# Submission – Proposal P1028 – Regulation of Infant formula – Infant formula products for special dietary use

Comments from Public Health Services, Department of Health and Human Services, Tasmania, 28 September 2017

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Public Health Services, Department of Health and Human Services, Tasmania (PHS, DHHS-TAS) appreciates the opportunity to comment on Proposal P1028 – Infant formula products for special dietary use. This submission addresses a number of the specific questions raised in the consultation paper.

PHS, DHHS-TAS supports Infant Formula Products for Special Dietary Use (IFPSDU) to be retained in Standard 2.9.1 to reduce duplication of compositional and safety requirements that align with general provisions for infant formula products.

PHS, DHHS-TAS supports the continued prohibition for nutrition content claims and health claims in Standard 2.9.1 which is in line with the Ministerial Policy *Guidelines on the Regulation of Infant Formula Products.* PHS, DHHS-TAS acknowledges that IFPSDU are required to state on the label the condition the formula is suitable for and nutritional modifications of the product. For this reason PHS, DHHS-TAS supports a greater rigor with the regulation of these products and the scientific justification for their nutritional modifications to prevent misleading nutrition content and health claims.

Infants are a vulnerable population group and those with a specific dietary condition, disorder or disease are even more vulnerable. Products for special dietary use therefore need to be commensurate with this level of risk and should be restricted to medical supervision and clearly stated on the label 'not suitable for general use'. PHS, DHHS-TAS views are further discussed in the following questions.

**Question 2** What are the advantages and/or disadvantages of these options, in particular creating an 'infant formula product for special medical purposes' subcategory? If you support creation of a separate category for IFPSMP, should pre-term products be included?

The three options proposed include:

**Option 1** – deleting current subcategories within Division 4, and creating one category for infant formula for special dietary use.
**Option 2** – retain three subcategories and narrow their scope based on product use, highly specialised nature and risk.
**Option 3** – create four subcategories to cover products for transient gastroenterological conditions and feeding problems.

**PHS, DHHS-TAS supports Option 1** to create the one category defined as infant formula for special medical purposes.

Reasons include:

- Consistent with the EU and Codex.
  - In the EU most special purpose formulas are regulated as foods for special medical purposes specifically designed for infants.
  - Codex Standard 72-1981 also includes all special purpose formulas as formulas for special medical purposes intended for infants.
  - Both regulations do not break down infant formula for special purpose into subcategories.

- Ensures all formula designed for special dietary purposes are under the guidance of medical supervision.
  - Inclusion of all products that are designed for special dietary purposes in the one category ensures this vulnerable population group are managed under medical supervision. This minimises unnecessary weaning from breastmilk and ensures diagnosis and management of true conditions.
  - Option 2 would allow some products for transient gastrointestinal conditions to be included into general infant formula. This may run the risk of healthy infants being placed on a modified formula unnecessarily such as lactose free or partially hydrolysed formula for colic. Whilst the risk may be low these formulas were not intended for the 'healthy infant' and the long term implications of this are unknown. In addition these products may place an economic burden on the family due to the price difference between standard formulas.
  - Medical guidance is consistent with the EU and Codex standards.

- Clarity between the subcategories is not required
  - In the current Standard 2.9.1 the three sub-categories are based on different categorisation with no consistency between the groupings.
    - 2.9.1 – 13 – based on birth weight
    - 2.9.1 – 14 – based on metabolic condition
    - 2.9.1 – 15 - based on composition
  - Suggestions have been made to categorise according to risk but again this poses difficulties. For example lactose free formula could be considered low risk for a transient gastrointestinal condition or severe risk for an infant with galactosemia.
  - By including all infant formula for special dietary use into the one category specific requirements for the various subcategories may not be required. This is similar to

Codex, the EU and the US where formulas for special dietary purpose are based on the standard infant formula (for healthy infants) except where the compositional requirements must be modified to meet the special nutritional requirements arising from the disease, disorder or medical condition. In the EU these are evaluated by EFSA before being placed on the market. This is similar in the US where the manufactures must submit information for review to the US FDA.

