

## National Allergy Strategy Submission

### Proposal P1028: Infant formula - 2<sup>nd</sup> Call for Submission - 7<sup>th</sup> July 2023

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#### Submission

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This submission reflects the views of the National Allergy Council, authorised by the National Allergy Council

The National Allergy Council submission will address issues within its scope, mainly relating to food allergy. The following is a summary of the National Allergy Council's views, and we have commented on each of the points in the tables of the Call for Submissions (CFS).

#### Special Medical purpose Products for Infants (SMPPi)

- The National Allergy Council supports the creation of SMPPi as a new category of infant formula within Standard 2.9.1 and supports the proposed restriction of sale to medical practitioners, dietitians, medical practice, pharmacy or responsible institution or majority seller to protect the sale of these products for a vulnerable population.
- The National Allergy Council supports the proposed definition for SMPPi to the Code (stated under section 3.1.4. of the 2<sup>nd</sup> CFS).
- The National Allergy Council supports formula based alternative proteins outside of those specified for infant formula (cow's milk, goat's milk, sheep's milk and soy), such as formula based on rice specifically for managing cow's milk allergy, be classified under SMPPi .
  - Inclusion of these formula in this category will ensure that formula available for sale in Australia with alternate protein sources will be appropriate for infant growth and development per the requirement to substantiate this in the pre-market assessment.
  - This will address the National Allergy Council's concerns about the use of alternative protein sources being used in infant formula, which do not have clinical evidence for promoting appropriate growth and development in infants. There are currently two examples of this in the Australian market:
    - I. Sprout formula, based on pea and rice protein. There are no growth studies to support this protein source in infant formula.
    - II. Allula rice formula. While there is a systematic review showing appropriate growth and development of rice protein based infant formula, clinical trials demonstrating growth and development for this specific formula have not been published and were not included in that review.

#### *Extensively hydrolysed formula under SMPPi:*

- Extensively hydrolysed formula (eHF) will be classified under SMPPi and are used for the dietary management of cow's milk protein allergy and malabsorptive gastrointestinal conditions. The National Allergy Council recommends that FSANZ specifically define what can be classified as an extensively

hydrolysed cow's milk formula, for new formula seeking to enter the Australian market. This would enable appropriate classification of eHF.

- There are currently two formula in the Australian market subsidised by the Pharmaceutical Benefits Scheme (PBS) - Aptamil Peptijunior and Nestle Alfare, with Nestle's product to be discontinued from November 2023. Aptamil Allerpro is an eHF available over the counter, it contains lactose and is suitable for cow's milk protein allergy, but not infants with severe cow's milk allergy (anaphylaxis).
- The National Allergy Council is aware that there are many other eHF on the market in Europe which may seek to enter the Australian market. As Nestle Alfare will be exiting the Australian market later this year, there will only be one company providing eHF to Australia. Given previous formula shortages, Australia is likely to require more product availability. In response to reports of reactions in the European community to eHF and the finding in the Dutch EuroPrevall study showing <50% resolution of cow's milk allergy with eHF, Nutten et al (2020) undertook an analysis of 76 eHF products on the European market. They found wide variability in the extent of hydrolysed proteins between formula. Those eHF with a greater proportion of peptides >1200 daltons, correlated with in vitro allergenicity, indicating insufficient hydrolysis in some formula for the management of cow's milk allergy.
- The National Allergy Council is concerned about the risk to infants with cow's milk allergy without a definition for eHF formula for new formula entering the Australian market and recommends that FSANZ adopt a definition for eHF either for a specific peptide (Dalton) size or proven hypoallergenicity in clinical trials.

