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 the 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 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.

Federal Register of Legislative Instruments F2009L03244

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