



7 July 2023

Food Standards Australia New Zealand (FSANZ)

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FSANZ Call for Submissions: P1028 – Infant formula

Special Medical Purpose Products for Infants (SMPPi)

A&AA (Allergy & Anaphylaxis Australia) supports the proposal by FSANZ (Food Standards Australia New Zealand) to create a new category of infant formula that has been developed for a specific disease, disorder, or medical condition within Standard 2.9.1. A&AA supports the proposed sale restriction of a SMPPi (Special Medical Purpose Products for Infants). That is, these products must only be sold from or by a medical practitioner or dietitian; a medical practice, pharmacy or responsible institution or a majority seller of that SMPPi, to help manage the risk associated with unsupervised or inappropriate use. It is important for caregivers to have access to appropriate medical advice, whether that be directly from the pharmacist, or they are referred by the pharmacist to evidenced based information and support. We understand that some may have concerns about emergency access to formulas, however our belief is that caregivers are very aware of the stock they have and purchase ongoing stock with more than a day or two to spare.

A&AA supports FSANZ in recategorising low lactose and lactose free formulas from general to SMPPi as these are formulas for a specific medical condition. Furthermore, there is a concern that caregivers, who have infants with likely cow's milk allergy, not yet diagnosed by a medical practitioner, may purchase these products in a supermarket, mistakenly believing that they are appropriate.

A&AA recommends that infant formula not based on cow's milk, goat's milk, sheep's milk, and soy protein isolate should be classified under SMPPi. Where such formulas are being introduced to the Australian market, A&AA recommends FSANZ complete a pre-market assessment that includes growth, development and hypo-allergenicity data for new infant formula additions to SMPPi.

Allergy & Anaphylaxis Australia – *Your trusted charity for allergy support*

Use of terms 'VEGAN'

A&AA supports the tightening of the restrictions around marketing of infant formula on formula can, and in advertising, including website. We believe that plant protein formulas should not be able to use the term VEGAN on can/in marketing because a vegan claim is very different to a "free from" claim. Under international ISO standard, vegan products can have a PAL (Precautionary Allergen Labelling) on them for milk/egg/fish, as long as good manufacturing processes are adhered to. This is problematic and unsafe as many people in the community expect vegan products to be completely free from milk, egg and fish despite A&AA and others trying to dispel this assumption. Note, the *Sprout* product has a PAL statement on the can and website and is made in a facility that also produces "cow's milk and soy products," but on the [website](#), it claims to be vegan. A caregiver that reads the formula information as vegan may not look for a PAL for milk/egg/fish.

Data can be provided to FSANZ on request on the number of case reports of anaphylaxis A&AA has received due to assumptions being made that vegan products are dairy/egg free. The confusion around vegan foods is also evident by the number of vegan food recalls that have been conducted by FSANZ because of milk and egg content.

Hypoallergenic formula

A&AA supports the need for a definition of EHF (Extensively Hydrolysed Formula). We have concerns that if there is not a clear definition of EHF in Australia that products that are unsuitable for infants with cow's milk allergy, due to inadequate hydrolysis or milk contamination, may enter the Australian/New Zealand market because they are unable to enter Europe or the USA.

Low lactose and lactose free

A&AA has concerns about the number of cases of children with cow's milk allergy being given foods with low lactose/lactose free claims who then have anaphylaxis. We therefore recommend inclusion of a statement on low lactose and lactose free infant formula saying the product contains cow's milk protein and is not suitable for infants with cow's milk allergy. As infant formulas are a first food, parents and caregivers of infants with newly diagnosed cow's milk allergy need as much information and support as possible. This warning on an infant formula may help prevent a life-threatening emergency.

A&AA is concerned that health professionals and early childhood education and care staff as well as the wider community are not well informed about the difference between "low lactose/lactose free" products and "dairy or milk free." There is confusion amongst these groups about the difference between lactose intolerance and milk allergy. Furthermore, there are still people in the community that do not appreciate that milk allergy is potentially life threatening. We acknowledge that the advice is to always read the statement of ingredients, but oversight does occur in busy environments.

A&AA have received a number of complaints from caregivers whose children have been given lactose free milk, yoghurt or cheese in childcare and school settings, believing that it was suitable for children with cow's milk allergy.

Data can be provided to FSANZ on request on the number of case reports of anaphylaxis A&AA has received due to lactose free products being given to children with cow's milk allergy on the incorrect assumption that they were suitable.

Protein source

A&AA supports FSANZ proposal for the co-location of the protein source statement to sit alongside the name of the food.

Although this may be outside the scope of this submission, A&AA urges FSANZ to consider current communications on shortages or recalls of infant formula, especially for infants with special dietary needs. As there are often limited options for infants with cow's milk allergy and other special dietary needs, the shortage/recall of infant formula need to be managed with the understanding that, for some, the formula is the infants only source of nutrition. Infant formula shortages cause caregivers and sometimes the health professionals that care for them great anxiety.

It is A&AA's belief that if infant formula is categorised as a SMPPi, the manufacturer should be required to notify FSANZ as soon as possible, so the general public are made aware of the shortage sooner rather than later. This 'heads -up' affords caregivers and health professionals the time to consider options for the infant with special dietary needs before stock is depleted. In recent years, the TGA (Therapeutic Goods Administration) changed legislation mandating pharmaceutical companies to communicate shortages of medications to the TGA when they are made aware of stock issues. This communication then assists health professionals and people requiring medications to work through options in case there is a 'no stock available' notification. A&AA urges FSANZ to consider this request for SMPPi formulas that require a prescription and also formulas categorised as a SMPPi that do not require a prescription.

A&AA would be pleased to be involved in future communication of the new regulations on infant feeding to consumers once the regulations are finalised.

Your faithfully,

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