Queensland Government

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Standards Management Officer
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Dear Sir / Madam

Submission – Consultation paper – Proposal P1028: Infant Formula

Thank you for the opportunity to provide a submission on the call for submissions regarding Proposal P1028: Infant Formula.

This submission provides technical advice and comments related to this issue. The submission does not represent a Queensland Government position, which will be a matter for the Queensland Government should notification be made by the FSANZ Board to the Australia and New Zealand Ministerial Forum on Food Regulation.

This submission first provides comments on the process of Proposal P1028 followed by responses to number of specific questions raised in the consultation paper.

Process of consultation for Proposal P1028

It has been difficult to adequately respond to the consultation document because of the range and detail of the issues canvassed. The process would have been facilitated by splitting the main components (composition, safety and food technology and provision of information) into three separate consultation papers.

Many of the questions require the input for health professionals and professional bodies involved in supporting infant feeding. These include maternal child health nurses, paediatric dietitians and researchers working in the area of infant feeding. These groups may have found it difficult to respond to the consultation paper because of the short timeframes and the technical detail required. Most are likely to need to respond outside working hours. Consequently the valuable technical and practical expertise of these stakeholders may not be reflected in the responses

received to the consultation paper. It would be of concern if the responses are dominated by those from industry and jurisdictions.

FSANZ is encouraged to find a mechanism to seek the view of the key stakeholders involved in supporting infant feeding so an appropriate balance of comments can be provided and considered.

Consideration should be given to whether the breadth of technical and policy issues presented in Proposal P1028 may hinder consideration of the final Approval Report by members of the Australia and New Zealand Ministerial Forum on Food Regulation. This could be addressed by spitting the proposal into two separate proposals, composition and labelling. This has the potential to reduce the possibility of a request for a review of the whole proposal if there are contentious issues.

Supporting Document 1: Definitions and Nutrient Composition

Section 2 - Definitions and Terminology

Q 1.2 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*

The use of 'under the age of 4 to 6 months' in the definition in Standard 2.9.1 of the revised Code is confusing. The objective is to have standards that will result in a formula that meets the nutritional needs of infants in the first months of life. The standard should not centre around the use of 4-6 months for the introduction of complementary feeding.

The use of 'up to around 6 months' aligns with the infant feeding guidelines of Australia and New Zealand and the definition in the Ministerial Policy Guideline on the Regulation of Infant Formula Products. It does not preclude the introduction of solids earlier than 6 months.

It is considered that Option 3 together with Option 2, "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding and, as part of a progressively diversified diet, of infants from 6 months of age" best describes the role of infant formula.

Neither the current definition nor Option 1 make it clear that infant formula is suitable after the introduction of solids (around 6 months). Infant formula is intended to provide a suitable replacement for breast milk from birth to twelve months of age, which includes meeting all nutritional requirements of young infants, and, together with solid foods, meeting the nutritional requirements for older infants.

Section 3 - Protein

Q1.3 Do you support a higher minimum of 0.5 g/100 kJ for infant formula based on isolated soy protein? Please provide your rationale?

There is no objection to continuing with the higher minimum for infant formula based on isolated soy protein. This is based on the rationale in the consultation paper that a higher minimum is

required in order to ensure that amino acid levels can be met due to soy and other plant proteins having different amino acid profiles. Also the digestibility of plant proteins can be lower than that of milk proteins.

Protein level

However the EU regulations have reduced that the maximum level of protein to maximum level of protein from 0.7 g/100 KJ. Aligning with the EU regulations would ensure the percentage of energy as protein does not exceed 12%.

SD Appendix 1 shows that the claimed protein content of the selection of infant formulas available in Australia and New Zealand ranges between 0.46 and 0.54 g/ 100 kJ. A reduction in the maximum therefore should not create a problem for industry.

Protein source

The definition of infant formula product in Standard 2.19.1 requires it to be based on milk or other edible constituents of animal or plant origin. It is noted that FSANZ's preliminary view is that the source of protein does not need to be further specified. Under the EU regulations, the permitted sources of protein in infant formula are specified and include cow and goat's milk proteins or isolated soy proteins.

