FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Supporting document 2

Assessment of the Application in relation to the Ministerial Policy Guideline on the *Regulation of Infant Formula Products* – Application A1074 (Approval)

Minimum L-histidine in Infant Formula Products

FSANZ has had regard to the Ministerial Policy Guideline on the *Regulation of Infant Formula Products* (the Policy Guideline) in our assessment of this Application. The Policy Guideline includes specific policy principles relating to composition, labelling and advertising, as well as overarching principles. The table below summarises our assessment in relation to these specific policy principles, with particular focus on the principles for composition.

Specific Policy Principles	**Approach**	**Does the assessment meet the Policy Principles?**
Overarching		
(a) The regulation of infant formula products should recognise that breastfeeding is the normal and recommended way to feed an infant.	FSANZ acknowledged in its report that breastfeeding is the recommended way to feed an infant.	
(b) The regulation of infant formula products should not be inconsistent with the national nutrition policies and guidelines of Australia and New Zealand that are relevant to infant feeding.	Not applicable to this Application. The proposed change to the minimum requirement for L-histidine is not inconsistent with current national nutrition polices and guidelines for infant feeding. There is no deviation proposed from the current nutrient reference value for infants	Not applicable

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
	for protein; the minimum total protein content is unchanged.	
(c) The regulation of infant formula products should be based on risk analysis, taking into account the vulnerability of the population for whom they are intended and the importance of these products in the diets of formula fed infants.	A comparative nutritional safety assessment approach was taken for the assessment of this Application.	Yes
Composition		
(d) The composition of infant formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole source of nutrition up to six months of age.	Toxicological data was not considered in the assessment of this Application. A minimum level of L-histidine is already required in infant formula products and the Applicant's request is to reduce this level. L-histidine is an essential amino acid and is required (along with other essential amino acids) in infant formula products for protein quality purposes. The assessment has determined that a minimum L-histidine level of 10 mg/100 kJ is adequate to support the growth of formula-fed infants compared to breastfed infants. Also, that the plasma levels of L-histidine in breastfed infants and those fed infant formula products with a lower amount of L-histidine are physiologically equivalent.	Yes
(e) The composition of follow-on formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical or functional outcomes) of healthy full term breastfed infants at the appropriate age when follow-on formula used as the principal source of liquid nourishment in a progressively diversified diet.	See comments for specific policy principle (d).	Yes
(f) The essential composition of infant formula and follow on formula should be prescribed in regulation and must satisfy the	L-histidine is an essential amino acid and a minimum level of L-histidine is already mandated in Standard 2.9.1 to provide for	Yes

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
nutritional requirements of infants.	the nutritional requirements of formula-fed infants. It is proposed that this existing requirement is amended.	
(g) Compositional requirements for infant formula and follow-on formula products should only be mandated in regulation where there is sufficient evidence to demonstrate that they are safe and essential for normal growth and development of infants.	The safety of L-histidine and its role in infant nutrition is internationally recognised, and there is an existing mandatory requirement for a minimum level to be present in infant formula products.	Yes
(h) The composition of breast milk should be used as a primary reference for determining the composition of infant formula and follow-on formula.	The levels of L-histidine in breast milk were used as the primary reference to determine the appropriate amount that should be required in infant formula products. The Comparative Nutritional Safety Assessment found that the level of L-histidine in breast milk is variable with an *average* level of 10 mg/100 kJ; the same as the proposed *minimum* required level.	Yes
(i) Pre-market assessment, relative to principles (d) and (e), should be required for any substance proposed to be used in infant formula and follow-on formula that: i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or ii. has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.	Not applicable to this Application as L-histidine is not a new substance to be regulated.	Not applicable
(j) Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated beneficial role in the normal growth and development of infants or children, or a technological role, taking into account, where relevant, the levels of comparable substances in breast milk. A substance's role in normal growth	Not applicable to this Application as L-histidine is not a new substance to be regulated.	Not applicable

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
and development is substantiated where there is appropriate evidence to link the physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood. Particular caution should be applied by the Authority where such links are less clear.		
Labelling and advertising		
(k) The labelling and advertising of infant formula products should be consistent with the World Health Organization International Code of Marketing of Breast Milk Substitutes as implemented in Australia and New Zealand.	Not applicable to this Application. No amendments to current labelling requirements for L-histidine in infant formula products were made as part of this Application. No issues were identified in relation to the potential for misleading or deceptive conduct with the proposed reduction in minimum requirement for L-histidine in infant formula products.	Not applicable
(l) The labelling and advertising of infant formula products should not represent those products as an equivalent to, or better than, breast milk.		
(m) The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products.		
(n) The Authority should: i. ensure that the prohibitions and restrictions on nutrient content, health, therapeutic, and prophylactic claims in the Food Standards Code are clear and effective for infant formula products; and ii. consider whether the current labelling regime is leading to consumers being mislead about the quality or effectiveness of an infant formula product.		