composition of the ingredient |
| □ |  | B.2 Calculation of energy factor |
| □ |  | B.3.1 Substantiation of energy factor – Bomb calorimetry |
| □ |  | B.3.2 Substantiation of energy factor – Classical dietary energy balance |
| □ |  | B.3.3 Substantiation of energy factor – Isometric tracer methods |
| □ |  | B.3.4 Substantiation of energy factor – Breath hydrogen test |
| □ |  | B.3.5 Substantiation of energy factor – Ileal intubation and ileostomy effluent |
| □ |  | B.4 Other factors |
| **Nutrition content and health claims (3.2.6)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Nutrition content claims |
| □ |  | A.2 Amendment to existing high level or general level claim |
| □ |  | A.3 Amendment to nutrient profiling scoring criterion or method |
| □ |  | A.4 Variation of required elements of systematic review in Schedule 6 |
| □ |  | B.1.1 Description of food or property of food in food-health relationship |
| □ |  | B.1.2 Description of health effect in food-health relationship |
| □ |  | B.1.3 Description of food-health relationship |
| □ |  | B.2.1 Description of search strategy for relationships (original literature only) |
| □ |  | B.2.2 Food-health relationship based on updating systematic reviews |
| □ |  | B.3 Summarising literature for proposed food-health relationship |
| □ |  | B.4 Assessment of data from human studies |
| □ |  | B.5 Information for setting conditions |

**Checklist for applications for substances added to food**

This Checklist is in addition to the Checklist for Guideline 3.1.1 and will assist you in determining if you have met the information requirements as specified in Guidelines 3.3.1–3.3.3.

|  |
| --- |
| **Food additives (3.3.1)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Nature and technological purpose information |
| □ |  | A.2 Identification information  |
| □ |  | A.3 Chemical and physical properties  |
| □ |  | A.4 Impurity profile  |
| □ |  | A.5 Manufacturing process |
| □ |  | A.6 Specifications |
| □ |  | A.7 Food labelling  |
| □ |  | A.8 Analytical detection method |
| □ |  | A.9 Additional functions |
| □ |  | B.1 Toxicokinetics and metabolism information |
| □ |  | B.2 Toxicity information |
| □ |  | B.3 Safety assessments from international agencies |
| □ |  | C.1 List of foods likely to contain the food additive |
| □ |  | C.2 Proposed levels in foods |
| □ |  | C.3 Likely level of consumption |
| □ |  | C.4 Percentage of food group to contain the food additive |
| □ |  | C.5 Use in other countries (if applicable) |
| □ |  | C.6 Where consumption has changed, information on likely consumption |
| **Processing aids (3.3.2)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Type of processing aid |
| □ |  | A.2 Identification information  |
| □ |  | A.3 Chemical and physical properties  |
| □ |  | A.4 Manufacturing process  |
| □ |  | A.5 Specification information  |
| □ |  | A.6 Analytical method for detection |
| □ |  | B.1 Industrial use information (chemical only) |
| □ |  | B.2 Information on use in other countries (chemical only) |
| □ |  | B.3 Toxicokinetics and metabolism information (chemical only) |
| □ |  | B.4 Toxicity information (chemical only) |
| □ |  | B.5 Safety assessments from international agencies (chemical only) |
| □ |  | C.1 Information on enzyme use on other countries (enzyme only) |
| □ |  | C.2 Toxicity information of enzyme (enzyme only) |
| □ |  | C.3. Allergenicity information of enzyme (enzyme only) |
| □ |  | C.4. Overseas safety Assessment Reports |
| □ |  | D.1 Information on source organism (enzyme from microorganism only) |
| □ |  | D.2 Pathogenicity and toxicity of source microorganism (enzyme from microorganism only) |
| □ |  | D.3 Genetic stability of source organism (enzyme from microorganism only) |
| □ |  | E.1 Nature of genetic modification of source organism (enzyme from GM source microorganism) |
| □ |  | F.1 List of foods likely to contain the processing aid |
| □ |  | F.2 Anticipated residue levels in foods |
| □ |  | F.3 Information on likely level of consumption |
| □ |  | F.4 Percentage of food group to use processing aid |
| □ |  | F.5 Information on residues in foods in other countries (if available) |
| □ |  | F.6 Where consumption has changed, information on likely consumption |
| **Substances used of a nutritive purpose (3.3.3)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Purpose of the use of the substance |
| □ |  | A.2 General data requirements for supporting evidence  |
| □ |  | B.1 Identification |
| □ |  | B.2 Chemical and physical properties |
| □ |  | B.3 Impurity profile |
| □ |  | B.4 manufacturing process |
| □ |  | B.5 Specification for identity and purity |
| □ |  | B.6 Analytical method for detection |
| □ |  | B.7 Proposed food label |
| □ |  | C.1 Toxicokinetics and metabolism, degradation products and major metabolites  |
| □ |  | C.2 Animal or human studies |
| □ |  | C.3 International safety assessments  |
| □ |  | D.1 List of food groups or foods likely to contain the nutritive substance |
| □ |  | D.2 Proposed maximum levels in food groups or foods |
| □ |  | D.3 Likely level of consumption |
| □ |  | D.4 Percentage of food group to use nutritive substance |
| □ |  | D.5 Use in other countries (if available) |
| □ |  | D.6 Where consumption has changed, information on likely consumption  |
| □ |  | E.1 Need to permit addition of vitamin or mineral |
| □ |  | E.2 Demonstrated potential to address deficit or health benefit |
| □ |  | F.1 Nutritional purpose (other than vitamins and minerals) |
| □ |  | G.1 Consumer awareness and understanding |
| □ |  | G.2 Actual or potential behaviour of consumers |
| □ |  | H.3 Demonstration of no adverse effects on any population groups  |
| □ |  | H.3 Demonstration of no adverse effects on any population groups  |

