



## **INC SUBMISSION ON APPLICATION A1074 – MINIMUM L-HISTIDINE IN INFANT FORMULA PRODUCTS**

**20 December 2012**

### **INTRODUCTION**

This submission has been prepared by the Infant Nutrition Council (INC). The INC represents the majority of companies marketing infant formula and companies who manufacture infant formula in Australia and New Zealand.

INC aims to:

1. Improve infant nutrition by supporting the public health goals for the protection and promotion of breastfeeding and, when needed, infant formula as the only suitable alternative; and
2. Represent the infant formula industry in Australia and New Zealand.

INC is a responsible group that voluntarily restricts its marketing practices to support government policies for the protection and promotion of breastfeeding.

#### Members:

- Abbott Nutrition;
- Bayer Ltd;
- Fonterra Co-operative Group Ltd;
- H. J. Heinz Company Australia Ltd & H. J. Heinz Company NZ Ltd;
- Nestlé Australia Ltd & Nestlé New Zealand Limited;
- Nutricia Pty Ltd; and
- Pfizer Nutrition.

#### Associate Members:

- Biolife New Zealand Pty Ltd;
- Dairy Goat Co-operative (NZ) Ltd;
- Murray Goulburn Co-operative Co Ltd (Aust);
- Sutton Group (NZ);
- Synlait Milk Ltd (NZ);
- Westland Milk Products (NZ).

INC believes that breastfeeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breast milk the only suitable and safe alternative is a scientifically developed infant formula product. For these infants, infant formula is the sole source of nutrition for around the first 6 months. It is important that scientific advances in infant nutrition are captured and incorporated into these products to ensure the best possible outcome for infants who do not receive breast milk.

We welcome the opportunity to provide written comment to Food Standards Australia New Zealand (FSANZ) in response to the *Call for Submissions – Application A1074 – Minimum L-histidine in Infant Formula Products*.

## **EXECUTIVE SUMMARY**

INC supports safe and nutritious infant formula products manufactured and imported in Australia and New Zealand. *Application A1074 – Minimum L-histidine in Infant Formula Products* proposes that the level of L-histidine in infant formula products as contained in the Australia New Zealand Food Standards Code (the Food Standards Code) be reduced from 12mg/100kJ to 10mg/100kJ.

The lower level of L-histidine would align with levels in Codex and in the EU and would remove a trade barrier that currently exists in relation to infant formula products sourced from the EU.

FSANZ assessed the proposal and concluded that the lower level was safe and maintained normal growth and development of infants. This conclusion reached by FSANZ on the proposal would see the Food Standards Code amended to reduce the minimum level of L-histidine in infant formula products from 12mg/100kJ to 10mg/100kJ.

INC supports the FSANZ conclusion and the proposal to amend the Food Standards Code to reduce the minimum level of L-histidine in infant formula products from 12mg/100kJ to 10mg/100kJ.

## COMMENTS

Nestlé Australia Ltd and Nestlé New Zealand Ltd (Nestlé) have proposed that the minimum requirement for the essential amino acid, L-histidine, in infant formula and follow-on formula be reduced. The current requirement for L-histidine in infant and follow-on formula, as stated in the Table to Clause 22 in Standard 2.9.1 *Infant Formula Products* of the Food Standards Code, is a minimum of 12mg/100kJ.

The key reason for proposing this change is that the applicant, Nestlé, sources infant and follow-on formula for the Australian and New Zealand markets from Europe. The different L-histidine requirements results in additional costs and a risk of continual supply into the market, particularly for products for the most vulnerable infants such as those with medical conditions. While these products represent a small part of the total formula market in Australia and New Zealand, harmonised L-histidine requirements would allow the same recipe to be used for these markets and for Codex-compliant and EU markets.

### ***International comparisons***

The current L-histidine requirement for Australia and New Zealand as contained in the Food Standards Code is higher than the requirements in both the *Codex Standard for infant formula and formulas for special medical purposes intended for infants: CODEX STAN 72-1981*, Revised 2007 and the EU and as such, represents a trade barrier. This could potentially be cause for concern for continual supply of some products for this vulnerable population group.

### ***Safety***

Evidence demonstrates that the proposed minimum level of 10mg/100kJ of L-histidine is safe and will promote normal growth and development in infants. The studies identified by the applicant and FSANZ compared formula-fed infants to breastfed infants and found that infants given formula containing lower amounts of L-histidine (i.e. containing L-histidine  $\leq 10.5$  mg/100kJ) had growth measures comparable to breastfed infants. Also, the studies showed no differences in growth between formula-fed infants consuming products containing either 12 mg/100 kJ or 10 mg/100 kJ of L-histidine.

The level of 10 mg/100 kJ of L-histidine is used throughout the EU and in Codex-compliant countries. There are no known reports of inadequate normal growth and development due to insufficient L-histidine in any of these countries.

The amino acid minimum requirements in the Food Standards Code are based on the breast milk composition findings from a 1989 FAO/WHO commissioned Expert Consultation on Protein Quality Evaluation. In 2004, the FAO/WHO commissioned a report from the ESPGHAN International Expert Group to provide a proposal on nutrient levels in infant formula, based on scientific analysis. The recommendations from this report<sup>1</sup> concerning amino acid minimum levels were adopted into Annex I of the revised Codex Standard on Infant Formula<sup>2</sup> (2007). This included the requirement for L-histidine levels to be 41mg/100kcal (9.8 mg per 100kJ) based on the mean of human milk studies.

FSANZ reviewed studies analysing amino acid composition of breast milk as a means to benchmark the adequacy of L-histidine levels in infant formula products. These were used to calculate an average concentration of L-histidine which was 24 mg/g crude protein in breast milk. FSANZ found that this was comparable to the average concentration reported by

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<sup>1</sup> Koletzko et al 2005

<sup>2</sup> p14 *CODEX-STAN 72-1981* Revised 2007

several scientific expert panels and international policy organisations. Using appropriate composition data for protein, fat and carbohydrate in breast milk, FSANZ found that 24 mg L-histidine/g crude protein was equivalent to 10 mg L-histidine/100 kJ.

## **CONCLUSION**

In the absence of safety concerns and noting that the proposed minimum level of 10mg/100kJ of L-histidine maintains normal growth and development of infants, FSANZ proposes that this lower minimum level of L-histidine be included in the Food Standards Code. This would more closely align the Food Standards Code with Codex and EU levels.

INC supports the FSANZ conclusion and the proposal to amend the Food Standards Code to reduce the minimum level of L-histidine in infant formula products from 12mg/100kJ to 10mg/100kJ.

## **REFERENCES**

Koletzko B, Baker S, Cleghorn G, Neto UF, Gopalan S, Hernell O, Hock QS, Jirapinyo P, Lonnerdal B, Pencharz P, Pzyrembel H, Ramirez-Mayans J, Shamir R, Turck D, Yamashiro Y, Zong-Yi D “Global standard for the composition of infant formula: recommendations of an ESPGHAN coordinated international expert group”. *Journal of Pediatric Gastroenterology and Nutrition* 2005, 41(5):584–599

*Standard for infant formula and formulas for special medical purposes intended for infants: CODEX STAN 72 – 1981, Revised 2007. Codex, 2011*