Dietitians Australia
The Leading Voice of Nutrition

P1028 Paper 2 – Infant formula nutrient composition

Response to consultation
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Recipient

Food Standards Australia New Zealand

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[redacted]

About Dietitians Australia

Dietitians Australia is the national association of the dietetic profession with over 8000 members, and branches in each state and territory. Dietitians Australia is the leading voice in nutrition and dietetics and advocates for food and nutrition for healthier people and healthier communities. Dietitians Australia appreciates the opportunity to provide feedback to Food Standards Australia New Zealand regarding infant formula nutrient composition.

The Accredited Practising Dietitian (APD) program provides an assurance of safety and quality and is the foundation of self-regulation of the dietetic profession in Australia. Accredited Practising Dietitians have an important role in supporting parents and carers to nourish infants, and supporting companies with product formulation, regulatory compliance and consumer education.

This submission was prepared by members of the Dietitians Australia Food Regulatory & Policy Committee and Paediatric & Maternal Health Interest Group following the Conflict of Interest Management Policy and process approved by the Board of Dietitians Australia. Contributors include Dietitians Australia members with wide ranging expertise in areas including public health, food systems, food industry, infant feeding, lactation and academia.

Summary

Infants in Australia should be exclusively breastfed for the first six months of life, and continue breastfeeding as part of an increasingly diversified diet into the second year of life and beyond. Breastmilk is the best source of nutrition to achieve optimal growth, development and health in early years. The government recognises this in the Infant Feeding Guidelines[1] and Australian National Breastfeeding Strategy.[2] When breastfeeding or breast milk is not an option, infant formulas (including follow-on formula) can be used under the guidance of appropriately qualified health professionals, particularly dietitians.

Dietitians Australia recommends:

1. FSANZ prioritise public health and safety, as per policy guidelines.
2. Any novel proteins must conduct a comprehensive pre-market assessment before being permitted in infant and follow-on formula, including impact on bioavailability of nutrients.
3. Choline be made a mandatory ingredient, at levels consistent with EU standards.
4. FSANZ reviews the use of voluntary ingredients, including DHA and other LCPUFAs, in infant and follow-on formula products, including:
    a. Marketing of formulas as ‘premium’ due to addition of voluntary nutritive ingredient
    b. Equity issues associated with cost of ‘premium’ and ‘standard’ formulas, and potential growth and development benefits of different products
    c. Use of voluntary nutritive ingredients in past 20 years, and the evidence for benefits or risks of these ingredients
    d. Consider prohibiting voluntary nutritive ingredients, and instead making nutritive ingredients mandatory if they mimic the composition of breastmilk and are proven to benefit infant growth and development
5. FSANZ adopt a minimum level for linoleic acid of 120mg/kJ (Option 1).
6. Regular review of infant and follow-on formula regulation, as science and market trends are constantly evolving.

Discussion

General questions

1. In addition to your submissions from previous Consultations for this Proposal, do you have any further comments on how any of our proposed options in this paper would affect market opportunities for infant formula?

Policy principles

Dietitians Australia strongly supports the FSANZ view that protection of public health and safety is paramount always, and highlights this is particularly true for infant formula products, including follow-on formula. The FSANZ objectives, as per s18 of the FSANZ Act,[3] and the Policy Guideline on the Regulation of Infant Formula[4] endorsed by the Ministerial Council (now Food Ministers Meeting) both place infant health, safety, growth and development as the key considerations in infant formula regulation. Accordingly, trade issues should be a relatively minor consideration in this review.

We support and encourage regular review of infant and follow-on formula regulation, as science and market trends are constantly evolving.

Scope

The consultation paper states the scope of P1028 is limited to formula products for infants aged 0 to 6 months, excluding formula products for infants aged 6 to 12 months. This is inconsistent with standard 2.9.1 of the Code which includes compositional requirements, food additive and contaminant provisions that apply to formula products for infants aged 0 to 12 months. Few exceptions in the standard apply for formula products for infants aged 6 to 12 months (energy, protein).

If P1028 applies only to formula for infants aged 0 to 6 months, there will be 2 sets of provisions which will be close to duplicates. We recommend FSANZ consider the evidence behind having 2 sets of provisions and whether 2 sets would present a benefit to public health and safety.

Protein sources

Dietitians Australia strongly supports the FSANZ proposal that protein sources should be specifically defined to include only cow's milk protein, goat's milk protein, protein hydrolysates of one or more proteins normally used in infant formula, and soy protein isolate. Other proteins including plant-based proteins (eg rice or pea + rice) are becoming more popular in the general community, but not yet proven to be as safe, digestible or efficacious for optimal growth in infant populations as soy or mammalian protein sources. Any novel proteins must conduct a comprehensive pre-market assessment including amino acid composition and nutrient bioavailability before being permitted in infant and follow-on formula products.

Choline

Dietitians Australia supports the FSANZ proposal for mandatory inclusion of choline in infant formula products. However, we do not support the range proposed by FSANZ as this risks insufficient choline intake for infants who rely on formula as their sole source of nutrition. We recommend FSANZ adopt a range consistent with EU 2016/127 which is supported by more recent evidence than that in the Codex, and will better support infants aged 0 to 6 months who have little to no solid food intake to meet the choline requirement of 125mg/day listed in the NHMRC Nutrient Reference Values.[5]

In August 2021, researchers at the George Institute for Global Health examined a sample of 89 infant formula products from the FoodSwitch Monitored dataset from 2019. They defined infant formula as products suitable for infants up to 12 months of age, as defined in FSANZ Standard 2.9.1. Of these 89 products, 59 (66%) products contained choline in the ingredients list. Therefore, only one-third of products on the market would require reformulation. Several companies who have formula products without choline also have formula products with choline, so therefore should have the expertise to add choline as required.

