Dietitians Australia
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P1028 Infant formula

Response to consultation
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Recipient

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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 Regulatory & Policy Advisory Working Group 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.

Recommendations

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. Breastfeeding confers health benefits on both the mother and the infant. The government recognises this in the Infant Feeding Guidelines and Australian National Breastfeeding Strategy.[1,2] When breastfeeding or breast milk is not an option, infant formulas can be used under the guidance of appropriately qualified health professionals, particularly dietitians.

Dietitians Australia recommends FSANZ:

1. Exclude modified protein, low lactose and lactose free products from the Infant Formula Product category
2. Categorise products containing modified proteins, thickeners and reduced lactose content under SMPPi for medically supervised administration only
3. Provide standardised feeding guides, aligned with NHMRC Infant Feeding Guidelines to ensure they are not developed at manufacturers' discretion and do not promote overfeeding
4. Provide standardised preparation instructions and diagrams, aligned with NHMRC Infant Feeding Guidelines, using images and language similar to the World Health Organization guide on preparing infant formula to ensure consistency across brands
5. Require manufacturers to advise consumers to discard formula after 1 hour rather than 2, consistent with the NHMRC Infant Feeding Guidelines
6. Retain the definitions for 'protein substitute' and 'medium chain triglycerides'
7. Retain novel foods and nutritive substances in the scope of P1028
8. Impose conditions on the use of novel foods including dried marine micro-algae and oil derived from marine micro-algae, rich in DHA, due to the potential for use for marketing purposes

9. Provide clearer restrictions for carry-over additives which should not be permitted in infant formulas
10. Set a maximum level for arsenic and investigate the levels of arsenic in rice-based formulas
11. Retain the guideline on advice regarding additional vitamin and mineral supplementation
12. Adopt a minimum level of 120 mg/100 kJ for linoleic acid and adopt a range for choline that is also consistent with EU 2016/127
13. Not permit the use of shading in the Nutrition Information Panel (NIP) subheadings for 'Vitamins', 'Minerals' and 'Additional'
14. Explicitly address and prohibit claims relating to sleep, reflux, comfort, and others that may sit outside the definition of a health claim
15. Use age ranges (eg 0-6 months, 6-12 months) rather than stages on labelling
16. Restrict changes in product formulation notifications to a set period of time, eg 6 months, and prohibit the use of transition guides.

Discussion

1 Introduction

1.1 The Proposal

Dietitians Australia notes the introductory statement on page 7 has not changed since earlier consultations. Dietitians Australia again recommends that the following statement be strengthened: 'Although breastfeeding is the recommended way to feed infants, a safe and nutritious substitute for breast milk is needed for infants who are not breastfed'.

Dietitians Australia believes it is fundamental that FSANZ acknowledges the crucial importance and health benefits of breastfeeding , where parents are willing and able to do so, for mothers and infants and the broader community. This message should be reflected in all materials that FSANZ produces in relation to infant formulas. The NHMRC Infant Feeding Guidelines Information for Health Workers (page 1)[3] has stronger language that FSANZ should consider adding to all relevant consultations and publications:

"The World Health Organization (WHO) states that 'breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants'. Breastfeeding is beneficial to infants, mothers, families and society, and is viewed as the biological and social norm for infants and young child feeding. A safe and nutritious substitute for breast milk is needed for infants when breastfeeding is not possible."

Table 1.3 Products included in the scope of P1028

Dietitians Australia recommends that protein sources be specifically defined such that they only include cow's milk protein, goat's milk protein and soy protein isolate. We do not support the inclusion of protein hydrolysates of one or more proteins normally used in infant formula in this definition for reasons described in section 2.4.2 below. Other proteins including other 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 promoting 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.

2 Regulatory framework

2.4.1 Infant formula products

Dietitians Australia agrees that the regulatory framework for infant formula products intended for healthy infants is retained.

2.4.2 Modified infant formula products

The marketing of infant formula undermines breastfeeding and the health of children. Through promotion of and increasing the rates of breastfeeding globally, the WHO estimates that 800,000 deaths of children under 5 years and 20,000 incidents of breast cancer in mothers can be prevented annually.[4]

For these reasons, Dietitians Australia does not support the proposal to include modified protein and lactose free/low lactose formulas in the low risk Infant Formula Product (IFP) category. These products may be associated with a health halo effect and lead to further confusion for carers and parents. There is no medical need for modified protein products and only rare need for low lactose and lactose free products. Any product deemed necessary for medical purposes should be categorised under Special Medical Purpose Products for infants (SMPPi).

The Australasian Society of Clinical Immunology and Allergy (ASCIA) does not recommend using partially hydrolysed formula for dietary management of allergy.[5] Infants with severe allergy, such as Cow's Milk Protein Allergy, who are not breastfed are given extensively hydrolysed or amino acid based (elemental) infant formula products under the guidance of a health professional.

