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

FSANZ *Application Handbook* – Part 3 – Amendment No. 6 – 2013

I give notice of the making of this instrument under subsection 23(1) of the *Food Standards Australia New Zealand Act 1991*. The instrument commences on the date specified in clause 3.

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

15 August 2013

1 Name

This instrument is the *FSANZ Application Handbook – Part 3 – Amendment No. 6 – 2013.*

2 Variation to Part 3 of the FSANZ *Application Handbook*

The Schedule varies the guidelines in Part 3 of the FSANZ *Application Handbook*.

3 Commencement

These variations commence on the first day of the month immediately following the date of registration on the Federal Register of Legislative Instruments.

Schedule

[1] Section 3.1 (General requirements) is varied by

[1.1] inserting in 3.1.1.B at the end of the first paragraph

"The electronic version of the Executive Summary must be separated from the other parts of the application."

[1.2] inserting in 3.1.1.B at the end of the second paragraph

"Where an application must address more than one guideline, similar or related information can be combined and cross-referenced to avoid duplication within an application.

Note:
For example, an application for a new nutritive substance to be added to infant formula, could combine the response to parts 3.3.3.C and 3.6.2.B, or combine information relevant to 3.3.3.D with information relevant to part 3.6.2 A.1.

"

[1.3] omitting from 3.1.1B "hard copies" and substituting "the hard copy"

[1.4] omitting from 3.1.1.C "Two paper copies of the application must be provided." and substituting "One paper copy of the application must be provided."

[1.5] inserting at the end of 3.1.1.C

"The electronic version of the application should be searchable to assist FSANZ staff to search for key words or phrases."

[1.6] omitting 3.1.5A and substituting

"***A. 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, please indicate a reason.

The amount of data required for the assessment of an application will vary depending on the complexity of the issues, the levels of scientific assessment required and the impact on consumers of the proposed change to the Code.

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

Note:

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

When a literature search is undertaken, the applicant 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:

(e) identify the source, author(s) and year the data was produced

(f) 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

(g) be representative of the Australian and New Zealand populations

(h) be analysed using appropriate statistical techniques.

1. Data related to safety studies

(a) Studies submitted for safety assessment purposes should be designed and conducted in accordance with the principles and intent of good laboratory practice (GLP). For safety assessments of chemicals, reference should be made to the following:

- OECD Principles on Good Laboratory Practice
  http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm

- and relevant OECD Guidelines for the Testing of Chemicals
  http://www.oecd.org/env/ehs/testing/

- 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.

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

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

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

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

3. Data related to epidemiological/intervention studies in humans

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

(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.

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)

(c) 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:

- Equator Network: overview of reporting guidelines
  http://www.equator-network.org/index.aspx?o=1032
- GRADE: Grades of Recommendation, Assessment, Development, and Evaluation
  http://www.jclinepi.com/content/jce-GRADE-Series
- CONSORT Statement: Consolidated Standards Of Reporting Trials
  http://www.consort-statement.org/
- PRISMA Statement (formerly QUOROM) : Preferred Reporting Items for Systematic Reviews and Meta-Analyses
  http://www.prisma-statement.org/
- STARD Statement: Standards for Reporting Studies of Diagnostic Accuracy
  http://www.consort-statement.org/resources/downloads/other-instruments/
- MOOSE Statement: proposal for reporting meta analyses of observational studies in epidemiology
  http://www.consort-statement.org/index.aspx?o=1347
- STARLITE Statement: Standards for Reporting Literature searches
  http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1629442/pdf/i1536-5050-094-04-0421.pdf
- STROBE Statement (& STREGA): STrengthening the Reporting of OBservational studies in Epidemiology.
  http://www.strobe-statement.org/"

[1.7] omitting 3.1.6 and substituting

"**3.1.6 Assessment procedure**

The applicant must indicate what they consider is the appropriate procedure to be adopted in assessing the application i.e. general, minor, major or high level health claim. This is a requirement under paragraph 22(2)(e) of the FSANZ Act. FSANZ must have regard to the applicant's suggestion. However, FSANZ makes the final determination of the appropriate procedure during the administrative assessment, including the appropriate cost recovery level within those procedures, taking account of the purpose and complexity of the application."

