Comments from the Victorian Departments of Health and Human Services, Education and Training and Economic Development, Jobs, Transport and Resources

The Victorian Departments of Health & Human Services; Education & Training and Economic Development, Jobs, Transport & Resources (the departments) welcome the opportunity to respond to the issues raised in the Consultation paper for Proposal P1028 – Regulation of infant formula products for special dietary use.

The departments recognise that breastfeeding is the normal and recommended way of feeding infants and that the regulation of infant formula has implications for the health outcomes of both formula-fed and breastfed infants.

The departments support regulations for special purpose infant formulas that:

- Reflect, with appropriate risk management strategies, the Ministerial Policy Guideline – Regulation of Infant Formula Products, which recognises that infants that require special purpose formulas are an even more vulnerable population group than infants generally.
- Enable an uninterrupted supply of valid imported special purpose infant formulas, in recognition that for many special purpose formulas, there is a reliance on international products (particularly from the European Union).
- Are simplified for industry and for enforcement purposes and aligned with the European Union (EU) regulations and Codex where appropriate.
- Encourage positive innovation by industry for this vulnerable population group. In this context, positive innovation would seek to improve the health outcomes of formula-fed infants to be closer to breastfed infants, provide legitimate specialised clinical formulas where certain conditions require them, and ensure that the products on the market are effective based on accepted scientific evidence.

Comments to specific questions have been provided below.

Q1 Are any other overseas regulations relevant to IFPSDU?

There are no other regulations that we are aware of that need to be considered other than the Codex, European and United States regulations mentioned.

Q2 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 products developed for pre-term and low birthweight infants be included or retained as a separate subcategory? Please provide your rationale.

FSANZ has presented three options for categorising the range of special purpose infant products:

1. No subcategories within the overall category of special purpose formula products. This approach aligns most closely with both Codex and EU regulations and is the option **supported by the departments**. Further details are provided below.
2. Retain the existing 3 subcategories of products: products based on a protein substitute, products for preterm and low birth weight infants and products for metabolic, immunological, renal, hepatic and malabsorptive conditions. This notes

the potential for some 'lower risk' products for transient gastroenterological conditions such as partially hydrolysed formulas to be moved into general formula regulations.

3. Add a fourth subcategory for 'transient gastroenterological conditions' to cover products such as those aimed at managing colic and constipation and rename the subcategory for metabolic, immunological, renal, hepatic and malabsorptive conditions 'formula for special medical purposes'. This is FSANZ's preferred option.

The departments **do not support** Options 2 and 3 for the following reasons:

1. **Inconsistency with international regulations.**

   The grouping of special purpose formulas into subcategories is not consistent with the EU or Codex. With the majority of special purpose formulas in Australia and New Zealand being imported from the EU, this has the potential to create trade issues.

   We note that in the EU, special purpose formulas are regulated as a 'food for special medical purposes specifically designed for infants' with the exception of hydrolysed formula, which is captured under general formulas. Similarly, Codex Standard 72-1981 includes all special purpose formulas under 'Formulas for special medical purposes intended for infants'. The departments note that Australia and New Zealand would be the only countries to include subcategories.

2. **Disassociation of special purpose products from the medical domain.**

   Special purpose formulas are intended to be used for the special dietary management of medical conditions, where breastmilk and /or standard infant formulas cannot be used, and where a specialised formula is either needed or is beneficial for managing the condition. Options 2 and 3 involve separating some special purpose products from a medically determined and supervised need.

   Option 2

   It would be undesirable for any special purpose formula to be categorised as 'general formula', as suggested under Option 2. The implications of this would include the absence of access limits and labels advising carers to use these products under medical supervision. The acute nutritional risk of some formulas, if consumed by healthy infants, may be low but these products are not necessarily benign or without consequences. For example, lactose is important for calcium absorption and the development of a desirable gut microbiome[1], which is increasingly being linked to long term health outcomes[2,3]. Consumption of a lactose-free formula may impair the development of a healthy gut microbiome, and there is some evidence for this in infants with allergic disease[4]. In infants unsupervised by health professionals, it may also lead to the unnecessary longer term avoidance of dairy products.

   The use of special purpose formula under medical supervision is also important to minimise unnecessary weaning from breastfeeding and avoid the failure to diagnose and manage true conditions, which may extend beyond infancy to unnecessarily restrictive diets in younger years.

