SUBMISSION FROM SA HEALTH

31 May 2016

Consultation Paper - Proposal P1028 – Infant Formula

SA Health welcomes the opportunity to respond to FSANZ's preliminary assessment of a broad range of issues related to infant formula. SA Health notes the objective of this Proposal is to revise and clarify standards relating to infant formula in the Code, and to consider the application of Ministerial policy guidance on the regulation of infant formula products, and alignment with international regulations.

SA Health's comments are focussed on issues raised in supporting documents SD2 and SD3, and include the views of staff working in public health nutrition, food standards and development, and paediatric dietitians at SA Health's Women's and Children's Hospital.

SD1: Definitions and Nutrient Composition

Q1.2 Which of the following options to amend the definition (b) of infant formula in the revised Code "satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months" provides greater clarity on the role and scope of infant formula?

(1) "satisfies by itself the nutritional requirements of infants less than 6 months of age"
(2) "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding "
(3) Option 1 or 2 followed by and, as part of a progressively diversified diet, of infants from 6 months of age
(4) no change

SA Health suggests the following amended definition of infant formula to provide greater clarity on the role and scope of infant formula; this suggested definition is a combination of option 2 and 3 but modified to reflect the NHMRC Infant Feeding Guidelines[1] advice encouraging exclusive breastfeeding to *around* six months of age, and that from 12 months infant formula is no longer required as the main drink and can be replaced by full fat cow's milk (or other suitable milk alternatives):

> "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding at around 6 months of age, and as part of a progressively diversified diet until 12 months of age".

[1] National Health and Medical Research Council (2012) Infant Feeding Guidelines. Canberra: National Health and Medical Research Council

SD2: Safety & Food Technology

Section 3: Preparation, use and storage directions to manage microbiological hazards

3.2 Directions to prepare bottles individually

SA Health supports FSANZ's preliminary view that it is appropriate to retain the labelling requirement that each bottle should be prepared individually, in line with national and international guidelines noted in SD2.

3.3 Directions for the storage of made up formula

SA Health supports FSANZ's preliminary view to maintain the status quo of the current standard in relation to labelling directions about refrigerated storage of made up formula at 4°C or less, and use within 24 hours.

FSANZ could consider seeking feedback from CALD caregivers, and low literacy and numeracy caregivers, in regard to the labelling legibility of written and pictorial advice for safe and correct preparation and storage, and ways that this could be improved as per issues highlighted in Q3.17 regarding a consistent approach to format across product labels to assist consumer understanding.

3.4 Directions on water used to reconstitute powdered infant formula

SA Health supports FSANZ's preliminary view to maintain the status quo of the current standard in relation to using cooled previously boiled water to make up infant formula.

3.5 Discarding leftover formula

SA Health supports FSANZ's preliminary view to maintain the status quo of the current standard in relation to the labelling provision to include words and pictures in the directions for the preparation and use of infant formula instructing that formula left in the bottle after a feed must be discarded.

3.6 Standardised directions for preparation and use

SA Health suggests FSANZ consider seeking additional caregiver feedback (including those from CALD backgrounds and those with low literacy/numeracy) about their understanding of the varying words and pictures on infant formula from different manufacturers, and whether there is a need to standardise this information (including the discarding of leftover formula) to improve understanding for caregivers. SA Health paediatric dietitians are of the view that standardised and simplified words and pictures, and use of larger pictures and font could be beneficial to CALD caregivers or those with low literacy/numeracy. Tin space for larger pictures and font would be possible in the absence of line marketing/promotion on the back of tins for 'stage 1, 2, 3' products from the manufacturer.

Section 4: Other safe preparation and storage issues

4.1 Date marking of food

SA Health supports FSANZ's preliminary view to maintain the status quo of the current standard in relation to the requirement for date marking to appear on infant formula.

4.2 Storage instructions for opened infant formula

SA Health supports FSANZ's preliminary view to maintain the status quo of the current standard in relation to the requirement for storage instructions covering the period after the infant formula product has been opened.

4.3 Measuring scoop

SA Health paediatric dietitians noted that while there are few reported case studies about using the wrong measuring scoop, it does happen anecdotally, and are of the view that there should be mandatory use of the wording *only the enclosed scoop should be used* on infant formula.

SA Health would like to see further consideration of this issue in proceeding consultations, including consumer feedback about differing scoop sizes (and differing ratios of formula to water) across infant formula brands from caregivers of CALD backgrounds, those with low literacy and numeracy, and from low socioeconomic backgrounds.

Section 5 – Warning, advisory and other statements

5.1 Legibility requirements for warning statements

To inform proceeding consultations as part of the review of standard 2.9.1, SA Health suggests that if FSANZ were able to seek further views from consumers of a range of backgrounds (including low literacy and numeracy) on a number of labelling issues relevant to infant formula, this issue could also be included for their feedback.

5.2 Adding other foods to formula

Q2.3 What evidence can you provide that could be used to estimate the prevalence of the practice of caregivers adding other foods to infant formula in Australia and New Zealand?