Primary lactose intolerance (or congenital lactose intolerance) and galactosaemia are rare genetic conditions, for which lactose-free products are used. These products should not routinely be available on the everyday market. Applying SMPPi labelling provisions to lactose-free and low lactose products would limit channels through which these products could be sold. Their ease of availability can lead to confusion and undermine breastfeeding.[6] If an infant requires a lactose free formula, it should be based on recommendation from a health professional, used under medical supervision and available at pharmacies only.

While the FSANZ argues that the products are low risk to healthy infants, Dietitians Australia does not agree. There is limited evidence of the long term impact on infant growth or health, and therefore caution should be exercised.

Dietitians Australia does not support the removal of the definition for protein substitute. More detail is provided in section 3.3 below.

We do support a requirement for pre-market approval of any infant formula product that deviates from the baseline infant formula or follow-on protein composition (such as use of an alternative protein source).

Reflux is normal and common in babies and usually resolves on its own. In most cases, reflux is not harmful and does not need medical treatment. For products with thickening agents, these ingredients should only be identified in the ingredients listing with no other marketing on pack. There is little to no evidence to support the use of thickening agents to treat or manage reflux. Reflux can instead be treated, for example, with postural changes during and after feeding. Where there is a medical need to use thickeners, products should be categorised under SMPPi and administered only under medical supervision.

2.4.3 Special Medical Purpose Products for Infants (SMPPi)

Dietitians Australia supports FSANZ's proposed approach to remove the category of IFPSDU within Standard 2.9.1 and the current specific subcategories contained within Division 4, and replace it with a new category of 'Special Medical Purpose Products for infants (SMPPi)'. We also support the proposal to regulate any special medical purpose product specifically formulated to be suitable for infants <12 months of age under Standard 2.9.1. We understand and support FSANZ's caveat: 'some of these specialised products may also be suitable and consumed up to three years of age or older,

and FSMP that are formulated for those one year and older (and not to be consumed by those < 12 months of age) will continue to be regulated by Standard 2.9.5.'

2.4.4 Human milk fortifiers and pre-term supplementary products

Dietitians Australia supports the proposal to include modular products such as human milk fortifiers and pre-term supplementary products in the SMPPi category. We do not support the proposed delineation between infant formula products and SMPPi products as outlined in 'Section 2.5 Preferred option'. Dietitians Australia opposes the inclusion of partially hydrolysed protein and lactose free/low lactose products in 'Infant Formula Products' for the reasons provided under section '2.4.2 Modified infant formula products' above. Where there is a proven medical need, these products should instead be included in the SMPPi category and regulated as such.

Proposed categories for Standard 2.9.1

As stated and justified in sections above, Dietitians Australia opposes the inclusion of partially hydrolysed protein and lactose free/low lactose products in 'Infant Formula Products'. These products need to be moved to the SMPPi category. We do support the other proposed changes outlined in 'Figure 2: Proposed categories for Standard 2.9.1' to implement the revised regulatory framework.

3 Definitions

3.1 Definitions for infant formula products

3.1.4 Preferred option

Dietitians Australia supports the preferred option to retain the proposed definition from the 2021 CP3 for infant formula and to include the existing definitions in the Code for infant formula products and follow-on formula. We support the proposed definitions for infant formula product, infant formula and follow-on formula as described.

3.2 Definition for SMPPi

Dietitians Australia supports the preferred option for the new definition for Special Medical Purpose Products for infants (SMPPi), as described.

3.3 Definition for protein substitute

Dietitians Australia does not support the removal of the definition for 'protein substitute'. Retaining the definition will help in identifying protein sources. Dietitians Australia also does not support labelling of protein sources that are not medically recommended, such as "partially hydrolysed" proteins.

As stated in section 2.4.2 above, ASCIA does not recommend using partially hydrolysed formula for dietary management of allergy.[5] Dietitians Australia recommends partially hydrolysed proteins be

listed on the ingredients list and nutrition information panel only to reduce marketing of non-medically recommended products.

3.4 Other definitions

3.4.1 Soy-based infant formula

Dietitians Australia supports the removal of the definition for 'soy-based infant formula'.

3.4.2 Pre-term formula

Dietitians Australia supports the removal of the definition for 'preterm' from Standard 2.9.1, acknowledging that SMPPi encompasses "products for all situations where breast milk or infant formula is not suitable to meet nutrition requirements of infants with a disease, disorder or medical condition." The category would adequately include pre-term formulas, which are specifically formulated to satisfy particular needs of infants born prematurely or of low birthweight, where breast milk, the ideal food for preterm infants, is not available.