Further, we understand several smaller businesses use contract manufacturers so costs of implementing Food Standards Code amendments may not be as large as estimated, as they would be shared by several companies contracting the same manufacturer.

DHA and other LCPUFAs

The Policy Guideline on the Regulation of Infant Formula[4] outlines several principles relevant to the composition of infant and follow-on formula products. Of note are:

- (g) "Compositional requirements for infant formula and follow-on formula products should only be mandated in regulation where there is sufficient evidence to demonstrate that they are safe and essential for normal growth and development of infants."
- (h) "The composition of breastmilk should be used as a primary reference for determining the composition of infant formula and follow-on formula."
- (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 or 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..."

The evidence on the necessity of LCPUFAs in infant formula (including follow-on formula) is inconclusive, with randomised controlled trials, cohort studies, reviews and meta-analyses having varied conclusions. The literature suggests LCPUFAs may have a role in immunological development[6-9] but the evidence of other developmental benefits are not convincing.[10-13]

Voluntary nutritive ingredients, in particular LCPUFAs, are used by companies to market their formula products as 'premium'. These are typically sold at a higher price than 'standard' formulas. This presents an equity issue, and contravenes objectives 2 and 3 as stated in s18 of the FSANZ Act[3] - the provision of adequate information relating to food to enable consumers to make informed choices; and the prevention of misleading or deceptive conduct.

Dietitians Australia recommends FSANZ reviews the use of voluntary ingredients, including DHA and other LCPUFAs, in infant and follow-on formula products, including:

- Marketing of formulas as 'premium' due to addition of voluntary nutritive ingredient
- Equity issues associated with cost of 'premium' and 'standard' formulas, and potential growth and development benefits of different products
- Use of voluntary nutritive ingredients in past 20 years, and the evidence for benefits or risks of these ingredients
- Consider prohibiting voluntary nutritive ingredients, and instead making nutritive ingredients mandatory if they mimic the composition of breastmilk and are proven to benefit infant growth and development

2. With the proposed approaches for Standard 2.9.1 or Schedule 29 in this Consultation paper, will small or large businesses be disproportionately impacted if a new permission or restriction does not align with international regulations or standards?

We understand several smaller businesses use contract manufacturers so costs of implementing Food Standards Code amendments may not be as large as estimated, as they would be shared by several companies contracting the same manufacturer. Any potential business impacts must be weighed against the critical need to protect the safety of infants in this particular category.

Minimum linoleic acid requirement

3. Do you support retaining the current minimum requirement for linoleic acid (9% total fatty acids) in infant formula?

Dietitians Australia supports Option 1, to adopt EU 2016/127 minimum LA level of 120 mg/100 kJ. This option is the most consistent with Specific Policy Principles (b to j) in the Policy Guideline on the Regulation of Infant Formula[4] and FSANZ Act s18(1)(a) and s18(2)(a-d).[3] This option supports alignment with the most recently updated regulation standards internationally (EU 2016/127 Annex 1, 5.4),[14] is closer to minimum LA levels noted within breast milk of the ANZ population (140mg/100kJ)[15(p34)] and with NHMRC Nutrient Reference Values (NRVs) for infants 0-12 months of age (n-6 Adequate Intake 4.4-4.6 g/day).[16] The lower level in Option 2 risks infants who rely solely on formula for nutrition not getting sufficient LA necessary for normal growth and development.

As stated in the consultation paper,[15(p35)] the FSANZ label survey showed that most products in the market already exceed this standard. Dietitians Australia found similarly that all but 1 product listing LA content available in major retailers exceeds the EU standard. This product lists an LA content of 118.82mg/kJ and would need only slight reformulation to meet the 120mg/kJ minimum. Therefore, Option 1 would have a minimal impact on industry, and a positive impact on infant health, so should be adopted.

4. Are there any technical issues related to increasing the linoleic acid minimum in Standard 2.9.1 to align with the higher EU 2016/127 level of 120 mg/100 kJ?

As stated in the consultation paper,[15(p35)] the FSANZ label survey showed that most products on the market already exceed this standard, indicating there are no significant technical issues related to increasing the linoleic acid minimum to 120mg/100kJ as proposed by Option 1.

5. Can you provide data on the linoleic acid levels in commercially available infant formula internationally? This information can be provided as 'Commercial in confidence' if required.

Dietitians Australia does not have this data.

Soy-based infant formula

6. Do you support setting a separate iron maximum for soy-based infant formula?

Dietitians Australia supports the proposed approach to retain an iron range that applies to all infant formula. As stated in the consultation paper, processing methods for soy-based formulas reduce the phytate content of these formulas, therefore diminishing iron bioavailability concerns.

We recommend pre-market assessment of nutrient bioavailability in infant and follow-on formula based on novel proteins not yet used in infant formula (eg iron bioavailability in formula based on pea protein).

7. Do you support setting a separate phosphorus range for soy-based infant formula?

Dietitians Australia recommends FSANZ investigate the evidence supporting the different phosphorus ranges for soy-based and mammalian-milk based formulas in EU 2016/17. FSANZ must consider whether the lower end of the range, 6mg/100kJ, is sufficient for soy-based formulas.

Further, we recommend pre-market assessment of nutrient bioavailability in infant and follow-on formula based on novel proteins not yet used in infant formula (eg phosphorus bioavailability in formula based on potato protein).

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