



Nestlé Submission

Consultation Paper for Application 1173 (A1173) Minimum protein in follow-on formula

13 June 2019

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A1173: Minimum protein in follow-on formula

This submission is made on behalf of Nestlé Australia Ltd and Nestlé New Zealand Limited (Nestlé).

Nestlé is a manufacturer and importer of a wide variety of foods for the Australian and New Zealand markets and is globally one of the largest manufacturers of infant formula products and other foods. Nestlé currently imports and markets infant formula products which are regulated in section 2.9.1 of the Australia New Zealand Food Standards Code ('the Code'), and formulated supplementary foods for young children (otherwise known as Toddler Milk Drinks), regulated in section 2.9.3 of the Code.

Nestlé thanks FSANZ for the consultation paper for Application 1173 (A1173), and welcomes the opportunity to consider the issues and preliminary views proposed, and to provide comment and information to Food Standards Australia New Zealand (FSANZ) relating to the regulation on minimum protein in follow-on formula. We thank FSANZ for their consideration of the comments, issues and views raised in this submission.

Comments on the Consultation Paper

Nestlé is the Applicant in relation to A1173.

Nestlé is a member of the Infant Nutrition Council (INC) and our views reflect those of that in the INC submission.

Nestlé supports a reduction to the minimum level of protein in follow-on formula in Standard 2.9.1 of the Food Standards Code to 0.38 g/100 kJ. This protein level will bring it closer to the levels in breastmilk, and satisfies Policy Guideline on the Regulation of Infant Formula Products, for composition with Policy principle h) "*The composition of breastmilk should be used as a primary reference for determining the composition of infant formula and follow-on formula*".

The request made in the application is to decrease the minimum level of protein, an already-permitted nutritive substance in follow-on formula for infants 6 to 12 months of age, to achieve growth rates, measured by infants' length, weight, and head circumference, that are more comparable to breastfed infants. In 2 randomised, double-blind, controlled intervention studies (Inostroza *et al.*, 2014; Ziegler *et al.*, 2015), the effects on infant growth, of a low protein formula were compared to a high protein formula, and also to a breastfed reference group. Outcomes from those clinical studies demonstrated both the safety and efficacy of protein at the proposed minimum level of 0.38g/100kJ (1.6 g total protein/100 kcal).

Nestlé also concurs with FSANZ's dietary assessment that the older infant 6-12 months of age is likely exceeding the AI of protein (currently 14g per day). From around 6 months of age, protein will come from other sources of the diet – namely, complementary infant foods. FSANZ estimated, using a more complex assessment methodology including other foods and beverages, "*...the mean protein intake of 9-month old infants at 24 g/day based on AUSNUT protein data, 21 g/day on the current standard and 20 g/day with the proposed reduction in minimum protein content*". The mean protein intakes from Australian infant dietary studies (Lioret *et al.*, 2013; Kavian *et al.*, 2015) also showed that protein dietary intakes for the older infant are above the AI. As such, it is highly unlikely that infants in Australia and New Zealand would be under-consuming protein.

In terms of the proposed variation to Standard 2.9.1 in Attachment A to the Consultation paper, Nestlé considers that this is a departure to the current regulatory status quo and framework in relation to the sources of protein the regulatory minimum should apply to. This is because the proposed variation in Attachment A, limits the scope to milk-based formulas and to soy, but excludes all other types of protein sources. The current definition of Infant formula product in Standard 2.9.1 is: “***infant formula product means a product based on milk or other edible food constituents of animal or plant 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.***”

Nestlé supports the INC preferred position to align the types of protein sources to the existing regulatory status quo and as such supports the following INC proposed variation:

Based on current provisions of the Food Standards Code 2.9.1—9:

(2) Follow-on formula must have:

- (b) a protein content of no less than 0.38 g/100 kJ and no more than 1.3 g/100 kJ;
 - (i) despite subsection 2(b), 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.

For comparison purposes as follows is the current clause:

(2) Follow-on formula must have:

- (b) a protein content of no less than 0.45 g/100 kJ and no more than 1.3 g/100 kJ;

Nestlé considers that the above proposed variation is safe for the summary reasons outlined above, and as detailed in the Application. FSANZ pre-market assesses and regulates on the quality, and quantity of protein, and requires the protein source statement for labelling. The above proposed variation maintains the current regulatory status quo on protein and helps facilitate future innovation, in the best interests of the consuming population, when breastfeeding is not possible.

References

Inostroza J, Haschke F, Steenhout P, Grathwohl D, Nelson SE, Ziegler EE (2014). Low-protein formula slows weight gain in infants of overweight mothers. *J Pediatr Gastroenterol Nutr* 59(1):70-77. DOI:10.1097/MPG.0000000000000349.

Kavian, F.; Scott J.A., Perry, R.; Byrne, R. and Magarey, A. (2015). Assessing Dietary Intake and Growth of Infants. In: *Maternal and Paediatric Nutrition Journal* 1(1) DOI: 10.4172/2472-1182.1000101

Lioret S, McNaughton SA, Spence AC, Crawford D, Campbell KJ (2013). Tracking of dietary intakes in early childhood: the Melbourne InFANT Program. *Eur J Clin Nutr* 67(3):275-281. DOI:10.1038/ejcn.2012.218.

Ziegler EE, Fields DA, Chernauek SD, Steenhout P, Grathwohl D, Jeter JM, et al. (2015). Adequacy of infant formula with protein content of 1.6 g/100 kcal for infants between 3 and 12 months. *J Pediatr Gastroenterol Nutr* 61(5):596-603. DOI:10.1097/MPG.0000000000000881.