



# Infant Nutrition Council

Industry supporting both  
Breastfeeding & Infant Formula

AUSTRALIA & NEW ZEALAND

13 June 2019

## INC SUBMISSION ON APPLICATION A1173 – MINIMUM PROTEIN IN FOLLOW-ON FORMULA

### INTRODUCTION

This submission has been prepared by the Infant Nutrition Council (INC). The INC represents the majority of companies marketing infant formula and toddler milk drinks (formulated supplementary foods for young children) 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 and toddler milk drink industry in Australia and New Zealand.

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

#### Members:

- A2 Infant Nutrition Ltd
- Aspen Nutritionals Australia Pty Ltd
- Danone Nutricia Early Life Nutrition
- Fonterra Co-operative Group Ltd
- H J Heinz Company Australia Ltd and H J Heinz Company (New Zealand) Ltd
- Nestlé Australia Ltd and Nestlé New Zealand Limited
- Synlait Milk Ltd

#### Associate Members:

- Abbott Australasia Pty Ltd
- Adams Australia Pty Ltd
- Australian Dairy Park
- Bakels Edible Oils (NZ) Ltd
- Bayer Ltd
- Blend and Pack
- Bodco Dairy Ltd
- Bubs Australia Ltd
- Burra Foods
- Cambricare New Zealand Ltd
- Mataura Valley Milk Ltd
- NIG Nutritionals
- New Zealand New Milk Ltd
- Nuchev Food Pty Ltd
- Nu-Mega Ingredients
- Oceania Dairy Limited
- Peerless Foods
- Reckitt Benckiser
- Saputo Dairy Australia Pty Ltd
- Snow Brand Aust Pty Ltd

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- DSM Pty Ltd
- Freedom Foods
- Fresco Nutrition Ltd
- GMP Dairy Ltd
- GrainCorp Ltd
- Jamestrong Packaging Pty Ltd
- Spring Sheep Milk Co
- Tatura Milk Industries
- The H&H Group
- Wattle Health Australia Ltd
- Westland Co-operative Dairy Company Ltd
- Winston Nutritional New Zealand
- Yashili Dairy New Zealand

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 A1173 – Minimum protein in follow-on formula*.

Yours sincerely

A handwritten signature in black ink that reads "Jan Carey". The signature is written in a cursive style with a large, looped initial "J" and a long, thin vertical stroke extending downwards from the end of the name.

Jan Carey  
Chief Executive Officer

## EXECUTIVE SUMMARY

INC supports the need to ensure that infant formula products available in Australia and New Zealand are safe and nutritious. The Call for Submissions for *Application A1173 – Minimum protein in follow-on formula* proposes that the level of protein in follow-on formula as contained in the Australia New Zealand Food Standards Code (the Food Standards Code) be reduced for milk-based follow-on formula from 0.45g/100kJ to 0.38 g/100kJ.

INC proposes that, consistent with current provisions in the Food Standards Code, the protein level for all follow-on formula be reduced from 0.45g/100kJ to 0.38 g/100kJ but with conditions placed on that.

The lower level of protein would align with international provisions such as the EU amended follow-on formula regulations and the Codex proposed draft Follow-up Formula Standard. This helps to facilitate harmonisation and trade.

FSANZ assessed the application and concluded that the lower level was safe and maintained normal growth and development of older infants. FSANZ also concluded that an amendment to the Food Standards Code should be limited to a reduction in the minimum level of protein in milk-based follow-on formula from 0.45g/100kJ to 0.38 g/100kJ but not for soy-based follow-on formula.

INC is concerned that the drafting for implementation proposed by FSANZ does not cover the range of protein sources in the definition of infant formula products in Standard 2.9.1 and thus creates a regulatory gap. INC suggests a preferred option for alternative drafting for consideration that proposes the minimum level of protein in follow-on formula is reduced from 0.45g/100kJ to 0.38 g/100kJ conditional on appropriate supporting evidence. This future proofs the Food Standards Code, avoids creating regulatory gaps (covers all protein sources) and avoids losing clarity.

Two other options for drafting are provided which are not consistent with the current provisions but which nonetheless address the regulatory gap.

## COMMENTS

1. INC supports a reduction to the minimum level of protein in follow-on formula in Standard 2.9.1 of the Food Standards Code but does not support the drafting of the amendment to the Food Standards Code as presented in Attachment A – Draft variation to the *Australia New Zealand Food Standards Code* to the Call for Submissions document.

### ***The minimum level***

2. International developments to reduce the protein level in follow-up formula are being taken to better align the protein level in such formula with the levels of protein occurring in human breast milk. The reduced minimum level proposed in the application, is within the range of protein levels in human milk.
3. Relevant information presented by the applicant was assessed by FSANZ in a nutritional safety assessment. This included two infant growth and tolerance trials of milk-based formulas with reduced protein levels, estimated dietary protein intakes of older infants, and breast milk protein levels. FSANZ agreed that normal growth and development of infants consuming follow-on formula can still be achieved with the reduced protein level when compared to the growth and development of full-term breastfed infants.
4. Similarities can be drawn with the EU regulations and drafted Codex requirements (at Step 7) covering formulas for this age group, where the protein minimum has been reduced.
5. In 2018, the EU reduced the minimum level of protein in follow-up formula to 0.38/100kJ for the milk protein sources permitted in the EU. The draft Codex Follow-up Formula (FUF) standard for the older infant also allows for reduced protein levels, retaining the minimum at 0.45g/100KJ but with a footnote stating that protein levels between 0.38-0.45g/100kJ are permitted for but require clinical evidence.
6. INC additionally notes that both the EU and Codex calculate protein in milk-based follow-up formula using a nitrogen conversion factor (NCF) of 6.25 whereas Australia and New Zealand use a NCF of 6.38 resulting in a difference of 2% in protein levels.
7. INC supports amending the Food Standards Code to reduce the minimum protein level in follow-on formula products from 0.45g/100kJ to 0.38 g/100kJ conditional on appropriate supporting evidence for the protein source used. Older infants will continue to receive protein of sufficient quality as required by minimum amino acid profile requirements. Additionally, at around 6 months, the older infant is consuming a progressively diversified complementary diet based on solid foods and providing additional protein from these foods. On this basis INC considers that the safety and protection of formula fed older infants is maintained.
8. Regulatory changes overseas have the potential to create trade barriers where Australian and New Zealand regulations are not aligned with such changes. Amending the Food Standards Code to reduce the minimum protein level in follow-up formula is intended to remove the prospect of trade barriers relating to protein levels in the future.