[1.8] inserting the following paragraph before the Note to 3.1.7

"Applicants must provide a non-confidential general summary of any confidential commercial information in enough detail for it to be useful for assessment. This allows FSANZ to address the information in general terms as part of the assessment."

[1.9] omitting 3.1.8 and the Note to 3.1.8 and substituting

"**3.1.8 Exclusive Capturable Commercial Benefit (ECCB)**

The applicant should indicate whether or not the application is expected to confer an exclusive capturable commercial benefit (*see Part 2.1.4*). The applicant must provide a justification for the applicant's assertion."

[1.10] omitting from the Note to 3.1.9.A "agreements" and substituting "Agreements"

[1.11] omitting the Note to 3.1.11 and substituting

"

Note:

An example of when more than one guideline might apply is where an application involves adding a nutritive substance to infant formula. In this case, the checklists for Part 3.1 (General requirements), 3.3.3 (Nutritive substances) and 3.6.3 (Special purpose foods – Other foods) would be relevant.

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[2] Section 3.2 (Standards related to labelling and other requirements) is varied by

[2.1] omitting from the third paragraph of 3.2.1 (General food labelling)

"(d) nutrition information labelling

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

and substituting

"(d) nutrition information labelling
(e) nutrition content and health claims.

The additional information requirements relating to the above matters are presented in 3.2.2 to 3 2.6."

[2.2] omitting from A.2 in 3.2.1 (General food labelling) "proposed labelling change" and substituting "proposed change"

[2.3] omitting from B in 3.2.5 (Nutrition information labelling)

"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."

and substituting

"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."

[2.4] inserting after 3.2.5 (Nutrition Information Labelling)

"3.2.6 Nutrition content and health claims

The following information is required to amend Standard 1.2.7. This information is required in addition to that specified in Section 3.1 – General requirements and in Section 3.2.1 – General food labelling.

This section is divided into two parts. Part 1 addresses the application requirements for amendments to Standard 1.2.7 other than adding new food-health relationships to Schedules 2 (permitted high level health claims) and 3 (permitted general level health claims) of the Standard. Part 2 is for applications to add a new food-health relationship to Schedules 2 (high level health claims) or 3 (general level health claims) in Standard 1.2.7.

Note:

Applications to make a change to the list of high level health claims in Schedule 2 of Standard 1.2.7 and to add a general level health claim to Schedule 3 of Standard 1.2.7 (as described in clause 16 of Standard 1.2.7) are required to be considered using the high level health claims procedure. Other applications seeking to amend Standard 1.2.7 will be assessed using the general, minor or major procedure as applicable.

For further general information about these procedures, refer to Part 2.2 of the FSANZ *Application Handbook*.

Part 1: Amendments to Standard 1.2.7, other than adding new food-health relationships to Schedules 2 and 3

A. Information related to nutrition content claims in Schedule 1 of Standard 1.2.7

If the application relates to nutrition content claims in Schedule 1 of Standard 1.2.7, the following information must be provided:

(a) justification for any proposed change

(b) 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 A.2 in Section 3.2.1 of the Application Handbook
  (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 1, 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.

B. Information related to the amendment of an existing high level or general level health claim in Schedules 2 or 3 of Standard 1.2.7

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 Part 2 of Section 3.2.6 of the *Application Handbook*. If the application seeks to delete an existing high level or general level health claim from Schedules 2 or 3, then it must contain sufficient detail to justify why the relationship should not be regarded as causal.

If the application seeks to vary the relevant population in Column 3 of Schedules 2 or 3 to cover a wider population group than the age-sex range covered by the existing food-health relationship, then the application must include a justification for the proposed variation.

If the application seeks to vary the dietary context statement in Column 4 of Schedules 2 or 3, then the application must include a justification for the proposed variation.

If the application seeks to vary the conditions in Column 5 of Schedules 2 or 3 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.

