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

EXPLANATORY STATEMENT

AMENDMENTS TO FOOD STANDARDS AUSTRALIA NEW ZEALAND APPLICATION GUIDELINES

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

Amendment No. 4 – 2010

1. Purpose

1.1 Background

Applications need to include certain mandatory information and format requirements as determined by Food Standards Australia New Zealand (FSANZ) in writing and in advance – these mandatory requirements are contained in Part 3 of the FSANZ *Application Handbook* (Handbook).

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

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

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

1.2 Application 'Guidelines'

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

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

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

The guidelines are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*, but are not subject to sunsetting or disallowance. For the purposes of section 23, Part 3 of the Handbook which was originally approved by the FSANZ Board in March 2007, fulfils these requirements.

1.3 Proposed Amendments to Part 3 (Mandatory Requirements)

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

- Assessments of applications should generally be able to proceed without past delays where FSANZ has had to seek further information or data from an applicant to enable assessment of the application to proceed. This will assist in ensuring that statutory timeframes are met.

- Part 3 fulfils the intention of the FSANZ Act amendment that there be clearly defined application requirements, including the requirement to provide supporting material with applications.

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

There are also amendments relating to clarification of information and data requirements related to the food additives, processing aids, natural toxicants and contaminants and novel foods sections of the Handbook. These amendments have been identified as a result of a recent review of information requirements which were contained in 'guidance documents' and which should more appropriately be included in the Handbook in order to make them a legal requirement. The amendments generally do not add any additional requirements to potential applicants.

In addition to the proposed amendments on which public consultation was sought, FSANZ has also included several further minor technical or clarifying amendments which arose as a consequence of issues raised in submissions. As they are linked to issues on which consultation was sought, in the interests of minimising the number of amendments made the Handbook each year, these additional minor amendments have also been included and are as indicated in Attachment 2.

The amendments are set out in Attachment 1.

2. Consultation

A list of over 500 people with an interest in the Handbook are on a stakeholder mailing list for consultation on amendments. This list was originally compiled for consultation on the initial development of the Handbook in 2006-07 and has been maintained and updated since then as required. Current and past applicants are included in this mailing list. This mailing list was sent an email alert calling for submissions on 7 April 2010. Email alerts were included as part of the publication of the Food Standards Notification Circular. Over 4000 people are on the mailing list for this alert.

The closing date for comments was 5 May 2010. Comments from four submitters were received. FSANZ has responded to each of the issues raised by the submitters, and in some cases (as indicated in the Table in Attachment 2), has adjusted the amendments that were consulted on to address the concerns raised. Submitters generally supported the amendments, with the exception of those issues mentioned in Attachment 2.

3. Impact Analysis

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

Two options are identified in relation to the proposed amendments:

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

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

3.1 Affected Parties

Parties affected by the amendments to Part 3 include:

- potential applicants from industry and consumers generally, who may be affected either positively or negatively; and
- FSANZ.

3.2 Benefit Cost Analysis

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

3.2.1.1 Benefits

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

3.2.1.2 Costs

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

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

3.2.2.1 Benefits

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

- Applicants will have more certainty about when a product could be introduced into the market as their applications will be assessed by FSANZ without delays waiting for key information to be provided for the assessment to proceed.

3.2.2.2 Costs

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

3.3 Comparison of Options

FSANZ considers the impact of various regulatory (and non-regulatory) options on all sectors of the community. There was no other option other than to proceed with the amendments.

4. Commencement

The Part 3 variations will take effect on 1 July 2010 to coincide with the date of effect of the FSANZ Amendment Regulations 2010 (No. 1).

Following registration, the amendments to Part 3 will be made to the *Application Handbook* and an updated version made available to the public on the Federal Register of Legislative Instruments by 1 July 2010.

5 Proposed Amendments to Parts 1 and 2 of the Handbook (Information only)

Parts 1 and 2 of the Handbook are for information only and are not included in the legislative instrument relating to the changes to Part 3. However, for the sake of completeness and transparency, reference has been made to them in this draft Explanatory Statement and attachments, and as submitters also made comment on the proposed amendments to Part 2, reference has been made to them in this Explanatory Statement and submitters' comments addressed.