**Checklist for applications for contaminants and**

**natural toxicants**

This Checklist is in addition to the Checklist for Guideline 3.1.1 and will assist you in determining if you have met the information requirements as specified in Guidelines 3.4.1–3.4.3.

|  |
| --- |
| **Chemical contaminant and natural toxicant maximum levels (3.4.1)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Nature of contaminant or natural toxicant |
| □ |  | A.2 Analytical detection method |
| □ |  | B.1 Toxicokinetics & metabolism information |
| □ |  | B.2 Toxicity studies |
| □ |  | B.3 Human studies relevant to safety |
| □ |  | C.1 List of foods where maximum level is proposed |
| □ |  | C.2 Survey data on contaminant or toxicant levels in foods |
| □ |  | C.3 Information on levels of consumption |
| □ |  | C.4 Where consumption has changed, information on likely consumption |
| **Microbiological limits (3.4.2)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | 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)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | 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 applications for new foods**

This Checklist is in addition to the Checklist for Guideline 3.1.1 and will assist you in determining if you have met the information requirements as specified in Guidelines 3.5.1–3.5.3.

|  |
| --- |
| **Foods produced using gene technology (3.5.1)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Nature and identity |
| □ |  | A.2 History of use of host and donor organisms |
| □ |  | A.3 Nature of genetic modification  |
| □ |  | B.1 Characterisation and safety assessment |
| □ |  | B.2 New proteins |
| □ |  | B.3 Other (non-protein) new substances |
| □ |  | B.4 Novel herbicide metabolites in GM herbicide-tolerant plants |
| □ |  | B.5 Compositional analyses |
| □ |  | C Nutritional impact of GM food |
| □ |  | D Other information |
| **Novel foods (3.5.2)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A. Exclusive use |
| □ |  | B.1 Type of novel food |
| □ |  | B.2 Information on potential beneficial outcomes |
| □ |  | B.3 Chemical and physical properties  |
| □ |  | B.4 Impurity profile  |
| □ |  | B.5 Manufacturing process |
| □ |  | B.6 Specification for identity and purity |
| □ |  | B.7 Analytical detection method  |
| ***C.1 Plant or animal extracts*** |
| □ |  | C.1.1 Extraction and composition |
| □ |  | C.1.2 Effects of food processing or preparation |
| □ |  | C.1.3 Current use |
| □ |  | C.1.4 Potential adverse effects |
| ***C.2* *Plant and animal extracts*** |
| □ |  | C.2.1 Method or extraction and composition of extract |
| □ |  | C.2.2 Use as a food in other countries |
| □ |  | C.2.3 Toxicity studies |
| □ |  | C.2.4 Safety assessments from other agencies |
| ***C.3* *Herbs (both non-culinary and culinary) including extracts*** |
| □ |  | C.3.1.1 History of use |
| □ |  | C.3.2 Composition |
| □ |  | C.3.3 Method of extraction and composition of extract |
| □ |  | C.3.4 Use in other countries |
| □ |  | C.3.5 Potential allergenicity |
| □ |  | C.3.6 Toxicity studies |
| □ |  | C.3.7 Safety assessments from other agencies |
| ***C.4* *Single chemical entities & dietary macrocomponents*** |
| □ |  | C.4.1 Toxicokinetics and metabolism |
| □ |  | C.4.2 Toxicity studies |
| □ |  | C.4.3 Safety assessments from other agencies |
| ***C.5* *Microorganisms (including probiotics)*** |
| □ |  | C.5.1 Potential pathogenicity |