C. 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 of Standard 1.2.7, 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) justification for any proposed change, including the public health rationale where applicable, for why the Schedules should be varied

(c) 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 (c).

D. Information related to variation of the required elements of a systematic review in Schedule 6 of Standard 1.2.7

If the application seeks to vary any of the required elements of a systematic review as described in Schedule 6 of Standard, 1.2.7, 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.

Part 2: Amendments to add food-health relationships to Schedules 2 and 3 of Standard 1.2.7

If the application seeks to add a new food-health-relationship to either Schedule 2 or 3, the application must provide 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 Schedules 2 or 3), then this is equivalent to a new relationship and appropriately suitable data must be provided, as outlined below.

A. The scope of the food-health relationship

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 Schedules 2 and 3 of Standard 1.2.7) 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.

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.

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

The application must contain the information in either B1 or B2, 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.

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 (eg 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, or
- 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.

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 Sections B.1 (a)-(f) and B.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.

C. 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.

D. Assessment of the data from human studies

The application must include a scientifically argued 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.

E. 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."

[3] **Section 3.3** (Standards Related to Substances Added to Food) is varied by

[3.1] inserting after the first paragraph of **Section 3.3.1** (Food additives)

"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."

[3.2] inserting immediately before A in **Section 3.3.1** (Food additives).

"

Note:

FSANZ is required by section 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 function 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 therefore the application should address these matters. The Guideline is 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.

"

[3.3] omitting A.1(d) in 3.3.1 (Food additives) and substituting

"(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."

[3.4] omitting from A.5 in 3.3.1 (Food additives)

"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)."

[3.5] omitting from A.6 in 3.3.1 (Food additives)

"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."

and substituting

"Information is also required for the presence of known allergens (see clause 4 of Standard 1.2.3) in the commercial product."

[3.6] omitting from B in 3.3.1 (Food additives)

"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."

[3.7] omitting from the first Note under C in 3.3.1 (Food additives).

"FSANZ will undertake a dietary exposure assessment"

and substituting

"FSANZ may undertake a dietary exposure assessment"

[3.8] inserting the following paragraph after the first paragraph in 3.3.2 (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."

[3.9] inserting immediately before A in 3.3.2 (Processing aids)

"

Note:

FSANZ is required by section 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 therefore the application should address these matters. The Guideline is 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.

"

[3.10] omitting the Note under A.1 in 3.3.2 (Processing aids) and substituting

"The various functions performed by processing aids are listed in the relevant clauses of Standard 1.3.3."

[3.11] omitting the third paragraph of A.5 in 3.3.2 (Processing aids) and substituting

"The presence of known allergens (see clause 4 of Standard 1.2.3) in processing aid preparations must be identified."

[3.12] omitting from A.6 in 3.3.2 (Processing aids)

"Where residues from a chemical processing aid are likely to be present in the final food, an analytical method must be provided to detect and quantify the amount of the processing aid remaining in the final food."

and substituting

"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)."

[3.13] omitting from B in 3.3.2 (Processing aids)

"The chemical 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."

[3.14] omitting from 3.3.3 (Nutritive substances)

“

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.

”

and substituting

“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.

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 substance and considered under Section 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 section 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 Guideline is the Fortification of Food with Vitamins and Minerals.

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

The 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.

”

[3.15] inserting immediately before A.1 in 3.3.3 (Nutritive substances)

“

Note:

An application to extend the use of a currently permitted nutritive substance should indicate that the technical information required in the following parts (A.1–A.7) meets the current identity and purity specifications.

”

[3.16] omitting from B in 3.3.3 (Nutritive substances)

“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.”

[3.17] omitting from the Note to C in 3.3.3 (Nutritive substances)

“FSANZ will undertake a dietary exposure assessment”

and substituting

“FSANZ may undertake a dietary exposure assessment”

[3.18] omitting from C.1 in 3.3.3 (Nutritive substances)

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

and substituting

"This part includes information about the nutrient content of foods containing the nutritive substance such as total fat and saturated fat, total sugars, sodium, and energy content."

