Consultation Paper - P1028 Regulation of Infant formula – Infant formula products for special dietary use

Submission by SA Health (Department for Health & Ageing)

28 September 2017

SA Health welcomes the opportunity to comment on the Consultation paper – Proposal P1028 Regulation of Infant formula – Infant formula products for special dietary use. SA Health has approached consideration of the issues raised in the Consultation paper with the aim of

- Supporting relevant components of the Ministerial Policy Guideline for the *Regulation of Infant Formula Products*
- Achieving consistency or compatability with Codex and the EU regulations relevant to infant formula products for special medical purposes.

Q1 Are there any other overseas regulations relevant to IFPSDU?
SA Health is not aware of any other relevant regulations.

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 pre-term products be included?

Option 1
SA Health supports the Option 1 approach to delete the current subcategories in Division 4[1], noting that this is the option most consistent with Codex (and EU) regulations. As such this supports the expectation within the Ministerial Policy Guideline for the *Regulation of Infant Formula Products* that 'the regulation of infant formula products in Australia and New Zealand should be consistent to the greatest extent possible with Codex standards and guidelines'.

SA Health suggests further exploration of the concern raised by FSANZ that Option 1 would not assist in differentiating product to manage the higher risk associated should a healthy infant consume a highly specialised product. Current access to many IFPSDU is restricted either by prescription (e.g. formulas on PBS include those for metabolic, renal, gastro, allergy), prohibitive costs, and/or only available from health care services or pharmacies (e.g. Novalac range (including Rice), Aptamil, Allerpro are not on PBS). If a revised Standard 2.9.1 ensures access to IFPSDU is restricted (this would be in line with Standard 2.9.5 Foods for Special Medical Purposes, (see Division 2 below), then the above concern should not eventuate.
Division 2: Sale of food for special medical purposes requires

- Restriction on the persons by whom, and the premises at which, food for special medical purposes may be sold. A food for special medical purposes must not be sold to a consumer, other than from or by:

(a) a medical practitioner or dietitian; or
(b) a medical practice, pharmacy or responsible institution; or
(c) a majority seller of that food for special medical purposes.

[1] The existing three categories under Division 4 – IFPSDU are:

1. Products for specific dietary used based on a protein substitute
2. Products for metabolic, immunological, renal, hepatic and malabsorptive conditions
3. Products formulated for premature or low birthweight infants.

Impacts to a proposed new arrangement for sale of infant formula products for special medical purposes will require further exploration; however SA Health considers this would encourage evidence based formulas being available only under medical supervision for medically determined conditions. SA Health is aware there are number of formulas available in supermarkets (e.g. lactose free, soy, AR, Comfort, A2, HA, Goat) and therefore accessible for purchase by well-intended parents to feed their infant for 'conditions' that have not been medically diagnosed, and/or may not have strong evidence of effectiveness. These issues of appropriate classification (general formula vs infant formula products for special medical purposes) and subsequent access will need further consideration.

Further in support of the Option 1 approach, SA Health supports the reframing of existing Division 4: *Infant formula products for special* ***dietary use*** to *Infant formula products for special* ***medical purposes***; see Q3.

Option 2

SA Health does not support Option 2 to retain the three present categories[1], with "potentially transferring products for transient gastroenterological conditions or the partially hydrolysed protein formula into general infant formula based on the low risk to a healthy infant from consumption of these products".

- SA Health considers that IFPSDU are intended for infants with a medical condition under medical supervision; hence it is appropriate that such products be captured under an 'infant formula products for special medical purposes' category. While the above mentioned formulas may be low risk to healthy infants, they have been designed for medical conditions and should be captured and labelled as such.

Option 3

SA Health does not support Option 3 to 'Divide the second subcategory 'products for metabolic, immunological, renal, hepatic and malabsorptive conditions' to better reflect the range of products on the market, with the creation of a new subcategory of infant formula products for special medical purposes (IFPSMP) within the IFPSDU Division'.

- SA Health considers that 'compositional flexibility and labelling consistent with their risk' can still be achieved in a revised Standard 2.9.1 without any sub-categories (as per the Option 1 approach).
- The Option 3 approach for IFPSDU subcategories is inconsistent with Codex and the EU regulations.

