EXPLANATORY STATEMENT

AMENDMENTS TO
FOOD STANDARDS AUSTRALIA NEW ZEALAND
APPLICATION GUIDELINES

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

Amendment No. 3 – 2009

1. Purpose

Section 23 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) empowers Food Standards Australia New Zealand (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.

1.1 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.

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 FSANZ *Application Handbook* (Handbook) which was originally approved by the FSANZ Board in March 2007, fulfils these requirements.

1.2 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 delays where FSANZ seeks 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 proposed amendments relate to the correction of typographical errors and the clarification of the meaning of the text.

FSANZ wishes to make it explicit (currently it is implicit) in the *Application Handbook* that any studies and results reported in an application need to be performed on equivalent samples to the commercial product on which approval is being sought.

This request should be self-evident, but there may be cases where this has not been the situation, which could be misleading. Therefore, FSANZ will request that applicants provide a statement to that effect for any such studies. Also, there may be good reasons why this is not possible in which case a justification and explanation is required. These could include toxicological, efficacy and nutritional studies.

Details of the amendments as amended following consultation are set out in Attachment 1.

2. Consultation

Applicants from the food industry are the group potentially affected by these amendments. FSANZ wrote to key industry organisations namely the Australian Food and Grocery Council, the New Zealand Grocery Council and the Australian Beverages Council foreshadowing the proposed amendments. FSANZ staff also met with representatives from these organisations. Industry already understood that FSANZ required some additional information in order to conduct risk assessments of some new substances.

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. This mailing list was sent an email alert calling for submissions on 1 July 2009. Alerts were also included in the Food Standards Notification Circulars of 3, 15 and 29 July 2009. Over 4000 people are on the mailing list for this alert.

The closing date for comments was 7 August 2009. Comments from four submitters were received (see Attachment 2). FSANZ has responded to each of the issues raised by submitters, and in some cases (as indicated in the Table in Attachment 2) has amended the amendments that were consulted on to address the concerns raised.

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 their completion of the assessment of their applications is delayed due to insufficient information.
- Part 3 of the *Application Handbook* would not accurately reflect the Code.

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

3.2.2.1 Benefits

- Applicants will be able to release products into the market in a timely manner.
- FSANZ will not have to assess applications which are deficient in relevant data thus freeing-up resources for other work.

3.2.2.2 Costs

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

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

These variations commence on the date of the registration of the instrument.

5 Proposed Amendments to Part 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, 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.

In addition to the correction of a typographical error, the proposed amendments clarify the role of FSANZ in relation to pre-lodgement advice and how applications can be lodged. Some minor amendments were made to these items following consultation.

The recommended amount of money to be allowed for bank charges for the payment of fees from overseas bank accounts has been increased.

In response to a submitter's comment, an additional Item [3] was inserted after consultation to clarify what information an applicant is expected to provide to FSANZ.

A new Part on the treatment of confidential information (different and in addition the information on confidential commercial information already included) is to be inserted.

Details of these amendments following consultation are set out in Attachment 3.

ATTACHMENTS

1. Amendments to Part 3 of the FSANZ *Application Handbook*
2. Stakeholder comments on amendments to *Application Handbook*
3. Amendments to Part 2 of the FSANZ *Application Handbook*

ATTACHMENT 1

Amendments to Part 3 of the FSANZ *Application Handbook*

Schedule Amendments

Item [1]

These amendments clarify the form of an application and clarify the requirements in relation to the provision of data and references and the confirmation of an exclusive capturable commercial benefit.

Items [2], [3], [4], [5] and [6]

These amendments add statements to the effect that the material that has been tested toxicologically should be representative of the commercial substance. If not it should be explained and justified.

Item [7]

This amendment corrects a spelling mistake.

FSANZ *Application Handbook* – Part 3 – Amendment No. 3 – 2009

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. 3 – 2009.

Commencement

These variations **will commence** on the date of the registration of this instrument.