[3.19] inserting the following paragraph at the end of C.5 in 3.3.3 (Nutritive substances)

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

[3.20] omitting the heading to D in 3.3.3 (Nutritive substances) and substituting

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

[3.21] omitting the first Note to F in 3.3.3 (Nutritive substances) and substituting

"

Note:

In addition to the information specified in this part, some of the information derived from Section C – Information on dietary intake of the nutritive substance, will be used also to assess the impact on consumers of the nutritive substance.

"

[4] **Section 3.4** (Standards related to contaminants and natural toxicants) is varied by omitting the first two paragraphs of 3.4.3 (Prohibited and restricted plants and fungi) and 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 1.4.4 – Prohibited and 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 from Standard 1.4.4. This information is in addition to that specified in Section 3.1 – General Requirements."

[5] **Section 3.5** (Standards related to new foods) is varied by

[5.1] omitting the Note following the first paragraph in 3.5.2 (Novel foods) and substituting

"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.

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/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 section 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 and the Addition to Food of Substances other than Vitamins and Minerals. The 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.

"

[5.2] omitting from A in 3.5.2 (Novel foods)

"(b) the brand of the food."

and substituting

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

[5.3] omitting B.2 in 3.5.2 (Novel foods) and substituting

"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."

[5.4] omitting the heading to B.7 in 3.5.2 (Novel foods) and substituting

"7. Analytical method for detection of a novel food ingredient"

[5.5] omitting from C

"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."

[5.6] omitting the heading for C.(VI)3 in 3.5.2 (Novel foods) and substituting

"3. Information on the use of this microorganism in food or as a food in other countries"

[5.7] omitting the first sentence in the first Note to D in 3.5.2 (Novel foods) and substituting

"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."

[5.8] omitting D.1 and D.2 in 3.5.2 (Novel foods) and substituting

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

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 D.1 (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."

[5.9] omitting E.1 in 3.5.2 (Novel foods) and substituting

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

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

This part 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."

[6] Section 3.6 (Standards related to the composition of food products) is varied by

[6.1] omitting the heading and substituting

"Standards related to special purpose foods and standardised foods"

[6.2] omitting from the first paragraph of 3.6.2 (Special purpose foods)

"

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

and substituting

"

- 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."

[6.3] omitting the Note and paragraph preceding A in 3.6.2 (Special purpose foods) and substituting

"

Note:

FSANZ is required by section 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 Guideline is available at http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx.

The following information is required to change the compositional and/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 Section 3.1 – 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:

- Guideline 3.3.1 for a food additive
- Guideline 3.3.2 for a processing aid
- Guideline 3.3.3 for a nutritive substance (including an increase or decrease in energy content or macronutrient amount)
- Guideline 3.4.2 microbiological limits
- Guideline 3.5.2. for a novel food or novel food ingredient
- Guideline 3.2.1 for general food labelling
- Guideline 3.2.3 for food allergens
- Guideline 3.2.4 for labelling for consumer information and choice
- Guideline 3.2.5 for nutrition information labelling."

[6.4] omitting A.1, A.2 and A.3 in 3.6.2 (Special purpose foods) and substituting

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

This 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.

2. Purpose of the compositional change

This 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.

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

This 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 the Handbook).

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

This part demonstrates how the compositional change would contribute to achieving the intended purpose of the special purpose food.

This must include clinical studies that examine the nutritional suitability of the food, for the target population.

This part 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.

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.

"

[6.5] omitting B.1, B.2, and B.3 in 3.6.2 (Special purpose foods) and substituting

"***1. Data to enable the dietary exposure of the target population to be estimated***

Information on the dietary exposure of a food additive, processing aid, novel food or novel food ingredient, or dietary intake of a nutritive substance (as indicated elsewhere in the Handbook) for the target population.

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."

[6.6] omitting the paragraph preceding C.1 in 3.6.2 (Special purpose foods) and substituting

"The application must contain the following information when it relates to a change to labelling requirements:"

[6.7] omitting C.3 in 3.6.2 (Special purpose foods) and substituting

"**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 practice. 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.

