

# NUTRICIA

Australia

Submission regarding Application A1074, Minimum L-histidine in Infant Formula Products

20<sup>th</sup> December 2012

*Food Standards Australia New Zealand  
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Canberra BC ACT 2610*

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Dear Sir/Madam,

Nutricia Australia Pty Ltd wishes to provide comments on the Application A1074, Minimum L-histidine in Infant Formula Products.

**Nutricia supports the adoption of the proposed lower minimum.**

Nutricia supports breast feeding as the preferred and optimum method of feeding an infant. If, however, breast feeding or breast milk is not available for the infant, the only suitable alternative method of feeding is an infant formula product.

We make particular note of the documents released by Food Standards Australia New Zealand (FSANZ) on this application. We support the conclusion provided in the Executive summary to the Comparative Nutritional Safety Assessment, that “the requested lowering of the minimum requirement for L-histidine in infant formula products from 12 mg/100kJ to 10 mg/100kJ is appropriate and safe.”

As mentioned in the Comparative Nutritional Safety Assessment, the level of L-histidine at a minimum of 10 mg/100kJ is consistent with the amino acid profiles in breast milk as listed in Codex Alimentarius Standard 72-1981 Revision 2007 (*Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants*) and the EU Commission Directive 2006/141/EC of 22 December 2006 (*on infant formulae and follow-on formulae*).

The information contained in the Comparative Nutritional Assessment (Supporting document 1) discussed the comparison of amino acid profiles, including L-histidine, in studies of breast milk. This was used at least in part as the basis for assessing the appropriate levels of individual amino acids in infant formula products.

We acknowledge that the levels of individual nutrients in breast milk can be regarded as one assessment tool for evaluating the appropriate nutrient profile of an infant formula product. In many circumstances, particularly where individual nutrients identified and isolated from breast

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milk are not available to be added to infant formula products, evaluation of the appropriate nutrition profile is appropriately based upon growth and development outcomes of infants. These outcome based studies form the basis of a significant body of research that has demonstrated the normal growth and development of infants that have been fed infant formula products over a large number of years.

We acknowledge the limited data and variability of the data that was available for assessing the composition of breast milk, in terms of the amino acid profile. This particularly relates to data available for breast milk from mothers in Australia and New Zealand. The variability of the data includes variation in analytical techniques used and which technique may be the most appropriate and also the allowance that must be made for inherent variations in breast milk composition.

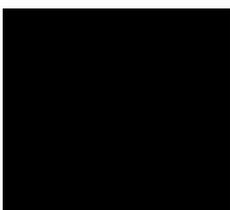
These variations include those due to the varying ages of the mothers that provided milk for testing, varying diets of those mothers, varying ethnic backgrounds and genetic influences of the mothers and their infants, varying stages of lactation and variations in breast milk during any 24 period for any mother. In this sense breast milk cannot be seen as a single homogenous substance for nutrient comparison.

As previously indicated, we support the approach that focuses upon the growth and development outcomes for infants, in this case using infant formula that contains a minimum of 10 mg L-histidine per 100 kJ. We strongly agree with the conclusion where it states:

“There is also published evidence that growth of formula-fed infants consuming a formula containing 10 mg L-histidine/100kJ is comparable with breastfed infants. These studies measured physiological outcomes (anthropometric measures) and bio chemical measures (plasma amino acid concentration) breastfed and formula-fed infants.”

This outcome-based approach has implications for the assessment of a wider range of ingredients used in infant formula products into the future.

Yours sincerely,



Regulatory Affairs Manager