Most of the amendments are administrative in nature and reflect the amendments to the FSANZ Regulations arising from the 2009 review of FSANZ's cost recovery arrangements. Other amendments are minor in nature and include text clarifying the purpose of the guidance documents for potential applicants, correction of a typographical error and updates to web addresses.

A further amendment ensures that potential Applicants consider implementation issues as part of their Application.

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

ATTACHMENTS

1. Amendments to Part 3 of the FSANZ *Application Handbook*

2. Submitters' and FSANZ comments

3. Amendments to Parts 1 and 2 of the FSANZ *Application Handbook*

ATTACHMENT 1

Draft Amendments to Part 3 of the FSANZ *Application Handbook*

Schedule Amendments

Item [1], [6.1] and [9.1]

These amendments clarify the purpose of the guidance documents to assist applicants, as well as removing unnecessary duplication of text sourced from the *Australia New Zealand Food Standards Code*.

Items [2], [3.1] and [9.2]

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

Items [4], [5], [6.2]-[6.9], [7.1], [7.3], [9.3]-[9.7] and [9.9]-[9.10]

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

Items [3.2], [7.2], [8] and [9.8]

These amendments correct typographical errors.

Item [10]

The amendments to the Checklist assist applicants in ensuring they have met all mandatory requirements.

FSANZ *Application Handbook* – Part 3 – Amendment No. 4 – 2010

Food Standards Australia New Zealand Act 1991

Preamble

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

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

Citation

These amendments may be collectively known as the FSANZ *Application Handbook* – Amendment No. 4 – 2010.

Commencement

These variations **will commence** on 1 July 2010.

SCHEDULE

[1] ***Each Part of the Application Handbook*** *in* Column 1 o*f the following table is varied by omitting the corresponding* Note *in Column* 2

Column 1 **Part**	**Column 2** **Note**
3.2.1	Following D.2.
3.2.3	Preceding A
3.2.5	Following B.3.
3.3.1	Preceding A Following D.4
3.3.2	Preceding A Following G.4.
3.3.3	Following D.6 Following H.2.
3.4.1	Preceding A Following D.2. Following E.2.
3.4.2	Preceding A Following E.1. Following F.2.
3.4.3	Preceding A
3.5.1	Preceding A 2nd Note following D.2.
3.5.2	Following G.2.
3.5.3	Preceding A
3.6.1	Preceding A Following E.2.
3.6.2	Following E.2.

Column 1 Part	Column 2 Note
3.7.1	Preceding A Following C.1.
3.7.2	Preceding A Following B.1. Following C.2.

[2] ***Each Part of the Application Handbook*** *in* Column 1 o*f the following table is varied by –*

[2.1] *omitting the heading and related text as indicated in* Column 2

Column 1 Part	Column 2 Heading and related text
3.2.1	A
3.3.1	A
3.3.2	A
3.3.3	A
3.4.1	A
3.4.2	A
3.4.3	A
3.5.1	A
3.5.3	A
3.6.1	A
3.6.2	A
3.7.1	A
3.7.2	A

[2.2] *renumbering the remaining headings from* B *onwards, commencing with* A

[3] ***Part 3.1*** *is varied by –*

[3.1] *omitting* 3.1.4, *substituting –*

3.1.4 JUSTIFICATION FOR THE APPLICATION

The application must contain a statement or statements regarding the justification for the application. The following general issues should be considered depending on the stated purpose of the application:

(a) the need and/or advantages for the proposed change;
(b) any public health and/or safety issues related to the proposed change e.g. details of target groups and at-risk population groups;
(b) any nutrition issues related to the proposed change e.g. nutritional purpose of adding a nutritive substance to each type of food or composition ;
(c) if for a food additive or processing aid, its technological function or need;
(d) potential impact on trade;
(e) any consumer choice issues related to the proposed change;
(f) any evidence that the food industry generally or other specific companies have an interest in, or support, the proposed change to the Code (this item is mandatory for applications relating to food additives, processing aids, nutritive substances, novel foods, irradiated foods); and

(g) the costs and benefits for industry, consumers and government associated with the proposed change, if available.

