



20 December 2012

Project Officer Application A1074
Food Standards Australia New Zealand
PO Box 10559
The Terrace
WELLINGTON 6036

FS350-117-1074

Dear Sir/Madam

Application A1074 – Minimum L-Histidine in Infant Formula Products – Call for Submissions

Thank you for the opportunity to comment on this application. The Ministry for Primary Industries (MPI) has the following comments and recommendations to make.

General comments

MPI supports Option 1, that is to prepare a draft variation to Standard 2.9.1 to reduce the minimum requirement for L-histidine in infant formula products from 12 mg/100 kJ to 10 mg/100 kJ. We are satisfied that the proposed reduction is justified and will result in harmonisation with international standards. MPI agrees that there are no public health and safety concerns with a minimum L-histidine level of 10mg/100kJ based on international evidence, with regard to normal growth and development.

MPI welcomes the consideration of the Policy guidelines for Infant Formula Products as part of the assessment of this application, and found the inclusion of Attachment C to the Call for Submission report very helpful.

Comments on Supporting Document 1

MPI has reviewed the Comparative Nutritional Safety Assessment (CNSA), contained within Supporting Document 1, and has the following comments for consideration by FSANZ.

In both the Executive Summary on page ii and the Conclusion on page 14, it is noted that a reduction of the L-histidine content to 10 mg/100 kJ is equivalent to the reduction in the protein content of less than 0.1 mg

protein/100 kJ. MPI suggests that the derivation of this value (0.1 mg protein/100 kJ) is provided in Section 3 of the CNSA.

MPI appreciates that breast milk varies in composition for a variety of reasons. Table 3 shows a broad range from 18 to 40 mg/g protein. The following points could be considered, in terms of representing the data in Table 3, and commentary on the data:

- Section 3.2, last paragraph (page 10) states that “the EC SCF report questions the reliability of the measurement in studies conducted before 1985”. Table 3, illustrating the breast milk reference values, includes studies conducted before 1985 (e.g. Dep. Health Soc.Sec. (1977), Chavalittamrong (1981)). MPI suggests that FSANZ provides some discussion outlining why these studies were included. Alternatively, these studies could be excluded from the calculation of the reference values.
- The deviations and significance of the study reference values in Table 3, such as the value of 40 mg/g from Harzer et al 1986 would be of interest, as this could be correlated to the time and study conditions (such as methodology and analytical method sensitivity). We note that this study was not provided by the applicant. As the value of 40 mg/g protein is an outlier, it would be helpful to know that this value is indeed valid and should be included.
- The reasons for including the studies noted above could be included in the Approval Report. We note that the average value changes in the one gram range, depending on which studies are excluded.
- Figure 1 on page 12 compares the mean values and range overlap of all reports included in the FSANZ assessment and visualises the broad range. A further figure showing the mean and range of the values in the studies cited in Table 3 could be added to the CNSA.
- Section 3.4 (page 12) states that “Reducing the minimum requirement for L-histidine to 10 mg/100 kJ with a minimum level of 0.45 g protein/100 kJ would give 22 mg L-histidine/g. Table 3 shows an average of 24 mg L-histidine/g protein in breast milk (or 23 mg/g if the conversion factor of 6.38 is used). While the proposed value of 22 mg L-histidine/g is in the range of the reported concentration in breast milk, it could be noted that this value is still below the average reported in Table 3.

Section 3.5.2 (page 13), last paragraph states that:

“The limitation of studies listed in Appendix 2 is that the studies have been conducted from birth up to the age of 4-6 months of age, whereas Standard 2.9.1 applies to infant formula products for infants up to 12 months of age. However, the evidence cited by the Applicant is still relevant to the assessment of the safety to infants aged 6-12 months on the basis that the greatest health impact will occur during 0-6 months of age, where formula consumption represents the sole source of nutrition.”

As FSANZ will be aware, a paper entitled ‘Composition Requirements for Follow-Up Formula’ by Koletzko *et al*/has was tabled at the recent Codex Committee on Nutrition and Foods for Special Dietary Uses, and is in press for publication. This papers notes that new data on infant amino acid requirements are emerging, which may require revised definitions of minimum contents of non-dispensible and conditionally indispensable amino acids in IF and FUF

in the future. This paper includes a value for L-histidine in follow-on formula, which could be added to the evidence provided in the CNSA.

Yours sincerely

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Manager Food Science and Risk Assessment