SCHEDULE

[1] ***Part 3.1*** *is varied by* –

[1.1] *omitting* 3.1.1*, substituting* –

3.1.1 FORM OF THE APPLICATION

An application must be in the form prescribed below.

A. Language

The application and abstracts of supporting information must be presented in English. Supporting information written in another language should be accompanied by a full English translation if the information is of high relevance to the application.

B. Format

The application must contain an 'Executive Summary' that provides a synopsis of all of the data supporting the application.

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

The application must be sequentially numbered on each page and hard copies of the application must be capable of being laid flat when opened.

The hard copy and electronic copy of the application must be identical.

C. Copies

Applications must be lodged in both electronic and paper copy at the same time or received within 24 hours of each other.

Two paper copies of the application must be provided.

An application must not be sent by facsimile.

Electronic copies should be provided on floppy disc or CD or other device, or as an attachment to an email or through the FSANZ website.

The application must include full electronic and hard copies of all references referred to in the application.

[1.2] *omitting from* 3.1.5 *the first* Note*, substituting* –

Note:

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

Good quality data are always preferable regardless of the nature of the application. In the absence of good quality data, data of lesser quality may still be useful in the assessment of an application. The better the quality of the data, however, the more likely an application will achieve a favourable and timely outcome.

[1.3] *omitting* 3.1.8*, 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*).

[2] ***Part 3.3.1*** *is varied by inserting immediately after the* Note *following* **C Information related to the safety of the food additive** –

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] ***Part 3.3.2*** *is varied by* –

[3.1] *inserting immediately after* **C Information related to the safety of a chemical processing aid** –

The substance or preparation (including enzyme 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] *omitting the heading for* C.5*, substituting* –

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

[4] ***Part 3.3.3*** *is varied by* –

[4.1] *inserting immediately after the* Note *following* **C Information related to the safety of the nutritive substance** –

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.

[4.2] *omitting from the Note following* C.2 –

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

substituting –

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

[4.3] *omitting F.1(e), substituting* –

(e) evidence that the nutritional profile of the specified substitute food[2] can be aligned with the primary food.

[5] ***Part 3.5.1*** *is varied by inserting immediately after* **C Information related to the safety of the genetically-modified food** –

Where it is difficult to obtain sufficient quantities of the novel protein for biochemical or toxicological analysis, it is essential to ensure that the protein tested is biochemically equivalent to that expressed *in vivo* in the GM food.

[6] ***Part 3.5.2*** *is varied by* –

[6.1] *inserting immediately after the* Note *following* **C Information on the safety of the novel food** –

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

[6.2] *omitting the heading* F.1*, substituting* –

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

[7] ***Part 3.5.3*** *is varied by omitting the heading* D.2*, substituting* –

2. Information on dosimetry and record keeping

ATTACHMENT 2

Stakeholder comments on amendments to *Application Handbook*

Submitters:

Mr Jon Carapiet (Private)
New Zealand Food Safety Authority (Jenny Reid) (supports all amendments)
Cumming Food Consultants (Marion Cumming)
Food Technology Association of Australia (Tony Zipper)

[Item] **Issue**	**Submitter**	**FSANZ Comment / Action**
MANDATORY REQUIREMENTS IN PART 3		
[1.1] FSANZ has not given adequate consideration to what is a realistic time frame for receipt of electronic or paper copy, given that applications may be received from companies or jurisdictions in countries other than Australia or New Zealand. The risk of retaining the 24-hour time frame is that an applicant may not remember to submit the electronic format later to ensure that the 24 hour time frame of receipt is achieved. A realistic timeframe is 72 hours. The risk of retaining the 24-hour time frame is that an applicant may not remember to submit the electronic format later to ensure that the 24 hour time frame of receipt is achieved. It is easier and more practical to ensure that both formats of an application are submitted or dispatched at the same time.	Cumming Food Consultants (CFC)	*No further change proposed* The amendment clearly indicates that the intention is for both electronic and paper copies to be lodged at the same time. However, the 24-hour timeframe is to allow flexibility if the electronic and hard copy versions of the application do not arrive at the same time. This is intended to be beneficial for applicants. Having a longer time-frame between the receipt of a hard copy and electronic copies, such as proposed by CFC could severely compromise FSANZ's ability to meet the statutory 15-day deadline for the completion of an Administrative Assessment.

