



Advanced Dietitians Group
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7 July 2023

Food Standards Australia New Zealand
submissions@foodstandards.gov.au

RE: Proposal P1028: Infant formula - 2nd Call for Submission - 7th July 2023

Submission

I am submitting this response as an Accredited Practising Dietitian specialising in paediatrics and food allergy, as co-director of Advanced Dietitians Group, a private dietetic clinic in Perth, Western Australia. I am also responding in my capacity as the ASCIA representative on the FSANZ Allergen Collaboration and the FSANZ Scientific Advisory Group for Food Allergy, in relation to the issues in P2018 regarding food allergy, partially and extensively hydrolysed formula and lactose free/low lactose formula.

1. Infant formula and follow on formula:

- I support the specification that infant formula and follow on formula be based on cow's milk, goat's milk, sheep's milk or soy proteins, or to support infant growth and development.
- I support the changes to the revised nutrient composition of infant formula, maximum contaminant levels and restrictions of food additives but will leave specific comments on these areas to other experts.
- I recommend that lactose free and low lactose formula move to SMPPi, reasons below.

2. Special Medical Purpose Products for Infants (SMPPi).

- I support the creation of this category for infant formula for the dietary management of a disease or condition, and the proposed definition.
- I also support the continued restriction of sale of SMPPi to medical practitioners, dietitians, health care facilities, pharmacies and majority sellers as infants requiring special products will benefit from health professional input into managing the presenting symptoms or diagnosis.
- I am supportive that this will move products based on alternate protein sources to the category of SMPPi, such as those based on rice or other plant proteins as this will require the manufacturer to prove its suitability for growth and development for infants. I have concerns about two formula currently on the Australian market:
 - Allula Rice formula – targeted for infants with cow's milk allergy, this company has not run a trial on its own formula to prove appropriate growth and development and uses a systematic review of other products to market its formula to health professionals. The competitor rice-based formula does have studies showing growth in infants.
 - Sprout plant-based formula – this formula is marketed as a vegan formula and is based on pea and rice protein. There are no studies at all showing that this protein base supports infant growth and development. This formula is produced in a facility that also

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produces formula based on cows' milk protein and whilst Sprout does have a precautionary allergen statement on the label, to my knowledge the company has not undertaken allergen testing of their product and the level of contamination is unknown. This product poses a risk not only in growth and development, but also to infants with cow's milk allergy if parents think this is an appropriate choice for their infant with cow's milk allergy. In our practice, and in my experience over the past few years in the allergy clinic in Perth Children's Hospital, we have cautioned parents of children with cow's milk allergy against the use of this formula, particularly when there were shortages of specialised formula.

- There are two categories of formula that FSANZ needs to consider in relation to SMPPi:
 - i) Extensively hydrolysed formula
 - These formula are indicated for the dietary management of cow's milk protein allergy and malabsorptive gastrointestinal conditions.
 - A common definition for eHF for cow's milk allergy is for resolution of symptoms in 90% of infants with cow's milk allergy.
 - Australia currently has access to two eHF on the PBS (Aptamil Pepti-Junior and Nestle Alfare) and one over the counter (Aptamil Allerpro which contains lactose).
 - Nestle Alfare will be discontinued from November 2023, leaving Australia at risk of supply shortage with have occurred with the Aptamil products in the past, so there is a need for other products to be able to be sold in Australia and New Zealand.
 - There are many eHF on the European market however tolerance to these formula by children with cow's milk allergy can be as low as 50% indicating poorer quality formula or incomplete hydrolysis. European and US food standards authorities are currently exploring a definition and standard for eHF to improve consistency and safety of these formula in infants with cow's milk allergy.
 - I recommend FSANZ adopt a definition for eHF to protect vulnerable infants with cow's milk allergy. This could either be based on 90% efficacy in children with cow's milk allergy, or the Dalton size of proteins, stipulating the percentage of proteins that must be under 1200 Daltons for the classification of hypo allergenicity, as suggested by Nutten et al (2020)¹ in their analysis of eHF on the European market showing large variability in protein hydrolysis between products.
 - If poorer quality eHF enter the Australian market that are not tolerated by infants with cow's milk allergy, eHF will be seen as an unsafe formula for this population which may increase prescriptions for amino acid formula and increase costs to Medicare.
 - ii) Lactose free and low lactose formula
 - I recommend that lactose free and low lactose formula move to the category of SMPPi.
 - In my clinical practice in food allergy over the past 15 years, I have counselled families on a weekly basis on the difference between lactose intolerance and cow's milk allergy. There is a lack of basic knowledge about what lactose is, and parents often assume that lactose free products are appropriate to give to their children with cow's milk allergy. We have had many cases where lactose free formula has been recommended to infants

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with clear signs of cow's milk allergy, both IgE and non-IgE symptoms; by other family members, child health nurses, GPs and pharmacists. There is a need for clearer labelling of these products.

