

Explanatory Statement

Amendments to the FSANZ *Application Handbook* Amendment No. 6 – 2013

1. Authority

Under section 22 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), an application to amend the Australia New Zealand Food Standards Code (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.

Section 23 of the FSANZ Act empowers Food Standards Australia New Zealand (the Authority) 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.*

If the guidelines¹ are not met, the Authority has the power under section 26 of the FSANZ Act to reject the application after a 15-day Administrative Assessment. The guidelines referred to in section 23 are contained in Part 3 of the FSANZ *Application Handbook* (Handbook). The guidelines are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

2. Purpose and operation

The purpose of the Instrument is to amend Part 3 of the Handbook in order to improve the quality of guidance available to potential applicants.

3. Documents incorporated by reference

These amendments do not incorporate any documents by reference.

¹ FSANZ refers to these 'guidelines' in Part 3 of the Handbook as 'sections' e.g. Section 3.6.2

4. Consultation

Nearly 400 people with an interest in the Handbook are on a stakeholder mailing list for consultation on the amendments. This mailing list contains all previous applicants, in addition to industry representatives, consultants and consumers. Everyone on the mailing list was emailed the call for submissions and each call for comment. Submissions were also called for in the Food Standards Notification Circular which is published on the Authority's website. Email alerts are included as part of the publication of the Food Standards Notification Circular. Over 4800 people are on the mailing list for this alert.

The Authority received 12 submissions from industry and government in the first round of consultation which was held from 8 November to 6 December 2012. Due to the high level of interest and the complexity of comments raised by these submitters, the Authority substantially revised both of the proposed guidelines relating to infant formula and nutrient content and health claims.

A second round of comment was called on the amended guidelines from 29 April to 11 June 2013. Twelve submissions were received from government and industry. The Authority further revised the guidelines in response to those comments. All submissions are available on the FSANZ website².

5. Impact analysis

The Office of Best Practice Regulation advised that a regulation impact statement (RIS) was not required for the amendments to Part 3 as RISs have already been prepared for the substantive changes in regard to infant formula and nutrition, health and related claims. The OBPR agreed that the other changes are likely to have a minor impact on business or the not-for-profit sector (RIS ID: 14394).

Two options were identified in relation to the proposed amendments to Part 3:

Option 1 – Proceed with the amendments.

Option 2 – Not proceed with the amendments.

Parties affected by the amendments to Part 3 include:

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

In relation to Option 1, for applicants and the Authority, this option would not result in any discernible costs as the information would be required of applicants for an assessment to proceed, whether or not the requirements were mandatory.

The Authority would not be required to assess applications which do not meet mandatory information requirements, thus freeing-up resources for other work. Applicants whose applications have been accepted because they have provided the relevant data with their application, would have their applications assessed by the Authority within statutory timeframes and without undue delays, thus facilitating release of products into the market in a timely manner. The Authority's assessments will be more efficient because the required information will be supplied up-front. Staff will no longer have to wait for key information to be provided, minimising delays.

² <http://www.foodstandards.gov.au/code/changes/applying/Pages/consultationopportunities3880.aspx>

There will also be an efficiency gain for affected applicants as the mandatory information will be collected and incorporated into applications in a single process before acceptance by the Authority. For example, any costs associated with responding to the Authority's requests for further information will be reduced. In addition, as the Authority is proposing to reduce the number of hard copies of the full application and references from two to one, this will result in less direct costs to applicants.

Option 2 would not result in any discernible benefits. Applicants providing insufficient information would experience protracted assessment timeframes, as the Authority would not be able to complete its assessment in the absence of missing information.

The Authority has therefore decided to proceed with Option 1.

Amendments to Parts 1 and 2 of the Handbook are for information only and therefore an impact analysis was not required.

6. Statement of compatibility with human rights

The instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under subsection 23(4) of the FSANZ Act.

7. Amendments to Part 3 (mandatory requirements)

Many of the amendments are mechanical in nature and relate to correcting typographical errors, reducing the duplication of text, updating hyperlinks and clarifying the nature and extent of information that is required from applicants. Additional notes to assist applicants in understanding the Authority's information requirements are also included.