#### **Lactose free and low lactose formula**

- Consistent with previous submissions, the National Allergy Council has ongoing concerns about the risks of lactose free formula being used inappropriately as an alternative formula for infants with cow's milk allergy. The National Allergy Council recognises that there is a paucity of published evidence in relation to this issue, but makes the following points:
  - The National Allergy Council has unpublished data from surveys conducted with staff working in children's education and care services, conducted in October 2021. For staff who use alternate products for children with cow's milk allergy, 24% of respondents (54 of 221) stated that they used lactose-free products (National Allergy Council, 2021, unpublished data; data is available to FSANZ on request). This is concerning as it is unsafe and demonstrates a lack of knowledge about the term lactose free.
  - Acknowledgement of confusion in the community about the difference between lactose intolerance and cow's milk allergy are also raised in the literature in relation to both health professionals and consumers and patients (Di Costanzo & Canani, 2018; Walsh et al, 2016).
  - During consultations for the National Allergy Council's food service project, stakeholders across different food service sectors highlighted the need for an educational piece around the difference between lactose intolerance, milk allergy, and lactose free and dairy free products and their appropriate use. This education is now incorporated into all the online National Allergy Council All About Allergens training courses for food service staff. We have also developed a series of assets for use on social media aimed at the general public, food industry and food service, to increase awareness and prevent further confusion (Attachment A).
- The National Allergy Council recommends that lactose free and low lactose formula move to the category of SMPPi for the following reasons:
  - The purpose of a lactose free formula is consistent with the proposed wording for inclusion in the Code to define SMPPi '*...limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food...*'.

- Restricted sale under SMPPi is likely to facilitate better care of the infant with symptoms consistent with allergy or malabsorption as health professional involvement is required.
- Restricted sale as SMPPi may prevent parents mistakenly using lactose free or low lactose products as a treatment for the symptoms of cow's milk allergy.
- In light of the confusion around lactose intolerance and milk allergy, the National Allergy Council recommends that lactose free and low lactose formula be clearly labelled "not suitable for infants with cow's milk allergy" (or similar wording). It would be a missed opportunity if this was not included.
- The National Allergy Council notes that within section 2.3.4 "Composition: low lactose or lactose free" on page 15 of FSANZ's 2<sup>nd</sup> CFS for P1028, there are several incorrect statements which highlights the confusion between lactose intolerance and cow's milk allergy. We would like to specifically comment on two statements:

*"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."*

In relation to this statement, the National Allergy Council would like to state the following:

- The prevalence of lactose intolerance is unknown.
- The correct/preferred terminology for cow's milk protein intolerance is "non IgE mediated cow's milk allergy" (Fiocchi et al, 2022).
- The 2-5% statistic refers to IgE mediated cow's milk allergy not lactose intolerance (Osborne et al, 2010).

*"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."*

- This statement appears to refer to the use of lactose free formula in relation to cow's milk protein intolerance which is also confusing - lactose free formula contain cow's milk protein and would not be suitable for an infant with cow's milk protein intolerance.
- The National Allergy Council recommends that FSANZ adopts the commonly used definitions outlined by Boyce et al (2010) - that is, IgE mediated allergy and non-IgE mediated allergy to describe immune mediated reactions. Other reactions to foods fit into the non-immune mediated categories - such as carbohydrate intolerances and carbohydrate malabsorption, including lactose intolerance. For cow's milk based reactions, we also refer FSANZ to the World Allergy Organization DRACMA guidelines, which are currently being revised (Fiocchi, 2022).
- We do note that in section 7 of SD3, relating to lactose free and low lactose formula, there is no reference to cow's milk protein allergy or intolerance. We also note that FSANZ has somewhat addressed the inconsistency in the 'living document', however we disagree with these formula remaining under the infant formula category, and believe they fit better under SMPPi.

#### **Labelling for Infant products:**

- We have provided specific comments to the draft variations in Tables 8 and 8.1 and 8.2 below in relation to labelling (Appendix 2).
- The National Allergy Council supports 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.
- The National Allergy Council supports retaining allergen declaration statements as per schedule 3 in standard 1.2.3.

- The National Allergy Council supports the proposal to remove permission for follow on formula to be represented as lactose free or low lactose.