FSANZ's preliminary view is not supported as it has the potential to allow new sources of protein to be used in infant formula without pre-market assessment. Some plant based sources of protein may contain anti-nutrient factors that can interfere with digestibility of the formula which needs to be carefully considered before being added to infant formula. This is not consistent with the Ministerial Policy Guideline on the Regulation of Infant Formula Products that states that pre-market assessment is required for substances used in infant formula that do not have a history of safe use in Australia and New Zealand. Clearly defining what is meant by protein source removes the ambiguity around what substances require pre-market assessment.

Supporting Document 2: Safety and Food Technology

Section 5 - Warning, Advisory and other Statements

FSANZ's preliminary view to maintain the current requirement to label the protein source is supported as it ensures correct identification of products suitable for infants with particular dietary requirements. However, currently some companies use a specific description of protein source such as whey dominant or casein dominant which could be considered a nutrition content claim.

FSANZ should give consideration to prescribing protein source using primary protein source words such as cow's milk, goat's milk, soy milk, and not subgroups of protein.

FSANZ's preliminary view that the protein source statement must be immediately adjacent to the name of the food and that the name of the food to which the protein source must be immediately adjacent is the prescribed name 'Infant Formula' is supported.

Labelling of infant formula

FSANZ should give consideration to a mechanism whereby caregivers are able to clearly differentiate infant formula from other similar products to reduce the safety risks associated with infants accidently being given an inappropriate formula or toddler milk. Infant formula may be the sole or principal source of nutrition for some infants. Therefore there is a greater level of risk to be managed. Currently the labelling of infant formula, follow-on formula and toddler formulas is similar and essentially only differentiated by a numbering system i.e Stage 1, Stage 2 and Stages 3 and 4.

Anecdotal evidence suggests that caregivers may choose the wrong stage of formula because the tins are almost identical. This is a potential safety issue. Research has also demonstrated that consumers have difficulty in distinguishing between advertising for infant formula and for toddler milk because of the similarity in packaging (Jones and Iverson, 2010).

Section 6 - Nutritive Substances and Novel Foods in Infant Formula

Q 2.15 Should all or only certain substances proposed for use in infant formula require pre-market assessment? Please provide your rationale for your preferred position?

Specific policy principles (i) and (j) in the Ministerial Policy Guideline on the Regulation of Infant Formula Products are quite clear on this issue.

- pre-market assessment should be required for any substance proposed to be used in infant formula and follow-on formula:
    - that does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or
    - has a history of safe use in these products in Australia and New Zealand but has a different form/structure or is produced using substantially different technique or technology; and
- Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated beneficial role in the normal growth and development of infants.

The Policy Guideline makes it clear that that '*infants are a vulnerable population group because they have immature immune systems and organs and dependent on adults for feeding. For some infants, infant formula products may be the sole or principal source of nutrition. For these reasons there is a greater level of risk to be managed compared to other population groups. The regulatory framework for infant formula should include requirements commensurate with this level of risk.'*

That all substances proposed to be added to infant formula should require pre-market assessment is strongly supported. Infant formula products should continue to be excluded from the scope of Proposal P1024. This approach has the advantage of removing the uncertainty about which substances require pre-market assessment.

Therefore further discussion is essential on ensuring substances that are not nutritive as defined by the Food Standards Code, but are added for a physiological, biochemical and/or functional effect are captured in the requirement for pre-market assessment.

FSANZ has noted that subclause 6(1)(b) permitting substances *naturally present in an ingredient of the infant formula product* has been interpreted to mean that a nutritive substance that occurs naturally in milk can be extracted, purified and added back in to milk, either at the level naturally found or at higher levels. However, a new extraction and re-addition of a substance from milk, for the purposes of innovation for a specific nutritional or physiological purpose, is not consistent with the original intention of subclause 6(1)(b) and such processes should be subject to pre-market assessment of safety and suitability.

Consideration needs to be given to whether controls are needed in relation to probiotics in infant formula. A number of infant formula products include probiotics and it is assumed interest in including probiotics in these products will continue if not increase in the future as more research is carried out on probiotics. It is noted the Food Standards Code currently permits lactic acid producing microorganisms to be added to infant formula but it is unclear whether other probiotic

microorganisms can be added or not. Considering infants, particularly premature babies and neonates, do not have fully developed immune systems and may be vulnerable to some microorganisms, it is important that individual probiotics are subject to premarket safety assessment and approval before they may be added to infant formula.

