P1028 Paper 3 – Infant formula regulatory framework and definitions

Response to consultation
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Recipient

Food Standards Australia New Zealand

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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.

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 Regulation & Policy Advocacy Working Group and Paediatric & Maternal Health Interest Group, with contributions from the Adverse Food Reactions 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, academia, infant feeding and lactation. We would also like to acknowledge the expert advice of paediatric dietitians at Starship Child Health Directorate, Auckland City Hospital.

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. Breast milk 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. Any infant formula product or additive in a product that claims to treat or manage a health condition must meet strict criteria including definition of the health condition and strong evidence that the product or additive treats that condition.
2. All claims on standard or special use infant formula products are prohibited unless underpinned by strong evidence that investigates the magnitude of clinical effect when compared with breastfed infants as the benchmark, and is free from conflicts of interest.
3. Infant formula products for standard use or special medical purposes include an advisory statement such as ‘infant formula is not needed for healthy children older than 12 months unless under the guidance of a health professional’.
4. FSANZ, in partnership with relevant government agencies, investigates a plain packaging mandate for infant formula products in hospital settings.
5. FSANZ considers regulating feeding volumes listed on infant formula product packaging and mandating an advisory statement that parents and carers should follow infant feeding cues.
6. FSANZ considers regulation of preparation instructions so they are aligned with the NHMRC and WHO guidelines.
7. FSANZ actively engage with practising healthcare professionals.
8. FSANZ allows more than 4 weeks for stakeholders to respond to consultations.

Discussion

General comments

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. The FSANZ objectives, as per s18 of the FSANZ Act, and the Policy Guideline on the Regulation of Infant Formula 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.

Scope

We are pleased to see that our recommendations in response to papers 1 and 2 have been applied in paper 3 to recognise that infant formula is for 0–12 month-olds, not just 0-6 month-olds. This change is consistent 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.

Marketing undermines breastfeeding

Page 33 of the consultation paper states 'FSANZ is unaware of evidence demonstrating that the availability of general or specialised infant formulas is a factor associated with breastfeeding cessation.' However, there is exhaustive evidence that promotion of infant formula directly undermines breastfeeding.[3-5]

Recommendation: FSANZ revisits the evidence on this point and ensure final decisions on P1028 reflect the evidence that marketing of infant formula directly undermines breastfeeding.

For many parents, hospitals are the first exposure to infant formula. Parents and carers who experience challenges with breastfeeding may use infant formula products before being properly supported by an expert in lactation such as an appropriately trained dietitian, midwife or lactation consultant. If infant formula is introduced before the birthing parent and infant have had a proper chance try breastfeeding, the birthing parent's breast milk supply may be severely disrupted. Further, introduction of a formula product in a hospital setting may introduce a perceived 'tick of approval', indicating to parents and carers that formula feeding or a particular brand of formula is superior to breastfeeding.

Recommendation: FSANZ, in partnership with relevant government agencies, investigates a plain packaging mandate for infant formula products in hospital settings, to avoid promotion of particular infant formula brands and undermining breastfeeding.

Feeding volumes

Feeding volumes recommended on infant formula packaging in Australia are not regulated by FSANZ or any other body, instead being at the manufacturer's discretion. Some volumes indicated on product packaging may be significantly greater than feeding volumes recommended by the Infant Feeding Guidelines,[1] making formula-fed infants at greater risk for overfeeding and unhealthy rapid weight gain. Feeding volumes are also for exclusively formula fed babies and do not explicitly state that less is required if a baby is being breastfed as well as formula-fed. Further, infant formula product packaging does not typically acknowledge that parents and carers should respond to infant hunger-fullness cues to achieve feeding goals. This may be more or less than the feeding volume recommended on the packaging. Feeding practices are a key consideration in supporting optimal growth and development in infants who are solely or partially fed infant formula products.

Recommendation: FSANZ consider regulating feeding volumes listed on infant formula product packaging and mandating an advisory statement that parents and carers should follow infant feeding cues, with a link (written short form or QR code) to reputable information such as that on a federal government website.

Preparation instructions

Preparation instructions on infant formula product packaging in Australia are not regulated by FSANZ or any other body, instead being at the manufacturer's discretion. Best practice is to provide instructions in line with the NHMRC Infant Feeding Guidelines[1] and World Health Organization safe preparation instructions.[6] Some products have instructions that do not follow these guidelines, putting infants at risk of illness or non-optimal growth and development.

Recommendation: FSANZ considers regulation of preparation instructions so they are aligned with the NHMRC and WHO guidelines.

