Allergy & Anaphylaxis Australia

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Allergy & Anaphylaxis Australia (A&AA) Submission: P1028 - Infant formula

Background

Allergy & Anaphylaxis Australia (A&AA) is a charitable, non-profit organisation established in 1993 to support and assist those affected by allergy and anaphylaxis. A&AA is dedicated to assisting individuals, their caregivers and all in the community in the management of allergic conditions including food allergy. A&AA's aim is to enable individuals and their families to enjoy an optimal quality of life whilst minimising risk to their health and wellbeing.

A&AA strives to raise awareness of allergy in the community and provides evidence-based information, resources and services to support children and adults living with allergic disease including food allergy. A&AA has members across all states and territories of Australia. We have a Medical Advisory Board that consists of several allergy specialists who are also members of Australia's peak medical body, ASCIA (the Australasian Society of Clinical Immunology and Allergy).

Summary

A&AA supports the creation of a new category Special Medical Purpose Products for infants (SMPPi) within Standard 2.9.1, and supports the proposed labelling requirements for inner packages, preferably with the addition of ingredient listing.

A&AA remains concerned that formula claiming lactose free or low lactose could be mistakenly fed to an infant with a milk allergy.

A&AA remains concerned that that partially hydrolysed infant formulas may be recommended by health practitioners for the mitigation or prevention of allergy.

A&AA strongly advocates for Standard 2.9.1 to indicate that infants around the age of 6 months and not before 4 months should be offered foods in addition to the infant formula product.

Special Medical Purpose Products for Infants

A&AA notes the current FSANZ proposal that that IFPSDU products remain within Standard 2.9.1. A&AA has previously supported this approach and continues to do so.

The creation of a new category, Special Medical Purpose Products for infants (SMPPi) within standard 2.9.1 is consistent with our support for the retention of such products within 2.9.1 whilst providing a clear distinction from other products for special dietary use.

New definitions

With respect to possible new definitions (section 3.4.4 of the Call for Submissions) A&AA accepts the option of not introducing new definitions, provided that such products are not exempted from full ingredient and allergen declaration.

A&AA remains concerned that Foods for Special Medical Purposes (Standard 2.9.5) whilst subject to allergen labelling, appear to be exempt from ingredient labelling. For several allergy related gastrointestinal disorders, declaration of ingredients other than common allergens can be of critical importance. See labelling issues below.

Low Lactose and Lactose-free

A&AA notes with regret that "FSANZ considers a separate statement about the unsuitability of lactose-free IFP for infants with milk allergy is not warranted." See Call for Submissions at 5.1.6. However, the paper does not address a warning statement for low lactose IFP for infants. Would FSANZ accept that a warning statement is justified for low lactose products? A&AA recognises that even lactose-free IFP for infants may contain milk products other than lactose, and that allergen labelling would require appropriate declaration.

The concern remains that in a busy environment and with people who are not well informed there remains a possibility that "low lactose" or "lactose-free" could be considered synonymous with "dairy or milk-free". There are many health professionals who do not understand the difference between milk intolerance/lactose intolerance and milk allergy. Many health professionals still do not believe that milk allergy can be just as potentially life-threatening as peanut or seafood allergies.

Partially hydrolysed protein

FSANZ notes submitters' views at 3.3.3 viz

> Partially hydrolysed infant formulas are not recommended for dietary management or treatment of allergy and are considered ineffective to prevent or reduce the risk of allergy and related conditions.
>
> Partially hydrolysed infant formulas are not placed on the market for management or prevention of allergy.
>
> Extensively hydrolysed or amino acid based infant formulas may be recommended for infants with diagnosed allergy. These would be used under medical supervision and/or listed on the Pharmaceutical Benefits Scheme.

A&AA notes that the FSANZ preferred option is that such products intended for the dietary management of a diagnosed condition, disorder or disease (such as allergy) will be categorised as SMPPi. A&AA supports this option. A&AA also understands that any claim or implication that a partially hydrolysed product is effective in the prevention or mitigation of allergy would be a non-permitted health claim.

