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Food Standards Australia New Zealand (FSANZ)

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

As a specialty paediatric food allergy dietitian and researcher I have the following responses and comments related to Proposal P1028- Infant formula specific to food allergy and whilst these views are my own I am involved in many key nutrition and allergy professional organisations both nationally and internationally including an Advanced Accredited Practicing dietitian member of Dietitians Australia, a Dietitian committee member of ASCIA, an advisory panel member of the National Allergy Council (NAC) and the National Centre for Allergy Research Food allergy advisory group (NACE).

Responses:

1. **Special Medical Purpose Products for infants (SMPPi):** I fully support the creation of a new category, Special Medical Purpose Products for infants (SMPPi) within standard 2.9.1 and feel this will provide an avenue for improved regulation and risk minimisation for consumers and health professionals using and recommending infant formula targeted for use in food allergy.
2. **Lactose free and low lactose formulas:**
  - a. It is my recommendation that low lactose products be moved to Category 2- SMPPi category where POS health professional advice is available. Low lactose products are targeted to a specific medical condition and despite the lack of published reported cases of cow's milk allergic infants being inappropriately recommended low lactose formulas this is a common error we see made by both parents and health professionals. Inappropriate use places infants with cow's milk allergy at risk of allergic reactions including anaphylaxis.
  - b. To further mitigate risk of inappropriate use of low lactose formulas being used for infants with cow's milk allergy I would recommend the inclusion of a front of packaging message "Not suitable for infants with cow's milk allergy".
  - c. This confusion regarding terminology and incorrect interchangeability of cow's milk protein allergy and lactose intolerance is evident even within the original proposal in Section 2.3.4 which incorrectly referred to lactose intolerance as "cow's milk protein intolerance (lactose intolerance)". I believe this has been partially amended by FSANZ but there is still a sentence in the P1028 2<sup>nd</sup> Call for submissions – Living document that states "This can be seen in infants who have experienced food intolerance, such as cows milk protein intolerance (non IgE mediated)". This should be amended to "This can be seen in infants who have experienced **non IgE mediated cows milk protein allergy**" to ensure P1028 is consistent with international allergy

body definitions and classifications <sup>1</sup> and to not perpetuate the confusion between lactose intolerance and cow's milk protein allergy.

### 3. Protein requirements:

- a. **Partially hydrolysed cow's milk formula:** I would support that infant formula based on partially hydrolysed protein do not need to be classified as SMPPi but do recommend as per **2.3.5 Provision of information** that the ingredients list +/- label include "partially hydrolysed protein" information. From an allergy perspective and as per the current Australian and international infant guidelines <sup>2,3</sup> for allergy prevention there is no clinical indication for partially hydrolysed protein in the prevention or treatment of cow's milk allergy however, it is useful for clinicians to be able to differentiate between tolerance of infant formula based on intact cow's milk protein versus partially hydrolysed proteins in the diagnosis of cow's milk allergy.
- b. I would strongly support that all infant formula not based on cow's milk, goat milk, sheep milk, soy protein isolate or hydrolysed cows milk protein be categorised under SMPPi and pre-market assessment is undertaken to ensure the clinical efficacy of the protein composition to support growth and development of infants. My specific concern relates to a product we have on the market in Australia that is based on rice and pea protein. Pea protein has no safety/efficacy data and no growth data for use in infant formula. <https://sproutorganic.com.au/products/infant-formula>. Whilst rice based formula have been used for sometime in Europe and there are growth and hypoallergenicity studies both in healthy and cows milk allergic populations <sup>4-8</sup> a new rice based formula has launched into the Australian market targeted for use in allergy without specific growth and hypo-allergenicity studies.
- c. Specific to products targeted for cows milk protein allergy <sup>9</sup> I would strongly recommend that P1028 includes definitions for hypo allergenicity. Until recently all hypoallergenic formula available in Australia had undergone premarket assessment regarding safety and efficacy, including growth outcomes for infants with cow's milk allergy as part of the requirements for use in US or European markets this is no longer the case and poses a risk to the Australian market.
  - i. For formula made from non-cows milk sources there is still a risk of cross contamination with cows milk protein if made in facilities manufacturing cows milk based formulas. Formulas targeted for use for cows milk allergy under the SMMPi should have demonstrated hypo allergenicity.
  - ii. EHF- The US and European legislation have acknowledged the need for a definition of extensively hydrolysed protein to ensure clinical efficacy and safety in the treatment of cows milk allergy. The US requires premarket assessment studies to be completed demonstrating that 90% of infants with cows milk allergy tolerate the product and Europe is moving towards including a specific recommendation of Dalton size of peptides and level of residual intact cow's milk protein present to be marketed as an EHF as studies have shown that there is considerable variation in the Dalton size and residual cows milk protein in many products currently marketed as EHF in Europe <sup>10</sup>. This is extremely relevant to the Australian market as in late 2023 with Alfare (Nestle) being discontinued we will be limited to only 2 EHF products both supplied from the same company (Nutricia). A change in the European legislation to tighten the definition of EHF or supply issues with Nutricia will leave the Australian market exposed to importation of inferior EHF products no longer permitted in Europe or the US markets.