| □ |  | C.5.2 Effects on gut microflora |
| □ |  | C.5.3 Use as a food in other countries |
| □ |  | C.5.4 Human toleration studies |
| ***C.6* *Food ingredients derived from a new source*** |
| □ |  | C.6.1 Safety of the source organism, including allergen statement |
| □ |  | C.6.2 Composition |
| □ |  | C.6.3 Toxicity studies |
| □ |  | C.6.4 Overseas safety reports |
| ***C.7* *Foods produced by a process not previously applied to food*** |
| □ |  | C.7.1 Details of the new process |
| □ |  | C.7.2 Toxicity studies |
| □ |  | C.7.3 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.3 Information on levels of consumption |
| □ |  | D.4 Percentage of food group or market |
| □ |  | D.5 Where consumption has changed, information on likely consumption |
| □ |  | D.6 Information to show whether the food or ingredient will replace another food |
| □ |  | D.7 Use in other countries |
| □ |  | E.1 Nutritional impact information |
| □ |  | E.2 Public health impact |
| □ |  | F.1 Demonstrated consumer awareness and understanding |
| □ |  | F.2 Potential behaviour in response to foods |
| □ |  | F.3 Demonstration of no adverse effects on any population groups |
| **Irradiated foods (3.5.3)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Nature of the food or food ingredient to be irradiated |
| □ |  | A.2 Technological need  |
| □ |  | A.3 Food products likely to contain irradiated food  |
| □ |  | B Safety information |
| □ |  | C Nutritional impact |

**Checklist for applications for special purpose foods and**

**standardised foods**

This Checklist is in addition to the Checklist for Guideline 3.1.1 and will assist you in determining if you have met the information requirements as specified in Guidelines 3.6.1–3.6.3.

|  |
| --- |
| **Standardised foods (3.6.1)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Proposed compositional change |
| □ |  | A.2 List of foods likely to be affected  |
| □ |  | B.1 Nutritional content  |
| □ |  | C.1 Demonstrated consumer understanding of proposed change |
| □ |  | C.2 Potential adverse health or diet impacts |
| **Special purpose foods – Infant formula products (3.6.2)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Purpose of compositional change |
| □ |  | A.2 Data for supporting evidence  |
| □ |  | A.3 Specific information requirements*□ Characterisation of proposed substance in breast milk* *□ Nutritional safety and tolerance**□ Efficacy of proposed compositional change**□ Tolerance of proposed compositional change* |
| □ |  | B.1 Dietary intake or exposure of target population |
| □ |  | B.2 Level of consumption |
| □ |  | B.3 Information relating to the substance |
| □ |  | C.1 Safety or nutritional impact of labelling change |
| □ |  | C.2 Demonstrated consumer understanding of labelling change |
| □ |  | D Internationally recognised codes of practice and guidelines on labelling |
| **Special purpose foods – Other foods (3.6.3)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Identity and need of target population  |
| □ |  | A.2 Purpose of compositional change |
| □ |  | A.3 Safety of proposed compositional change |
| □ |  | A.4 Nutritional or performance impact |
| □ |  | B.1 Dietary exposure data |
| □ |  | B.2 Level of consumption |
| □ |  | C.1 Safety and nutritional impact of labelling change |
| □ |  | C.2 Demonstrated consumer understanding of labelling change |
| □ |  | D Internationally recognised codes of practice and guidelines |