"

[6.8] omitting the heading of 3.6.2 (Special purpose foods) and substituting

"3.6.3 Special purpose food – Other foods"

[6.9] inserting after 3.6.1 (Standardised Foods)

"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 and/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 Section 3.1 – 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:

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

Note:

FSANZ is required by section 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.

This Handbook sets out the application requirements to enable FSANZ to have regard to these Policy Guidelines during the assessment of an application.

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

A. Information related to composition

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.

2. General data requirements for supporting evidence

This part outlines the general evidential requirements whereas part 3 outlines 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. Further information on reporting of data and data quality is found in Part 3.1.5 in Guideline 3.1.

Applications 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:

Guidance about appropriate study design and reporting of studies is available in Part 3.1.5 of this Handbook.

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.

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

This part describes evidential requirements that must be addressed for a proposed change to the composition of infant formula products. It is divided into two components depending on the category of compositional change. Applications that relate 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 component (I). Applications that relate to a food additive or processing aid must address the requirements listed in component (II).

(I) Nutritive substance (including energy or macronutrient), novel food, or novel food ingredient

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

This part 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 and/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/or 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 Guideline 3.3.3 and Guideline 3.5.2.

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/or development (see (i) below) and, in certain circumstances, to ensure no adverse effects on the absorption of essential nutrients.

This part 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/or development over a minimum interval of 3 to 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/or development have been conducted for 3 to 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). These 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 Part 3.1.5A of this Handbook 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 (part D or E) or Guideline 3.5.2 (part 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 and/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 this Guideline (part A.3(I)(b)).

Note:

The beneficial role of substances in infant formula products may be determined by the measurement of physiological, biochemical and/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.

(II) For a food additive or processing aid

Compositional changes involving a food additive or processing aid must meet the respective safety requirements of Guideline 3.3.1 and Guideline 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

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 the respective Guidelines in this Handbook. The information provided must have a focus on infants.

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.

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

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

This 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.

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

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

"

[7] **Section 3.7.2** (Food processing and primary production) is varied by omitting the first paragraph and substituting

"An application to vary the Code is required to change the food processing requirements specified in Standard 1.6.2 – Processing Requirements or the primary production requirements specified in Chapter 4 – Primary Production Standards. These Standards apply to Australia only."

[8] **Appendix 1** is varied by

[8.1] omitting the Checklist for General requirements and substituting

"Checklist for General requirements

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

General requirements (3.1)

☐ 3.1.1 Form of application
☐ Application, abstracts and other key documents in English
☐ Executive Summary (separated from main application electronically and in hard copy)
☐ Relevant sections of Part 3 clearly identified
☐ Pages sequentially numbered
☐ Electronic copy (searchable)
☐ 1 hard copy
☐ Electronic and hard copy identical
☐ Hard copy capable of being laid flat
☐ All references provided (in electronic and hard copy)

☐ 3.1.2 Applicant details

☐ 3.1.3 Purpose of the application

☐ 3.1.4 Justification for the application
☐ Regulatory impact information
☐ Impact on international trade

☐ 3.1.5 Information to support the application
☐ Data requirements

☐ 3.1.6 Assessment procedure
☐ General
☐ Major
☐ Minor
☐ High level health claim variation

☐ 3.1.7 Confidential Commercial Information
☐ Confidential material separated in both electronic and hard copy
☐ Formal request including reasons
☐ Non-confidential summary provided

☐ 3.1.8 Exclusive Capturable Commercial Benefit
☐ Justification provided

☐ 3.1.9 International and other national standards
☐ International standards
☐ Other national standards

☐ 3.1.10 Statutory Declaration

☐ 3.1.11 Checklist/s provided with application
☐ 3.1 Checklist
☐ Any other relevant checklists for Parts 3.2-3.7

"

[8.2] omitting the Checklist for Standards related to Labelling and other Requirements and substituting

"Checklist for Standards related to labelling and other information requirements

This Checklist is in addition to the Checklist for Section 3.1 and will assist you in determining if you have met the information requirements as specified in Section 3.2.1 – General food labelling which is mandatory for all labelling applications. If your application relates to Sections 3.2.2–3.2.6 then the information required is in addition to 3.2.1.