- Ensures all products in this category are defined as a formula for special medical purposes.
  - This ensures these products are not marketed to 'healthy infants' and that there is a scientifically justified reason for their existence to assist with a medical condition. In the Ministerial Policy Guideline on Regulation of Infant Formula Products it states 'the composition of infant formula products for special dietary uses should be based on appropriate scientific evidence'.
  - Creating a new category 'products for transient gastrointestinal conditions' as proposed in Option 3 may legitimise the development of infant formula products for non-medical reasons with limited scientific evidence. Examples currently on the market include infant formula for normal infant behaviour such as crying, frequent waking, bowel changes which has the potential to undermine breastfeeding.

**Question 3** Do you support inclusion of a category definition for IFPSDU in the Code? Why or why not? Is the proposed definition of IFPSDU appropriate; if not, what should it say?

PHS, DHHS-TAS supports an overarching category definition for infant formula products for special dietary use (IFPSDU) to clearly distinguish these products from general infant formulas. We do not support the current definition proposed as it does not clearly state these products are for infants with a medically determined condition or that these products should be based on appropriate scientific evidence.

PHS, DHHS-TAS also recommends using the term infant formula products for special medical purposes rather than IFPSDU and that only one definition is required. This is in line with both Codex and the EU.

A proposed definition includes combining key aspects of the definition outlined in the paper for IFPSDU and infant formula products for special medical purposes:

The one definition proposed includes:

*Infant formula products for **Special Medical Purposes** means an Infant Formula Product that is specifically formulated for infants:*

*(a) who have a **medically determined** nutrient requirement or*
*(b) limited or impaired capacity to take, digest, absorb, metabolise or excrete food including another type of infant formula, and*
*(c) either partially or fully to satisfy the special nutritional needs of that infant, and*
*(d) is based on **appropriate scientific evidence**, and*
*(e) is to be used under medical supervision*

This definition would cover all infant formula products currently in Division 4 of the Standard 2.9.1 in addition to human milk fortifiers for premature infants.

**Question 4** If you support including a subcategory definition for IFPSMP in the Code, is the proposed definition of IFPSMP appropriate; if not, what should it say?

PHS, DHHS-TAS does not support a subcategory definition of IFPSDU. As outlined above PHS, DHHS-TAS supports one definition that covers infant formula products for special dietary use and that it be renamed to Infant Formula Products for Special Medical Purposes. This clearly distinguishes it from general infant formula and ensures that only products that are designed to meet the needs of an even more vulnerable population group are both medically determined and scientifically justified.

**Question 5** Are there any issues with the current definition for protein substitutes?

Discussions with clinical dietitians in the Tasmanian Health Service have indicated that the current terminology in the Code for defining these products in not the usual terminology used by dietitians and may cause confusion when explaining these to other medical staff or patients.

Suggestions were made to change the word 'protein substitutes' to 'protein composition'.

**Question 6** Is there a benefit to defining one or more of the following in the Code:
– Hypo-allergenic formula
– Partially hydrolysed formula
– Extensively hydrolysed formula
– Amino acid-based infant formula?

If yes, what are the benefits of including these definitions? And what should be the key elements of each definition?

Discussions with clinical dietitians in the Tasmanian Health Service have indicated these would only be useful to define if they were then used to define protein substitutes in the Code (as per question 4). If these are to be used the three that would need defining include partially hydrolysed, extensively hydrolysed and amino acid based formula.

(f) The term hypo allergenic formula should not be used to describe these formulas as the most recent evidence by Boyle et al (2016)[1] suggests that hydrolysed (including partially hydrolysed formulas) are not recommended to prevent allergy to cow's milk. In addition CFAR Infant Feeding Summit[2] (May 2016) also came to the same conclusion. The *Infant Feeding Guidelines*[3] state there is no evidence that partially hydrolysed infant formulas prevent allergic disease and may undermine breastfeeding. However, the *Infant Feeding Guidelines* do state that extensively hydrolysed infant formula for infants with a proven cow's milk allergy are recommended for those not breastfeeding. The use of the term hypo-allergenic is therefore misleading and should not be permitted on labels.

