



Supporting document 2

Regard to the Ministerial Policy Guideline – Application A1173 Minimum protein in follow-on formula

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.	Yes
(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.	The proposed reduction to the minimum protein requirement for milk-based follow-on formula is consistent with current national nutrition policies and guidelines for infant feeding. The Australian infant feeding guidelines advise caregivers to look for lower protein content when choosing a formula product (NHMRC 2012).	Yes

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Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
(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 nutritional safety assessment was conducted for the assessment of this Application.	Yes
Composition		
(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.	<p>The nutritional safety assessment reviewed two RCTs examining growth of infants fed lower protein formula. Both studies compared weight gain and anthropometric measures between a low protein and high protein formula and a breastfed reference group.</p> <p>In general, formula-fed infants demonstrate faster weight gain compared with breastfed infants. Therefore, slower weight gain that is more comparable to breastfed infants is assumed to be advantageous. The assessment concluded that both studies reported slightly lower growth rates in the lower protein formula fed infants, showing a consistent direction of the association of lower protein with growth trajectories similar to breastfed infants.</p>	Yes
(f) The essential composition of infant formula and follow on formula should be prescribed in regulation and must satisfy the nutritional requirements of infants.	Protein is an essential macronutrient and a minimum requirement is already given in Standard 2.9.1 to provide for the nutritional requirements of formula-fed infants. The protein requirements of older infants continue to be satisfied when fed a lower protein follow-on formula in addition to complementary foods.	Yes
(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	Refer to responses for (e) and (f)	

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Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
are safe and essential for normal growth and development of infants.		
(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 crude content of human milk was reviewed and used as the primary reference. The Nutritional Safety Assessment found that the lower minimum protein level requested by the applicant was within the range found in human milk 5 to 12 months post-partum.	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: <ul style="list-style-type: none"> 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 protein is already 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 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.	Not applicable to this Application as protein is already regulated.	Not applicable

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Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
<i>Labelling and advertising</i>		
(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.	<p>Not applicable to this Application.</p> <p>No amendments to current labelling requirements for protein in follow-on formula products were made as part of this Application.</p> <p>No issues were identified in relation to the potential for misleading or deceptive conduct with the proposed reduction in minimum requirement for protein in follow-on formula products.</p>	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: <ul style="list-style-type: none"> 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 misled about the quality or effectiveness of an infant formula product. 		

NHMRC (2012) Australian Infant Feeding Guidelines – Information for Health Workers. National Health and Medical Research Council, Canberra.
http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/n56_infant_feeding_guidelines.pdf