3.4.3 Medium chain triglycerides (MCTs)

Dietitians Australia does not support the removal of the definition for 'medium chain triglycerides' from Standard 2.9.1. It is our view that MCTs are not recommended as an additive to standard formulas for healthy infants.

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.[7] 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.[8] 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. 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]

3.4.4 New definitions

Dietitians Australia supports FSANZ's proposal to ensure any infant formula product or additive in a product that claims to treat or manage a health condition meets strict criteria including definition of the health condition and strong evidence that the product or additive treats that condition. It is our understanding that FSANZ intends to rely on medically accepted definitions for each condition. Dietitians Australia recommends that FSANZ identify clinical references for such definitions to be

included in relevant sections of the regulation. We expect that medical conditions would not include normal infant behaviours (eg sleep, reflux, crying or comfort).

4 Novel foods and nutritive substances

4.1 Pre-market assessment requirements

Table 4.1.2 Stakeholder views and FSANZ responses

Dietitians Australia agrees that a substance such as alpha-lactalbumin that is isolated and purified from a 'natural source' has been manipulated from that natural source. It cannot be automatically assumed that it is safe when added back into an infant formula product.

4.1.4 Preferred option

Dietitians Australia does not support the removal of novel foods and nutritive substances from the scope of P1028. Despite the proposed approach described in FSANZ's response to this issue in Table 4.1.2, Dietitians Australia believes that novel foods targeted at infants under 12 months should include the same rigorous rules and regulations as infant formula. We are concerned that the removal of this category from P1028 would impact the rigor of assessments.

Table 4.2.1 Proposed conditions for novel foods in relation to infants and young children

Dried marine micro-algae (Schizochytrium sp.) rich in DHA

Dietitians Australia is concerned that this ingredient could be used as a non-evidence based marketing opportunity for manufacturers.

The Policy Guideline on the Regulation of Infant Formula outlines several principles relevant to the composition of infant and follow-on formula products.[10] 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 long-chain polyunsaturated fatty acids (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 but the evidence of other developmental benefits are not convincing.[11-18]

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.[19]

Oil derived from marine micro-algae (Schizochytrium sp) rich in DHA and oil derived from marine micro-algae (Ulkenia sp) rich in DHA

Dietitians Australia believes that the provision of adequate information relating to food is necessary to enable consumers to make informed choices and to prevent 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 the addition of voluntary nutritive ingredients
- Equity issues associated with cost of 'premium' and 'standard' formulas, and potential growth and development benefits of different products - if there are proven benefits of particular ingredients, they should be mandatory ingredients in all formulas. If there is no proven benefit of voluntary ingredients, or uncertain risks, then those ingredients should not be permitted at all
- Use of voluntary nutritive ingredients in the past 20 years, and the evidence for benefits or risks of these ingredients
- Considering prohibiting voluntary nutritive ingredients, and instead making nutritive ingredients mandatory if they mimic the composition of breast milk and are proven to benefit infant growth and development

5 Safety and food technology

Table 5.1 Proposed MPL for infant formula products and SMPPi

Infant Formula Products

Locust bean gum

Dietitians Australia recommends clearer restrictions for carry-over additives which should not be permitted in infant formulas. Carry-over additives may present a risk to infants. Dietitians Australia encourages further investigation into the efficacy and safety of thickeners in infant formulas marketed as 'anti-reflux'. There is insufficient evidence to support thickeners as effective to prevent or reduce the impacts of reflux. Exposure of infants to food additives which do not provide benefit is unnecessary. Further, marketing of certain infant formulas as 'anti-reflux' may discourage parents and carers from breastfeeding in an effort to reduce reflux and reduce the associated stress. Where there is a medical need to use thickeners, products should be categorised under SMPPi and administered only under medical supervision.

Pectins (INS 440), Xanthan gum (INS 415), Sodium alginate (INS 401), Sucrose esters of fatty esters (INS 473)

Dietitians Australia strongly supports FSANZ's proposal not to permit these ingredients in infant formula products.

5.2 Contaminants

Table 5.2 Proposed ML for infant formula products and SMPPi

Arsenic

Dietitians Australia does not support FSANZ's preferred approach to have no maximum level for arsenic in infant formula products.

We recommend that FSANZ further investigates the levels of arsenic in rice-based formulas due to the increasing popularity of these formulas alongside the popularity of vegan and gluten-free diets and as a nutrition source for infants with Cow's Milk Protein Allergy.[5, 20-22] Many commercial first foods are also rice-based and have been the subject of research into arsenic exposure in infants across the globe.[23-28] The combination of rice-based infant formulas and first foods may increase arsenic exposure in infants. We recommend FSANZ carefully monitor trends in rice-based infant formulas and commercial first foods and take a conservative approach to arsenic limits in infant formulas to protect infant health and safety.

