



## Queensland Health

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Standards Management Officer  
Food Standards Australia New Zealand  
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Dear Sir / Madam

### **Submission – Proposal P1028—Infant formula – Consultation paper 2**

Thank you for the opportunity to provide a submission on *Consultation paper 2 – Nutrient composition* of Proposal P1028.

This submission provides comments on the proposed changes to the *Australia New Zealand Food Standards Code* (the Code). It was prepared by health professionals from Children's Health Queensland Hospital and Health Service, Health and Wellbeing Queensland, Preventive Health Branch and Food Safety Standards and Regulation Unit. The submission does not represent a Queensland Government position, which will be a matter for the Queensland Government should notification be made by the FSANZ Board to the Food Ministers' Meeting.

The Queensland Government remains committed to protecting, promoting, and supporting breastfeeding and optimal infant nutrition. It is also recognised that infant formula and other breastmilk substitutes have a legitimate role to play in circumstances where an infant cannot be breastfed.

In line with FSANZ's primary objective of protecting public health and safety, it is important that P1028's primary objective is to ensure infant formula:

- is safe for infants to consume
- has a nutrient composition that supports normal growth and development, particularly when is an infant's sole source of nutrition (i.e. from birth to around 6 months)
- improves health outcomes of formula-fed infants.

While alignment of Australian and New Zealand standards with international regulations is important, the health and safety of infants is the priority.

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### **Responses to questions for submitters**

3. *Do you support retaining the current minimum requirement for LA (9% total fatty acids) in infant formula? Please provide your rationale and any supporting evidence.*

Rather than a percentage of total fatty acids, expressing a minimum requirement for LA in mg/100kJ would be consistent with international practice and easier for clinicians to calculate if an infant is meeting their requirements for LA.

It is recommended that requirements aim to meet the EFSA recommendation for LA for young infants who are most vulnerable and cannot access LA from an alternative source. In the Australia and New Zealand populations the minimum LA concentrations in breastmilk were approximately 140 mg/100kJ. In order to meet the EFSA requirement, using the calculation of 800 ml of infant formula being consumed per day for infants less than 6 months who will be predominantly or solely fed by infant formula, this would equate to 107.5 mg LA per 100 kJ.

The calculation was completed as follows:

- Assumption of 800 ml of infant formula consumed per day
- Average calorie content of infant formula is 67kcal/100 ml
- $8 \times 67 = 546$  kcal per day or 2240 kJ consumed per day
- To meet recommendation of 2.4 g LA per day (2400 mg)
- Infant formula would need to contain 107.5 mg LA per 100 kJ.

Recognising that younger and smaller infants less than 2-3 months of age would on average be consuming lower volumes of infant formula per day (i.e., less than 800 ml per day) would support the recommendation for a minimum requirement to be expressed in mg per kJ of at least 100 mg LA/100kJ but ideally a minimum of 110 mg LA/100kJ to give them the best chance of meeting the EFSA recommendation for LA without any safety concerns. Internationally LA is added to infant formula at higher concentrations without impacting on the product therefore it can be successfully achieved if required.

4. *Are there any technical issues related to increasing the LA minimum in Standard 2.9.1 to align with the higher EU 2016/127 level of 120 mg/100 kJ?*

We are unable to comment from a technical perspective, however, multiple formula in the UK from different companies have more than 120 mg LA per 100kJ – refer to question 5 below.

5. *Can you provide data on the LA levels in commercially available infant formula internationally? This information can be provided as 'Commercial in confidence' if required.*

The following are infant formula products suitable from birth to 12 months currently available in the UK and Ireland:

	LA mg per 100mL	kcal per 100mL	LA mg per 100kJ
SMA Pro First	555	67	198
SMA Little Steps	475	67	169.6
SMA Advanced first formula milk	505	63	192
Kandamil First Infant Milk Stage 1	582	66	211

*6. Do you support setting a separate iron maximum for soy-based infant formula?*

Support is given for the FSANZ proposal based on considerations and conclusions from the 2016 and 2021 nutrition risk assessments, to retain the current minimum and maximum iron levels specified in Standard 2.9.1 and Schedule 29—9 for cow's milk-based formula and to adopt these for soy-based formula's. Retaining the broader permitted range accounts for the nutrient requirements of older infants and potential reduced bioavailability of iron in soy-based infant formula.