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

Note:

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

[3.2] *omitting from 3.1.11 –*

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

substituting

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

[4] ***Part 3.3.1*** *is varied by –*

[4.1] *omitting* B.2.*, substituting –*

2. Information to enable identification of the additive

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

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

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

[4.2] *omitting* B.5.*, substituting –*

5. Manufacturing process

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

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

[4.3] o*mitting* B.6., *substituting –*

6. Specification for identity and purity

This part includes a specification from one of the published sources identified in Standard 1.3.4 – Identity and Purity. If there is no published specification in one of the identified sources, a detailed specification must be provided. Specifications should include information on the name of the food additive, its chemical and physical properties, its purity, acceptable levels of impurities, the method of preparation, and analytical methods of determining purity.

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

[4.4] *omitting* B.8*., substituting* –

8. Analytical method for detection

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

[5] ***Part 3.3.2*** *is varied by* –

[5.1] o*mitting* B.2*., substituting* –

2. Information on the identity of the processing aid

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

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

[5.2] *omitting* B.4*., substituting* –

4. Manufacturing process

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

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

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

[5.3] *omitting* B.5*., substituting* –

5. Specification for identity and purity

This part includes a specification from one of the published sources identified in Standard 1.3.4 – Identity and Purity will be available. If a published specification is not available, a detailed specification must be provided. Specifications should include information on the name of the processing aid, its chemical and physical properties, its purity, acceptable levels of impurities, the method of preparation, and analytical methods for determining purity.

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

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

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

[5.4] *omitting* E.1.*, substituting* –

1. Information on the source micro-organism

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.

[5.5] *omitting* E.3.*, substituting* –

3. Information on the genetic stability of the source organism

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

[5.6] *inserting immediately after the heading for G.*2. –

The chemical identity of the residue must be stated.

[6] ***Part 3.3.3 i****s varied by* –

[6.1] *omitting the* Note *preceding* A*, substituting* –

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

[6.2] *omitting the* Note *and paragraph immediately following the* Note, *after the heading* **C Information related to the safety of the nutritive substance**, substituting–

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 nutritive substance at the levels proposed to be used in the food. Where an upper level of safety (UL) has been established, this will be considered. The NHMRC publication *Nutrient Reference Values for Australia and New Zealand including Recommended Daily 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 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.

[6.3] omitting C.1., substituting –

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

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

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

[6.4] *omitting* C.2.(b)*, substituting* –

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

[6.5] *omitting the heading* D*, and the following* Note*, substituting* –

D. Information on dietary intake of the nutritive substance

Note:

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

[6.6] *omitting the text immediately after* D.4*., substituting* –

This part includes any consumption information for food groups not included in the 1995 Australian National Nutrition Survey (NNS) or the 1997 New Zealand NNS which relate to this application. Data distinguishing likely consumption levels among target and non-target groups are preferred.

[6.7] *omitting the Note following* E.1*., substituting* –

Note:

The scientific evidence for a nutritional purpose must:

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

Refer to Part 3.1.5 for further information regarding data quality.

[6.8] *omitting the heading for* G.1*., substituting* –

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

[6.9] *omitting the heading for* G.3*., substituting* –

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).

[7] ***Part 3.4.1*** *is varied by* –

[7.1] *omitting* B.1*., substituting* –

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

This part includes information on the nature of the contaminant or natural toxicant, its chemical and physical properties, the source of the contaminant or natural toxicant, the factors that influence the level of contamination of food, the interaction of the contaminant or natural toxicant with the food, and current control measures and their effectiveness. In cases where particle characteristics may relate to the toxicity of the food contaminant, the applicant must provide information on particle size and morphology.

[7.2] omitting C.1., substituting –

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

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

[7.3] *omitting* D.2.*, substituting* –

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

This part includes the details of any surveys which have been conducted in Australia or New Zealand on the levels found in foods. If data derived from an analytical survey are used, details of how the survey was conducted and the analytical methods used must be provided.

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

[8] ***Part 3.4.3*** *is amended by omitting* –

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

substituting –

An application to vary the Code is required to add, modify or delete an entry in relation to a plant or fungi in Standard 1.4.1 – Prohibited and Restricted Plants and Fungi.

[9] ***Part 3.5.2*** *is varied by*

[9.1] *omitting the* Note *preceding* A*, substituting* –

Note:

For further information relating to the operation of the Novel Food Standard, particularly in relation to whether a particular food would be regarded as novel, refer to the FSANZ website at http://www.foodstandards.gov.au/consumerinformation/novelfoods/.

