

Project Officer Application A1173
Food Standards Australia New Zealand
PO Box 10559
The Terrace
Wellington 6036

13 June 2019

Dear Sir/Madam

Application A1173 – Minimum protein in follow-on formula (Call for submissions)

Thank you for the opportunity to comment on this application. The Ministry for Primary Industries (MPI) has the following comments to make.

MPI is generally supportive of the FSANZ assessment. The safety and suitability of follow-on formula at a minimum protein level of 0.38 g/100 kJ has been demonstrated and is consistent with the Ministerial Policy Guideline. Furthermore, the reduction in the minimum protein level is consistent with the recent reviews by EFSA and the Codex Committee on Nutrition and Foods for Special Dietary Uses.

Source of protein

MPI agrees that the reduction in the minimum protein content should be limited to milk-based formula of animal origin and should not be extended to other types of formula, including soy-based formula. It is noted that the draft variation refers to 'milk-based formula' but does not clarify that this is from animal origin. The equivalent European legislation refers specifically to cows' and goats' milk based formula ([Regulation \(EU\) 2016/127; amendment 2018](#)). Similarly the draft revised Codex standard for follow-up formula states that the minimum amount is applicable to cows' and goats' milk protein and that other minimum values may need to be applied for other protein sources ([REP19/NFSDU Appendix II](#)). MPI proposes that the draft variation is amended to reflect that the minimum protein content of no less than 0.38 g/100 kJ is specifically applicable to milk-based formula from animal origin.

Energy Density

The permitted range of energy density for follow-on formula is much wider than that permitted in the revised EU legislation and draft revised Codex Standard for follow-up formula which permit lower protein formulas (Table 1). As the permitted range of fat within follow-on formula is fixed, a lower protein formula with a higher energy density would require higher quantities of energy from carbohydrates. Consideration should be given to the balance of macronutrients of a low protein formula at a higher energy density; and whether there is a need to limit lower protein formulations to formula with an energy content of no more than 315 kJ per 100 mL.

Maximum protein level

Additionally, MPI notes that the maximum protein content for follow-on formula in Standard 2.9.1 is 1.3 g/100 kJ, which is significantly higher than the maximum protein content of follow-on formula in the revised EU legislation (0.6 g/100 kJ); the draft revised Codex standard for follow-up formula

(0.72 g/100 kJ) and current maximum in the Food Standards Code for Infant Formula (0.7 g/100 kJ)). The relevant EU and Codex reviews concluded that there was no physiological need for protein from follow-on formula in excess of 0.72 g/100 kJ; and that protein intakes of infants are generally well above their requirements ([EFSA 2014](#); [CX/NFSDU 16/38/6](#)). Furthermore, higher protein formulas have been associated with faster growth rates than breastfed infants which may be linked to later risk of overweight and obesity ([NHMRC, 2012](#)).

Whilst the maximum level of protein is outside the scope of this application, MPI considers that lowering the maximum protein content of follow-on formula would align with the NHMRC Infant Feeding Guidelines ([NHMRC, 2012](#)), and be consistent with the Ministerial Policy Guidelines, and should therefore be considered.

Table 1: Summary of energy and protein requirements in relevant regulations

	Energy (kJ/100 mL)		Protein (g/100 kJ)	
	Minimum	Maximum	Minimum	Maximum
Standard 2.9.1 draft variation follow-on formula	250	350	0.38	1.3
EU legislation (2016/127)	250	293	0.38	0.6
Draft revised Codex Standard for follow-up formula	251	293	0.38*	0.72
Standard 2.9.1 Infant formula	250	315	0.45	0.7

*A lower minimum protein level of between 0.38 and 0.43 g/100 kJ in follow up formula for older infants based on non-hydrolysed milk protein can be accepted. Such follow-up formula should be evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence.

Dietary Assessment

MPI supports the outcomes of the dietary assessment. However we note that the simulated diet for infants that was used in the NZ Total Diet Study could be used to construct a model diet for New Zealand infants ([New Zealand Food Safety, 2018](#), Appendix 3.3). The simulated diet is based on infants aged six to 12 months of age using data from the Baby Led Introduction to Solids (BLISS) study published in 2015.

To summarise, MPI is supportive of lowering the minimum protein content of follow-on formula but request that further consideration is given to clarifying that the minimum is applicable to milk-based formula of animal origin; the energy density of lower protein follow-on formula; the maximum permitted protein level; and consideration of a New Zealand model diet for infants.

Yours sincerely,



Manager Food Science and Risk Assessment