[Item] Issue	Submitter	FSANZ Comment / Action
[1.1] Electronic copying may not always be possible as access to some reference material is either not available electronically or only permitted by membership of an organisation or at a cost that imposes an extra burden on the Applicant. Applicants often use consultants who do not have unlimited access to all the required reference material etc e.g. some relevant toxicological data may only be available in journals, references that are old and archived or no longer published or out of print, etc.	FTAA	*No further change proposed* Comments noted. Scanning of documents is easily done if a hard copy of a document is available. If the articles are not easily found by an applicant, FSANZ will be in the same situation. Therefore, they should not be referenced if they are not available for consideration as part of the assessment. Electronic availability of all documents is crucial for FSANZ e.g. several team members may require access to material at the same time. In addition, FSANZ has 2 offices – in Canberra and Wellington and easy access to material is required. In addition, the Public Register is generally provided electronically, and access to the complete application is frequently requested. FSANZ should not be expected to bear the resource costs to scan documents not provided electronically by an Applicant.
[1.1] Insertion of reference to precautionary approach in the Note.	Jon Carapiet	*No further change proposed* The Handbook provides guidance to applicants on the nature of the data that needs to be submitted in order for FSANZ to make an assessment and, in that context, discussion of the precautionary principle does not assist applicants in preparing their application.
[1.1] Amendment to Note text suggested as concern about what 'good quality data' actually means – a definition is required.	FTAA	*No further change proposed* It is difficult to define good quality data because it involves a level of subjectivity. FSANZ exercises discretion in this area.
[1.3] Need for inclusion of reference to data on commercial risks.	Jon Carapiet	*No further change proposed* ECCB is defined in s.8 of the FSANZ Act. This suggested requirement is not part of this definition and therefore not relevant.

[Item] Issue	Submitter	FSANZ Comment / Action
[3.2] Insert reference to studies by independent organisations	Jon Carapiet	*No further change proposed* There are already requirements for an applicant to include sufficient information to enable FSANZ to address its s.18 objectives. An additional amendment (see below) to Part 2 covers this suggested amendment.
[5] Comment about biochemical equivalents.	Jon Carapiet	*No further change proposed* Biochemical equivalence is a scientifically valid approach to assessing potential toxicity and allergenicity of novel proteins. The requirement for biochemical studies also provides additional reassurance that the novel protein expressed in the GM plant corresponds to the expected protein. Additional safety studies would be required if significant differences were identified in the biochemical studies.
[6.1] Insert reference that assessment must be of the commercial product.	Jon Carapiet	*No further change proposed* As the nature and number of possible commercial products is not static, the assessment of the primary food, ingredient, or substance is the best approach to ensure more comprehensive coverage of the food supply. The assessment of individual commercial products is neither practical nor comprehensive.
[6.2] Comment regarding other environmental or economic impacts.	Jon Carapiet	*No further change proposed* FSANZ already considers economic impacts on relevant parties in the risk analysis. Typically this includes consideration of impacts on consumers, the food industry and government. FSANZ does not have a statutory responsibility to consider environmental impacts. Where necessary, these are considered by other agencies such as the OGTR (Australia) and ERMA (New Zealand).