- There is a lack of literature about this knowledge deficit in relation to lactose free products/lactose intolerance and cow's milk allergy, however this confusion in the community and amongst health professionals is often acknowledged in papers about management of these conditions.^{2,3}.
- In moving lactose free formula and low lactose formula to the category of SMPPi, it would be consistent with the SMPPi definition which is for formula for infants with '*...limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food...*'.
- Restricted sale under SMPPi for these formula will prompt health professional involvement which is likely to help with better care of the infant with symptoms of malabsorption or food allergy and improve safe use by reducing a trial of lactose free formula in an infant displaying signs of cow's milk allergy rather than lactose intolerance.
- I recommend that lactose free and low lactose formula be clearly labelled to show that they are not suitable for infants with cow's milk allergy to improve safe use.
- I note that within the 2nd CFS there are some ambiguous statements in relation to lactose intolerance/cow's milk protein intolerance/cow's milk protein allergy which have been partially addressed in the 'living document' but do highlight the confusion in this area. Specifically, in 2.3.4 "Composition: low lactose or lactose free":

...."Low lactose and lactose free formulas are intended for infants with cow milk protein intolerance (lactose intolerance), reported in 2 - 5% of infants within the first 1 to 3 months of life."

and:

....."Cow milk protein intolerance typically occurs earlier in an infant's life, is not seen as a late onset intolerance and resolves by the age of one. Because of this, formula currently on the market represented as being suitable for lactose intolerance are positioned as infant formulas suitable for infants aged 0 – 12 months."

- The statistic in the first statement appears to relate to IgE mediated cow's milk allergy prevalence⁴ as the prevalence of lactose intolerance is unknown. The preferred terminology for adverse reactions to cow's milk include IgE mediated cow's milk allergy, non-IgE mediated cow's milk allergy and lactose intolerance. I recommend FSANZ adopt the accepted terminology outlined in the papers by Fiocchi (2022)⁵ and Boyce et al (2010)⁶, for consistent messaging to industry, health professionals and the community.

3. Labelling for Infant products:

- In my opinion many of the proposed labelling changes for infant and follow on formula are an improvement for the health and wellbeing of this vulnerable population.
- I agree with all the proposed variations in relation to directions for preparation and use.
- I agree with the labelling requirement to refer to the product as infant formula or follow on formula and with the prescribed names on front of pack.

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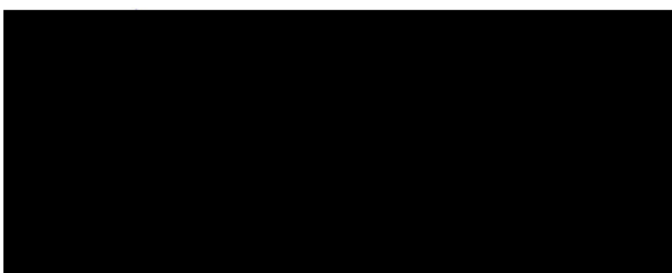
- I support retaining the requirement for the protein source statement to be included in the statement of the name of the foods and adding the requirement for this to be stated on the front of the package, to make it easy for consumers to see the protein source. As stated above I see no benefit for stating 'partially hydrolysed' but am not opposed to it.
- I support retaining the statement 'breastmilk is best for babies' as this supports breast feeding.
- I agree with stating what age to offer foods in addition to formula for both infant formula and follow on formula.
- I support retaining allergen declaration statements as per schedule 3 in standard 1.2.3.
- I agree with the variations proposed in relation to the nutrition information statement (NIS).
- I agree with the proposed variations and proposals in relation to low lactose or lactose free, as well as the proposal to remove permission for follow on formula to be represented as lactose free or low lactose.
- I disagree with lactose free and low lactose products remaining in the infant formula category and propose they are moved to SMPPi with labelling indicating they are not suitable for infants with cow's milk allergy.
- I support the restriction on health and nutrient claims for formula as I have seen the marketing of formula using words like 'comfort', 'colic' and 'reflux' result in parents changing formula many times, delaying them seeking professional help for infants with underlying health problems such as non-IgE mediated cow's milk allergy, sensory feeding difficulties, swallowing problems and gastrointestinal conditions or underlying growth and development issues. Specific case studies can be provided on request.
- I see no benefit of allowing 'partially hydrolysed' to be included in the name of the protein source but acknowledge this will make it easier for parents to see and make an informed choice. The new restrictions in relation to health claims will ensure that partially hydrolysed formula cannot make claims about allergy prevention (these formula are considered to be of no benefit for the prevention of allergic conditions⁷).
- I agree with the existing and new prohibited representations in relation to infant formula and follow on formula.

In conclusion:

I support the majority of changes proposed in P1028 but recommend that lactose free and low lactose formula move to SMPPi with labelling stating their unsuitability for infants with cow's milk allergy; and I recommend adoption a definition for extensively hydrolysed formula to improve the safety of new formula entering the Australian market.

Thank you for the opportunity to provide a submission.

Sincerely,





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References:

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