#### **In summary:**

- The National Allergy Council supports most of the proposed changes to the FSANZ Code in relation to Infant formula and SMPPi.
- We disagree with leaving lactose free formula under the infant formula category and recommend they are included under SMPPi.
- We recommend lactose free and low lactose products be labelled not suitable for infants with cow's milk allergy to increase the safe use of these products.
- We 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.
- We recommend that a definition for eHF be adopted to ensure that they are suitable in children with cow's milk allergy.
- We also recommend a strong education program, developed in consultation with key stakeholders to ensure consistency of messaging, once changes to the Code are in place.
- With regards to messaging relating to food allergy and infant formula, we recommend FSANZ engage with key stakeholder organisations including the National Allergy Council, ASCIA, Allergy & Anaphylaxis Australia and Dietitians Australia.

Thank you for the opportunity to provide a submission.

#### **References:**

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National Allergy Strategy. Unpublished data – survey in Children's education and care services, 2021. Data available on request.

Nutten s, Maynard F, Javi A, Rytz A, Simons PJ et al. Peptide size profile and residual immunogenic milk protein or peptide content in extensively hydrolysed infant formulas. *Allergy.* 2020; 75: 1446-1518.

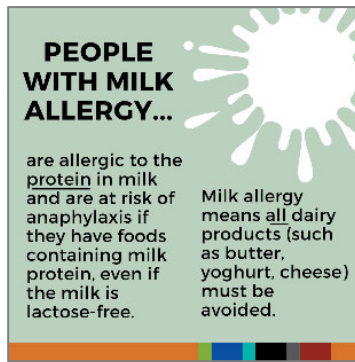
Osborne NJ, Koplin JJ, Martin PE, Gurrin LC, Lowe AJ, Matheson MC, et al. Prevalence of challenge-proven IgE-mediated food allergy using population-based sampling and predetermined challenge criteria in infants. *J Allergy Clin Immunol.* 2011; 127 (3):668-76.

Walsh J, Meyer R, Shah N, et al. Differentiating milk allergy (IgE and non IgE mediated) from lactose intolerance: understanding the underlying mechanisms and presentations. *British Journal of General Practice.* August 2016; e609.

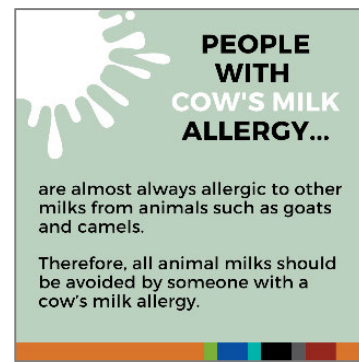
**Appendix 1: Assets for social media – Lactose intolerance and milk allergy education.**



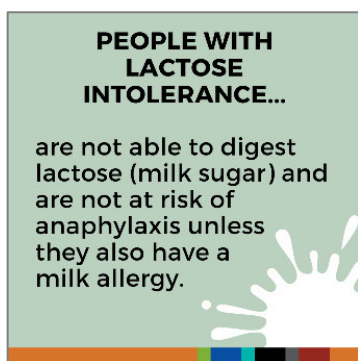
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## Appendix 2: Comments on Draft Variations to labelling

The National Allergy Council has limited our comments largely to allergy related matters within our scope; where the subject is outside the scope of the National Allergy Council, we have marked not applicable (N/A).

*Table 8 - Comparison between existing and new safety-related labelling requirements for infant formula and follow-on formula*

Existing labelling requirements	Draft variation in Attachment A to the 2 <sup>nd</sup> CFS	National Allergy Council comments (N/A where the National Allergy Council is not providing comment)
<b>Directions for preparation and use</b>		
(a) each bottle should be prepared individually.	Direction varied by replacing the word 'should' with 'must'.	N/A
(b) if a bottle of made up formula is stored prior to use, it must be refrigerated and used within 24 hours.	Direction varied by replacing the word 'made up' with 'prepared'.	N/A
(c) potable, previously boiled water should be used.	Direction varied by adding the word 'cooled' and replacing the word 'should' with 'must'.	N/A
(d) if a package contains a measuring scoop—only the enclosed scoop should be used.	Direction varied by replacing the word 'should' with 'must'.	N/A
Warning statements to follow instructions exactly	New directions (e) for powdered or concentrated formula—do not change proportions of the powder or concentrate or add other food except on medical advice (f) for ready-to-drink formula—do not dilute or add other food except on medical advice.	N/A
(g) formula left in the bottle after a feed must be discarded.	Direction varied by adding the words 'within 2 hours'	N/A
	New provisions <ul style="list-style-type: none"> <li>directions (a), (b), and (c) do not apply to ready-to-drink formula</li> </ul>	N/A