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

[9.2] *deleting* A*, substituting* –

A. Exclusive use of novel foods

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

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

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

[9.3] *inserting at the end of the* Note *following* B.1. –

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

[9.4] *omitting* B.6*., substituting* –

6. Analytical method for detection

The application should contain the following information:

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

[9.5] omitting C.(I)2. and C.(I)3., *substituting* –

2. Information on the effects of food processing or preparation

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

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

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

[9.6] *omitting* C.(VI)4*., substituting* –

4. Information on human toleration studies

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

[9.7] *omitting* C.(VII)1*., substituting* –

1. Information on the safety of the source organism

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

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

[9.8] *omitting the heading for* C.(VIII)*, substituting* –

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

[9.9] *omitting* C.(VIII)2.*, substituting* –

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

This part includes any published or unpublished reports of toxicity studies conducted in animals. It must also include any reports of toleration studies conducted in humans. The nature of the toxicity or toleration studies to be submitted will depend on the category of the novel food as set out in Part B1.

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

[9.10] *inserting immediately after the heading for* D.2. –

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

[10] Appendix 1 *is amended by* –

[10.1] *omitting the Checklist for* General Requirements (3.1)*, wherever occurring, substituting* –

General Requirements (3.1)	
☐ Form of application ☐ *Executive Summary* ☐ *Relevant sections of part 3 identified* ☐ *Pages sequentially numbered* ☐ *Hard copies capable of being laid flat* ☐ *Electronic and hard copies identical*	☐ Assessment procedure
☐ Applicant details	☐ Confidential Commercial Information ☐ *Confidential material separated in both electronic and hard copy*
☐ Purpose of the application	☐ Exclusive Capturable Commercial Benefit
☐ Justification for the application	☐ International standards
☐ Information to support the application	☐ Statutory Declaration

[10.2] *omitting* Support for the application *wherever occurring*

[10.3] *omitting the Checklist for* Nutritive Substances (3.3.3)*, substituting* –

☐ Identification information	☐ Proposed maximum levels in food groups or foods
☐ Information on chemical and physical properties	☐ Percentage of food group anticipated to contain nutritive substance

☐ Impurity profile information

☐ Manufacturing process information

☐ Specification information

☐ Analytical detection method

☐ Proposed food label

☐ Statement that the product being assessed is representative of the commercial product

☐ Toxicokinetics and metabolism information

☐ Animal or human toxicity studies

☐ Safety assessments from international agencies

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

☐ Food consumption data for new foods

☐ Nutritional purpose

☐ Need for nutritive substance in food

☐ Demonstrated potential deficit or health benefit

☐ Consumer awareness and understanding

☐ Actual or potential behaviour of consumers

☐ Demonstration of no adverse affects to any population groups

☐ Impact on food industry

☐ Impact on trade

[10.4] *omitting from the Checklist for* Chemical Contaminant and Natural Toxicant Maximum Levels (3.4.1) –

☐ Survey data on contaminant levels in foods

substituting

☐ Survey data on contaminant or toxicant levels in foods

[10.5] *inserting in* (VII) Food ingredients derived from a new source *in the Checklist for* *Novel Foods – safety information –

☐ Allergen statement

[10.6] *inserting in* (VIII) Foods produced by a process not previously applied to foods *in the Checklist for* *Novel Foods – safety information –

☐ Allergen statement

☐ Human toleration studies

ATTACHMENT 2

Submitters' and FSANZ's comments

Submitters:

Australian Government Department of Agriculture, Fisheries and Forestry [DAFF] (Narelle Marro)
New Zealand Food Safety Authority [NZFSA] (Jenny Reid)
Food Technology Association of Australia (Rob Richards)
SA Department of Health [SA Health] (Joanne Cammans)

