Proposal P1028
Infant Formula

Consultation Paper

Summary

NSW (as represented by the NSW Food Authority and the NSW Ministry of Health) welcomes the opportunity to comment on Proposal 1028 – Infant formula. The documents for consultation are broad and consider many issues.

NSW acknowledges the unique needs of infants (0-6 months) and supports the existing preface in the Ministerial Policy Guideline for Regulation of Infant Formula Products that *'breastfeeding is the normal and recommended way to feed an infant'.*

In addition to nutritional benefits, breastfeeding has important psychological and cognitive benefits to developing infants. As noted in the NHMRC Infant Feeding Guidelines, breastfeeding fosters bonding, mutual responsiveness and attachment between mother and infant through interdependence, regular close interaction and skin-to-skin contact during breastfeeding. There are also associations between breastfeeding and cognitive development, particularly for preterm infants.

The view that breastfeeding is the recommended way to feed an infant is maintained as the scientific consensus of the 2014 *Scientific Opinion of the European Food Safety Authority Panel on Dietetic Products, Nutrition and Allergies – Scientific Opinion on the essential composition of infant and follow-on formulae*[1] (EFSA panel). NSW suggests this is an important resource for the further development of this proposal.

NSW acknowledges there is a greater level of risk to be managed with infants (0-6 months) compared to other population groups, hence supports maintaining the comprehensive approach of Standard 2.9.1 of the Australia New Zealand Food Standards Code (the Code) compared to other standards. NSW notes this view is supported in the opening paragraphs of the recent European Union Regulation 2016/127[2], where more detailed requirements are prescribed for this vulnerable sub-population.

NSW supports the individual consideration of some matters in Standard 2.9.1, notwithstanding their broader inclusion in other areas of the Code (e.g. Nutritive

[1] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3760.pdf
[2] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0127&from=EN

Substances and Novel Foods), due to the vulnerable nature of infants as a sub-population.

NSW generally supports the overall direction that FSANZ are proposing for the majority of issues considered in SD 1, 2 and 3. Specific comment is offered on these issues where necessary.

NSW agrees that nutrition content and health claims are beyond the scope of Proposal 1028, as they are policy issues. NSW suggests that any consideration of policy must consider a holistic approach to infant feeding as it has broader social impacts that extend well beyond the provision of nutrients to infants. NSW notes the recent European Union Regulation 2016/127 maintains a prohibition on the application of such claims to infant foods. NSW suggests that European Union Regulation 2016/127 is another important resource for the further development of this proposal.

NSW suggests that broad and comprehensive stakeholder engagement and consultation will be necessary in the further development of this proposal. Infant feeding is a highly emotive issue, of broad interest to varying sectors. It may be appropriate to form a Standards Advisory Committee to guide and inform the further development of this proposal.

Specific Issues

Supporting Document (SD) 1

1.1 For all views presented in this SD, do you agree with FSANZ's preliminary view? If so, indicate this in your submission and provide your reasons where appropriate. If not, indicate this in your submission and provide your reasons including additional relevant evidence, current practice in complying with the Code, impact on manufacture or trade, technical justification or other relevant information.

In general, NSW supports alignment with international guidelines where they are based on up- to-date scientific evidence, and are relevant to the Australian context. Many of the changes proposed in Supporting Document 1 relate to alignment with Codex STAN72-1981. However, the European Union regulations for infant formula composition (EU2016/127) were recently updated to reflect recommendations made by the EFSA panel in their 2014 scientific opinion paper on the essential composition of infant formula. NSW suggests FSANZ consider the 2014 EFSA panel scientific opinion paper and the subsequent EU 2016/127 regulations in the further development of this proposal as it may provide a more contemporary review of the evidence base than the Codex standard.

There may also be trade benefits arising from this analysis, as many infant formula products made and marketed in Australia are also for sale in Europe.

Importantly, the view of the EFSA panel that nutrients and substances added to infant formula should only be added at levels necessary to achieve a benefit, should be a guiding principle in the consideration of nutrient values in Standard 2.9.1. The EFSA document clearly states that the minimum amount of addition is that required to achieve the nutritional requirement, and should

be the target for addition with the upper value designed to protect the infant from undue nutrient loading. The EFSA document further states that upper limits should not exceeded.

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?

NSW suggests that greatest clarity could be obtained from option 2 plus additional words:

"Satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding **at around 6 months**". This wording aligns with the 2013 NHMRC Infant Feeding Guidelines which advise introducing appropriate solid foods 'at around six months'.

1.4 Do you support retaining the current minimum requirement for LA (9% total fatty acids) in infant formula? Please provide your rationale.