General food labelling (3.2.1)	
☐ A.1 Proposed labelling change	☐ B.2 Proposed labelling to be understood and assist consumers
☐ A.2 Foods or food groups potentially affected	☐ B.3 Any adverse health or diet impacts
☐ B.1 Demonstrated consumer support for change	

Warning and advisory statements (3.2.2)	
☐ 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)	
A. Addition of allergen to list of declared foods	
☐ A.1 Demonstration that the food causes IgE-mediated allergy	☐ A.3 Severity of allergic reaction
☐ A.2 Incidence of allergic reaction	☐ A.4 Extent of use of allergen in foods
B. Removal of food derivative from the list of declared foods	
☐ B.1 Nature of food derivative	☐ B.4 History of safe use
☐ B.2 Use of food derivative and presence in final food	☐ B.5 Clinical information on safety of food derivative
☐ B.3 Dietary intake information	

Labelling for consumer information and choice (3.2.4)	
☐ A.1 Current labelling or alternative information inadequacies	☐ A.3 How proposed labelling change will assist consumers
☐ A.2 Information on lack of suitable alternatives available to consumers	☐ A.4 Information to demonstrate alternate measures in absence of labelling would not be effective

Nutrition information labelling (3.2.5)	
☐ A.1 Proposed change and how it will change nutrition information labelling	☐ B.3(II) Substantiation of energy factor – Classical dietary energy balance

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

Nutrition content and health claims (3.2.6)	
1. Amendments to Standard 1.2.7, other than adding new food-health relationships to Schedules 2 and 3	
☐ A. Nutrition content claims	☐ C. Amendment to nutrient profiling scoring criterion or method
☐ B. Amendment to existing high level or general level claim	☐ D. Variation of required elements of systematic review in Schedule 6
2. Amendments to add food-health relationships to Schedules 2 and 3 of Standard 1.2.7	
☐ A.1 Description of food or property of food in food-health relationship	☐ B.2 Food-health relationship based on updating systematic reviews
☐ A.2 Description of health effect in food-health relationship	☐ C. Summarising literature for proposed food-health relationship
☐ A.3 Description of food-health relationship	☐ D. Assessment of data from human studies
☐ B.1 Description of search strategy for relationships (original literature only)	☐ E. Information for setting conditions

"

[8.3] omitting the Checklist for Standards related to the Composition of food products and substituting

"Checklist for standards related to special purpose foods and standardised foods

This Checklist is in addition to the Checklist for Section 3.1 and will assist you in determining if you have met the information requirements as specified in Sections 3.6.1–3.6.3.

Standardised foods (3.6.1)	
☐ A.1 Proposed compositional change	☐ C.1 Demonstrated consumer understanding of proposed change
☐ A.2 List of foods likely to be affected	☐ C.2 Potential adverse health or diet impacts
☐ B.1 Nutritional content	

Special purpose foods – Infant formula products (3.6.2)	
☐ A.1 Purpose of compositional change	☐ B.3 Information relating to the substance
☐ A.2 Data for supporting evidence	☐ C.1 Safety or nutritional impact of labelling change
☐ 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*	☐ C.2 Demonstrated consumer understanding of labelling change
☐ B.1 Dietary intake or exposure of target population	☐ D. Internationally recognised codes of practice and guidelines on labelling
☐ B.2 Level of consumption	

Special purpose Foods – Other foods (3.6.3)	
☐ A.1 Identity and need of target population	☐ B.2 Level of consumption
☐ A.2 Purpose of compositional change	☐ C.1 Safety and nutritional impact of labelling change
☐ A.3 Safety of proposed compositional change	☐ C.2 Demonstrated consumer understanding of labelling change
☐ A.4 Nutritional or performance impact	☐ D. Internationally recognised codes of practice and guidelines
☐ B.1 Dietary exposure data	

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