Existing labelling requirements	Draft variation in Attachment A to the 2 <sup>nd</sup> CFS	National Allergy Council comments (N/A where the National Allergy Council is not providing comment)
	<ul style="list-style-type: none"> <li>direction (d) does not apply to concentrated formula and ready-to-drink formula.</li> </ul>	
<b>Other specific labelling requirements in Standard 2.9.1</b>		
Representations about food as an infant formula product.	<ul style="list-style-type: none"> <li>Provision varied to refer to food as infant formula or a follow-on formula</li> </ul>	The National Allergy Council supports this provision as clear labelling of foods is important for the community and for vulnerable populations.
Prescribed names 'infant formula' and 'follow-on formula'.	New provision <ul style="list-style-type: none"> <li>for the existing name of the food (the prescribed name) to be stated on the front of the package.</li> </ul>	The National Allergy Council supports this provision as clear labelling of foods is important for the community and for vulnerable populations.
Requirement for measuring scoop for an infant formula product.	Provision varied to apply to infant formula or follow-on formula.	N/A
Storage instructions must cover the period after the package has opened.	Provision varied to apply to infant formula or follow-on formula.	N/A
Print size is specified for warning statements, based on net weight.	Provision varied to apply to infant formula or follow-on formula.	N/A
Warning statement about following instructions exactly, by product type (e.g., powdered, concentrated and ready-to-drink)	Single warning statement applicable for all product types.	N/A
Warning statement 'Breast milk is best for babies'.	Retained	The National Allergy Council supports retaining this statement as we are an organisation that supports and promotes breast feeding as part of our infant feeding project. <a href="http://www.preventallergies.org.au">www.preventallergies.org.au</a>
Statement that infant formula may be used from birth.	<ul style="list-style-type: none"> <li>Statement varied by replacing the words 'infant formula product' with 'infant formula'</li> </ul> New provision <ul style="list-style-type: none"> <li>require the statement to appear on the front of the package.</li> </ul>	N/A

Existing labelling requirements	Draft variation in Attachment A to the 2 <sup>nd</sup> CFS	National Allergy Council comments (N/A where the National Allergy Council is not providing comment)
Statement that follow-on formula should not be used for infants aged under 6 months.	<ul style="list-style-type: none"> <li>Statement varied by replacing the words 'infant formula product' with 'infant formula'</li> </ul> <p>New provision</p> <ul style="list-style-type: none"> <li>requiring the statement to appear on the front of the package.</li> </ul>	N/A
Statement about age to offer foods in addition to formula.	Statement varied by clarifying it applies to infant formula and follow-on formula only.	The National Allergy Council supports this variation.
Protein source statement.	<ul style="list-style-type: none"> <li>Provision varied to require the specific animal or plant source(s) of protein and replace the word 'product' with 'food'</li> <li>Retained requirement for protein source statement to be included in the statement of the name of the food</li> </ul> <p>New provision</p> <ul style="list-style-type: none"> <li>requiring this information to be stated on the front of the package.</li> </ul>	<p>The National Allergy Council supports all three points in relation to the specific protein source statements and having it on front of pack, as this will make it easier to identify allergens.</p> <p>The National Allergy Council would like clarification that Plain English Allergen Labelling applies to infant formula and follow on formula so that milk and soy are easily identified.</p>
Statements relating to dental fluorosis.	Removed.	N/A
<b>Application of certain general labelling requirements in Part 1.2 of the Code</b>		
Date marking requirements in Standard 1.2.5	Retained.	N/A
General legibility requirements in Division 6 of Standard 1.2.1	Retained.	N/A



*Table 8.1 - Comparison between existing and new provision of information labelling requirements for infant formula and follow-on formula*