SA Health only has anecdotal evidence of caregivers adding other foods to infant formula. SA Health's Child and Family Health (C&FH) report their nurses are aware this may happen as part of cultural practices of certain families, however do not observe it directly in home visiting situations. C&FH nurses emphasise with caregivers the recommended practices for formula feeding in the situation where an infant is formula fed, along with the recommended age for introduction of solids (including signs of readiness).

Q2.5 What evidence can you provide that caregivers add other foods to infant formula to reduce the cost of the feed?

SA Health does not have evidence of this practice but acknowledges the risk factors for it are present in the community, i.e. low income families who may experience food insecurity and where tight food budgets may have the additional pressure of having to purchase infant formula for infants who are not breast-fed.

Q2.6 What evidence can you provide that demonstrates that caregivers have difficulty finding protein source information on the labels of infant formula, and that this affects their ability to make an informed choice? AND Q2.7 What evidence can you provide

that demonstrates consistent placement of the statement of protein source on the label would provide a benefit to caregivers?

SA Health can provide no evidence in relation to caregivers and the placement of protein source information.

Q2.8 If so, should there be a requirement to prescribe the position of the statement of protein source on the label e.g. on the front of the package?

Consistent location for information about any nutrient including protein is useful from a health professional perspective. SA Health does not have any evidence or view to justify information about the protein source on the front of pack. Back of pack is considered adequate.

Q2.10 What evidence can you provide on the prevalence of vitamin and mineral preparation use by Australian and/or New Zealand infants, either with or without medical supervision?

Some infants may be prescribed vitamin or mineral supplements under medical supervision for clinical deficiency.

Q2.13 What advice is given by health care professionals and/or state and territory government agencies on whether vitamin and mineral supplementation is needed for formula-fed (or breastfed) infants?

Individual advice is provided in clinical situations eg a clinical deficiency or for at risk groups such as preterm infants or dark skinned infants.

Q2.15 Should all or only certain substances proposed for use in infant formula require pre-market assessment? Please provide your rationale for your preferred position?

To ensure the safety for infants, SA Health supports the Ministerial Policy Guideline on the Regulation of Infant Formula Products[2], which requires pre-market assessment on any substance proposed to be used in infant formula (and follow-on formula) that

i. does not have a history of safe use at the proposed level in these products in Australia or New Zealand; or
ii. has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.

Furthermore, substances subject to pre-market assessment should have a substantiated beneficial role in the normal growth and development of infants or children, or a technological role, taking into account, where relevant, the levels of comparable substances in breast milk.

Q2.17 If only certain substances for use in infant formula should require pre-market assessment, where should the 'line' be drawn for the substances that do require pre-market assessment and those that do not? What is your rationale?

[2] Policy Guideline on the Regulation of Infant Formula Products

As stated in response to Q2.15, to ensure the safety of infants, SA Health recommends all substances proposed for use in infant formula should require pre-market assessment on all substances that have not yet been deemed safe in in Australia or New Zealand (in accordance with the Ministerial Policy Guideline on the Regulation of Infant Formula Products).

SD3: Provision of information

Q3.1 Should claims about specific ingredients be permitted on packaged infant formula?

If no, then why not? If yes, then how should they be regulated?

SA Health does not support claims about specific ingredients to be permitted on infant formula, and considers that allowing such claims directly contradicts the prohibition of claims on infant formula in standard 1.2.7.

We support the current permissions for declaration of nutrition information (2.9.1-21) and the labelling of nutritive substances (2.9.1 subclause 5(2), however suggest clarifying the wording to ensure the standard is clear (and not open to interpretation) that this information is only permitted within a nutrition information panel, but not elsewhere on the label or in a format that constitutes a nutrient content claim. This is in line with the intention of Standard 1.2.7 regarding claims on infant formula. Furthermore, highlighting such ingredients via claims might lead to the impression of caregivers that the infant formula is equivalent to, or better than breastmilk. Such labelling claims on infant formula would be in conflict with the Ministerial Policy Guideline on the Regulation of Infant Formula Products specific policy principles for labelling and advertising of infant formula, particularly “The labelling and advertising of infant formula products should not represent those products as an equivalent to, or better food than, breastmilk.

If there is enough evidence for inclusion of particular ingredients in infant formula, then these ingredients should be mandated for allowable composition, and there is no need to make a content claims about them.

In summary, SA Health suggests that consideration be given to clarifying the ingredient allowances in 2.9.1 against the prohibitions in 1.2.7 regarding nutrient content claims and health claims.

Q3.2 Do caregivers or health professionals find nutrition information about macronutrient subgroups to be of value for informing product choice?

SA Health’s view is that health professionals find nutrition information about fat and protein subgroups to be useful; however believe this information is not useful for caregivers and therefore not necessary on the label. Most caregivers would not understand these terms or their rationale (unless they are health professionals or have a science background).

Q3.3 Should the Standard include permissions to declare nutrition information about macronutrient subgroups (in addition to mandatory nutrition information currently set

out in clause 16 of the existing Code and section 2.9.1–21 of the revised Code) in the nutrition information statement?

SA Health supports maintaining the status quo, i.e. under 2.9.1-21 to list macronutrients and micronutrients; and consider clarifying in the standard that listing macronutrient subgroups on the label is not permitted.