**Checklist for applications for food production**

This Checklist is in addition to the Checklist for Guideline 3.1.1 and will assist you in determining if you have met the information requirements as specified in Sections 3.7.1–3.7.2.

|  |
| --- |
| **Food safety standards (3.7.1)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Public health and safety data |
| □ |  | B.1 Projected costs to food industry |
| **Food processing and primary production (3.7.2)** |
| **Check** | **Page No.** | **Mandatory requirements** |
| □ |  | A.1 Public health and safety data |

**Amendment history**

**Note 1**

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

This is a compilation of Part 3 as in force on **1 March 2016** (up to Amendment No. 7 – 2016).

Prepared by Food Standards Australia New Zealand on **5 January 2016**.

**Table of instruments**

| **Title** | **Date of FRLI Registration** | **Date of Commencement** | **Application, Saving or Transitional Provisions** |
| --- | --- | --- | --- |
| FSANZ *Application Handbook* – Part 3 | 1 August 2007(F2007L02114). | 2 August 2007 |  |
| FSANZ *Application Handbook* – Part 3 – Amendment No. 1 – 2008 | 5 June 2008 (F2008L01697) | 5 June 2008 | - |
| FSANZ *Application Handbook* – Part 3 – Amendment No. 2 – 2008 | 9 December 2008(F2008L04594) | 9 December 2008 | - |
| FSANZ *Application Handbook* – Part 3 – Amendment No. 3 – 2009 | 25 August 2009 (F2009L03244) | 25 August 2009 | - |
| FSANZ *Application Handbook* – Part 3 – Amendment No. 4 – 2010 | 2 June 2010 (F2010L01483) | 1 July 2010 | - |
| FSANZ *Application Handbook* – Part 3 – Amendment No. 5 – 2011 | 7 July 2011(F2011L01439) | 1 August 2011 | - |
| FSANZ *Application Handbook* – Part 3 – Amendment No. 6 – 2013 | 19 August 2013(F2013L01586) | 1 September 2013 | - |
| FSANZ *Application Handbook* – Part 3 – Amendment No. 7 – 2016 | 5 January 2016 (F2016L00022) | 1 March 2016 | - |