Existing labelling requirements	Draft variations in Attachment A to the 2 <sup>nd</sup> CFS	National Allergy Council Comments (N/A where the National Allergy Council is not providing comment)
General requirements for statement of ingredients in Standard 1.2.4.	Retained. New provision <ul style="list-style-type: none"> <li>• permitting an optional format for declaring added vitamins and minerals that are required nutritive substances in the statement of ingredients</li> <li>• if optional format used, the statement of ingredients need not list the added vitamin and mineral in descending order of ingoing weight, provided that the statement of ingredients lists all added vitamins together under the subheading 'Vitamins' and lists all added minerals together under the subheading 'Minerals'.</li> </ul>	N/A
Allergen declaration requirements in Division 3 of Standard 1.2.3.	Retained.	The National Allergy Council is supportive of retaining allergen declaration requirements for infant formula.
Requirement for the statement 'genetically modified' in Standard 1.5.2.	Retained.	N/A
<b>Declaration of nutrition information in the nutrition information statement (NIS)</b>		
Requirement to declare energy, protein, fat, carbohydrate, vitamins, minerals, permitted nutritive substances, inulin-type fructans, galacto-oligosaccharides (or a combination of inulin-type fructans and galacto-oligosaccharides).	Retained. New provision <ul style="list-style-type: none"> <li>• requiring choline, inositol, and L-carnitine to be declared in the NIS for infant formula.</li> </ul>	N/A
	New provision <ul style="list-style-type: none"> <li>• permitting declaration of specified fatty acids and whey and casein in the NIS</li> <li>• if declared, these sub-group nutrients must appear in the NIS in the prescribed format.</li> </ul>	N/A

Existing labelling requirements	Draft variations in Attachment A to the 2 <sup>nd</sup> CFS	National Allergy Council Comments (N/A where the National Allergy Council is not providing comment)
Nutrition information declared per 100 mL made up formula; guidance indicates per 100 mL concentrated or per 100 g powder also permitted.	Provision varied to require the unit quantity of food expressed in per 100 mL.	N/A
Nutrition information must be expressed in terms of the product as reconstituted according to directions on the package.	Provision varied to clarify it applies to powdered and concentrated formula.	N/A
Average energy content, average amount.	<ul style="list-style-type: none"> <li>Retained average energy content</li> <li>Provision varied to require the average quantity for nutrients, substances, and nutritive substances</li> </ul> New provision <ul style="list-style-type: none"> <li>for how average quantity must be calculated.</li> </ul>	N/A
	New provision <ul style="list-style-type: none"> <li>requiring a prescribed format for the NIS</li> <li>include subheadings 'Vitamins,' 'Minerals,' 'Additional' in the NIS for infant formula and follow-on formula; and the subheading 'Other nutrients' in the NIS for infant formula</li> <li>subheadings must be printed in a size of type that is the same or larger than the nutrient names in the NIS.</li> </ul>	N/A
Weight of one scoop (for powdered formula), the proportion of powder or concentrate required to reconstitute formula according to directions (for powdered and concentrated formula).	Provision varied to prohibit this information from appearing in the NIS, and to apply to infant formula or follow-on formula.	N/A
<b>Other information requirements</b>		
Prohibition for nutrition content and health claims, and therapeutic claims	New Note <ul style="list-style-type: none"> <li>Explains that existing prohibitions for nutrition content and health claims, and therapeutic claims in Standard 1.2.7 apply to infant formula and follow-on formula.</li> </ul>	The National Allergy Council is supportive of the variation to apply prohibitions for nutrient, health and therapeutic claims for infant formula.