Q3.4 Should it be mandatory to declare all or only specified macronutrient subgroups in the nutrition information statement? If so, which macronutrient subgroups and for what reason? For example, any subgroup of protein (whey, casein, alpha-lactalbumin etc.), or specific proteins (only whey and casein).

As per 3.3, SA Health does not consider that macronutrient subgroups should be permitted to be listed in the nutrition information statement unless there is convincing evidence warranting their declaration. SA Health is concerned that these various components are currently promoted by industry in their consumer marketing, and as such constitutes a nutrient content claim. Highlighting such macronutrient subgroups may lead the caregiver to the impression that the formula is equivalent to, or better than breastmilk. This is potentially in conflict with the Ministerial Policy Guideline on the Regulation of Infant Formula Products specific policy principles for labelling and advertising of infant formula, particularly “The labelling and advertising of infant formula products should not represent those products as an equivalent to, or better food than, breastmilk”.

Q3.5 If only specified macronutrient subgroups, what principles should be applied to determine which nutrients may be declared (e.g. for those fats with a specific compositional requirement, or for those nutrients that caregivers have a general understanding of their nutritional purpose in foods).

N/A; as per 3.3 and 3.4, SA Health does not consider that macronutrient subgroups should be permitted to be listed in the nutrition information statement.

Q3.6 If nutrition information about macronutrient subgroups is provided, is there potential for caregivers of formula-fed infants to be misled about the nutritional value of formula?

SA Health is of the view there is the potential for caregivers of formula-fed infants to be misled about the nutritional value of the formula, as per response to 3.4.

Q3.8 Is there any evidence that caregivers and health professionals are confused by the differences between ingredient declarations and nutrition information declarations?

SA Health has no evidence that caregivers and health professionals are confused by the differences between ingredient declarations and nutrition information declarations. However the same labelling principle applies to all food labels. Not permitting the listing of macronutrient subgroups would help minimise potential confusion.

Q3.9 Do stakeholders believe that the names of ingredients should align with nutrient declarations in the nutrition information statement?

SA Health does not consider this is necessary; the ingredient listing and nutrition information have different purposes; the former is about ingredients, the other is about the nutrition information.

Q3.10 Which base units of expression do stakeholders find to be of greatest value?

SA Health paediatric dietitians consider the base unit of 'per 100mls' to be of greatest value

Q3.11 Is there any evidence that caregivers are confused by the use of different base units of expression?

SA Health does not have such evidence.

Q3.12 In addition to the current requirement to declare nutrition information per 100 mL as consumed, should it be mandatory or voluntary to declare per 100 g of powder (or per 100 mL for liquid formula) as sold?

SA Health does not consider mandatory declaration of per 100g of powder necessary. Whilst per 100g of powder is useful for health professionals, this information is available from the manufacturer and is not necessary on the infant formula tin for caregivers.

Q3.14 Should the voluntary use of the base unit of per 100 kJ be permitted?

SA Health does not consider the voluntary use of the base unit of per 100 kJ is necessary or should be permitted. Whilst per 100 kJ is useful for health professionals, this information is available from the manufacturer and is not necessary on the infant formula tin for caregivers.

Q3.16 Is nutrition information on infant formula products used by caregivers to inform their purchase decisions?

Anecdotally, SA Health is of the view that nutrition information on infant formula products is used by caregivers to inform their purchase decisions. SA Health recommends FSANZ conduct consumer research with caregivers to develop deeper understanding about how they use this information (unprompted), followed by how they might use it with an understanding of the minimum composition requirements of infant formula, and that optional ingredients are permitted but not mandated as essential components.

Q3.17 Would a consistent approach to format across product labels assist consumer understanding of this information?

SA Health considers a consistent approach to format across product labels would assist consumer understanding of nutrition information, and other information elements (e.g. information about safe preparation and storage).

SA Health would like to raise the issue of line marketing of infant formula tins and marketing materials (i.e. infant formula -"stage 1" from birth; follow-on formula -"stage 2" from 6 months; toddler milks - "stage 3" from one year; and "stage 4" - junior from 2 years) as unnecessary and potentially misleading to caregivers as essential for normal growth and development, particularly beyond 12 months of age. Infant formula is adequate for infants 0-12 months in conjunction with complementary foods at around 6 months of age. SA Health recommends further exploration of this issue (including how consumers perceive this

advertising on infant formula tins) as part of the proceeding consultations in reviewing Standard 2.9.1.

Q3.19 How can changes in the composition in an infant formula product be communicated to caregivers and health professionals?

SA Health paediatric dietitians suggest that changes in composition or scoop size should be directly communicated to health professionals and via a factual sticker on the infant formula product for a defined period.

Q3.20 What information about the change in composition would caregivers and health professionals find useful?

Health professionals such as paediatric dietitians would find information about changes in allowed nutrients (permitted by the Food Standards Code), additions and/or removal of ingredients; changes to the nutrition profile of the formula (macronutrients and micronutrients), or changes in the scoop size.

SA Health suggests FSANZ seek feedback from caregivers about the (level of) information they would find helpful in relation to composition or scoop size changes.