SA Health reaffirms that all IFPSDU are only appropriate under medical supervision for medically determined conditions where breast milk or general infant formula is not suitable. If there were to be subcategories, labelling requirements should be consistent across all sub-categories; stating for use under medical supervision and the medical condition(s) the product is specifically designed for. Different statements depending on 'level of risk' would be problematic given some IFPSDU may be used for both 'less serious' and 'more serious' conditions.

Q3 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?

SA Health supports the inclusion of a single overarching category definition of *infant formula products for special* ***medical*** *purposes (*rather than for *special* ***dietary*** *use).* This terminology would be consistent with that used in Codex and the EU regulations.

Subsequently, SA Health proposes a potential definition (below) for IFPSMP, which combines elements of the definition proposed for IFPSDU and IFPSMP sub-category (pages 17-18 of the Consultation Paper), and Paragraph 5 of the EU Commission Delegated Regulation 2016/128 supplement to EU Regulation 609/2013 regarding the specific composition and information requirements for food for special medical purposes.

- Paragraph 5 states the importance of setting "principles and requirements" in order to ensure that food for special medical purposes are "safe, beneficial and effective for the persons for whom they are intended on the basis of generally accepted scientific data".
- This is reflected in part b) of the below proposed definition, and supports policy principle (p) within the Ministerial Policy Guideline for the *Regulation of Infant Formula Products* that 'the composition of infant formula products for special dietary uses in Australia and New Zealand should be based on appropriate scientific evidence.
- It would also be consistent with the requirement for high level health claims to be substantiated by evidence; given IFPSMP are required to clearly specify on the label the medical use for which the product is intended, it is appropriate that such products are also required to be substantiated by evidence.

<u>Modified definition for overarching category re: Infant formula products for special medical purposes</u>

Infant formula product for special medical purposes means an infant formula product that is
a) specifically formulated for infants to satisfy, either partially or fully, the special nutritional requirements for infants who have medically determined
(i) nutrient requirements, or
(ii) limited or impaired capacity to take, digest, absorb, metabolise or excrete food including another type of infant formula product;
b) safe, beneficial and effective for the medical condition of the infant based on generally accepted scientific data;*
(c) to be used under medical supervision.

SA Health considers the definition suggested above covers the special dietary needs referred to in the Ministerial Policy Guideline for the *Regulation of Infant Formula Products*, i.e. premature or low birth weight infants; infants with metabolic, immunological, renal, hepatic and malabsorptive conditions. It also covers the range of infant formula products (including human milk fortifiers) and conditions described in Figure 1 (page 15 of the Consultation Paper) for those shown to be beneficial and effective for infants based on generally accepted scientific data.

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?

- SA Health does not support a subcategory definition for IFPSMP; rather IFPSMP should be the overarching term and definition as outlined in Q3 above.

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

- In line with SA Health's support for Option 1 for an over-arching category definition of *infant formula products for special **medical** purposes* without specific sub-categories, SA Health does not see a need to define protein substitutes.
- SA Health also notes protein substitutes are not defined in Codex or the EU regulations; however prescribing protein sources (as per the EU regulations) could be further considered.

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?

- In line with SA Health's support for Option 1 for an over-arching category definition of *infant formula products for special **medical** purposes* without specific sub-categories, SA Health does not see a need or benefit to defining the above formula types. In addition, other nutrients in these products may also be modified.

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

- In line with SA Health's support for Option 1 for an over-arching category definition of infant formula products for special medical purposes without specific sub-categories would capture all IFPSMP including pre-term products. Therefore SA Health does not see a need or benefit to defining pre-term products.

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

- Paediatric dietitians from SA Health's Women's and Children's Hospital (WCH) advise no benefits of including age and weight parameters in the regulatory definition, and on the contrary – confusing- to have age and weight parameters. In practice the decisions are based on clinical need, not just age and weight.

Q9 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?