Consultation process

Dietitians Australia would like to highlight concern that the highly technical nature of the issues and the volume of the work required to address the issues raised in the P1028 part 3 consultation paper may hinder responses from relevant health care professionals who do not have the time and resources necessary to adequately address the issues. Health care professionals such as paediatric dietitians, lactation consultants, maternal/child health nurses, midwives and paediatricians play a vital role in educating and supporting parents and carers to provide appropriate nutrition for their infants. It is imperative to ensure that the expertise and views of these key health care professionals are appropriately represented in the consultation process before any decisions are made regarding changes to the regulation of infant formula products for special medical use, or standard use.

Recommendation: FSANZ actively engage with practising healthcare professionals, such as outreach to major paediatric hospitals with specific questions related to practice.

Recommendation: FSANZ allows more than 4 weeks for stakeholders to respond to consultations.

Novel foods

1. To manufacturers: Please provide information on whether the substances listed in Table 5 are used in infant formula products, food for infants and formulated supplementary food for young children.

No comment.

Specialised infant formulas

2. Is a definition of soy-based formula needed for the purpose of food additive permissions and aluminium requirements?

No comment.

3. Is a definition of pre-term formula needed for the purpose of food additive permissions and aluminium requirements?

A definition of pre-term formula is necessary as these formulas have different composition to meet the particular nutrition requirements of preterm infants. The definition should be amended to recognise that breastmilk is the ideal food for preterm infants, with or without a fortifier as recommended by health professionals on an individual basis.[7]

Recommended definition, with additions in red: An infant formula product specifically formulated to satisfy particular needs of infants born prematurely or of low birthweight where breastmilk, the ideal food for preterm infants, is not available.

4. Are definitions needed for any of the new terms proposed to be introduced as conditions for the use of food additives in CP1, such as gastrointestinal reflux, gastrointestinal disorders, or impairment of the gastrointestinal tract, inborn errors of metabolism etc.?

Yes, all of these require clear definitions as diagnosed medical conditions and listed in the Food Standards Code. Medical conditions would not include normal infant behaviours (eg sleep, colic, crying or comfort).

Any infant formula product or additive in a product that claims to treat or manage a health condition must meet strict criteria including definition of the health condition and strong evidence that the product or additive treats that condition.

Products for medical uses

5. To health professionals: Is there any evidence that current practice in relation to low lactose products or the manganese content of products for metabolic, immunological, renal, hepatic and malabsorptive conditions pose a health concern or risk?

Dietitians Australia is not aware of any evidence that use of low lactose products supervised by a health professional poses a health risk or concern.

6. To industry submitters: How many and what types of low lactose IFPSDU are on the market? And what is their maximum level of lactose?

Dietitians Australia conducted a market scan of infant formulas available at major retailers in August 2021. We found 3 products marketed as low lactose:

- Aptamil Gold+ Lactose Intolerance, <0.006g lactose per 100mL prepared feed
- Nestlé NAN L.I. Infant Formula for Babies with Lactose Intolerance, <0.007g lactose per 100mL prepared feed
- S-26 Alula Gold LI, 0.0034g lactose per 100mL prepared feed

Products with a protein substitute

7. To industry submitters: What types of partially hydrolysed IFP are on the market?

Dietitians Australia conducted a market scan of infant formulas available at major retailers in August 2021. We found 4 products labelled as using a partially hydrolysed protein source:

- S-26 Alula Gold DelicateEze
- Nestlé NAN Supremepro 1
- Nestlé NAN Supremepro 2
- Aptamil Prosyneo Sensitive

The level of protein denaturation was not available on the label or in online product information for any of these products. None of these products were listed on the Australian Pharmaceutical Benefits Scheme when checked on 23 September 2021.

8. To health submitters: You have told us that partially hydrolysed IFP are not efficacious in preventing allergy; are they useful in the dietary management of allergy?

The Australasian Society of Clinical Immunology and Allergy (ASCIA)[8] does not recommend using partially hydrolysed formula for dietary management of allergy. Infants with severe allergy, such as Cow's Milk Protein Allergy, who are not breastfed are given extensively hydrolysed or amino acid based (aka elemental) infant formula products under the guidance of a health professional.

Compositional requirements

9. Regarding options for the regulation of molybdenum and chromium, which option do you prefer and why?

No comment.

10. To industry submitters: What type of products contain MCT oil?

Infant formula products that contain MCT oil are typically designed and used for preterm infants.