[Item] Issue	Submitter	FSANZ Comment / Action
MANDATORY REQUIREMENTS IN PART 3 [Item No.]		
[1] The omission in Part 3.3.2 in the Table references the note following E.4. E.4 does not appear in the Handbook.	SA Health NZFSA	*Text corrected*
[2] In the change of web address being made in clause 3.5.2, the location of the web reference needs to be made clearer.	NZFSA	*Text corrected for both amendments.*
[3.4] The Part being amended is not 3.1.6, but 3.1.4	NZFSA	*Text corrected*
[5.1] Agree with the proposed new text, however suggest that it is also a requirement to provide the INS number of an additive, if a number has been allocated	NZFSA	*Noted – no further action. FSANZ believes the amendment as proposed provides sufficient information for FSANZ to identify the additive. If an INS number exists, these are easily located.*
[5.4] It is suggested that this section be further strengthened by changing '*should* provide a suitably robust analytical method' to '*must* provide'. 'suitably robust' is very subjective – perhaps inclusion of a definition or an example	SA Health DAFF	*Noted – no further action at this stage. The issue is under consideration by an Implementation Sub-committee (ISC) Working Group on Food Analysis. Outcomes from this will feed into future amendments to the Handbook.*
[6.3] It is suggested that this section be further strengthened by changing '*should* provide a suitably robust analytical method' to '*must* provide'.	SA Health	*Noted – no further action at this stage. The issue is under consideration by an ISC Working Group on Food Analysis. Outcomes from this will feed into future amendments to the Handbook.*

[Item] Issue	Submitter	FSANZ Comment / Action
[7.1] Deletion of 'does' from Note.	DAFF NZFSA	*Text corrected*
The proposed new text does not mention the term 'nutritive substance' (and needs to do so, in order to differentiate 'novel foods' from 'nutritive substances').	NZFSA	*Noted – the text has been adjusted to make the intent of the note clearer*
[7.10] The proposed new text does not seem to fit under section G.2.	NZFSA	*This amendment is a mistake and has been now omitted.*
[8] C.1 in Part 3.4.1 has a typo that could be fixed – '**it's** degradation products' should be '**its** degradation products'	NZFSA	*Amendment not included for consultation, however, as machinery in nature will be included in amendments.* *Consequential numbering to change, as [9] which also relates to Part 3.4.1 will be included under [8].*
[11.1] There is a typographical error – 'particular' should read 'particularly'	NZFSA	*Text corrected*
[11.3] Might be able to be phrased more clearly e.g. 'Such an' could be replaced by 'The'.	NZFSA	*Noted – amendment made to text.*
[12] The checklist for General Requirements is contained in Appendix 1. However this is not apparent in the drafting instructions – include for clarity.	NZFSA	*Text corrected*

[Item] Issue	Submitter	FSANZ Comment / Action
<u>NON-MANDATORY REQUIREMENTS IN PARTS 1 AND 2</u> [Item No.]		
[3] Text confusing. Timeline might be more useful with simplified text. Perhaps include direction to Part 2.2.5 for levels	DAFF	*Text amended*
[5] Under the Level 3 text, underneath (d), there should be a return.	NZFSA	*Text corrected*
Amendments suggested to Part 1.2 of Handbook relating to Chapter 4 Standards.	DAFF	*Amendment not included for consultation, however, as machinery in nature included in amendments.*
Diagram in Part 1.4 of Handbook may need updating for cross-referencing purposes once amendments made.	DAFF	*Not necessary*

[Item] Issue	Submitter	FSANZ Comment / Action
Text unclear in Part 2.1.5 of the Handbook as to what should be separated. Suggest including reference to confidential.	DAFF	*Noted – suggested amendment not included for consultation. However, no further action as Part 2.1.5 refers to confidential information and repetition of terminology not considered necessary.*

[Item] Issue	Submitter	FSANZ Comment / Action
OTHER [Item No.]		
For easy readability; it is recommended that any future amendments to the Handbook be provided with titles of the Part and more text information for ease of reference.	SA Health	Noted – will bear comment in mind for future amendments.
Consider that new or substituted text to be inserted should be placed in quotation marks, to differentiate it from the operative text of the amending instrument.	NZFSA	*Noted – no further action as this suggestion is not consistent with current drafting practice used by FSANZ (or the Australian Government).*
Question if the reference to 'Part 3.1.5' is the correct way to refer to Section 3.1, clause / paragraph 3.1.5 (on page 36 of the current Application Handbook). Reference should probably be to 'clause 3.1.5' (and a reference to Part 3 or 'General Requirements' could be added for additional clarification if considered necessary).	NZFSA	*Noted – comments considered. However, the Handbook is not formatted with all text presented as numbered 'clauses' or 'paragraphs' etc as in legislation or the Code – so it is not appropriate to use that terminology.*
[1] – Part 3 Additional omissions have been included to remove Notes in various guidelines in which duplicate the note in the amendment to Part 3.1.4, as well as removing unnecessary duplication of text sourced from the Code.	FSANZ	*Noted – these were inadvertently not included in the amendments on which public consultation was sought. However, as machinery in nature included in these amendments.*
[12] – Part 3 Has FSANZ reviewed the checklists set out in Appendix 1 against the new proposed information requirements being added to Part 3, to see whether the checklists are still accurate (or whether additional matters need to be included in the checklists to reflect new or more detailed information requirements)?	NZFSA	*Amendments made to a number of checklists.*
[2] – Part 3 Replacement weblinks for two Notes in Part 3 were included for consultation. However, as these Notes included as part of later amendments, they are no longer included.	FSANZ	*Amendments omitted and subsequent amendments re-numbered.*