   It is also unclear from a regulatory point of view whether special purpose formula could be permitted under general formula. That is, it is not clear how these formulas would be distinguished from general formula when the compositional criteria for general formula is mandated and health and nutrition claims are prohibited.

Option 3

The proposal for Option 3, in which only one of the four subcategories is defined as 'formula for special medical purposes', implies not all specialised formulas fit under the description of a medical purpose. However, the formulas that fall outside this subcategory, including those for allergies, preterm and low birthweight infants, constipation and reflux, are also for medical conditions.

FSANZ has not demonstrated to our satisfaction that there is a need for some formulas for medical conditions (such as metabolic disorders) to have different regulatory requirements to other formulas for medical conditions (such as allergies).

To ensure special purpose formulas exist purely to provide valid dietary management for medical conditions, all special purpose formulas should be clearly described and defined as medical purpose products. This would aid in discouraging the marketing of these products to healthy infants.

3. **Express permission for formula products not supported by scientific evidence.**

Under Option 3, the creation of a new subcategory for transient gastroenterological conditions, which is designed to cover products such as colic and constipation, will for the first time expressly permit special purpose products that are not recommended by paediatric specialists (according to Victorian paediatric dietitians consulted). There are a small number of products on the market that do not clearly fit within the current subcategories of IFPSDU, and therefore could be considered to be making prohibited health claims. The numbers of these products appear to have reduced in recent years since the gazettal of Standard 1.2.7 on health and nutrition claims and the clear prohibition of claims on infant formula. The creation of a sub-category for these formulas may make their presence on the market appear legitimate. Contrary to the Ministerial Policy Guideline, this sets an expectation that the formulation and targeting of special purpose infant formulas does not need to be based on science.

The policy guideline recognises that the regulation of infant formula has implications for the health outcomes of both formula-fed and breastfed infants. Care needs to be taken to discourage the proliferation of (non-evidence-based) formulas that medicalise normal infant behaviours, such as crying, frequent waking and variable bowel habits, and risk undermining breastfeeding. For example, some literature suggests that Australian babies may be unnecessarily weaned from breastmilk to a lactose-free formula because their irritability is wrongly assumed to be lactose intolerance[5].

A number of concerns have been raised with the departments by paediatric dietitians and breastfeeding specialists about special purpose formulas that are not supported by evidence and not recommended by paediatric specialists, including formulas for colic and hypoallergenic formulas for healthy infants.

4. **Lack of regulatory clarity with subcategories.**

The creation of subcategories is problematic for compliance and enforcement purposes. Currently, there is no consistency in the grouping of the subcategories: some are based on composition (for example, formulas based on protein substitutes) and others are based on the condition (for example, metabolic conditions). They are also not risk based, for example formulas based on protein substitutes for severe

allergies, and formulas for preterm and low birthweight babies are all serious conditions but not included within the subcategory designed for serious conditions (formulas for special medical purposes).

The seriousness of the condition does also not necessarily equate to the risk of the product to healthy infants. If subcategories were redefined into potentially serious and less serious conditions, difficulties in categorising products and enforcing the regulations would remain. For example, a lactose free formula can be used to treat both the serious inborn error of metabolism, galactosemia, and also temporary lactose intolerance following gastroenteritis. Additionally, formulas based on protein substitutes exist on a spectrum from partially to extensively hydrolysed. Some infants with allergies can only be managed with an amino acid based formulas while other infants can be managed on a less hydrolysed formula.

Subcategories would only be necessary if there were distinctly different regulatory requirements for composition, labelling and access and the departments do not believe this to be the case.

What we propose

- The departments support **Option 1**: one category of special purpose formula. FSANZ has raised a disadvantage of this option; that this would not assist in differentiating highly specialised products. This issue does not appear to be adequately justified, as discussed above. However, it is noted that the removal of subcategories could reduce a level of protection for infants by not limiting permitted special purpose formulas to specific conditions. Risk management strategies are discussed below to ensure some protection for these infants and their carers.
- All special purpose formulas intended to fall under this division of the Standard should be called “Infant Formula for special medical purposes”, which is more consistent with the EU and Codex regulations, and will serve to inform manufacturers and carers that these products are for medical conditions.
- This should be accompanied by a clear definition which sets out the intended purpose of these formulas and clearly distinguishes them from general formula (see Question 3).
- Detailed compositional requirements should not be described in the regulations to ensure adequate flexibility for appropriate innovation and to ensure supply where there is a reliance on overseas products. If certain compositional requirements for specific products must exist, these can be specified without the need for a subcategory (see section under Composition for further discussion).
- A requirement within this division for these products to be safe and effective for the intended condition based on generally accepted scientific data. A requirement for these products to be evidence-based is commensurate with the level of risk for these infants and reflects the Ministerial policy guideline. This would ensure products marketed as Formula for Special Medical Purposes are legitimate products for the nominated condition, and would encourage positive innovation by the industry whereby products are beneficial for the intended infants. This requirement would also provide greater consistency in the Code and address the current situation whereby high level claims about health conditions on general foods require evidence but claims about health conditions on infant formula do not.

This is also consistent with the recently updated regulations for food for special medical purposes (including formula) in the EU which states in the preamble that it should be ensured that these products are 'safe, beneficial and effective for the persons for whom they are intended on the basis of generally accepted data'.

- Access limitations, similar to foods for special medical purposes under Standard 2.9.5, should also be considered as a strategy to encourage the appropriate use of these products.
- This approach would avoid the clarity and enforcement issues that are likely to arise from the allocation of products into subcategories, if these are retained.

Q3 Do you support including 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?

The departments **support an overarching category definition** for special purpose formula in order to clearly establish the purpose of these products and enable them to be distinguished from general formulas via labelling and access controls. Note we support the category being renamed to 'infant formula products for special medical purposes', but will continue to refer to them as 'special purpose formulas' to avoid confusion with FSANZ's proposed subcategory named 'formula for special medical purposes'.

The departments **do not support the proposed definition** for special purpose formulas as it does not clearly establish that all IFPSDU should be for conditions that are medically-determined, medically supervised and based on appropriate scientific evidence in line with the ministerial policy guideline.

We propose that IFPSDU be renamed 'infant formula products for special medical purposes' with the following definition:

> *Infant formula product for special medical purposes means a product that:*
>
> *(a) is specifically formulated for the **partial** or **full** dietary management of infants who have medically determined*
>
> *(i) altered nutrient requirements, or*
>
> *(ii) limited or impaired capacity to take, digest, absorb, metabolise or excrete food including another type of infant formula product, and*
>
> *(b) is considered to be safe, beneficial and effective in the dietary management of the specified condition based on generally accepted scientific data, and*
>
> *(c) is to be used under medical supervision.*

We believe this definition would cover all types of formulas that FSANZ has referred to in the four subcategories, including formulas for colic and constipation, should they be determined to be legitimate ways of managing these conditions based on generally accepted scientific data. With the reference to 'partial or full dietary management', this would also capture human milk fortifiers, which FSANZ has indicated may not be covered by the current definition.

This definition is similar to international definitions (such as EU).

Q4 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?

No, the departments do not support a subcategory for IFPSMP, or the proposed definition, for reasons outlined under Q2. FSANZ has explained that products for metabolic, immunological, renal, hepatic and malabsorptive conditions are higher risk in that they are often incomplete sources of nutrition and should not be consumed by healthy infants. This is the basis for a separate subcategory.

The creation of a separate category in regulations would only be justified if specific regulatory requirements were needed for these products. As a subcategory, these products do not have specific compositional requirements that differentiate them from other subcategories.

There are also no current regulatory access limitations on products in this higher risk subcategory. FSANZ has indicated these are likely unnecessary as the requirement for prescription in many cases and price of these products limits their availability.

The labelling requirements to state which condition they are intended for, that they are not for general use, and should only be used under medical supervision should be present on all special purpose formulas, not just those that fall under this subcategory.

The departments can therefore see no benefit of this subcategory (and accompanying definition), and note that it would place Australia and New Zealand regulations at odds with Codex and the EU, from where the majority of the special purpose products are sourced.

Q5 Are there any issues with the current definition for protein substitutes?

The departments note that neither Codex nor the EU has definitions for protein substitutes (but the EU has prescribed sources and methods for processing).

The benefit of a definition for protein substitutes in the Code is not clear. It is also not clear whether a similar approach to the EU would be preferred.

Discussions with Victorian paediatric dietitians have indicated that if a definition were to remain, the existing definition is appropriate. However they note that these formulas are very varied and are for the management of a range of allergy-related conditions. Furthermore, those designed to treat specific allergies are not just protein modified, but also contains modified fats (for example, long chain and medium chain triglycerides) and carbohydrates (for example, lactose free, use of glucose polymers). The dietitians have indicated the most important need is for the specific condition and the compositional modifications to be clearly identified on these products.

Q6 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?

The departments note that these are not currently defined in the Code. Similar to previous questions, there is not a clear rationale for defining the various degrees of hydrolysed proteins. The departments do support the requirement to clearly specify what condition the formula is targeting and what modifications make it suitable.

Defining these formula based on their composition might present similar issues to setting compositional requirements for special purpose products more generally in terms of ensuring imported products remain compliant. These definitions would also not address the accompanying modifications of other nutrients that occur in these products, outlined in Q5.

Science is advancing in this area and the definitions may also become outdated quickly. For example, we are advised that hypo-allergenic formulas are no longer recommended for the prevention of allergy in healthy infants and cannot be used in established allergies[6] hence a definition for these products could be misleading.

Q7 Are there any issues with the current definition for pre-term products?

Similar to other questions on definitions, the departments question the need for a definition for preterm and low birthweight products. The only difference between the requirements for this product and other specialised products is the prescribed name of 'pre-term' and the warning statement 'suitable only for pre-term infants under specialist medical supervision'. All special purpose formulas should be required to state the condition they are designed to manage, include information on the composition that makes them suitable for this condition and include a statement that reflects the warning statement, for example, 'not for general use, suitable only for XX condition under medical supervision'.

This is more consistent with the Codex and EU approaches.

Q8 What, if any, are the benefits of including age and weight parameters in the regulatory definition for pre-term products?

Notwithstanding the questioned need for a definition for these products, the departments are advised by paediatric dietitians that the use of pre-term products depends more on the weight rather than the age of the infant. Not all pre-term infants (those born <37 weeks of gestation) require a pre-term formula. However, for those pre-term infants that do require these formulas, the use of them is short term and they are generally not recommended after the infant is discharged from hospital. If a pre-term infant needs additional nutrients post discharge, this is usually managed in other ways (for example by the use of adult modular products or by concentrating standard formula).

Until recently these products have only been available for in-hospital use and this has prevented the inappropriate prolonged use of these products by older pre-term infants (which may place the infant at risk of over feeding). However we are aware of one preterm formula that is aimed at infants post discharge and is available over the counter (S26 Premgro). Access limitations and labelling (which may include direction regarding age or weight parameters) may be more effective than regulatory weight or age parameters for ensuring the appropriate use of these products.

Q9 What is the general composition of human milk fortifiers for premature or low birthweight infants? What are the uses of these products other than premature or low birthweight infants?

Human milk fortifiers contain additional protein and specific minerals to meet the increased need for these in preterm and low birthweight infants. They usually require monitoring of the infant's renal function and blood electrolytes and are generally not designed for long term use (generally, they are ceased after the infant reaches 2.5kg)[7].

They are not used for other purposes, according to paediatric dietitians consulted by the departments.

Other fortifying 'modular' macronutrient products are frequently used to fortify both breastmilk and standard formula for infants such as Polyjoule (carbohydrate), Calogen (fat) and Duocal (carbohydrate and fat). These products are also used in adults and are regulated under Standard 2.9.5.

Q10 Is there a need to prescribe a name for IFPSDU – what are the implications for subcategories?

Q11 Is there a need to prescribe names for any the IFPSDU subcategories? If yes, what benefit would this provide?

There appears to be two key issues to manage with respect to prescribed names. The first is to ensure special purpose formulas can be distinguished from general formulas and that the condition for which the product has been specifically formulated and the accompanying nutritional modifications are clearly stated. There is currently a requirement within Standard 2.9.1 to include such a statement.

The other issue is ensuring products that are imported and using overseas labelling remain compliant. FSANZ has indicated that the drafting can, for example, allow for products that comply with the EU labelling, that is to state 'food for special medical purpose'.

Given the importance of representing these products to consumers as specifically formulated for the dietary management of medical conditions, the departments support a prescribed name for all special purpose products, to distinguish these from standard formula. This should be, 'formula for special medical purposes', and should be required to be stated on the front of labels, which is consistent with the approach for EU products. The departments also support, in principle, drafting that permits products that comply with certain international naming requirements, provided the labelling clearly establishes the purpose of these products and distinguishes them from standard formula.

The departments do not see the need for prescribed names for other individual products but support retaining the requirement for the condition and the nutritional modifications to be clearly stated. Consideration needs to be given to how the requirement for the statement of the condition and associated nutritional modifications is drafted, while continuing to prohibit nutrient content and health claims. One option might be to identify the condition on the front of label, while requiring a complete list of the nutritional modifications to appear on the rear of the label. There are instances found online of overseas products highlighting certain nutritional modifications in the form of nutrient content claims on the front of pack (for example, see Attachment 1).

Composition

General comments

The departments support broad compositional requirements that allow for specialised products to deviate from the mandatory compositional requirements for the intended condition, based on generally accepted scientific evidence, consistent with the EU.

The departments question the need for any compositional requirements for special purpose products. We note the EU and Codex do not set specific compositional requirements for individual formulas for special medical purposes, with the exception of the EU specifying the method for protein hydrolysates.

The current compositional requirements listed in Standard 2.9.1 for lactose modified and hydrolysed protein products do not appear to be risk based, and it is not clear why these requirements would be regulated while the composition for products for more serious conditions are not. If detailed compositional requirements are not in place for special purpose products, the requirement for these products to be based on accepted scientific data would be particularly important to ensure the appropriate composition of these formulas.

Base compositional requirements

The departments are concerned about barriers to trade for these products given FSANZ is proposing to align the composition of standard infant formula to the Codex levels, rather than the recently updated EU levels, which no longer align with Codex. With the majority of special purpose formula being imported from the EU, and the requirement that these formulas only deviate from the mandatory compositional requirements of standard infant formula where required by the condition, this could lead to many of these formula being non-compliant with the Code. During the consultation on infant formula in 2016, the departments supported aligning the majority of the compositional requirements for standard formula with the EU, with a few exceptions. The reliance on products from the EU provides further reason to align with the EU levels where appropriate.

Optional Ingredients

The departments support drafting that specifically excludes optional ingredients from permissions for special purpose formulas, unless specifically needed to manage the intended condition. The inclusion of unnecessary components, or unnecessary amounts of components, has been recognised to place a burden on the metabolic and other physiologic functions of the infant, particularly under conditions of stress, which would be expected for many medical conditions[8].

Pre-market approval of new substances for special purpose formula

The current wording regarding composition in Division 4 also lacks clarity regarding the requirement for pre-market approval for new ingredients for special purpose formulas. The permission for the composition of special purpose products to deviate is provided by the statement: 'the compositional requirement of this Standard does not apply to the extent that it would prevent the sale of an infant formula product that had been specifically formulated for…'. It is arguable that this may also apply to the compositional requirement to add only substances permitted by the Standard.

It is important that the regulations clearly specify that the requirement for pre-market approval remains for nutritional modifications that would involve the addition of a substance not approved in infant formula generally. This should cover bioactive substances as well as nutritive substances.

Q12 Are any specific compositional requirements (energy/macronutrient etc.) needed in the Code for formula intended for premature or low birthweight infants, or for those suffering metabolic etc. conditions? If so, what are they?

The departments do not have a firm view on whether compositional requirements are needed for products for these conditions. Victorian paediatric dietitians have noted that specific compositional requirements may not be required provided the label clearly states the intended condition and modifications made.

Q13 Are any specific compositional changes needed in the Code for protein substitutes? If so, what are they and what is your justification for them?

See comments above.

Q14 Are any specific compositional requirements (energy/macronutrient etc.) needed in the Code if a new subcategory of formula for special medical purposes were created? If so, what are they?

See comments above, noting the departments do not support the creation of this subcategory.

Q15 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?

The inclusion of a specific requirement for products to be safe, beneficial and effective for managing the intended condition is an imperative risk management strategy given the lack of prescribed compositional requirements, the particular vulnerability of this population and infants' reliance on these products as a significant source of nutrition.

However the wording of this requirement needs to better reflect that in the EU regulations, which is that these products are safe, beneficial and *effective for the persons for whom they are intended* on the basis of generally accepted scientific data. FSANZ's suggested wording in the question, '..safe, beneficial and effective in **meeting the specific nutritional requirements** of the intended infant subpopulation' has a slightly different meaning. This distinction is important because, for example, a product aimed at managing colic or constipation may meet the nutritional requirements of infants with these conditions, but may not be beneficial or effective in managing the condition itself (which is the reason for its use).

This would be consistent with the ministerial policy guideline and the principles outlined in the EU regulations. Consumers and health professionals alike would also have the expectation that a special purpose product would be beneficial for, or effective in, managing the intended condition.

Q16 Are there issues with the current requirements for micronutrients and nutritive substances in IFPSDU products?

There needs to be clarification that special purpose products cannot add new substances (nutritive substances or bioactive substances) unless there is pre-market assessment of their safety and suitability.

Q17 Do you have any information to support including a minimum and maximum amount of chromium in IFPSDU? If yes, should this be considered only in relation to certain categories of IFPSDU?

No.

Q18 Do you have any information to support including a minimum and maximum amount of molybdenum in IFPSDU? If yes, should this be considered only in relation to certain categories of IFPSDU?

No.

Q19 Could one category of IFPSDU be used for all additional food additives, or should additional or modified subcategories be devised (noting the possible four subcategories in section 2.2).

The departments do not have a view on this at this time.

Q20 Do you support the proposed amendments listed in Table 7 for IFPSDU at the amounts shown?

The departments support the proposed amendments for food additives.

Q21 Can you provide information on suitable international safety assessment, a demonstrated history of safe use in the context of IFPSDU, and a technological justification for:

a) Calcium carbonates

b) Calcium citrates

c) Phosphoric acid

d) Sodium alginate

e) Xanthan gum

f) Locust bean (carob bean) gum

g) Pectins

h) Sodium carboxymethylcellulose

i) Sucrose esters of fatty acids

j) Starch sodium octenylsuccinate

The departments have no information to provide.

Q22 Are there any technologically justified concerns with changing the permissions for citric and fatty acid esters of glycerol (472c) to:
a) MPL of 9000 mg/L for liquid products
b) MPL of 7500 mg/L for powdered products?

The departments have no information to provide.

Q23 What is the technological justification for the use of diacyltartaric and fatty acid esters of glycerol (472e) in IFPSDU? Are there any technologically justified concerns with the removal of this permission?

The departments have no information to provide.

Q24 Do you support retaining the current maximum PRSL for any IFPSDU? Please provide your rationale.

The departments do not have a view on retaining the maximum potential renal solute load for any of the special purpose formula, however have been advised by paediatric dietitians that the availability of this information on labels for all special purpose formulas is very important. Many infants using these formulas tend to be more unwell, and the use of fluid restrictions and fortified feeds are common. The PRSL of all special purpose formulas is essential information to manage the burden on the infant's kidney function.

Q25 To what extent is pre-term infant formula used following hospital discharge and how do caregivers access it (for example, by prescription)?

Consultation with paediatric dietitians has indicated that there is limited use of pre-term infant formula post hospital. Some pre-term infants continue to have raised nutritional requirements which are more frequently managed by modifications using standard infant formula. To our knowledge there is only one formula product in Australia aimed at pre-term infants post discharge, S26 Premgro, which is available through pharmacies and does not require a prescription. It is only intended to be used until an infant reaches the 25th centile for weight, or reaches six months corrected age. Often it is ordered by a health service for the infant directly from the company through a 'home enteral nutrition' service, which allows closer monitoring and guidance regarding usage[a].

Q26 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.

The departments would support a non-prescribed statement that includes certain required elements, in line with the current requirements under Standard 2.9.1-14(2) c, d, e. That is, the statement needs to state that the product is not for general use, must be used under **medical** supervision, the condition for which the product has been formulated and the nutritional modifications made.

General infant formula requires the label to state, 'before you decide to use this product, consult your doctor or health worker for advice'. The wording requirement for special purpose products to use under medical supervision needs to convey a greater level of medical supervision than the statement required for general formula.

We are also aware of carers donating or on-selling special purpose formulas through social media or internet baby forums. While it would be beyond Standard 2.9.1 to influence this, clear labelling about the medical use and supervision for these products may help deter inappropriate use.

Q27 Are there any specific FSMP labelling requirements that you consider applicable to a particular type of IFPSDU?

No.

Q28 Are there any specific FSMP labelling requirements that should apply to all IFPSDU?

The departments support the following labelling requirements for all special purpose formula:

- A prescribed name 'Formula for special medical purposes', located on the front of the tin, with provisions that permit equivalent international wording (for example, the EU requirements for 'food for special medical purposes')
- A statement indicating that the product is not suitable for general use and should be used under medical supervision, the condition for which the product has been formulated, and the nutritional modifications made.
- A complete list of nutritional modifications needs to be clearly stated, for enforcement purposes. These should be required to be listed on the rear of the label with the nutrition information table. Some or all of these modifications

[a] Personal communication with Aspen Nutritionals, which distributes S26 in Australia

should not be permitted to be marketed on the front of the tin. These products are formulated to manage specific conditions and the presence of individual ingredients should not be used for marketing purposes.

- In line with Standard 2.9.5, labels should also state any precautions and contraindications associated with the formula and whether or not the formula is suitable for use as a sole source of nutrition.
- All special purpose products should be required to list the potential renal solute load given their intended use for infants with various medical conditions.

Q29 What specific labelling requirements for the safe preparation and use of IFPSDUs are being used that contradict the general requirements set out in subsection 2.9.1—19(3) of Standard 2.9.1?

The departments have no information to provide.

Q30 What evidence can you provide to support concerns regarding inappropriate access to any IFPSDU?

The departments are not aware of any studies that have specifically measured the inappropriate access and use of special purpose products. However some studies provide an insight into perceptions around some special purpose formulas, which supports the need for access controls.

For example, one study looked at participants' views on advertisements of special purpose formulas that would fall into the transient gastroenterological conditions subcategory. It found these decrease mothers' confidence in their ability to breastfeed; the advertisements conveyed an expectation of failure with breastfeeding, and that formula is a solution to fussiness, spitting up, and other normal infant behaviours[9].

Other literature discussed how these formulas for transient conditions encourage those parents who perceive their infants to be fussy, gassy, or colicky to purchase lactose-reduced, protein hydrolysate, soy, or pre-/probiotic containing formulas as a remedy, contrary to the currently available research as summarized by the highest quality systematic reviews[10].

Another discusses how low lactose and lactose-free formulas can be misused for functional lactose overload and cause premature weaning from breastfeeding[11]. There is also some discussion that hypoallergenic formulas are not recommended for allergy prevention in healthy infants and have been overused, in the absence of data on metabolic consequences and long-term outcomes of these products[12].

Maternal and child health nurses, lactation consultants and paediatric dietitians report from their experiences that some healthy infants are inappropriately using special purpose products, and in some cases, weaning from breastmilk to do so. This is predominantly related to special purpose formulas marketed as helping typical infant issues such as colic, constipation, lactose-free formulas available on supermarket shelves.

A consumer survey by the infant formula industry[13] indicated carers are confused by the numerous infant formula products on shelves, and that 40% of carers do not decide which formula product they will buy until they are standing at the supermarket shelf. Almost 30% of carers were interested in formulas that helped their child settle best, allergies and other health concerns. Friends and family, and parent forums, when looking

online, are also a principal source of information for carers seeking to buy formula. Limiting the distribution of special purpose formulas to pharmacies and other appropriate outlets may help reduce confusion for first time formula feeding carers when selecting a formula in the supermarket, and ensure advice is at hand when a special purpose formula is required.

The departments are also aware that some carers are offering their own supply of special purpose formula through social media sites, if no longer needed by their own infant.

The departments support further consideration being given to regulatory limits on access for special purpose formulas, including balancing the need for access to these products against reducing the risk of inappropriate use.

Applying limited access for special purpose formulas would be consistent with the risk management approach in the Code for Standard 2.9.5 - Foods for Special Medical Purposes (for adults). FSANZ indicates these access limitations were considered necessary given the minimally prescribed compositional requirements for these products, and to discourage manufacturers from positioning inappropriate products as FSMPs to take advantage of the less restrictive compositional requirements. FSANZ suggests that the situation for special purpose formula is different because the base composition is specified. However, it is recognised that infants requiring these products are even more vulnerable than other infants, and manufacturers have no restrictions on how they may modify formulas (and no current requirement for these to be effective). It is not clear why the rationale that applied for access limits for adults requiring special purpose products does not equally apply to those for infants. It would be inconsistent for adult medical purpose nutritional products to have greater access limitations than infant medical purpose nutritional products.

While we believe consideration should be given to access limitations that closely align with those in Standard 2.9.5, we note that since these were put in place, there has been a significant increase in online purchasing generally. The advantage of limiting access to pharmacies was the assumed guidance by the pharmacist or pharmacist's assistant. Online pharmacy sites offer for sale many special purpose products (for example, post-discharge preterm formula). Consideration should also be given to how online purchasing might be managed and what may be done to encourage interaction with the pharmacy staff for these products.

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Attachment 1

International products that present compositional modifications as marketing claims