NSW suggests that FSANZ consider the limits placed in EU 2016/127 (120mg/100kJ) on LA in the further development of this Proposal. These limits are driven from the 2014 EFSA panel opinion paper and suggest a higher value than that in Codex (70mg/100kJ).

1.5 What issues, if any, do you have with the current approach to regulation of the source of fat in infant formula? Please provide your rationale.

NSW suggests that consideration is given to specifying a minimum mandatory level of docosahexaenoic acid (DHA) in infant formula, in line with the EU 2016/127 regulation and the 2014 EFSA panel opinion paper. DHA is an essential structural component of nervous tissue and the retina, and is involved in normal brain and visual development.

NSW is concerned that the maximum guideline level for DHA set by Codex is similar to the minimum level recommended by the EFSA panel opinion paper.

1.8 What issues, if any, do you have with the current approach to regulation of the source of carbohydrate in infant formula? Please provide your rationale.

NSW suggests that the views of the EFSA panel concerning the appropriateness of adding sucrose, fructose and glucose to standard infant formula be considered in the further development of this proposal.

NSW understands that fructose is unsuitable as it may pose a risk to infants with hereditary fructose intolerance; hence sucrose as a disaccharide containing fructose is equally unsuitable for the same reason.

NSW understands that addition of glucose in large quantities can lead to increases in the osmolality of infant formula, placing undue strain on infants in metabolising nutrients from the formula.

1.10 If you consider minimum folate requirement should include natural folate, should dietary folate equivalents (DFE) be applied? Please provide a rationale in support of your view.

NSW suggests that the position of DFE in EU 2016/127 be considered in the further development of this application.

Consultation with paediatric dietetic professionals indicates that the nutrient values listed on infant formula products are frequently relied upon for dietetic interventions. DFEs have been accepted in practice for 10 years so that these professionals would assume that folate represents DFEs.

Listing folate without applying the conversion factor for folic acid may lead to an underestimation of folate levels.

Supporting document (SD) 2

2.1 For all views presented in this SD, do you agree with FSANZ's preliminary view? If so, indicate this in your submission and provide your reasons where appropriate. If not, indicate this in your submission and provide your reasons including additional relevant evidence, current practice in complying with the Code, impact on manufacture or trade, technical justification or other relevant information.

NSW notes that a number of questions in SD2 relate to the experiences and perceptions of caregivers. NSW does not have information regarding caregiver experiences of infant formula, and it is suggested that targeted consultation is required to ensure that caregiver experiences are adequately reflected.

2.12 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?

Specific medical advice is recommended for vitamin and mineral supplementation for infants as per principles outlined in the NHMRC Infant Feeding Guidelines 2012.

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

NSW believes that novel foods and nutritive substances should be regulated within Standard 2.9.1 of the Code to ensure the safety and suitability of infant formula. This approach is consistent with the current Ministerial Policy Guideline for the Regulation of Infant Formula[3], where the specific vulnerability of infant is acknowledged *'there is a greater level of risk to be managed compared to other population groups'*.

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http://www.health.gov.au/internet/main/publishing.nsf/Content/4DCF744789D1AF64CA257BF0001C9622/$File/Policy%20Guideline%20on%20the%20Regulation%20of%20Infant%20Formula%20Products.pdf

With regard to novel foods or nutritive substances and infant formula, NSW notes the following matters of relevance in the current Ministerial Policy Guideline for the Regulation of Infant Formula:

Specific Policy Principles – Overarching principles

c) The regulation of infant formula products should be based on risk analysis, taking into account the vulnerability of the population for whom they are intended and the importance of these products in the diets of formula fed infants.

Specific Policy Principles – Composition

d) The composition of infant formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole source of nutrition up to six months of age.

i) Pre-market assessment should be required for any substance proposed to be used in infant 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 which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.*

j) 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 and children, or a technological role, taking into account, where relevant, the levels of comparable substances in breastmilk. A substance's role in normal growth and development is substantiated where there is appropriate evidence to link the physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood. Particular caution should be applied by the Authority where such links are less clear.

Additional Policy Guidance

Expert Group

FSANZ should consider establishing an independent scientific expert group that may provide advice prior to pre-market assessment, based on scientific criteria established by the Authority, on whether:

i) a substance proposed to be added to infant formula products has a history of safe use in infant formula or follow-on formula in Australia and New Zealand; and

ii) there is evidence available that the substance has a substantiated beneficial role in the normal growth and development of infants or children.