Existing labelling requirements	Draft variations in Attachment A to the 2 <sup>nd</sup> CFS	National Allergy Council Comments (N/A where the National Allergy Council is not providing comment)
		By not having claims on the packaging, parents of infants may seek health professional help earlier for infants displaying signs of feed intolerance, rather than trying many different types of formula which can delay diagnosis of health conditions.
	<ul style="list-style-type: none"> <li>• Provision varied to apply to infant formula that is represented as lactose free or low lactose</li> <li>• Removed permission for follow-on formula to be represented as lactose free or low lactose</li> <li>• Retained requirement to declare lactose and galactose in the NIS.</li> </ul> <p>New provisions</p> <ul style="list-style-type: none"> <li>• requiring the words 'lactose free' or 'low lactose' to be included with the name of the food on the front of the package</li> <li>• an explicit prohibition for the words 'lactose free' and 'low lactose' elsewhere on the label.</li> </ul>	<p>The National Allergy Council is supportive of all five variations proposed in relation to low lactose and lactose free formula.</p> <p>Furthermore:</p> <ul style="list-style-type: none"> <li>• The National Allergy Council recommends that lactose free and low lactose formula be categorised under SMPPi rather than formula for general use.</li> <li>• The National Allergy Council has unpublished data confirming confusion in the community in relation to appropriate formula for infants with cow's milk allergy, with 25% of workers in children's care and education services who responded to the survey, indicating they use lactose free formula as an alternative for cow's milk allergy.</li> <li>• Moving lactose free and low lactose formula to SMPPi will enable health professional assistance in the infant's presenting problems, expedite diagnosis and reduce the inappropriate use of lactose free formula in infants with cow's milk allergy.</li> <li>• Published studies in relation to the management of cow's milk allergy and lactose intolerance highlight the confusion between the two in both parents and health professionals.</li> <li>• The National Allergy Council proposes that lactose free and low lactose formula be required to bear a statement on the label that clearly indicates they are not suitable for infants with cow's milk allergy.</li> </ul>
Partially hydrolysed protein.	New provision	<ul style="list-style-type: none"> <li>• The National Allergy Council supports permitting the words 'partially hydrolysed' in the statement of ingredients next to the protein source in the ingredients list.</li> </ul>

Existing labelling requirements	Draft variations in Attachment A to the 2 <sup>nd</sup> CFS	National Allergy Council Comments (N/A where the National Allergy Council is not providing comment)
	<ul style="list-style-type: none"> <li>for infant formula that is represented as partially hydrolysed, requiring the words 'partially hydrolysed' immediately adjacent to the statement of protein source</li> <li>permitting the words 'partially hydrolysed' or any word or words having the same or similar effect in the statement of ingredients</li> <li>The requirement applies to infant formula only. Representations about partially hydrolysed follow-on formula would not be permitted.</li> </ul>	<ul style="list-style-type: none"> <li>The National Allergy Council sees no benefit of the words "partially hydrolysed" being allowed on front of pack or in the name of the formula as there is no demonstrated benefit for these formula over other formula based on cow's milk, however we acknowledge that this will make it clearer for parents to identify when modifications have been made to formula.</li> <li>The National Allergy Council is satisfied that under standard 1.2.7 applying to infant formula, partially hydrolysed formula would be prohibited from making statements relating to nutrition content, health claims, and therapeutic claims including the use of partially hydrolysed formula for the prevention of cow's milk allergy, which is not supported in the literature. ASCIA's infant feeding guidelines specifically do not support partially hydrolysed formula for allergy prevention.</li> <li>The National Allergy Council supports not permitting representation about partially hydrolysed for follow on formula.</li> </ul>
Stage labelling.	<p>New provisions</p> <ul style="list-style-type: none"> <li>permit the use of the number '1' on infant formula and the number '2' on follow-on formula to identify for consumers that the product is infant formula or follow-on formula, respectively</li> <li>if used, the number must appear on the front of the package of the product and immediately adjacent to the relevant age statements for infant formula and follow-on formula.</li> </ul>	N/A
Product differentiation.	<p>New provision</p> <ul style="list-style-type: none"> <li>requiring that a food represented as infant formula or follow-on formula must not be also represented as another food.</li> </ul>	The National Allergy Council supports this provision.