[Item] Issue	Submitter	FSANZ Comment / Action
[3] – Part 3 Inclusion of an amendment to 3.1.11 to reflect the adjustments to the Checklist as well as including the correction of a typographical error	FSANZ	*Noted – these were inadvertently not included in the amendments on which public consultation was sought. However, as machinery in nature included in these amendments.*
[5] Proposed amendment to 3.3.2 (F.1.)	FSANZ	*This text has been omitted as it combines a number of data requirements that are not related to this Part. This Part will need to be revised again very soon as a result of internal work to re-align data requirements for the enzyme processing aids. In the interim, the existing text is adequate.*
[8] and [9] – Part 3 Both items related to Part 3.4.1, and need to be combined.	FSANZ	*Items combined and subsequent amendments re-numbered.*
A minor amendment to Part 2.1.7 to change a reference from Project Coordinator to Project Manager in line with current FSANZ terminology.	FSANZ	*Amendment not included for consultation, however, as machinery in nature included in amendments and subsequent amendments re-numbered.*
Additional text has been included in [6.2] – Part 3, to insert an line under 'must'. This mandatory requirement has also been included in an amendment to the checklist for 3.3.3.	FSANZ	*Amendment not included for consultation, however, as machinery in nature included in amendments.*

ATTACHMENT 3

Draft Amendments to Part 2 of the FSANZ *Application Handbook*

Schedule Amendments

Item [1]
These amendments reflect recent changes to the FSANZ website.

Item [2]
This amendment provides further information to assist potential applicants.

Item [3] and [5]
This amendment updates information.

Items [4], [7] and [8]
These amendments reflect the amendments to the FSANZ Regulations which take effect on 1 July 2010.

Item [6]
This amendment corrects a typographical error.

SCHEDULE

[1] ***Each Part of the Application Handbook*** *in* Column 1 o*f the following table is varied as indicated* in Column 2 –

Column 1 **Part**	**Column 2** **Web Addresses**
1.2	*omitting –* http://www.foodstandards.gov.au/thecode/foodstandardscode.cfm *substituting –* http://www.foodstandards.gov.au/foodstandards/foodstandardscode/
2.1.6	*omitting –* http://www.foodstandards.gov.au/standardsdevelopment/standardsworkplan.cfm *substituting –* http://www.foodstandards.gov.au/foodstandards/changingthecode/standardsworkplan.cfm

[2] ***Part 1.1*** *is varied by omitting –*

Potential applicants are encouraged to discuss their application with FSANZ prior to submission in order to clarify the nature of the application and to identify the information required in the application.

substituting

Potential applicants are encouraged to discuss their application with FSANZ prior to submission in order to clarify the nature of the application and to identify the information required in the application. Potential applicants are also strongly encouraged to discuss their potential application and possible amendments to the Code with relevant food enforcement agencies prior to making an application or any discussion with FSANZ. This may assist in identifying and resolving any implementation issues or concerns before an application is made and ensures that these issues are addressed before the assessment of any application. This may also result in a substantial cost saving for potential applicants in considering the need for any application or preparing an application.

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

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

[3] ***Part 1.2*** *is varied by omitting –*

Chapter 4 Primary Production Standards (Australia only) – production and processing of seafood, poultry meat, meat and specific cheeses. As at June 2007, this Chapter is still largely under development.

substituting

Chapter 4 Primary Production Standards (Australia only) – production and processing of seafood, poultry meat, meat and specific cheeses and other commodities.