There are more detailed amendments relating to the requirements for general applications, as well as those relating to special purpose foods, nutrition content and health claims, food additives and processing aids. In addition, a number of references have been updated to assist applicants e.g. references to the latest nutrition surveys for Australia and New Zealand have been included.

7.1 Infant formula products and other special purpose foods

In 2011, the Food Regulation Ministers approved a *Policy Guideline on the Regulation of Infant Formula Products*. As this Ministerial Policy Guideline has implications for the Authority's regulatory processes for infant formula products, amendments have been made to Part 3.6.

These amendments involve the inclusion of a new guideline (Section 3.6.2) on infant formula and the amendment and re-numbering of the current Section 3.6.2 to 3.6.3 to cover other special purpose foods. The new 3.6.2 requests information on breast milk composition, as well as evidence for physiological equivalence from consumption of the substance in an infant formula product with that of breast milk and evidence of a potential beneficial health outcome. These amendments align with the specific principles in the Ministerial Policy Guideline, except for specific principle (i) which requires pre-market approval for any change in formulation. This principle has not been addressed in the amendments because the regulatory framework in relation to specific principle (i) will be considered in the upcoming review of the infant formula product regulations.

The new 3.6.2 will also carry over the information requirements to assess the impact of compositional and labelling changes from the current 3.6.2, as well as information requirements demonstrating consistency with internationally recognised codes of practice.

The current Section 3.6.2 on special purpose foods has been re-numbered to 3.6.3 and re-named to cover 'other special purpose foods'. The amendments provide clarification of the types of products that may be considered to be 'other special purpose foods', and the information requirements on the physiological need of the target population.

7.2 Health and nutrition content claims

A new guideline (Section 3.2.6) has been inserted to accommodate the new Standard 1.2.7 – Nutrition, Health and Related Claims.

Section 3.2.6 is divided into two parts. The first part addresses the information requirements for:

- nutrition content claims in Schedule 1
- amendments to existing general level and high level health claims in Schedules 2 and 3
- amendments to the nutrient profiling scoring criterion or method in Schedules 4 and 5
- amendments to required elements of a systematic review in Schedule 6 of Standard 1.2.7.

The second part is for applications to add a new food-health relationship to Schedules 2 or 3 in Standard 1.2.7 i.e. the requirements to substantiate a new food-health relationship for either a high level or general level health claim.

All other applications to amend Standard 1.2.7 must follow existing general information requirements (Section 3.1) and general labelling requirements (3.2.1) of the Handbook.

7.3 Food additives, processing aids, nutritive substances and novel foods

The instrument amends existing requirements to ensure consistency with the current Standards, and to ensure consistency in requests for information for food additives and processing aids. Some duplication of requested information has been removed. Other minor editing has been made to clarify the requested information.

Specific amendments have been made to the requirement for information relating to analytical methods to identify and qualify the presence of substances added to food such as food additives and processing aids.

The Instrument also amends the guidelines for applications for nutritive substances (3.3.3) and novel foods (3.5.2).

8. Commencement

The Part 3 variations commence on the first day of the month immediately following the date of registration of the instrument.

Related amendments to Parts 1 and 2 (information only) will be included with Part 3 in an updated Handbook compilation and made available to the public on the Authority's website³ on the same day as the registration of Part 3 as a legislative instrument.

³ <http://www.foodstandards.gov.au/foodstandards/changingthecode/informationforapplicants/>

9. Amendments to Part 3

Items [1.1]–[1.5]

These items amend the administrative requirements for applications in relation to the number of hard copies and searchability of electronic copies of applications.

Items [1.6]–[1.9], [2.2], [3], [5.1]–[5.9], [6.1]–[6.7], [7]

These items include corrections of inconsistencies, clarification of data and information requirements, updating of references and hyperlinks, as well as removal of duplication of text.

Items [1.10], [2.3], [4]

These items correct typographical, capitalisation and grammatical errors.

Items [2.1], [2.4],

These items relate to the insertion of a new guideline (3.2.6) for nutrition content and health claims and consequential amendments.

Items [1.11], [6.8]–[6.9]

These items relate to the insertion of a new guideline (3.6.2) for infant formula products and consequential amendments.

Item [8]

These items make consequential amendments to the Checklists to reflect the inclusion of new guidelines and amendments to other guidelines.