11. To health submitters: Are there any health concerns from current practice using products that contain MCT oil?

MCTs have high water solubility and are easily absorbed by preterm infants with an immature digestive system and even by those with low intraluminal bile salts and pancreatic lipase levels.[9] Greater MCT compared to long-chain saturated fatty acid absorption means a higher total fat absorption and a slight benefit for the absorption of calcium that would otherwise be bound to unabsorbed long-chain saturated fatty acids. However, the improved fat absorption does not generally lead to a higher energy intake because MCTs have lower energy content. A Cochrane meta-analysis comparing infants fed high MCT versus low MCT formula shows little or no difference in the pattern of growth for any primary short-term growth outcomes.[10] There are some disadvantages with a high MCT formula. Formulas with a large MCT component in infant formula, bring a risk of essential fatty acid deficiency.[11] MCTs also increase the osmolality of the formulas, which is associated with a higher risk of osmotic diarrhoea. Evidence to date indicates that the provision of fat in preterm formula as MCTs may be beneficial if limited to not more than 40% of fat intake.[9] Medium-chain triglycerides are not recommended as an additive to standard formulas for healthy infants.

Evidence for IFPSMP

12. To industry submitters: Do infant formula manufacturers hold scientific evidence that supports the purpose of Division 4 products, including for reflux, colic, diarrhoea, and similar products (i.e. for less serious conditions)?

Dietitians Australia understands companies do not hold any strong scientific evidence that supports products marketed as for reflux, colic, diarrhoea, 'comfort', 'sleep' or similar products.

13. If so, what type of scientific evidence is held by companies and what is its strength of evidence?

Dietitians Australia understands companies do not hold any strong scientific evidence that supports the efficacy of products marketed as for management of reflux, colic, diarrhoea or other functional gastrointestinal disorders. Reflux, colic and loose stools are common in infants and while distressing for parents and carers, these symptoms generally do not require long-term intervention for infant health.[12-14] If a parent or carer is concerned about symptoms of reflux, colic or diarrhoea, an assessment should be made by a qualified health professional such as a paediatrician.

Division 4 infant formula products that are not underpinned by strong evidence undermine breastfeeding. Parents and carers might stop breastfeeding if an infant has colic or a functional gastrointestinal disorder, believing that the product will nourish the infant better than breastmilk, despite breastmilk being the best food for infants.

Recommendation: All claims on standard or special use infant formula products should be prohibited unless underpinned by strong evidence that investigates magnitude of clinical effect when compared with breastfed infants as the benchmark, and is free from conflicts of interest (ie not funded by infant formula or dairy companies).

Product use beyond infancy

14. What is the maximum labelled age on products suitable for use beyond infancy?

Infant formula products for standard use or special medical purposes should include an advisory statement such as 'infant formula is not needed for healthy children older than 12 months unless under the guidance of a health professional'. Products marketed for beyond this age, such as toddler milks, should not be promoted on infant formula packaging. Toddler milks are not necessary for a child's growth and development. From 12 months of age, a healthy toddler may drink full cream cow's milk instead of infant formula for a nourishing liquid source of protein, carbohydrate and fat.[1]

Labelling of IFPSMP

15. Do you support FSANZ's preliminary views for IFPSMP labelling?

Adopt an approach consistent with section 2.9.5—12 for date marking information to be made either in accordance with Standard 1.2.5 or for the words 'Expiry date' or similar words to be used on the label

Dietitians Australia supports this proposal.

For lactose-free and low lactose formulas, maintain existing labelling requirements and clarify that IFPSMP labelling provisions would not apply

Primary lactose intolerance and galactosaemia are rare, therefore lactose-free products should not routinely be available on the everyday market. Their ease of availability can lead to confusion and undermine breastfeeding. Applying IFPSMP labelling provisions to lactose-free and low lactose products would limit channels through which these products could be sold. If an infant requires a lactose free formula, it should be based on recommendation from health professionals and available at pharmacies only.

Extend the exemption from the 'breast milk is best' warning statement to all IFPSMP

Oppose. Breast milk is the ideal food for most infants including preterm and very low birth weight infants.[7] There are very few medical conditions under which breast milk is contraindicated, such as an infant with galactosaemia or a lactating parent with active infectious blood-borne disease, so a general exemption for all IFPSMP is not appropriate.

Extend the exemption from the statement about offering other foods in addition to IFPs to all IFPSMP

Oppose. Infants and toddlers over the age of 6 months should consume an increasingly varied diet with solid foods. This is true for most infants including many with medical conditions. Parents and carers with concerns about giving their infant solid foods should consult an appropriate health professional such as a paediatrician or dietitian.

The general directions for preparation and use requirements are appropriate for IFPSMP, and there are no additional, specific directions that should be mandated

Dietitians Australia supports this proposal, noting that instructions should follow WHO[6] and NHMRC[1] guidelines.

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