It is assumed that in addition to partially hydrolysed infant formulas, other formulas including rice-based formulas such as Novalac Allergy if intended for the dietary management of a diagnosed allergy would be categorised as SMPPi.

Whilst noting that partially hydrolysed infant formulas are not placed on the market for the management or prevention of allergy, that absence of intent may not prevent practitioners from recommending such products for that purpose. An advisory statement such as "Not recommended for the mitigation or prevention of allergies" would make this clearer for health professionals and parents/carers.

Protein Source

A&AA strongly supports the retention of the requirement for the co-location of the protein source statement with the name of the food. This enables caregivers to immediately identify infant formulas which are problematic both with respect to listed allergens but also other protein sources including non-listed allergens which need to be avoided.

Labelling

With respect to labelling it appears evident that SMPPi products within 2.9.1 would be subject to the allergen declaration requirements of standard 1.2.3, in either its current form or pending format. A&AA notes the detailed FSANZ argument in SD3 section 2.2 (Allergen declarations) and concurs with that position.

Section 8.2 of the Call for Submissions. Standard 2.9.5—16 (1)(b) provides for the labelling of inner packages of Foods for Special Medical Purposes and includes allergen labelling. One advantage of relocating IFPSDU products to Standard 2.9.5 would have been the application the labelling requirements of section 16 (1)(b). A&AA agrees that the proposed category of Special Medical Purpose Products for infants (SMPPi) include the same requirements as detailed in Standard 2.9.5—16 (1)(b). However, the FSMP labelling requirements for inner packages do not appear to include ingredient listing. A&AA urges the inclusion of ingredient listing. Some infants are allergic to foods other than the major allergens, so it is essential that they have access to the full list of ingredients in the product. As an example, for Australian children with a condition called FPIES the most common triggers are rice and oats (not major allergens).

A&AA reiterates its position on allergen labelling for products within Standard 2.9.5, Foods for Special Medical Purposes. Products regulated by standard 2.9.5 are generally exempt from the labelling requirements under Part 1.2 of chapter 1 (see section 2.9.5—3) except when specifically required. See section 2.9.5—10 (2) and (3). This approach seems unduly cumbersome. A&AA would expect standard 1.2.3 as a whole, and the relevant parts of standard 1.2.1 plus the relevant schedules to apply to such products under 2.9.5. In general, there seems no obvious reason why all products falling under standard 2.9.5 should not be subject to standard 1.2.3 in full.

Additional foods

A&AA notes at 8.12.4 in SD1 the following statement in reference to Standard 2.9.1—19(4)(c):-

> The requirement in Standard 2.9.1 for a statement about offering foods in addition to infant formula products supports infant feeding guidance to introduce additional foods in an infant's diet. The timing of this introduction is subject to growth and developmental need, as advised by health professionals, and in any case should generally occur from six months.

As indicated at 8.12.4 this is contrary to advice from ASCIA. The wording in Standard 2.9.1 should reflect the wording in ASCIA's Infant Feeding and Allergy Prevention Guidelines:

- When your infant is ready, at around six months, but not before four months, start to introduce a variety of solid foods, starting with iron rich foods, while continuing breastfeeding.
- All infants should be given allergenic solid foods including peanut butter, cooked egg, dairy and wheat products in the first year of life. This includes infants at high risk of allergy.

- Hydrolysed (partially and extensively) infant formula are not recommended for prevention of allergic disease.

The current wording essentially advises carers to delay the introduction of solids beyond the date prior to which to introduction of solids may be the most efficacious preventing the development of allergies. Whilst FSANZ claims that "Standards within the Code are legislative instruments and are not health guidance documents", the current wording of 19(4)(c) is exactly that, guidance of a health nature.

A&AA strongly advocates for 19(4)(c) to be amended to reflect ASCIAs wording on food introduction (as above).

Yours faithfully,

Maria Said
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Allergy & Anaphylaxis Australia