In summary I:

1. Fully support the inclusion of the proposed SMPPi category
2. Recommend low lactose products are categorised in SMPPi category and labelled as not suitable for infants with cows milk allergy
3. Support products based on anything other than cow, sheep or goat milk or soy protein be moved under the category of SMPPi to ensure they support the growth and development of infants.
4. Recommend P1028 includes legislation to ensure products targeted at allergy have demonstrated safety and efficacy data including growth outcomes for infants with cow's milk allergy.
5. Recommend P1028 adopts a definition of hypo allergenicity, particularly for EHF formulas.

Thank you for consideration of my comments

Yours sincerely,

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## References

1. Cianferoni A, Spergel JM. Food Allergy: Review, Classification and Diagnosis. Allergology International 2009; 58:457-66.
2. ASCIA Guidelines Infant Feeding and Allergy Prevention. <https://www.allergy.org.au/hp/papers/infant-feeding-and-allergy-prevention>; 2020. [Cited 2020 21/12/2020.].
3. de Silva D, Halken S, Singh C, Muraro A, Angier E, Arasi S, et al. Preventing food allergy in infancy and childhood: Systematic review of randomised controlled trials. Pediatr Allergy Immunol 2020.
4. Fiocchi A, Barrio-Torres J, Dupont C, Howells HE, Shamir R, Venter C, et al. Hydrolyzed rice formula for dietary management of infants with cow's milk allergy. World Allergy Organ J 2022; 15:100717.
5. Anania C, Martinelli I, Brindisi G, De Canditiis D, De Castro G, Zicari AM, et al. Hydrolyzed Rice Formula: An Appropriate Choice for the Treatment of Cow's Milk Allergy. J Clin Med 2022; 11.
6. Vandenplas Y, Brough HA, Fiocchi A, Miqdady M, Munasir Z, Salvatore S, et al. Current Guidelines and Future Strategies for the Management of Cow's Milk Allergy. J Asthma Allergy 2021; 14:1243-56.
7. Dupont C, Bocquet A, Tome D, Bernard M, Campeotto F, Dumond P, et al. Hydrolyzed Rice Protein-Based Formulas, a Vegetal Alternative in Cow's Milk Allergy. Nutrients 2020; 12.
8. Bocquet A, Dupont C, Chouraqui JP, Darmaun D, Feillet F, Frelut ML, et al. Efficacy and safety of hydrolyzed rice-protein formulas for the treatment of cow's milk protein allergy. Arch Pediatr 2019; 26:238-46.
9. Health Professional Guide for Milk Substitutes in Cows Milk Allergy. 2022.].
10. Nutten S, Maynard F, Jarvi A, Rytz A, Simons PJ, Heine RG, et al. Peptide size profile and residual immunogenic milk protein or peptide content in extensively hydrolyzed infant formulas. Allergy 2020; 75:1446-9.