FSANZ Consultation Paper -Proposal P1028

– response from Dept of Nutrition and Dietetics, The Children's Hospital at Westmead, Sydney

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Summary

The Paediatric Dietitians at the Children's Hospital at Westmead, Sydney welcome the opportunity to comment on this proposal, recognising the need for standards for infant formula that currently fall outside the Infant Formula regulations. There are issues around composition, labelling and access. Given that many products are imported, it is essential for ongoing supply that standards align particularly with European and US standards. We suggest that all modified products should be covered by a definition aligned to Foods for Special Medical Purposes (standard 2.9.5). There is considerable overlap in the 4 divisions proposed under infant formula for special dietary use and we believe that all modified formulas need to be covered by standards to protect this vulnerable group of consumers. There may also need to be clarification of what is included in an infant formula product in this category given that several products are not suitable for use as a sole source of nutrition.

We propose the following definition for all modified products
Infant formula product for special medical purposes means an infant formula product for special dietary use, to be used under medical supervision, that is specifically formulated for infants who have
(i) medically determined nutrient requirements, or
(ii) limited or impaired capacity to take, digest, absorb, metabolise or excrete food or certain nutrients contained therein, or metabolites including another type of infant formula product
The product may or may not be suitable as the sole source of nutrition.

Please see below for responses to individual questions posed in the proposal.

Q1 Alignment with international regulations – given that many FSMP are not produced in Australia or New Zealand and Australasian alternatives are not available it is crucial that Australasian food Standards should not restrict products that meet appropriate international food standards. In attempting to align with Codex (EU) and USA, FSANZ is recognising this. Is it useful to outline which countries do not have Food Standards that FSANZ sees as similar? Where for instance do Food standards in Japan, China, India sit?

Q2 The proposed frame work suggests creating 4 divisions under infant formula for special dietary use:

- products for special dietary use based on a protein substitute
- Products for transient gastroenterological conditions
- Products of premature or low birthweight infants
- Products for special medical purposes

In commenting on this proposed framework there are several issues:

- Whether the product could do harm to the general population – that is true of many infant formulas for metabolic, immunological, renal, hepatic and malabsorptive conditions, and potentially preterm formula which can be depending on their composition be suboptimal as a formula for healthy full term, normal weight infants. It is less likely (except perhaps in delaying appropriate management) in the first 2 categories.
- The making of health claims. The current lack of standards to cover formula currently modified for specific disorders, potentially can or could result in inappropriate labelling. Under Standard 1.2.7 health claims are not allowed on infant formula, but there are products sold online through pharmacies that make health claims. Presumably these are not being used under medical supervision, although to be making the claims they do they are presumably viewed in the manufacturers mind as foods for special medical purposes.
- Availability of some of these products online
- How are products to be categorised between the products for transient gastroenterological conditions and products for special medical purposes. There is also considerable overall between category 1 (protein substitutes) and 4 (special medical purposes)

All modified formula need regulation and all categories could all be included within Products for Special Medical Purposes. The formula range in these categories from those available on prescription, to formula available over the counter for issues such as gastro intestinal reflux or constipation. While the use of many of these products is well supported by scientific evidence, those marketed for transient gastrointestinal conditions may be less so.

If a health claim is made by naming a medical condition for which this product can be used, then the product is surely a food for special medical purposes. It should be necessary for products to be appropriate for the conditions they claim to treat. By separating out the transient gastroenterological conditions it may give them legitimacy that may or may not be appropriate, unless in coming under the general standards, they are unable to make a health claim.

Whilst infant formulas for special diet/medical purposes best fit under 2.9.1, it is important to maintain a link to 2.9.5 given that several of these products are used after 1 year of age.

Of relevance and this should perhaps be clarified in the new standard – the statement (1.5) that FSMP and IFPSDI are not used to treat or cure disease state is an oversimplification of current treatment uses, although useful from a regulatory point of view.

Q3 and 4

There is considerable overlap in the definition of Infant Formula Products for special dietary use and the infant formula for special medical purpose. It is unclear why both definitions are needed.

It is important that all modified infant formula are captured under the code to allow enforcement around composition and claims. This includes both those used as a sole and partial source of nutrition and long term/ short term use.

It seems more appropriate to simplify the proposed 2 definitions to one in line with EU definition:

Infant formula product for special medical purposes means an infant formula product for special dietary use, **to be used under medical supervision**, that is specifically formulated for infants who have
(i) medically determined nutrient requirements, or
(ii) limited or impaired capacity to take, digest, absorb, metabolise or excrete food **or certain nutrients contained therein, or metabolites** including another type of infant formula product

It is important to include: "or certain nutrients contained therein, or metabolites". At a cellular level we do not metabolise or excrete "food".

It will be necessary to re-define infant formula product in this context. The current definition of infant formula product in 2.9.1 is" ***infant formula product*** means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant" There are several infant formula products for special medical use that do not meet this category eg several infant formula for metabolic conditions are designed to be used in conjunction with breast feeding or standard infant formula to provide sufficient intake of the nutrient/ metabolite that is affected eg phenylalanine in PKU. The specialised infant formula is nutritionally inadequate if used as a sole and sometimes principal liquid source of nourishment. The same is true for several products used for preterm infants eg human milk fortifier, which should be captured.

Q5 and 6

Infant formula based on a protein substitute are used for a range of metabolic, immunological, renal, hepatic and malabsorptive conditions (foods for special medical purposes). The definition should not therefore relate to reducing/ preventing/ managing allergy or hypersensitivity reactions.

The definition is important only in regulating composition .

In any terminology used it is appropriate that names align with those used in prescribing under PBS.

Q7 and 8.

Preterm formula should be included under foods for special medical purposes under medical supervision. Inclusion of age and weight categories would then be inappropriate in a food standard.