When read together, these extracts from the Policy Guideline are interpreted by NSW to require pre-market safety assessment by the Authority (FSANZ) of substances proposed to be used in infant formula. Evidence of substantiated benefit to the growth and development of an infant, or a technological role, where relevant, with regard to the levels of comparable substance in breastmilk is also required of a substance in order to be considered eligible for addition to infant formula.

2.31 Should the carry-over principle for food additive apply to infant formula? Please provide your rationale.

NSW notes that Codex permits carry over in very limited instances. It would seem appropriate that the Code reflect these specific permissions of the carry over principle, but in general not permit carry over.

3.1 Should claims about specific ingredients be permitted on packaged infant formula?
• If no, then why not?
• If yes, then how should they be regulated?

NSW notes that the current Ministerial Policy Guideline contains advice relevant to this issue:

Specific Policy Principles – Labelling and Advertising

(l) The labelling and advertising of infant formula products should not represent those products as an equivalent to, or better food than, breastmilk.

(n) The Authority should:
i) ensure that the prohibitions and restrictions on nutrient content, health, therapeutic, and prophylactic claims in the Food Standards Code are clear and effective for infant formula products; and
ii) consider whether the current labelling regime is leading to consumers being mislead about the quality or effectiveness of an infant formula product.

NSW interprets the current Policy Guideline to prohibit nutrition content and health claims on infant formula on the basis that such claims may represent those products as an equivalent to, or better food than, breastmilk.

NSW continues to support such a prohibition in support of the fundamental principle of 'breastfeeding is the normal and recommended way to feed an infant[4]'.

NSW further notes the commentary concerning claims in EU 2016/127:

'Nutrition and health claims are promotional tools'.

4 http://www.health.gov.au/internet/main/publishing.nsf/Content/4DCF744789D1AF64CA257BF0001C9622/$File/Policy%20Guideline%20on%20the%20Regulation%20of%20Infant%20Formula%20Products.pdf

'Given the particular role of infant formula in the diet of infants, the use of nutrition and health claims should not be allowed for infant formula'.

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

Yes. Anecdotal evidence gleaned from consumer discussion of infant formula products on product review websites and parenting fora (e.g. productreview.com.au) show that some parents do seek out formulas with particular protein and fat subgroups in the belief that they offer better nutrition or digestive benefits.

3.3 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 2.90.1-21 of the revised Code) in the nutrition information statement?

Identifying macronutrient subgroups in the nutrition information statement on infant formula is important for infants who have specific nutritional needs. This would apply to infant formula specifically designed for a particular condition, disease or disorder such as food intolerance or allergy. For healthy infants, it should not be necessary to declare macronutrient subgroups.

However, while there may not be evidence for the benefits of one macronutrient subgroup over another in a healthy infant's diet, parents and caregivers do seek out infant formulae based on the presence or absence of particular macronutrient subgroups. In addition, the presence of this information on pack allows health professionals to clearly advise parents of children with specific nutritional needs. NSW considers the nutrition information statement on the back of the pack is an appropriate location for this information, as well as being widespread industry practice. However, NSW notes that some infant formula labels characterise the addition of some materials with language beyond that required to identify the substance (e.g. 'enriched with alpha lacta-albumin'. NSW considers that only the name of the substance is necessary to achieve the intended purpose of declaration. NSW suggests that FSANZ consider how this may be better defined in the further development of this Proposal.

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

NSW agrees with FSANZ that, as all infant formula are consumed in liquid form, a volumetric declaration for nutrition information is more appropriate than a weight-based declaration for the product as sold. The current volumetric declaration of the average amount of each nutrient per 100mL as consumed allows nutrition information to be accurately compared between products. However, nutrition information per 100g of powder may be of assistance in clinical settings. It is noted that both Codex and EU 2016/127 permit declarations of nutrition information per 100g of powder and it would appear prudent to align with these international regulations.

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

The Standard needs to be clear about nutrition information requirements, and FSANZ is requested to consider the possible merit of a standardised and prescribed approach for provision of this information. NSW recommends the following be included within this consideration:

- Align with the prescribed format for general purpose foods
- Assist caregivers in making product comparisons
- Provide clarity regarding nutrition information requirements.

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

Caregivers can be informed about changes via a 'new formulation' statement on the product accompanied by information on the product website, or accessed through a QR code, or in a brochure attached to the product.

Information regarding composition changes should be provided to health professionals and food regulators in writing. Key contacts for this information are: Chief Executives of local health districts, child and family health networks, primary health networks, paediatric services, residential services, prisons with mothers and children, private sector hospitals, neonatologists and dietitians.

ENDS

The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.