[4] ***Part 2.1.4 When are fees payable?,*** *is omitted, substituting –*

When are fees payable?

Fees are determined as part of the Administrative Assessment process. Fees are payable after the applicant has been formally notified of FSANZ's decision in relation to the appropriate assessment procedure under section 27 of the FSANZ Act.

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

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

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

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

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

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

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

Applications being considered under the Major Procedure,

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

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

Generally, fees must be paid in Australian dollars. However, New Zealand applicants may pay fees in New Zealand currency, the amount of which will be calculated using the official exchange rate on the day the fee is paid. For overseas applicants making deposits, Australian banks charge a fee on overseas EFT payments – please allow an additional $AUD20-25 for this charge, in addition to the FSANZ fees.

Refunds of the hourly charge and Administrative charge are partially or fully refundable, in accordance with the FSANZ Regulations. The fees are exempt from GST. Fees are indicated in the table below:

Procedure	Hours	Hourly Charge	Admin Charge	Total Fees $AUD	Indicative Total Fees $NZ[1]
Minor Procedure	Maximum of 100 hours	11,500	10,000	21,500	26,875
General Procedure	Maximum of 350 hours	40,250	10,000	50,250	62,815
	Maximum of 650 hours	74,750	10,000	84,750	105,940
	Maximum of 1000 hours	115,000	10,000	125,000	156,250
	More than 1000 hours	115,000+**	10,000	125,000+**	156,250+
Major Procedure	1200 hours or more	138,000***	10,000	148,000+***	185,000+

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

[5] ***Part 2.1.7*** *is varied by omitting where mentioned –*

Project Coordinator

substituting

Project Manager

[6] ***Part 2.1.8*** *is varied by omitting –*

Applicants may request that information, other than confidential commercial information, be treated confidentiality.

substituting –

Applicants may request that information, other than confidential commercial information, be treated confidentially.

[7] ***Part 2.2.5 General Procedure****,* Level 1 (up to 500 hours) *and* Level 2 (up to 850 hours) is *omitted, substituting –*

2.2.5 General Procedure

The General Procedure is the default assessment process and involves one round of public comment. For the purposes of cost-recovery under the Regulations, the General Procedure is split into four levels.

Level 1 (maximum of 350 hours)

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

(a) extending the use of a food or food additive that is permitted under a standard; or
(b) a new source organism for an enzyme; or
(c) a minor change to a labelling requirement; or
(d) a minor change to a compositional requirement for a food; or
(e) reducing a maximum residue limit.

This kind of application is likely to:

(a) involve an assessment of the risk to public health and safety of less than average complexity; or
(b) have a limited, or no, social or economic impact; or
(c) require a toxicological, nutritional, food technology, dietary modelling or microbiological assessment of less than average complexity; or
(d) require an assessment of risk management measures of less than average complexity; or
(e) involve the development of a basic community communications strategy to address public concern.

Level 2 (maximum of 650 hours)

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

(a) extending the use of a substance to a specific food; or
(b) a pre-market approval similar to a previous approval; or
(c) a new micro-organism; or
(d) changing a compositional requirement for a food; or
(e) inserting or increasing a maximum residue limit.

This kind of application is likely to:

(a) involve an assessment of the risk to public health and safety of average complexity; or
(b) have a low social or economic impact; or
(c) require a toxicological, nutritional, food technology, dietary modelling or microbiological assessment of average complexity; or
(d) require an assessment of risk management measures of average complexity; or
(e) involve the development of a community communications strategy to address public concern.

Level 3 (maximum of 1000 hours)

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

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

This kind of application is likely to:

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

Level 4 (more than 1000 hours)

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

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

This kind of application is likely to:

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

(h) require the establishment of external working groups to discuss and interpret scientific evidence and social perceptions.

[8] ***Part 2.2.7 Major Procedure*** *is omitted, substituting –*

2.2.7 Major Procedure

Assessment under the Major Procedure applies to:

(a) an application for the development of a new food regulatory measure; and
(b) an application for the variation of a food regulatory measure that:

    (i) involves such scientific or technical complexity that it is necessary to adopt this procedure in considering it; or
    (ii) involves such a significant change to the scope of the food regulatory measure that it is necessary to adopt this procedure in considering it.

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

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

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

This kind of application is likely to:

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