Supporting Document 3: Provision of Information

It is recognised that innovation by companies manufacturing infant formula can assist in achieving health outcomes for formula fed infants closer to those of breast-fed infants. However it is important to ensure that this the primary purpose of innovation and not for marketing purposes.

The emphasis on health outcomes for infants is consistent with the Ministerial Policy Guideline on the Regulation of Infant Formula which places the health and safety of infants, and the recognition that breastfeeding is the normal and recommended way to feed an infant, at the centre of decisions for infant formula regulation.

Section 2 - Issues under Consideration

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?

Claims about specific ingredients on packaged infant formula are strongly opposed.

If ingredients are added for a nutritional reason or a health effect, then claims on the label made about these ingredients constitute nutrition content or health claims.

The Food Standards Code prohibits nutrition content and health claims for infant formula except for a limited number of claims that identify products suitable for a particular condition, disease or disorder.

This is consistent with both the Ministerial Policy Guideline on the Regulation of Infant Formula Products and the Ministerial Policy Guidelines on Nutrition, Health and Related Claims.

It is considered that the industry practices identified by FSANZ in relation to both specific ingredients and claims about the health effects of consuming the products do constitute nutrition content or health claims.

Therefore is recommended that the Food Standards Code makes it clear that ingredient claims cannot be made of the labels of infant formula.

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?

It is acknowledged that the inclusion of macronutrient sub-groups would constitute a nutrition content claim as the Standard now applies.

It is not clear how the inclusion of macronutrient subgroups in the nutrition information statement may assist consumers to make informed choices. Consumers are more likely to be confused about the relevance of the information for their infant.

Permitting the declaration of macronutrient subgroups may encourage the production of a variety of different formulas which are not based on sufficient scientific evidence using breast milk and health outcomes of the breastfed infant as the primary references as required by the Ministerial Policy Guideline on the Regulation of Infant Formula Products.

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).

The declaration of specified macronutrient subgroups should not be permitted.

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

A consistent approach to the nutrition information statement is likely to assist caregivers in understanding this information. As noted by FSANZ, one advantage of a mandated format is that it may allow allows easier comparisons of nutrition information between products. In addition consumers are likely to be familiar with the tabular format of the Nutrition information Panel (NIP) used for general purpose foods which may assist consumers with their understanding of this information.

However the lack of research in this area is noted.

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

The inclusion of compositional changes on the front of an infant formula label is not supported as this would constitute a nutrition content claim. However there may be a need to examine alternative methods of informing consumers.

Related to this issue is an anecdotal account in relation to a change in infant formula composition. Recently one of the infant formula manufacturers replaced an existing product with a new product with a changed composition, new name, new packaging and an increase in price. A sticker was placed on the lid of the existing formula stating that it was being phased out and being replaced by a changed premium formula. The sticker also recommended that caregivers alternate between the existing and new formula to assist the infant to adjust to the new formula. However by the time these labels appeared supplies of the old formula were almost exhausted in the marketplace. This made it difficult for the parents to phase in the new formula. This combined with the uncertainty about the changes to the composition made it difficult for the parents to feel comfortable about changing to the new formula when the original advice was to use the old formula.

The website stated that the manufacturer could not provide specific details of the changes because of the requirements of the Food Standards Code. However quite a lot of information is provided about the changes parents might expect in the infant when they change to the new formula and about how to go about adjusting the infant to the new formula. This approach appears to be appropriate.

The issue is mainly about the communication in the marketplace which has caused the parents considerable anxiety and inconvenience. The information provided by manufacturer was that the old formula was being replaced by the new one starting in February 2016. The parents were

purchasing formula every two weeks and the stickers on the labels did not appear on stock sold in a major supermarket chain until May 2016.

Section 3 Requirements proposed to remain unchanged

The continued prohibition on nutrition content and health claims is strongly supported.

References

Berry, N., S. Jones, and D. Iverson, *Toddler milk advertising in Australia: the infant formula ads we have when we don't have infant formula ads.*, in *ANZMAC Annual Conference 2010: Australian and New Zealand Marketing Academy Conference 2010*. 2010, P. Ballantine & J. Finsterwalder (Eds.): Christchurch, New Zealand.

Should you require further information in relation to this matter, please contact Food Safety Standards and Regulation, Department of Health on (07) 3328 9310 or at foodsafety@health.qld.gov.au

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