



26 May 2011

Dear Sir/Madam

## Application Handbook – Proposed Amendments to FSANZ Application Handbook – Amendment No. 5 - 2011

Thank you for the opportunity to comment on the proposed amendments to the Application Handbook. The Ministry of Agriculture and Forestry (MAF) has the following comments to make. As a general comment, there is little commentary provided in the FSANZ document on the proposed changes. While the general commentary in Part 1.2 is helpful, it does not go into the detail of many of the proposed changes, so evaluation is difficult. As a further comment for future amendments to the handbook, a tracked changes version of the proposed changes, with a comment stating why the change is proposed, would be a useful attachment to the document.

### General comments

We understand that part 3 of the Application Handbook is a legislative instrument, for the purposes of the Legislative Instruments Act 2003 (Australia). Consequently, standard Office of Legislative Drafting and Publishing (OLDP) drafting should apply.

#### 1. Mandatory requirements, and the term ‘application guideline’

Paragraph 1 (Purpose) on page 2 of the proposed amendments states that Part 3 of the handbook contains mandatory requirements.

The word 'must' is explained in proposed amendment [3.1.], in a box on page 9, as identifying information that is mandatory.

The term ‘application guideline’ is then used in Part 3, which is at odds with the mandatory requirements. MAF suggests that FSANZ consider if this term should be defined.

#### 2. 'Note boxes'

MAF seeks clarification on the status of the note boxes. We wish to know if they are like the 'explanatory notes' in the Food Standards Code? We notice that a number of note boxes contain what could be regarded as obligations. For example on page 18, proposed amendment [7.3], the Note states that *'The application should address the following categories of studies'*, and on page 21, proposed amendment [8.7], the Note states that *'The application should address, as a minimum, the following categories of studies'*. In our view, if these Notes are requirements or obligations, they should be in the main body of Part 3 rather than in a note box.

#### 4. Use of 'and/or'



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The handbook frequently uses the term 'and/or'. This term can lead to ambiguity and should be avoided. The OLDP referred to this in the audit report for the code, and this has resulted in the term 'and/or' being removed from the Code in the recent Code maintenance proposal. For the purposes of the Application Handbook, a future amendment needs to determine whether it is 'and', 'or', or both.

### *Detailed Comments*

#### Schedule Amendments – Part 3

[1] - [3.4] - agree

[3.5] – As the replacement paragraph is the same as the existing paragraph, it appears that the proposed change for Section 3.1.3 'Purpose of the Application' is the deletion of the Note, and deletion of the sentence following the note. It is not clear why this change is proposed, as both the Note and the sentence following the note appear to provide useful guidance to the Applicant.

[3.6] – We note that some aspects of sub paragraphs 3.1.4 (b) to (e) have been relocated to Section 3.1.5 (a) to (c). It is not clear why 3.1.4 (c) is retained in 3.1.4, but is also repeated in the proposed text for Section 3.1.5 (c).

It would be helpful if FSANZ provides commentary on why the existing information in Section 3.1.4 (b) (c) and (d) are removed, and where they are now placed.

The new text proposed for 3.1.4 (b) contains an error – *change not changed*.

[3.7] – We note that Section 3.1.5 is significantly amended, and MAF considers that the proposed new structure of this section is improved. Some editing may be required. For example, there should be a comma after the word Index, and before etc, in section A (a), and the heading to A (2) could be improved. Suggested text is: *Data related to surveys of chemicals or other substances in food*.

[3.8] – agree

[3.9] – agree

[3.10] – The word 'guideline' is used in the proposed amendment, and while we understand what is meant by this word, it may not be clear to applicants that all of Part 3 is a 'guideline'. The term is used on the cover page to Part 3 of the Application Handbook. The term 'guideline' should be explained/defined in the Application Handbook, particularly in relation to the comment we make earlier in this submissions.

The proposed Note in this section is missing some words at the end of the sentence.

[4.1] - agree

[4.2] – This amendment proposes that part C of Section 3.2.1 is deleted. We note that this information is relocated in Section 3.1.4, A1 and A2. MAF agrees with this proposed amendment.

[5] agree

[6] – The proposed amendment to Section 3.2.5 (i.e. deletion of parts A and B) can be supported, however the terminology in the existing 'Note' at the beginning of Section 3.2.5 is now inconsistent with the proposed text (i.e. the Note still refers to 'nutrient content').