**Question 7** Are there any issues with the current definition for pre-term products?

PHS, DHHS-TAS questions the need for a definition for preterm and low birthweight infants. If the infant formula products under Division 4 of Standard 2.9.1 were to be categorised as one

category and redefined as Infant Formula Products for Special Medical Purposes then the following could be included on pre-term products:

- warning statement on label 'not suitable for general use, and should only be used for pre-term infants under specialist medical supervision' and
- the name must include the word 'pre-term'

This would reduce the need for a definition and would be consistent with the Codex Standards, EU and US regulations.

**Question 9** What is the general composition of human milk fortifiers for premature or low birthweight infants? ….and composition and uses for groups other than premature or low birthweight infants?

Discussions with clinical dietitians from the Tasmanian Health Service have indicated that the general composition of the human milk fortifier (HMF) is such that when it is combined with expressed breast milk (EBM) the macro and micro nutrient profile meets the estimated enteral requirements for pre term / low birth weight infants[4].

These products are not used for other purposes according to the paediatric dietitians consulted.

**Question 11** Is there a need to prescribe names for any the IFPSDU subcategories? If yes, what benefit would this provide?

PHS, DHHS-TAS supports a prescribed name for special purpose formula to distinguish this from general infant formulas. PHS, DHHS-TAS recommends the term 'formula for special medical purposes' which is in alignment with the EU. This clearly distinguishes these products from general infant formula and emphases to consumers the need for medical supervision.

Currently in Division 4 of Standard 2.9.1 it is a requirement that these products state the condition, disorder or disease for which the product is specifically formulated for, nutritional modifications that have been made to the product and a statement that these products are not suitable for general use and should be used under medical supervision. These provisions should be retained for all products in Division 4 of Standard 2.9.1. PHS, DHHS-TAS supports that these products clearly state on the back-of-pack the condition, disorder or disease and the nutritional modifications.

This is in alignment with PHS, DHHS-TAS submission in May 2016 where we recommended that for all infant formula declarations of ingredients or nutritional modifications (in the case of special purpose formulas) should be made on the back of a label underneath the Nutrition Information Table not on the front. This will still provide adequate information for health care practitioners to prescribe the correct formula whilst not being marketed as a nutrition content claim or health claim.

**Question 15** What benefit, if any, would the inclusion of a specific requirement for any IFPSDU to be demonstrated by generally accepted scientific data as: safe, beneficial and effective in meeting the specific nutritional requirements of intended infant subpopulation?

PHS, DHHS-TAS supports the inclusion of a specific requirement for any special purpose infant formula to be safe, beneficial and effective in meeting the specific nutritional requirements of the intended infant sub population based on appropriate scientific evidence. This is supported in the *Policy Guideline on Regulation of Infant Formula Products*.

The 'intended infant subpopulation' may need further clarification. PHS, DHHS-TAS has assumed this refers to an infant with a specific condition, disorder or disease.

**Question 16** Are there any issues with the current requirements for micronutrients and nutritive substances in IFPSDU products?

It is unclear in the current Standard 2.9.1 whether nutritive substances can be added to IFPSDU without pre-market approval. PHS, DHHS-TAS supports drafting that ensures special purpose formulas cannot add nutritive substances unless there is pre-market assessment of their safety and suitability.

**Question 25** To what extent is pre-term infant formula used following hospital discharge and how do caregivers access it (for example, by prescription)?

Discussions with clinical dietitians from the Tasmanian Health Service have indicated that pre-term infant formula is not used post-hospital discharge. Premature infants in Tasmania are not discharged until approximately term age so their nutritional requirements at discharge are different to the preterm infant.

**Question 26** Would you support the requirement for a statement that the product must be used under medical supervision, where the wording is not prescribed (an approach which harmonises with the overseas and international requirements)? Please describe your reasons why you do/do not support.

PHS, DHHS-TAS would support such wording.

