



australasian society of clinical immunology and allergy

20 October 2021

Food Standards Australia New Zealand (FSANZ)
PO Box 5423
Kingston ACT 2604
Email: submissions@foodstandards.gov.au

To whom it may concern,

Re: FSANZ Call for Submissions on Proposal P1028 – Infant Formula

On behalf of the Australasian Society of Clinical Immunology and Allergy (ASCIA) we are responding to the FSANZ call for submissions on Proposal P1028 – Infant Formula.
<https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx>

We understand that the purpose of this Proposal is to revise and clarify standards relating to infant formula (for use from birth to <12 months of age) comprising category definitions, composition, labelling and representation of products.

ASCIA submits the following answers in response to specific questions, with supporting evidence.

Questions related to definitions for specialised infant formulas (section 4.3)

Question 2

Is a definition of soy-based formula needed for the purpose of food additive permissions and aluminium requirements? If so, is the current definition appropriate?

Answer – ASCIA considers the current definition appropriate. Based on the two most recent position papers / references (ESPGHAN guidelines 2006[1] and American Academy of Paediatrics [2]). ASCIA supports limits to aluminium content in the absence of any further research in this area as per the two references [1, 2].

Question 3

Is a definition of pre-term formula needed for the purpose of food additive permissions and aluminium requirements? If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available.

Answer – Babies born pre-term have extra nutritional requirements and PSANZ (Perinatal Society of Australia and New Zealand) should be consulted.

Question 4

Are definitions needed for any of the new terms proposed to be introduced as conditions for the use of food additives in CP1, such as gastrointestinal reflux, gastrointestinal disorders, or impairment of the gastrointestinal tract, inborn errors of metabolism?

Answer – ASCIA recommends identification and definition of food additives used in IF. ASCIA requests more information about what is meant by terms such as gastrointestinal reflux, gastrointestinal disorders, or impairment of the gastrointestinal tract, inborn errors of metabolism? ASCIA is willing to consult with FSANZ regarding this, particularly as the broad term ‘gastrointestinal disorders’ may relate to specific allergy diagnoses.

Questions related to products for metabolic, immunological, renal, hepatic and malabsorptive conditions (section 5.5.2)

Question 5

To health professionals: Is there any evidence that current practice in relation to low lactose products or the manganese content of products for metabolic, immunological, renal, hepatic and malabsorptive conditions pose a health concern or risk? If you consider that there is a health concern or risk, please provide relevant details and data, where available.

Answer 5a ASCIA is aware that confusion exists in the community regarding lactose free formula being suitable for infants with cow’s milk allergy. ASCIA requests labelling of lactose free formula as being unsuitable for infants with cow’s milk allergy.

Answer 5b Manganese content of products for metabolic, immunological, renal, hepatic and malabsorptive conditions may pose a health concern or risk and this requires future research [2012]. Emerging evidence suggests that this may be particularly relevant for individuals reliant on this type of formula long term [3].

Questions related to products for specific dietary use based on a protein substitute (section 5.5.3)

Question 8

To health submitters: You have told us that partially hydrolysed IFP are not efficacious in preventing allergy; are they useful in the dietary management of allergy? Please provide supporting detail and data, where available.

Answer - A recent systematic review by Boyle et al investigated whether hydrolysed cows’ milk formulas can prevent allergic or autoimmune disease [4]. This review found “no consistent evidence that partially or extensively hydrolysed formulas reduce risk of allergic or autoimmune outcomes” and this is now reflected in the most recent ASCIA guidelines [5].

Question related to labelling of IFPSMP (section 5.7)

Question 15

Do you support FSANZ's preliminary views for IFPSMP labelling? Why or why not? Please provide supporting detail and data for your position, where available.

Answer - ASCIA supports a restriction on these products to be pharmacy only products as part of an overall risk management strategy and to reduce the risks associated with potential unsupervised and inappropriate use.

In addition, with reference to Supporting Document 1 (Nutrition Assessment Proposal P1028 – Infant Formula - Protein quality and Protein maximum level), ASCIA notes the following:

There are a few infant formulas now on the Australian and New Zealand market that use non animal protein sources, such as soy, extensively hydrolysed rice formula and a new vegan infant formula <https://sproutorganic.com.au/products/infant-formula>

ASCIA raises the concern that new formulas using novel protein sources can be sold without adequate trials assessing their ability to support normal growth in healthy term infants. As the protein source is plant based there is a risk that these products may also be used in cases who have additional requirements such as children with malabsorption.

Please contact ASCIA if you require further information.

Yours sincerely,

References

1. Bhatia, J., F. Greer, and N. and Committee on, *Use of Soy Protein-Based Formulas in Infant Feeding*. AAP Policy, 2008. **121**(5): p. 1062-1068.
2. Agostoni, C., et al., *Soy protein infant formulae and follow-on formulae : A commentary by the ESPGHAN committee on nutrition*. J Pediatr Gastroenterol Nutr, 2006. **42**(4): p. 352-361.
3. Roels, H.A., et al., *Manganese exposure and cognitive deficits: A growing concern for manganese neurotoxicity*. Neurotoxicology, 2012. **33**(4): p. 872-880.
4. Boyle, R.J., et al., *Hydrolysed formula and risk of allergic or autoimmune disease: systematic review and meta-analysis*. BMJ, 2016. **352**: p. i974-i974.
5. Netting, M.J.B.B.N.D.P., et al., *An Australian Consensus on Infant Feeding Guidelines to Prevent Food Allergy: Outcomes From the Australian Infant Feeding Summit*. J Allergy Clin Immunol Pract, 2017. **5**(6): p. 1617-1624.