[Item] Issue	Submitter	FSANZ Comment / Action
NON-MANDATORY INFORMATION REQUIREMENTS IN PART 2		
[1] Change to text suggested to clarify meaning:	FTAA	*Amendment made* FSANZ acknowledges the proposed wording was unclear.
[4] Comment about the duty of disclosure of an applicant to provide all information that is available to them that is relevant to assessment	Jon Carapiet	*Amendment made to Part 2.1.3 (new Item [3] in Schedule* The expectation that applicants should submit all information relevant to the consideration of the safety of a substance whether an explicit requirement of the Handbook or not, is a reasonable one. This is a requirement for both agricultural / veterinary chemicals and therapeutic goods applications.

ATTACHMENT 3

Amendments to Part 2 of the FSANZ *Application Handbook*

Schedule Amendments

Item [1]

This amendment clarifies FSANZ's role prior to the formal lodgement of an application.

Item [2]

This amendment clarifies how an application can be lodged with FSANZ.

Item [3]

This amendment inserts a statement about the duty of disclosure of information by an applicant.

Item [4]

This amendment updates the bank charge amount to be allowed for overseas applicants.

Item [5]

This amendment provides information on preferred requirements for confidential and other information provided as part of an application.

Item [6]

This amendment corrects a typographical error.

SCHEDULE

[1] ***Part 2.1.1*** *is varied by omitting –*

Applicants are strongly advised to consult with FSANZ prior to submitting an application to ensure that the application contains all the necessary information relevant to the proposed variation to the Code. This can be done via teleconference, video link or at a face-to-face meeting. Please contact the Standards Management Officer to make arrangements.

substituting –

It is the responsibility of applicants to prepare and finalise their own application for lodgement. However, prior to formally lodging their application, applicants are strongly advised that it is in their interests to consult with FSANZ to ensure that it contains all the required information. This can be done via a teleconference, a video link or at a face-to-face meeting in FSANZ's offices in Canberra (Australia) or Wellington (New Zealand). Please contact the Standards Management Officer to make arrangements.

[2] ***Part 2.1.2*** *is varied by omitting –*

Ideally, (if under 3 MB, or via a Zip file if larger than 3 MB) applications can be submitted electronically through the application form on the FSANZ website at xxxxxxx (site under development at 31 May 2008) or emailed to standards.management@foodstandards.gov.au. Alternatively, applications may be submitted by email to the Standards Management Officer at applications@foodstandards.gov.au or by post or courier to the following address:

substituting –

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

If under 3 MB, or via a Zip file if larger than 3 MB, electronic versions of applications can be emailed to the Standards Management Officer at applications@foodstandards.gov.au. The two hard copies (and the electronic version on CD, floppy disc or other electronic device if not emailed) should be sent by post or courier to the Standards Management Officer at the following address:

[3] ***Part 2.1.3*** *is varied by inserting at the end of the Part –*

An applicant should submit all information relevant to the consideration of the safety of a substance, whether the information is an explicit requirement of the Handbook or not.

[4] ***Part 2.1.4*** *is varied by omitting –*

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 $AUD10-15 for this charge, in addition to the FSANZ fees.

substituting –

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.

[5] ***Part 2.1.5*** *is varied by inserting at the end of the Part –*

2.1.8 Confidential and other information

Applicants may request that information, other than confidential commercial information, be treated confidentiality. To ensure that the information is protected as confidential information applicants will need to satisfy the following:

1. the information claimed to be confidential must be specifically identified and marked ‘Confidential’;

2. at the time of providing the information the applicant must state that the information is being provided in-confidence;

3. provide reasons for why the information should be treated as confidential. For example, disclosure of the information would cause the applicant to suffer a detriment or the information is not publicly available and known only to a limited number persons; and

In addition to the above, Applicants who provide unpublished manuscripts will need to indicate whether or not the author is aware that the manuscript has been provided to FSANZ.

[6] ***Part 2.2.6*** *is varied by omitting –*

One round of consultation is carried out with Government agencies only. A application would fall within this Procedure if its only effect would be:

substituting –

One round of consultation is carried out with Government agencies only. An application would fall within this Procedure if its only effect would be: