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Submission for FSANZ Proposal 1028 Consultation Paper 3

I appreciate the opportunity to comment on Proposal 1028, Paper 3 and have consulted with my Dietitian colleagues within the Department of Nutrition and Dietetics, the Children's Hospital at Westmead, Sydney, and other colleagues working in genetic metabolic dietetics within Australasia.

We submit the following comments to questions posed in Consultation Paper 3:

Response to General Questions:

Question: How effective do you believe the current regulatory measures for IFPSDU are? How could they be made more effective? If you think the requirements should be changed to better manage risk, please explain how and why. Please provide supporting detail and data, where available.

Answer:
The current regulatory measure of IFPSDU have been effective in providing a safe range of these products to the Australian population, with appropriate nutritional composition. Given the rarity of many of the disorders that many are used for and that all the highly-specialised products (eg for management of genetic metabolic disorders, renal disorders, many gastrointestinal disorders) are imported (mainly from the EU) it is important that any change in regulations continues to allow their use in Australia and New Zealand. The importance of these products in the medical management of a wide range of disorders is emphasised by their availability on PBS in Australia. Without these products, the risk of morbidity and mortality is high.

The retail market has seen a rise in the number of products that are available for less serious conditions such as "infants with delicate tummies", "digestive discomfort", colic, reflux and "sweet dreams.". These could be said to provide more choice for parents who have concerns about their child, equally they may also increase anxiety around what is normal behaviour in an infant or delay seeking more appropriate medical / dietary treatment.

We note the classifications used in the US around products available at the retail level (which would seem to encompass the retail products mentioned above) and those only from a pharmacy or institution. However currently in Australia there is some crossover as there would appear to be in the USA.

We support the specific policy principles relevant to IFSDU in the ministerial policy guideline (P9) ie:

o) Infant formula products for special dietary uses must be safe, suitable and meet the nutritional requirements to support the growth, development and dietary management of the infants for whom they are intended.
p) The composition of infant formula products for special dietary uses should be based on appropriate scientific evidence.
q) The labelling and advertising of infant formula products should clearly specify the special dietary or medical uses for which the product is intended.

We note and support the following:

- "IFPSDU that are sole or principal sources of nutrition are proposed to be regulated as IFP, whereas other infant products that serve a supplementary role are proposed to be regulated by Standard 2.9.5. Subsequent consideration will be given to any particular provisions relevant to infant products that are needed in Standard 2.9.5 at a later stage". E.g Human milk fortifiers

The distinction between an infant formula product and an infant formula (section 4.1 and 4.2): and the need for the both is unclear. In principle, we support that an IF/IFP be defined and this also provides context to appropriate decisions on the composition of IFPSDU.

The current division in standard 2.9.1 into 3 groups of IFPSDU is however confusing and overlapping. For instance, several IFPSDU products for metabolic disorders (eg PKU, MSUD, HCU) are based on L amino acids.

Question: Do you consider that the options proposed in this paper will ensure that IFPSMP are safe, suitable and meet the nutritional requirements of the infants for whom they are intended? If not, please explain why and provide supporting data and detail, where available.

Answer
We support that Infant formula products for special dietary use/ medical purposes (IFPSDU/ IFPSMP) continue to be regulated within the infant formula standard (2.9.1) as the compositional requirements are in the main, still required. This appears more appropriate than as part of 2.9.5 (Foods for special medical purposes) given the vulnerable age group. However, it is important that some of the acceptable composition provisions for these products is not extended to all IFP eg de-classification of lactose free as IFPSDU permitting all standard formula to be lactose free, addition of MCT to any IFPSDU and removal of requirement for some micronutrients as discussed further below. These changes do not meet the ministerial policy guideline that:

o) nutritional requirements to support the growth, development and dietary management of the infants for Infant formula products for special dietary uses must be safe, suitable and meet the whom they are intended.
p) The composition of infant formula products for special dietary uses should be based on appropriate scientific evidence.

We acknowledge that the current distinctions between groups of IFLSDU overlap and support the proposed renaming of Division 4 of 2.9. Infant formula products for special medical purpose (IFPSMP) with the following definition

- serves as a substitute for human milk, and replacement of infant formula and follow on formula
- is specially formulated for the dietary management of infants based on appropriate scientific evidence
- is for infants:
  - who have special medically determined nutrient requirements, or
  - who have limited or impaired capacity to take, digest, absorb, metabolise other IFPs or excrete the metabolites of other IFPs, and
  - whose dietary management cannot be completely achieved without the use of IFPSMP

- is a food that must be used under medical supervision.

Question: How effective do you believe the options proposed for IFPSMP will be? How could they be made more effective? Do they place an unreasonable cost burden on industry to achieve and/or maintain compliance? Please provide supporting detail and data, where available.

As health professionals working with the vulnerable infants whose treatment relies on appropriate IF and IFPSMP, it is important than Food standards legislation continue to support the best product possible. De-classification of lactose free as IFPSDU and so permitting potentially all standard formula to be lactose free, addition of MCT to any IFPSDU and removal of requirement for some micronutrients potentially does not do this.

We propose, as further explained below, that:

- Lactose free products are used only for those patients for whom lactose restriction is beneficial and not potentially for all infants.
- The current restrictions on the addition of MCT remain and that there is a scientific rationale for it to included
- Micronutrients for which there is a recognized need in the Nutrient Reference Values for Australia and New Zealand (NHMRC, 2006), and in recently revised Parenteral Nutrition guidelines (AUSPEN 2021) be added to products that do not naturally contain them.

Specific Questions (section 4.3)

Question 2) Is a definition of soy-based formula needed for the purpose of food additive permissions and aluminium requirements? If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available.

Answer: continue same definition

Question 3) Is a definition of pre-term formula needed for the purpose of food additive permissions and aluminium requirements? If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available.

Answer: Yes -a definition of pre-term formula is needed. The current definition is not as explicit as it should be to guide the use of pre-term formulae and transition to standard infant formulae.

The definition should give guidance on the gestational age and birthweight detail to further clarify the definition and highlight what age/weight range pre-term infant formula is appropriate for i.e. see highlighted section below added to current pre-term definition as a suggestion.

pre-term formula means an infant formula product specifically formulated to satisfy particular needs of infants born prematurely (below 37 weeks of gestation) or of low birthweight (<2.5kg WHO definition of low birthweight)

In addition to this, guidance on when to progress from a pre-term to standard infant formulae or cease the use of pre-term formulae should be provided given the higher protein content of pre-term formula and associated long term health / obesity risk associated with higher protein provision in infant feeding i.e. consider guidance to cease use of pre-term formulae at corrected age of 37/40 weeks or above unless guided by a specialist health professional to continue its use.
Ref: Weber et al (2014) Lower protein content in infant formula reduces BMI and obesity risk at school age: follow up of a randomized trial, *Am J Clin Nutr*, 99: 1041-51.

Question 4) Are definitions needed for any of the new terms proposed to be introduced as conditions for the use of food additives in CP1, such as gastrointestinal reflux, gastrointestinal disorders, or impairment of the gastrointestinal tract, inborn errors of metabolism etc.?

Answer: given the complexity and range of the specialized formula available and the range of severity of these conditions such definitions need not be included in food standards.

We support that IFPSDU/ IFPSMP should be:

- specially manufactured and formulated in accordance with appropriate scientific evidence that demonstrates the efficacy of the product in meeting its intended purpose.

Questions related to products for metabolic, immunological, renal, hepatic and malabsorptive conditions (section 5.5.2)

Question 5) To health professionals: Is there any evidence that current practice in relation to low lactose products or the manganese content of products for metabolic, immunological, renal, hepatic and malabsorptive conditions pose a health concern or risk? If you consider that there is a health concern or risk, please provide relevant details and data, where available.

Answer:

Low lactose products

We have no concerns over the existing regulations. The compositional requirements for lactose should remain to distinguish between products and for consistency across standards and should be extended to other IFPSMP if appropriate.

Lactose free or lactose reduced formulas are most commonly used for lactose intolerance, which is most usually a short-term illness following gastroenteritis or can be longer with other gut damage or dysfunction (hence many IFPSMP are lactose free). Congenital lactose intolerance is very rare and for most infants who have only been restricted to a lactose free/ low lactose formula (rather than those with other modifications to protein or fat) then re-introduction of lactose at some stage is usually tolerated.

It should be noted that whilst a galactose free diet is required to treat galactosaemia, current Australian guidelines for galactosaemia are to use soy formula (HGSA) due to residual lactose content and potential for confusion were other lactose free or low lactose products used.
Ref: https/www.hgsa.org.au/documents/item/50

We are concerned that provisions of IFPSMP are not proposed to extend to lactose free and low lactose formula for the reasons below which could negatively impact the health of a healthy infant if lactose is removed in standard formula:

- There is scientific support for lactose in formula particularly in the provision of galactose as a nutrient and positive impact on the gut microbiome https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6893676/

- Given that formula are devised to replace breast milk, it appears inappropriate to change the carbohydrate source. All mammalian milks provided lactose. Study of function of many of the components of breast milk is still under investigation

- the potential for soft claims around easy digestion and the perception by parents that lactose free and therefore potentially a dairy free diet is “healthy”. This has potential for flow on to ongoing avoidance of dairy impacting nutritional intake, particularly calcium intake

Manganese
In regards to manganese it is important to note that many IFPSMP are imported (predominantly from Europe). There is a need to maintain FSANZ standards in line with European and possibly US standards.

AI have been set for Manganese in Nutrient reference values for Australasia but it is also a potentially toxic nutrient. It is cleared by the liver via excretion in bile (with low bile excretion increasing potential for toxicity) so it may be that this was taken into consideration for hepatic and gastrointestinal products. However, that is supposition.

AUSPEN have recently reviewed trace mineral levels in parenteral solutions and commented on manganese.
https://custom.cvent.com/FE8ADE3646EB4896BCEA8239F12DC577/files/c87e9123ac5b4eca860514b4c9925e94.pdf

Questions related to products for specific dietary use based on a protein substitute (section 5.5.3)

Question 8) To health submitters: You have told us that partially hydrolysed IFP are not efficacious in preventing allergy; are they useful in the dietary management of allergy? Please provide supporting detail and data, where available.

Answer
We support that partially hydrolysed IFP are not efficacious in preventing allergy. They are also not useful in the dietary management of allergy.

Prevention of Allergy
The Australian Society of clinical allergy and immunology (ASCIA) have published the following in their infant feeding guideline **(**https://www.allergy.org.au/hp/papers/infant-feeding-and-allergy-prevention)**:**

- Based on a recently published review of studies, there is no consistent convincing evidence to support a protective role for partially hydrolysed formulas (usually labelled 'HA' or Hypoallergenic) or extensively hydrolysed formulas for the **prevention** of eczema, food allergy, asthma or allergic rhinitis in infants or children.

The review of studies referenced above is: https://www.bmj.com/content/352/bmj.i974

Dietary Management : partially hydrolysed formulas are not recommended in the dietary management of Allergy:

1. Partially hydrolysed formulas are definitely not suitable in the dietary management of allergy. Giving these formulas would be dangerous for an infant with cow's milk allergy (IgE mediated) with anaphylaxis or at risk of anaphylaxis to cow's milk. The only formulas that would be considered safe to give are amino acid infant formulas, soy formula (if >6mths) or a rice based formula.

2. Partially hydrolysed formulas are not safe to use in the management of infants with Non-IgE mediated cow's milk allergy. The proteins in these formulas are not broken down sufficiently to alleviate the symptoms of the condition and put a child at risk of poor growth due to on-going symptoms. Suitable formulas would be extensively hydrolysed infant formulas, soy formula (>6mths) or rice based formulas. Amino acid formulas are also suitable and would be a second or third option to be determined by a Paediatrician in consultation with a Paediatric allergist and immunologist or Paediatric gastroenterologist

References to support this statement:

1. https://www.mja.com.au/journal/2008/188/2/guidelines-use-infant-formulas-treat-cows-milk-protein-allergy-australian These guidelines have been updated by ASCIA:
2. https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Guide_CMA_Milk_Substitutes_2020.pdf
3. Diagnostic Approach and Management of Cow's-Milk Protein Allergy in Infants and Children Journal of Pediatric Gastroenterology and Nutrition: August 2012 - Volume 55 - Issue 2 - p 221-229. doi: 10.1097/MPG.0b013e31825c9482
4. Diagnostic Approach and Management of Cow's-Milk Protein Allergy in Infants and Children: ESPGHAN GI Committee Practical Guidelines. JPGN 2012;55: 221–229

Questions related to specific compositional requirements (section 5.5.3)

Question 9) Regarding options for the regulation of molybdenum and chromium, which option do you prefer and why? Please provide supporting detail and data, where available.

Answer:
The background paper notes that "Molybdenum and chromium content is not and is not proposed to be regulated in IF on the assumption that sufficient amounts are provided naturally but the product ingredients. The permission for addition of molybdenum and chromium does not apply to pre-term and metabolic etc. formula for the same reason. However, general protein ingredients are not used in protein substitutes based on amino acids."

It should be pointed out however that metabolic products for use in management of inborn errors of metabolism are also based on amino acids. These are currently supplemented with chromium and molybdenum (eg PKU Anamix infant, MSUD Anamix infant).

We support therefore option 1 on the basis of dietary requirements as outlined below:

1. Retain current mandatory requirement to be met naturally and/or through addition for protein substitutes – status quo

Both chromium and molybdenum have recommended Adequate intakes for infants in Australasia (NHMRC). It is therefore appropriate that these are added to infant formula within recommended amounts, if they are not naturally present, particularly given the formula may well be the sole source of nutrition for the infant.

While information on deficiency is limited for both of these nutrients, it has however been documented in long term parenteral nutrition in adults. It is recommended as a component of parenteral nutrition solutions for infants – see ref:
https://custom.cvent.com/FE8ADE3646EB4896BCEA8239F12DC577/files/c87e9123ac5b4eca860514b4c9925e94.pdf

Retaining current mandatory requirements under the proposed definition of IFPSMP under division 4 should ensure all IFPSMP whatever the previous group they were in meet requirements for these micronutrients. As previously noted the current division in standard 2.9.1 into 3 IFPSDU is confusing and overlapping given that several IFPSDU products for metabolic disorders (eg PKU, MSUD, HCU) are based on L amino acids.

Question 11) To health submitters: Are there any health concerns from current practice using products that contain MCT oil? Please provide supporting detail and data, where available.

Answer
Products containing MCT oil are extremely useful clinically in products for which there is a scientific

basis for use eg those for malabsorption, fatty acid oxidation disorders, chylothorax). This is in line with IFPSMP being:

- specially manufactured and formulated in accordance with appropriate scientific evidence that demonstrates the efficacy of the product in meeting its intended purpose.

MCT should however only be used where needed - being a saturated fat it may dilute out sources of essential fatty acids. There is no benefit for an infant with PKU for instance to have MCT in their formula compared to the fats used in standard formula – the fat composition should be in line with standard formula.

While breast milk does contain a small component of MCT fats unless this is considered a beneficial addition to all standard formula there is no rationale for it to be included in all IFPSMP.

Questions related to extension of use beyond infancy for IFPSMP (section 5.6.2)

Question 14) What is the maximum labelled age on products suitable for use beyond infancy? What are the parameters that indicate when the product is no longer appropriate?

Answer
We acknowledge that IFSPDU/ IFPSMP are used beyond infancy and that this should continue to be accommodated. Patient care will be compromised if this could not be continued and multiple case studies can be provided if required. An example is the use of Monogen for both infants and young children for inborn errors of metabolism and chylothorax. There is no maximum age that is appropriate for label but should be at the discretion of the health professional. In practice, however FSMP are labelled with an appropriate age range for which the product was designed.

Ideally IFPSDU should continue to be labelled as infant formula. However this would deny access to some products used over a wide age range eg Monogen. Consideration could be given to the addition of labelling for locally made products, along the lines of: "discuss the use of this product beyond infancy with your health professional "

Question related to labelling of IFPSMP (section 5.7)

Question 15) Do you support FSANZ's preliminary views for IFPSMP labelling? Why or why not? Please provide supporting detail and data for your position, where available.

Answer:

1. **Lactose free and low lactose free formula:**

We respectively disagree with the discussion and assumptions that lactose free IFP are suitable for all infants while special purpose formulas are not. There are many IFPSMP that meet the full nutritional requirement for an infant with modification to type of protein or fat. In the case of lactose free formula the modification is to the lactose. As discussed earlier there is evidence that lactose is a beneficial source of carbohydrates for infants and should not therefore be restricted unnecessarily.

Thus we recommend that IFPSMP labelling provisions should apply

2. **Distribution and access**

The rationale for FSANZ's preliminary views in relation to distribution and access to IFPSMP are:

- Supermarket sales of IFP will be restricted to general IF.
- Access to IFPSMP will be restricted to those medical practitioners, responsible institutions, or permitted sellers (to be defined in the Code, similar to Standard 2.9.5).

This would support that modifications be supported by evidence and appropriate advice be provided re use. However, it will be important to establish guidelines around labelling for IF and the use of such terms as “sensitive tummies” “unsettled babies”

There is currently some overlap between those products listed on PBS and availability in supermarkets - eg some low lactose formula and Aptamil Allerpro are available in Woolworths in NSW. An alternative would be to allow those less specialised products to be available in the supermarket, although this creates difficulties on how this is regulated.

3. Labelling of IFPSMP

We support FSANZ preliminary view that current labelling provision for IFPSDU be replaced by Subsection 2.9.5—10(1) FSMP advisory or warning statements, **except that these should also apply to low lactose and lactose free formula:**

(a) a statement to the effect that the food must be used under medical supervision
(b) a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food
(c) a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated
(d) a statement describing the properties or characteristics which make the food appropriate for the medical purpose
(e) if the food has been formulated for a specific age group—a statement to the effect that the food is intended for persons within the specified age group
(f) a statement indicating whether or not the food is suitable for use as a sole source of nutrition

Ideally the age range should be front of pack so that it is very clear if it is suitable for infants or pre-term infants. However this would eliminate some products used over a wide age range eg Monogen. An alternative would be to allow age range labelling to comply with European or United states requirements if the product is imported but ensure clear labelling for locally made products (as per ingredient listing). The proposed management of ingredient listing is considered to be appropriate.

4. Removal of breast is best requirement

Within the medical conditions that IFPSMP are used for and within individualised management of disorders, there are many infants who can be fed a combination of breast milk and IFPSMP. However for some conditions patients may be advised to limit breastmilk.

The “breast is best” statement is potentially upsetting to families with children with medical conditions that require limiting breastfeeding. It could it be modified to say “For most babies, breast is best – check with your health professional about the advice for your child” on products produced in Australia or New Zealand. For imported products CODEX or US requirements should be followed

5. Statement about offering of other food.

It is appropriate for this to comply with European or US regulations given the range of IFPSDU and number of imported products

6. Statement that the infant formula may be used from birth

The required statement in the proposed IPSMP labelling:

“if the food has been formulated for a specific age group—a statement to the effect that the food is intended for persons within the specified age group”
appears to negate this requirement