It is true that some preterm products (eg human milk fortifiers) may not currently meet the definition of an infant formula product as they may not "serve as the sole or principal liquid source of nourishment for infants". However if preterm products are captured under a special medical purposes definition this would not be an issue.

Q9 It is appropriate that human milk fortifiers be captured under Foods for special medical purposes, and to be used under medical supervision.

We are not aware that these are used other than for premature or low birth weight infants but if not controlled under the code there is perhaps potential for them to be used more widely

Q10 and 11 Prescribed names for IFSDU is complicated if there are 4 separate categories within that particularly given that many that would fit under foods for special medical purposes would also be protein substitutes. Given that many products are imparted in small quantities eg those for metabolic disorders requiring a prescribed name other food for special medical purposes could potentially limit supply.

In any terminology used it is appropriate that names align with those used in prescribing under PBS

Q12

It is appropriate that compositional requirements are based on standard formula as per EU and USA regulations.

There is some research to suggest that protein utilisation from amino acids is lower than from complete protein so there is some justification for slightly higher protein content of formulas for use in metabolic disorders of protein metabolism (Ref Van Spronsen FJ, et al. Key European guidelines for the diagnosis and management of patients with phenylketonuria. Lancet. 2017; online Jan;DOI.10.1016/s2213-8587(16)30320-5) , along with changes in amino acid content to suit the particular disorder. Depending on the final protein content range for standard infant formula, this may need special provision. Energy content should be within standard ranges for infant formula Premature and low birth weight formula also appropriately may have a higher energy and protein content and this should be acceptable under the new code.

Q13

It is appropriate that compositional standards for all infant formula are based on requirements ie NRV or any updated information. For instance it is feasible that micronutrient levels could be different in a plant based protein compared to cows milk. It is irrelevant whether the micronutrient is added or is contained as part of the protein source. The availability of the nutrient is also important, as is the content of natural constituents.

Note:
The recent paper by Gonzalez Ballesteros et al " Unexpected widespread hypophosphatemia and bone disease associated with elemental formula use in infants and children"
http://dx.doi.org/10.1016/j.bone.2017.02.003

There is ongoing debate about the use of soy formula for younger infants eg Concern in UK about phytoestrogen content of soy formula in infants <6months Chief Medical Officer Update 37. *Soy Formula*. London: Department of Health, 2004.
Other discussion articles include: 'Exposure to Soy-Based Formula in Infancy and Endocrinological and Reproductive Outcomes in Young Adulthood'; Brian L. Strom et al, JAMA, Aug 15, 2001-Vol 286, No. 7, p807-814
Cara J. Westmark Soy-Based Therapeutic Baby Formulas: Testable Hypotheses Regarding the Pros and Cons Front Nutr. 2016; 3: 59.
Published online 2017 Jan 18. doi: 10.3389/fnut.2016.00059

PMCID: PMC5241282

Q14

See Q12

Q15 It goes without saying that there should be scientific rationale for any variations to the standard composition. All ingredients should be safe. For products that are prescribed on PBS, this is part of the process in accepting them for listing. Including an assessment process for IFPSDU products is appropriate.

Q16
Requirements should be guided by review of current literature and scientific opinion, (given that Australasian NRVs not updated since 2006), and the appropriateness of levels of micronutrients in current formula and breast milk

Q17 No information, for general principles see response to Q13 and 16

Q18 No information, for general principles see response to Q13 and 16

Q19 Given that many specialised products are imported it is appropriate that products that meet EU regulation are not excluded. It seems appropriate to that FSANZ consider permitting a broader range of food additives consistent with EU and Codex regulations to allow for the broader technological needs of IFPSDU.

Additional or modified subcategories appears to over- complicate the issue.

Q20 -23 no comment

Q24 Renal Solute Load

Osmolality and renal solute load are different and important measures. It is appropriate to maintain the current recommendations on renal solute load but there perhaps should be consideration on standards around osmolality as well (perhaps in vulnerable groups such as preterm, malabsorption)

Q25
At Children's Hospital at Westmead, preterm and LBW formula are only used for inpatients. Patients are not discharged on these products. The products are labelled hospital use only so are used under

dietetic supervision for appropriate patients. We have however come across patients from other hospitals discharged with a supply of these products

We support the conclusion from the 2016 Cochrane review: Nutrient-enriched formula versus standard infant formula for preterm infanys following hospital discharge. It was concluded that preterm and LBW formuals are not required following hospital discharge.

Q26 There needs to be a balance between adequate labelling and maintaining supply of overseas products. However preterm/ LBW formula and human milk fortifier should be classed as a food for special medical purposes so that medical supervision is provided and access is limited.

If pre-term products became more readily available, the name of the product and "to be used under medical supervision" must be clear enough to differentiate these products from standard formula.

Q27 The labelling requirements of Section 9.6 Codex STAN 72-1981 and Codex STAN 180-19919 are appropriate for IFPSDU infants with metabolic, immunological, renal, hepatic or malabsorptive conditions.

Q28 Combining all categories in one would clarify labelling requirements for all. Any product that can not be used as the sole source of nutrition should have this stated on the packaging.

Q29 Not aware of any

Q30

Not aware of inappropriate access to IFPSDU except for previously raised concerns about preterm/LBW formula being used after discharge and availability of modified formula for constipation, reflux etc being available online through chemists. This latter access is a loophole in the use under medical supervision.

The modified formula range for colic, constipation and relux are in breach of the current food standard:

20 Prohibited representations

(1) The label on a package of infant formula product must not contain –

(g) subject to Division 3, a representation that the food is suitable for a particular condition, disease or disorder.

Cost of many of the specialised formula limits their use and the assessment process by the PBS reviews appropriateness and nutritional composition.