australasian society of clinical immunology and allergy

13 July 2023

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 goal of this proposal is to ensure that infant formula products are safe and suitable while also taking into account the scientific evidence, market developments, changes in international regulatory context and revised Australian and New Zealand policy guidance.

ASCIA's responses are outlined below.

Special Medical Purpose Products (SMPPi)

ASCIA supports the proposal to create a new category – Special Medical Purpose Products for infants (SMPPi) within standard 2.9.1. ASCIA supports formula based on alternative proteins outside of those specified for infant formula (cow's milk, goat's milk, sheep's milk and soy) such as rice and other plant-based formula products that are specifically intended for managing cow's milk allergy, being classified under SMPPi. This should ensure these formula products undergo appropriate pre-market assessment, showing they are suitable for infant growth and development.
This will help address ASCIA's concerns about two formula products on the market:

- **Sprout formula** https://sproutorganic.com.au/products/infant-formula is based on rice and pea protein and has no safety or efficacy data supporting infant growth and development. Sprout infant formula is manufactured in a facility that processes cow's milk and thus is not suitable for infants with cow's milk allergy as it contains traces of cow's milk protein. As Sprout formula is marketed as a plant-based formula, consumers may think that it is suitable for infants with cow's milk allergy, putting them at risk of allergic reactions and potential suboptimal growth and development in an already at risk population.
- **Alula Gold allergy formula** https://www.meandmychild.com.au/s26/gold/allergy-infant/ is based on rice protein and is intended for infants with cow's milk allergy. It has been launched in the Australian market without any specific studies to support the safety and efficacy of the product. Previously, all hypoallergenic formula products used in Australia and New Zealand have been used extensively in the US or European markets and have hypo-allergenicity and growth studies demonstrating safety and efficacy.

ASCIA recommends FSANZ complete a pre-market assessment that includes growth, nutrition and hypo-allergenicity data for infant formula products being introduced to the Australian and New Zealand market, that are targeted for use in infants with cow's milk allergy.

2.9.1-21 Labelling requirements for food represented as lactose free and low lactose formulas

Lactose free and low lactose cow's milk based infant formula are suitable for infants with lactose intolerance but **not** suitable for infants with cow's milk protein allergy. This distinction needs to be clear on product labelling. We suggest in addition to the labelling requirements set out in section 2.9.1-21, there be an additional requirement to include the statement "not suitable for use in infants with cow's milk protein allergy".

ASCIA would also like to correct misinformation in section 2.3.4 Composition: low lactose or lactose free. Firstly, cow's milk protein intolerance has the words "lactose intolerance" in brackets after it - this statement is not correct. The correct term for cow's milk protein intolerance is "**non IgE cow's milk allergy**"[1,2].

ASCIA recommends that lactose free and low lactose formula be moved to the category of special medical product for infants (SMPPi) to reduce the risk of inappropriate use for infants with cow's milk allergy. Inappropriate use places infants with cow's milk allergy at risk of allergic reactions including life threatening anaphylaxis. Clinical examples of cases where lactose free formula has been incorrectly recommended for cow's milk protein intolerance can be supplied to FSANZ on request.

ASCIA recommends low lactose formula products are categorised in the SMPPi category and should be labelled "not suitable for use in infants with cow's milk protein allergy".

2.9.1-6 Protein requirements

Infant formula based on partially hydrolysed cow's milk protein

ASCIA supports that infant formula based on partially hydrolysed protein do not need to be classified as SMPPi as there is no clinical indication for partially hydrolysed protein in the prevention or treatment of cow's milk allergy[3]. ASCIA does recommend that the ingredients list includes "partially hydrolysed protein" as tolerance of this may differ from intact cow's milk protein in some individuals.

ASCIA recommends labelling partially hydrolysed cow's milk formula products as "not suitable for infants with cow's milk allergy".

Definition of hypo-allergenicity

Currently, there is no definition for hypo-allergenicity in the code. Internationally there are two definitions used to ensure clinical efficacy and safety in the treatment of cow's milk allergy:

- Tolerated by more than 90% of infants with cow's milk allergy with a 95% confidence interval[4].
- A specific recommendation about Dalton size of peptides and level of intact cow's milk protein[5].

Extensively hydrolysed cow's milk formula

Australia currently has three extensively hydrolysed cow's milk formulas (EHF) products on the market. These are used as first line management for many forms of cow's mllk allergy. One of these formula (Alfare, Nestle), is being discontinued in late 2023. This will leave two EHFs on the market, manufactured and supplied by the same company (Nutricia). ASCIA is concerned that this which exposes Australian consumers to risk of supply issues. Furthermore, there is an additional risk that the Australian market may be swamped by EHF with higher Dalton sized proteins which are not suitable for cow's milk allergy[5].

ASCIA recommends FSANZ adopts a definition of hypo-allergenicity, defining requirements for an extensively hydrolysed cow's milk formula (EHF) products.

Please contact ASCIA if you require further information.

Yours sincerely,

Kathy Beck
Chair, ASCIA Dietitians committee

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CEO, ASCIA

References

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3. ASCIA Guidelines Infant Feeding and Allergy Prevention. https://www.allergy.org.au/hp/papers/infant-feeding-and-allergy-prevention; 2020.
4. American Academy of Pediatrics. Committee on nutrition. Hypoallergenic infant formulas. Pediatrics. 2000;106:346-349.
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