



# Request to Amend the Minimum Protein Requirement in Follow-on Formula in the Australia New Zealand Food Standards Code

## 1.0 EXECUTIVE SUMMARY

Dietary protein is an essential component of the diet, supplying the body with nitrogen and amino acids (EFSA, 2017), which are needed for the synthesis of nucleic acids, hormones and vitamins (IOM, 2005). Proteins are the major structural components of all cells in the body (IOM, 2005) and are essential in growth and development (Dupont, 2003), including the development of the brain and bones (Bonjour *et al.*, 2001). Proteins also function as enzymes and transport carriers (IOM, 2005).

The purpose of this application is to request an amendment to the Code, specifically **Standard 2.9.1** (Infant formula products) (FSANZ, 2017)<sup>1</sup>, **Division 3** (Infant formula and follow-on formula), **2.9.1–9** (Infant formula and follow-on formula – composition), **(2) (b)** which states “Follow-on formula must have a protein content of no less than 0.45 g/100 kJ and no more than 1.3 g/100 kJ”. We are requesting to vary the minimum protein requirement in follow-on formula from “no less than 0.45 g/100 kJ” (equivalent to 1.88 g protein/100 kcal) to “**no less than 0.38 g/100 kJ**” (equivalent to 1.6 g/100 kcal)<sup>2</sup>.

As Codex is revising a standard, and EU has already amended a standard, that permits a protein minimum of 1.6 g/100 kcal or 0.38g/100kJ (under set conditions) for follow-on formula, aligning Australian and New Zealand standards with these standards will help facilitate harmonisation opportunities and promote international trade (this is assuming other nutritional parameters do not present hurdles for harmonisation). This harmonisation will also reduce the number of future technical barriers to trade. Based on human milk composition data from Mitoulas *et al.* (2002), the proposed minimum protein quantity recommended in this application for follow-on formula for use by infants aged 6 to 12 months of 1.6 g total protein/100 kcal (0.38g/100kJ) more closely aligns with, yet still exceeds by approximately 25%, the levels of protein occurring in the breast milk of Australian mothers during the 6<sup>th</sup> and 12<sup>th</sup> months of lactation (an average of 1.26 g total protein/100 kcal, equivalent to 0.30g/100kJ).

This request to decrease the minimum level of protein, an already-permitted nutrient in follow-on formula for infants 6 to 12 months of age, is to achieve growth rates, measured by infants’ length, weight, and head circumference, that are more comparable to breastfed infants. This is done in accordance with the Australia and New Zealand’s Food Regulation Ministerial Council’s Food Regulation Standing Committee’s position (2011) which states “the composition of breast milk should be used as a primary reference for determining the composition of infant formula and follow-on formula” and “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 [...] of healthy full-term breastfed infants at the appropriate age**” (Australian and New Zealand Food Regulation Ministerial Council, 2011). In line with these guidelines, clinical and epidemiological evidence obtained via systematic review is presented to highlight the safety and potential efficacy associated with this reduction of protein. Dietary intake data of the relevant population group is also reviewed.

<sup>1</sup> Available at: <https://www.legislation.gov.au/Details/F2017C00332/Download>

<sup>2</sup> For the conversion from g/100 kJ to g/100 kcal, a conversion factor of 4.18 was used. As such, 0.45 g/100 kJ = 1.881 g/100 kcal (rounded to 1.88 g/100 kcal in this application) and 0.38 g/100 kJ=1.5884 g/100 kcal, rounded to 1.6 g/100 kcal in this application.