### ***Application of the reduced minimum level***

9. FSANZ determined that the lower minimum protein level should not apply to soy-based follow-on formula. INC considers there is inconsistency in the presentation of the exclusion of soy from the reduced protein minimum. The draft amendment proposed by

FSANZ for Standard 2.9.1—9(2)(b) as provided in Attachment A to the Call for Submissions, is problematic in terms of creating a regulatory gap for formulas based on non-milk edible food constituents of plant or animal origin other than soy, and introducing internal inconsistency to the Food Standards Code where this does not currently exist. The basis for this is as follows:

- A. The definition of **infant formula product** in Standard 2.9.1—3 of the Food Standards Code reads:

**infant formula product** means a product based on milk or other edible food constituents of plant or animal origin which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.

- B. The definition of follow-on formula in Standard 1.1.2—3 of the Food Standards Code reads:

**follow-on formula** means an infant formula product that:

- a) is represented as either a breast-milk substitute or replacement for infant formula; and
- b) is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.

- C. Standard 2.9.1—9(2) refers to the composition of all follow-on formula as:

(2) Follow-on formula must have:

- a) An energy content .....
  - b) A protein content of no less than 0.45 g/100 kJ and no more than 1.3 g/100 kJ; and
  - c) A fat content ...
- etc.

- D. Standard 2.9.1—9(2) currently applies to all follow-on formula including 'products based on milk or other edible food constituents of plant or animal origin'. By replacing Standard 2.9.1—9(2)(b) with a provision that refers only to 'milk-based formula' and 'soy-based formula', any other types of follow-on formula are left without requirements relating to protein and thereby creating a regulatory gap.

- E. To future proof the Food Standards Code and facilitate innovation, avoid creating a regulatory gap and avoid losing clarity, the amendment must address the protein levels for all follow-on formulas for all permissible protein sources. This would be consistent with the current regulatory framework which does not differentiate by protein source on the minimum amount even on infant formula for infants from birth (a more vulnerable population group) and where the formula is the 'sole source' of nutrition. Further, the Food Acts require that all products must be safe and suitable for their intended application. This necessitates research and risk assessments to assure that protein levels in infant formula products manufactured are appropriate for the source of protein used.

- F. Our preferred Option is the drafting presented at Option A below. This amendment encompasses all protein sources and is consistent with current provisions but includes a condition that a minimum protein of no less than 0.45 g/100 kJ applies unless there is appropriate evidence to support the use of a lower minimum. This is an efficient way of future proofing the Food Standards Code avoiding the need to process similar applications for the lower protein minimum to apply for other specific low-risk protein sources.

Option A Based on current provisions of the Food Standards Code 2.9.1—9:
(2) Follow-on formula must have: (b)(i) a protein content of no less than 0.38 g/100 kJ and no more than 1.3 g/100 kJ; (ii) despite subsection 2(b)(i), a protein content of no less than 0.45 g/100 kJ applies unless there is appropriate data to support no less than 0.38 g/100 kJ.

G. Option A above is the INC preferred position. If FSANZ was to pursue the current proposed drafting, INC considers that limiting the scope of protein sources to milk-based and soy creates a regulatory gap compared to the current status quo, and does not facilitate innovation. INC points out that the proposed amendment drafted along the lines of either Option B or C below will provide better regulatory coverage than the drafting FSANZ included in the Call for Submissions – but which still remains inconsistent with current provisions:

Option B Based on proposed texts in page 15 of the Call for Submissions:	Option C Based on current provisions of the Australia New Zealand Food Standards Code:
(b) the following protein content: (i) for a milk-based formula—a protein content of no less than 0.38 g/100 kJ and no more than 1.3 g/100 kJ; and (ii) for a formula based on other edible food constituents of animal or plant origin—a protein content of no less than 0.45 g/100 kJ and no more than 1.3 g/100 kJ;	(b) a protein content of no less than 0.45 g/100 kJ and no more than 1.3 g/100 kJ; whereas for a milk-based formula—a protein content of no less than 0.38 g/100 kJ and no more than 1.3 g/100 kJ.

10. All options (A, B and C):

- align with the international trend to lower protein levels in follow-on formula
- overcome regulatory gap identified in FSANZ proposed drafting.

11. Option A (which is the INC preferred position) retains the status quo and helps to future proof the Food Standards Code. Options B and C reflect the FSANZ assessment, with a proposed amendment to non-milk-based formulas (“other edible food constituents of animal or plant origin”), to be consistent with the current definition in the Code for infant formula products.