- Paediatric dietitians from SA Health's Women's and Children's Hospital (WCH) use human milk fortifiers for premature and low birthweight infants for a defined period until the infant reaches 2.5kg as the usual practice.
- Alternative fortifying products may be used: Polyjoule, Calogen, Duocal, and Protifar (protein) may used in breast milk and formula; breastmilk fortified with standard infant formula may be used for a preterm baby approaching term.

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

and

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

- In line with SA Health's support for Option 1 for an over-arching category definition of *infant formula products for special **medical** purposes* without specific sub-categories, SA Health supports the prescribed name for all infant formula products for special medical purposes to be compatible with Codex and the EU, for example 'formula for special medical purposes intended for infants'. The ability for consumers to clearly distinguish these products from general infant formula products is important. The prescribed name requirement is then complimented by the accompanying labelling requirements required by the current Standard 2.9.1 (and further considered at Q26-29).
- SA Health does not see a need for prescribed names for IFPSDU subcategories.

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?

- SA Health does not have a firm view at this stage.

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?

- SA Health does not have a firm view at this stage and needs more consideration. Paediatric dietitians from SA Health's Women's and Children's Hospital (WCH) note the need to consider that hydrolysed protein may be metabolised differently and might need to be higher compared with complete protein requirements.

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?

- SA Health does not support the creation of a new subcategory of FSMP, therefore do not think specific compositional requirements are needed.

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?

- SA supports this requirement as essential given vulnerability of infants; it is critical that IFPSDU are evidence based given they are for SMP and may be the sole source of nutrition for infants.
- As outlined in Q3, SA Health proposed a potential definition for IFPSMP, which supports
    - policy principle (p) within the Ministerial Policy Guideline for the *Regulation of Infant Formula Products* that 'the composition of infant formula products for special dietary uses in Australia and New Zealand should be based on appropriate scientific evidence';
    - the EU regulation principles and requirements in order to ensure that food for special medical purposes are "safe, beneficial and effective for the persons for whom they are intended on the basis of generally accepted scientific data".
- The above mentioned requirement would also be consistent with the requirement for high level health claims to be substantiated by evidence; given IFPSMP are required to clearly specify on the label the medical use for which the product is intended, it is appropriate that such products are also required to be substantiated by evidence.

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

- The current review of nutritive substances needs to be finalised prior to finalisation of P1028 to ensure that IFPSMP are protected and that all substances added to these products are pre-market assessed.

Q17-23

- SA Health has no information to provide.

Q24 Do you support retaining a maximum PRSL (potential renal solute load) for any IFPSDU? Please provide your rationale.

- Paediatric dietitians from SA Health's Women's and Children's Hospital support retaining the PRSL for all INFSDU. PRSL is important information for many unwell infants where minimising extra burden on kidney function is an important consideration.

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

- Paediatric dietitians from SA Health's Women's and Children's Hospital (WCH) report that pre-term infant formula is rarely used post hospital discharge, and is supplied through the WCH pharmacy.
- However, the more likely practice is to manipulate a term formula.

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.

- SA Health supports the requirement for a statement that the product must be used under medical supervision where the wording is not prescribed, but recommends required elements as per the current Standard 2.9.1 – 14 (2):
  (c) that the product is not suitable for general use and should be used under medical supervision; and
  (d) the condition, disease or disorder for which the product has been specially formulated and
  (e) the nutritional modifications, if any, which have been made to the product.

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?

Yes, SA Health supports the following labelling requirements for all infant formula products used for SMP

- that the product is not suitable for general use and should be used under medical supervision; and
- the condition, disease or disorder for which the product has been specially formulated and the nutritional modifications, if any, which have been made to the product. Such information should appear on the back of the container, and not be allowed on the front, which could be perceived by consumers as a marketing tactic.

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?

- Consider whether this needs to be expanded for the example of the addition of human milk modifiers to breast milk.

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

- SA Health's paediatric dietitians have raised that the ability to order infant formulas by on-line retailers (not formula manufacturers) is an issue, meaning the carer may not get the interaction/advice with pharmacy staff (which formula companies do support the importance of). Hence inappropriate formula may be ordered. Issues with the quality of the online product information from the retailer

have also been noticed anecdotally, which may encourage use of the product over breastfeeding.