Further evidence regarding the bioavailability of iron from soy-based formula is required to determine the impact of soy proteins, independent of phytates. Processing methods reduce the phytate content of soy-based formulas however there is further impact on bioavailability of iron in soy-based formula, independent of phytates.

Use of the minimum amount in Schedule 29—9 (0.2 mg/100kJ) will provide sufficient iron for infants 0 to 12 months based on modelling done by FSANZ and will better prevent the risk of inadequate iron stores in some population groups of older infants than use of the lower EU 2016/127 levels (0.07 mg/100 kJ). The maximum of 0.5 mg/ 100kJ is unlikely to pose a risk to infant health since estimated intakes will be below the NHMRC upper limit for iron.

*7. Do you support setting a separate phosphorus range for soy-based infant formula? Please provide your rationale and evidence to support your answer.*

Phytates are described in the consultation paper and how they can interfere with mineral absorption from soy formula. There is limited literature on phosphorous levels in soy formula and its effect on infant bone health compared to breast fed infants. Soy contains phytates that can bind minerals such as phosphorus reducing absorption; however, the amount of phytate in soy formula seems unknown. Therefore, more information/data about the phytate content of soy formula is needed before a decision can be made about a separate phosphorus range for soy-based infant formula.

Further to the questions posed by FSANZ in the consultation paper, it is noted that further assessment of some nutrients, has not been undertaken by FSANZ in the last five years. The Ministerial Policy Guideline on Infant Formula states that 'the essential composition of infant formula (and follow-on formula) should be prescribed in regulation and must satisfy the nutritional requirements of infants'. Prior to the call for submissions stage, further assessment including whether infant requirements are being met, may be beneficial.

The consultation paper proposes changing the current voluntary permissions for choline, l-carnitine, and inositol to be mandatory in all infant formula. However, there has been no consideration of the permissions for lutein and taurine, and the proposal to maintain the voluntary nucleotide permissions did not undergo further assessment. Given that lutein, taurine, and nucleotides have been voluntarily permitted for many years, an assessment of their benefit to infant growth and development is suggested. If these substances are beneficial to normal growth and development, mandating them in all infant formula could be considered. If they are not beneficial, then it would be important to consider removing the permissions, so that infants are not consuming unnecessary substances, and so that carers are not misled about their nutritional value to infant health.

The consultation paper refers to targeted consultation having been undertaken, but no details are provided. Based on previous rounds of consultation on P1028, submitters are typically from industry, and it is important to understand the views from a diverse range of stakeholders. It is suggested that prior to the call for submissions stage, targeted consultation with paediatric nutrition experts occur to determine whether infant nutrition requirements are best served by the proposed changes. Targeted

consultation with clinicians and health professionals may elicit more responses than the consultation process to-date.

In the 1st Call for Submissions, it is suggested that FSANZ include a stronger introductory statement on the importance of breast feeding and the role of infant formula along the following lines: “The World Health Organization (WHO) states that ‘breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants’. Breastfeeding is beneficial to infants, mothers, families and society, and is the biological and social norm for infant and young child feeding. The WHO International Code of Marketing Breastmilk substitutes 2017 update advocates all infants be breastfed and a safe and nutritious alternative for breast milk is needed for infants when breastfeeding is not possible”.

Should you require further information in relation to this matter, please contact Food Safety Standards and Regulation, Health Protection Branch, Department of Health on (07) 3328 9310 or at [foodsafety@health.qld.gov.au](mailto:foodsafety@health.qld.gov.au)

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