Existing labelling requirements	Draft variations in Attachment A to the 2 <sup>nd</sup> CFS	National Allergy Council Comments (N/A where the National Allergy Council is not providing comment)
Prohibited representations (including proxy advertising).	<p>Retained existing prohibited representations</p> <p>New provisions</p> <ul style="list-style-type: none"> <li>• Unless expressly permitted or required by the Code, prohibiting representations made in infant formula or follow-on formula about: <ul style="list-style-type: none"> <li>- information relating to another product (a name, number, picture, image, word or words).</li> <li>- ingredients</li> <li>- animal or plant sources of protein</li> <li>- the words 'partially hydrolysed' (or any word or similar words in the statement of ingredients)</li> <li>- the words 'lactose free' or 'low lactose'</li> <li>- a number used to identify for consumers that the product is infant formula or follow-on formula.</li> </ul> </li> </ul> <p>Included a Note to clarify existing prohibition for nutrition content and health claims, and therapeutic claims apply.</p>	The National Allergy Council supports the proposal for the new provisions, specifically in relation to 'partially hydrolysed' and 'lactose free or low lactose' formula (reasons above). We recommend that Lactose free and low lactose formula move to the SMPPi category.

Table 8.2 – New Labelling requirements for SMPPi

Draft variation in Attachment A to the 2 <sup>nd</sup> CFS	National Allergy Council Comments (N/A where the National Allergy Council is not providing comment)
<b>Standard 2.9.5 food for special medical purposes (FSMP) labelling requirements applied to SMPPi</b>	
<p>Requirements that a food may only be represented as an SMPPi if it complies with Division 4 in Standard 2.9.1</p> <p>Mandatory labelling information:</p> <ul style="list-style-type: none"> <li>• name of the food</li> <li>• lot identification</li> <li>• information on irradiated food</li> <li>• ingredient labelling</li> <li>• date marking</li> <li>• directions for use or storage</li> <li>• legibility requirements</li> <li>• Mandatory statements and declarations</li> <li>• Nutrition information about any other nutritive substance added to the product to achieve its intended medical purpose</li> </ul> <p>Inner package requirements</p> <p>Transportation outer requirements.</p>	<p>The National Allergy Council supports this requirement; our views specifically relate to the mandatory labelling in relation to specialised infant formula for the treatment of cow's milk allergy – these labelling requirements support the consumer to be able to identify the name of the food, the ingredients, directions on safe used and storage and any mandatory warning statements.</p>
<b>Standard 2.9.1 labelling requirements applied to SMPPi</b>	
<p>Permission for information on the source or sources of protein</p> <p>Prohibited representations:</p> <ul style="list-style-type: none"> <li>• a picture of an infant</li> <li>• the word 'humanised' or 'maternalised' or any word or words having the same or similar effect</li> <li>• the words 'human milk oligosaccharide,' 'human milk identical oligosaccharide' or any word or words having the same or similar effect</li> <li>• the abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect</li> <li>• information relating to another food.</li> </ul>	<p>As an organisation that supports and promotes breast feeding, the National Allergy Council supports the proposed prohibition of these representations on infant formula.</p>

Draft variation in Attachment A to the 2 <sup>nd</sup> CFS	National Allergy Council Comments (N/A where the National Allergy Council is not providing comment)
<b>Other Chapter 1 labelling requirements applied to SMPPi</b>	
<p>Existing prohibition for nutrition content and health claims, and therapeutic claims (a Note included in Division 4 of the primary draft variation)</p> <p>Information relating to foods produced using gene technology.</p>	<p>The National Allergy Council supports the existing prohibition for nutrition content and health and therapeutic claims. The National Allergy Council supports FSANZ's positions that SMPPi are intended for the dietary management of conditions, including food allergies, not for prevention or therapeutic benefits.</p> <p>N/A in relation to gene technology.</p>
<b>Labelling requirements <u>not</u> applied to SMPPi (Chapter 1, Standard 2.9.1 and Standard 2.9.5 FSMP)</b>	
<p>Name and address of supplier</p> <p>Labelling requirements relating to infant formula and follow-on formula in new Division 3 would not apply to SMPPi. For example:</p> <ul style="list-style-type: none"> <li>• Directions for preparation and use for infant formula and follow-on formula</li> <li>• Warning statements for infant formula and follow-on formula <ul style="list-style-type: none"> <li>– 'Follow instructions exactly'</li> <li>– 'Breast milk is best'</li> </ul> </li> <li>• Age-related statements for infant formula and follow-on formula</li> </ul> <p>Requirements for lactose and gluten claims for FSMP</p> <p>A prescribed name for SMPPi.</p>	

End of submission.