**Question 28** Are there any specific FSMP labelling requirements that should apply to all IFPSDU?

PHS, DHHS-TAS supports:

- A prescribed name *Formula for Special Medical Purposes* located on the front of the tin. Permission to modify wording to permit alignment with international products from the EU could also be included.
- Statement on label that the product is not suitable for general use.
- Statement of the condition, disease or disorder for which the product has been specifically formulated (on back-of-pack).
- Statement of nutritional modifications clearly stated on the back of the tin. These products are for specific conditions and individual ingredients should not be used for marketing purposes but for health professionals to determine their suitability.

**Question 30** What evidence can you provide to support concerns regarding inappropriate access to any IFPSDU?

PHS, DHHS-TAS is not aware of any studies that have measured the inappropriate access to special purpose products.

However, some studies on special purpose formulas for 'transient gastrointestinal conditions' such as colic and reflux have highlighted concerns regarding the marketing of these products for otherwise healthy infants. Mothers are persuaded by the credibility of this advertising and the use of language that sounds scientific or technical. There is the belief that these infant formulas can treat common aliments or resolve inconvenient but normal infant behaviours[5].

The risk is that these formulas may be perceived as an alternative to breastfeeding in addition to an economic cost associated with a higher price for these modified formulas[6]. Examples illustrated in these studies include the low lactose infant formulas for colic[7] where there is limited scientific evidence that these work for mild to moderate colic conditions.

Restricting access to these products and redefining them as an infant formula for special medical purposes that can only be used under medical supervision would ensure better health outcomes for all infants. Infants would receive a more thorough medical diagnosis and reduce parental anxiety associated with constantly changing formulas to address symptoms such as excessive crying that may be better addressed through other strategies.

PHS, DHHS-TAS supports regulatory limits on access for all special purpose formulas similar to that in Standard 2.9.5. However, since Standard 2.9.5 was developed there has been a significant increase in online purchasing and in Tasmania a growth in large pharmacy outlets which this current standard may not adequately address.

Recent research in Tasmania has shown that many of these special purpose foods are readily available in these large pharmacy outlets, particularly for transient gastrointestinal conditions and access to a qualified pharmacist is often minimal. The ready availability and marketing of these products in catalogues (both on-line[5] and in large pharmacy outlets) may compete with the initiation and/or duration of breastfeeding.

PHS, DHHS-TAS has also been made aware of the on-selling of some of these special purpose products via social media sites (see Appendix 1) and whist it states they want evidence of prescription there is no guarantee this will not be given to someone without a prescription. Consideration of how situations such as these can be minimised is warranted.

Appendix 1


09:44
Search in LMN Chat ( Mums...
ABOUT
DISCUSSION
PHOTOS
EVENTS
FILES
Yesterday at 13:37 •
I have 7 unopened tins of this is anyone using it I'm happy to give it away if u can prove ur baby is on it because it is prescription but my daughter will not drink it at all ...
Aptamil
LCP
EleCare
Hypoallergenic

## References


[1] Boyle RJ et al. Hydrolysed formula and risk of allergenic or autoimmune disease: systematic review and meta-analysis *BMJ,* 2016;352:i974.

[2] Centre for Food and Allergy Research https://www.mcri.edu.au/news/great-result-infant-feeding-guidelines

[3] NH&MRC (2012) *Infant Feeding Guidelines*. Canberra: National Health and Medical Research Council.

[4] Agostoni C et al. Enteral Nutrient Supply for Preterm Infants: Commentary From the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition Committee on Nutrition. *JPGN,* 2010;50(1):85-91.

[5] Berry N and Gribble K. Health and nutrition content claims on websites advertising infant formula available in Australia: A content analysis. *Maternal & Child Health,* 2016:1-8.

[6] Belamarich P et al. A critical review of the marketing claims of infant formula products in the United States. *Clinical Paediatrics,* 2016;55:437-442.

[7] Abrams SA. Is it time to put a moratorium on new infant formulas that are not adequately investigated? *Journal of Paediatrics* 2015;166:756-760.