We also note that the numbering system used for A and B is not consistent (i.e. *1. and 2.* in A, but *(I), (II), etc* in B).

*Comments on section 3.2.5 B (II) – Details on the calculation of the energy factor*

In 1(a) suggest expanding kJ/g to kilojoules per gram, for consistency with 2(a).

In the proposed text in Section 3.2.5 B (II) 1 (c) the word ‘of’ is missing between ‘amount’ and ‘energy’.

Further comments are as follows

- In B II 3, there is no mention of thermogenesis associated with colonic fermentation, which can be a significant component of energy loss. This could be accounted for adding in a new point (d), referring to fermentative thermogenesis.
- III. 4. Breath hydrogen is not an accurate measure of colonic fermentation as it depends on the individual bacterial population - whether or not it is methanogenic. This section would be improved if the limitations of this method were acknowledged.
- IV. There is a typographical error in the first line.  
Furthermore, should “*must include information on one of more*” be changed to “*must include all that are relevant of ---*”. Otherwise the applicant need only include one factor, even when others are operating.

[7.1] – agree

[7.2] – This new section is supported, however the title and text of paragraph 9 needs to be clearer. It appears that the additional functions referred to are ‘non-food additive’-type functions. The title could read ‘Additional (non food additive) functions.’

[7.3] – [8.2] – agree

[8.3] – agree, but we question if the words ‘or not’ are necessary in the proposed drafting.

[8.4] – [8.7] – agree

[8.8] – MAF supports the proposed amendments.

[8.9] – agree

[8.10] – MAF supports this proposed amendment, and is consistent with comments we have made previously about the need for more information for enzyme processing aids derived from genetically modified organisms.

[8.11] – agree

[8.12] - agree

[9.1] – MAF notes that the requirement for the applicant to provide information on the metabolic fate of the nutritive substance has been removed; however the rationale for this is not clear.

[9.2] [9.4] – agree

[9.5] – the second subparagraph should be (b), not (a).

In D 1 (a) we note that there has been a change from ‘demonstrated’ to ‘intended’, but these have different meanings. We also question if the Note in the box in existing D 1 is retained. It is not clear from the drafting. The Note refers to ‘demonstrated’ nutritional purpose.

[9.6] – [10.3] - agree

[11.1] – This states *Omitting D.1. and the following Note, substituting –*

MAF agrees with the change, but we cannot see the Note in the current version (1 July 2010) of the Application Handbook, so the text preceding the proposed amendment may need correcting.

[11.2] - agree

[12.1] – MAF supports this proposed amendment relating to GM crops. This clarifies the situation whereby open reading frames can occur, and more clearly recognises the potential for rearrangements within the DNA construct during insertion.

[12.2] – MAF supports the proposed amendment, whereby the requirement for detection methodology is replaced by a simple requirement for the sequence of the inserted DNA, so that a detection method can be devised.

We would comment however that the proposed drafting (*‘Information suitable for analytical purpose’*) could be improved, and also question its placement in section 4. Does this requirement fit under “Information on the labelling of GM food”?

[12.3] – this appears to be inserted within the [12.2] section, which we presume is a typographical error. MAF supports the changes to B, and welcomes new section 6 (Toxicity of novel herbicide metabolites in GM herbicide-tolerant plants).

[12.4] - agree

[13.1] – agree

[13.2] – agree, but the drafting could be improved.

[13.3] – [14.1] – agree

[14.2] – In clause A. 2. (c), ‘Biosecurity New Zealand’ should be replaced with ‘New Zealand MAF’.

[15.1] – agree

[15.2] - agree

[16] – Under Part B (Information related to the dietary exposure) - it should be clearer that this refers to “current” dietary exposure of the relevant substance in the particular target group. It could be interpreted that data on potential dietary exposure of the substance to target populations is sought. If this is the case, then that should be clear in the Application Handbook. Furthermore, if information on “dietary exposure” also relates to food categories or food types, then that should also be explicit.

Under Part C, it might be possible that a change in labelling requirements under the general labelling requirements could be sought. MAF suggests this is amended, so as to broaden this to “information as it relates to a change in labelling requirements, including Part 2.9 of the Code”.

Part B 1 refers to ‘altered energy intake’. In MAF’s view, this is too narrow and there should also be a reference to other nutrients.

[17] – [19] - agree

Yours sincerely