**Table of amendments**

| ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted |
| --- |
| **Provision affected** | **How affected** |
| **Part 3 cover page** | am. No. 5 – 2011, rs. No. 7 – 2016 |
| **Part 3.1**  | am. No. 1 – 2008, am. No. 5 – 2011, rep No. 7 – 2016 |
| 3.1.1 | am. No. 3 – 2009, am. No. 5 – 2011, am. No. 6 – 2013, rep. No. 7 – 2016 |
| 3.1.2 | am. No. 5 – 2011, rep. No. 7 – 2016 |
| 3.1.3 | rs. No. 5 – 2011, rep. No. 7 – 2016 |
| 3.1.4 | rs. No. 4 – 2010, rs. No. 5 – 2011, rep. No. 7 – 2016 |
| 3.1.5 | am. No. 3 – 2009, rs. No. 5 – 2011, am. No. 6 – 2013, rep. No. 7 – 2016 |
| 3.1.6 | am. No. 5 – 2011, rs. No. 6 – 2013, rep. No. 7 – 2016 |
| 3.1.7 | am. No. 5 – 2011, rep. No. 7 – 2016 |
| 3.1.8 | am. No. 1 – 2008, am. No. 3 – 2009, rs. No. 6 – 2013, rep. No. 7 – 2016 |
| 3.1.9 | am. No. 6 – 2013, rep. No. 7 – 2016 |
| 3.1.11 | am. No. 4 – 2010, am. No. 5 – 2011, am. No. 6 – 2013, rep. No. 7 – 2016 |
| **Chapter 3.1** |  |
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| 3.1.1 | ad. No. 7 – 2016 |
| **Chapter 3.2**  |  |
| Cover page | rs. No. 7 – 2016 |
| 3.2.1 | am. No. 1 – 2008, am. No. 4 – 2010, am. No. 5 – 2011, am. No. 6 – 2013, rs. No. 7 – 2016 |
| 3.2.3 | am. No. 4 – 2010, rs. No. 7 – 2016 |
| 3.2.4 | am. No. 5 – 2011, rs. No. 7 – 2016 |
| 3.2.5 | am. No. 1 – 2008, am. No. 4 – 2010, am. No. 5 – 2011, am. No. 6 – 2013, rs. No. 7 – 2016 |
| 3.2.6 | ad. No. 6 – 2013, rs. No. 7 – 2016 |
| **Chapter 3.3**  |  |
| Cover page | rs. No. 7 – 2016 |
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| 3.3.2 | am. No. 1 – 2008, am. No. 2 – 2008, am. No. 3 – 2009, am. No. 4 – 2010, am. No. 5 – 2011, rs. No. 7 – 2016 |
| 3.3.3 | am. No. 1 – 2008, am. No. 2 – 2008, am. No. 3 – 2009, am. No. 4 – 2010, am. No. 5 – 2011, am. No. 6 – 2013, rs. No. 7 – 2016 |
| **Chapter 3.4**  |  |
| Cover page | rs. No. 7 – 2016 |
| 3.4.1 | am. No. 2 – 2008, am. No. 4 – 2010, am. No. 5 – 2011, rs. No. 7 – 2016 |
| 3.4.2 | am. No. 1 – 2008, am. No. 4 – 2010, am. No. 5 – 2011, rs. No. 7 – 2016 |
| 3.4.3 | am. No. 4 – 2010, am. No. 6 – 2013, rs. No. 7 – 2016 |
| **Chapter 3.5**  |  |
| Cover page | rs. No. 7 – 2016 |
| 3.5.1 | am. No. 1 – 2008, am. No. 3 – 2009, am. No. 4 – 2010, am. No. 5 – 2011, rs. No. 7 – 2016 |
| 3.5.2 | am. No. 2 – 2008, am. No. 3 – 2009, am. No. 4 – 2010, am. No. 5 – 2011, am. No. 6 – 2013, rs. No. 7 – 2016 |
| 3.5.3 | rs. No. 1 – 2008, am. No. 3 – 2009, am. No. 4 – 2010, am. No. 5 – 2011, rs. No. 7 – 2016 |
| **Chapter 3.6**  |  |
| Cover page | rs. No. 6 – 2013, rs. No. 7 – 2016 |
| 3.6.1 | am. No. 4 – 2010, am. No. 5 – 2011, rs. No. 7 – 2016 |
| 3.6.2 | am. No. 4 – 2010, rs. No. 5 – 2011, rs. No. 6 – 2013, rs. No. 7 – 2016 |
| 3.6.3 | ad. No. 6 – 2013, rs. No. 7 – 2016 |
| **Chapter 3.7** |  |
| Cover page | rs. No. 7 – 2016 |
| 3.7.1 | am. No. 4 – 2010, am. No. 5 – 2011, rs. No. 7 – 2016 |
| 3.7.2 | am. No. 1 – 2008, am. No. 4 – 2010, am. No. 5 – 2011, am. No. 6 – 2013, rs. No. 7 – 2016 |
| **Appendix 1** |  |
| Checklist for General requirements | am. No. 4 – 2010, rs. No. 5 – 2011, rs. No. 6 – 2013, rs. No. 7 – 2016 |
| Checklist for Standards related to labelling and other information requirements | am. No. 4 – 2010, rs. No. 5 – 2011, s. No. 6 – 2013, rs. No. 7 – 2016 |
| Checklist for Standards related to substances added to food | am. No. 4 – 2010, rs. No. 5 – 2011, rs. No. 7 – 2016 |
| Checklist for Standards related to contaminants and natural toxicants | rs. No. 5 – 2011, rs. No. 7 – 2016 |
| Checklist for Standards related to new foods | am. No. 1 – 2008, am. No. 4 – 2010, rs. No. 5 – 2011, rs. No. 7 – 2016 |
| Checklist for Standards related to the composition of food products | rs. No. 5 – 2011, rep. No. 6 – 2013, rs. No. 7 – 2016 |
| Checklist for Standards related to special purpose foods and standardised foods | ad. No. 6 – 2013, rs. No. 7 – 2016 |
| Checklist for Standards related to food production | rs. No. 5 – 2011, rs. No. 7 – 2016 |