5.4 L(+) lactic acid producing microorganisms

Dietitians Australia supports FSANZ's preferred approach to clarify the permission that only non-pathogenic or non-toxigenic microorganisms may be used within the existing permission. We further support FSANZ's proposal to clarify that L(+) lactic acid producing microorganisms may only be added for acidification purposes.

Dietitians Australia agrees that microorganisms added to infant formula products for a probiotic purpose require pre-market assessment as a novel food prior to use. We also agree that the use of L(+) lactic acid producing microorganisms for acidification in SMPPi should only be used if supported by scientific data. We recommend, however, that FSANZ replace the terms "generally accepted" with "strong" in relation to scientific data and to explicitly define the strength of evidence required.

6 Nutrient composition

6.3 Infant formula products

Dietitians Australia does not support FSANZ's proposal to remove the guideline on advice regarding additional vitamin and mineral supplementation. We believe that tight regulation regarding additional supplementation should remain in place to ensure that nutrient composition of infant formula similarly matches breast milk and is maintained within safe levels. We believe that without tight regulation, this may lead to serious and potentially life-threatening safety and toxicity concerns.

Regarding FSANZ's proposal not to prescribe a standardised measuring scoop or ratio, we recommend that standardised feeding guides, preparation instructions and diagrams, aligned with NHMRC Guidelines, be provided and be consistent across brands. Further information is provided below under 'Labelling'.

We do not support the inclusion of partially hydrolysed proteins, low lactose and lactose free formulas in the infant formula product category for the reasons already stated in this response.

Table 6.3 Proposed nutrient composition for infant and follow-on formula

Linoleic acid

Dietitians Australia notes that the range for linoleic acid (LA) in infant formulas proposed in Table 6.3 is 90-330mg/100kJ. As previously recommended, we believe FSANZ should adopt the EU 2016/127 minimum LA level of 120 mg/100 kJ.

Dietitians Australia reiterates that this level is the most consistent with Specific Policy Principles (b to j) in the Policy Guideline on the Regulation of Infant Formula and FSANZ Act s18(1)(a) and s18(2)(a-d).[10,19] This option supports alignment with the most recently updated regulation standards internationally (EU 2016/127 Annex 1, 5.4), is closer to minimum LA levels noted within breast milk of the ANZ population (140mg/100kJ) and with NHMRC Nutrient Reference Values (NRVs) for infants 0-12 months of age (n-6 Adequate Intake 4.4-4.6 g/day).[29-31] The lower level risks infants who rely solely on formula for nutrition not getting sufficient LA necessary for normal growth and development.

As indicated previously, the FSANZ label survey showed that most products in the market already exceed this standard.[30] When reviewed at the time of FSANZ's second consultation, Dietitians Australia found similarly that all but 1 product listing LA content available in major retailers exceeds the EU standard. The single product we found listed an LA content of 118.82mg/100kJ and would need only slight reformulation to meet the 120mg/100kJ minimum. Mandating the higher level of 120mg/100kJ would have minimal impact on industry, and a positive impact on infant health. We therefore strongly recommend the EU 2016/127 standard be adopted.

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.[32]

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, therefore they are expected to 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.

7 Labelling

7.1 Safety and technology

Dietitians Australia supports revisions to the directions for preparation and use, with some recommendations for adjustment.

We are supportive of:

- a prescribed order of mandatory nutrition information on Nutrition Information Panels (NIPs) for ease of comparison
- a prescribed name on NIP for ease of comparison and this should not be at manufacturer discretion
- consistent 100 mL between brands and removal of voluntary use of other base units for consistency across brands
- retaining the requirement for the proportion of powder or concentrate required to reconstitute formula, and, if a powdered product, the weight of one scoop - we recommend this be stated more prominently on the NIP
- a prescribed format of the NIP for ease of comparison across brands.
- clarifying that information relating to the proportion of powder or concentrate required to reconstitute formula must not be located in the nutrition information statement - this information should be located in the same position as the weight of the scoop
- maintaining existing specific labelling requirements for 'lactose free' and 'low lactose' products as they are commonly used for marketing purposes. Low and no lactose formulas should be categorised under SMPPi and regulated as such

Dietitians Australia believes shading should not be used in the NIP to highlight nutrients as this may be perceived as a claim. We do support separation, bolding and lines as long as the use of these is consistent with labelling of macronutrients.

We recommend alignment of ingredient names with the statement of ingredients for ease of understanding and consistency.

We strongly agree that references to conditions such as 'anti-reflux' or 'colic' should not be permitted, including in the name of the product. Further, manufacturers should not be able to make claims like 'helps with sleep'. Specialised formulas may have additional ingredients, however, claims that additives provide relief for infant discomfort or improve cognitive function are not supported by robust scientific evidence.[15, 33-36] We recommend that Standard 2.9.1 explicitly addresses and prohibits these types of claims that may sit outside the definition of a health claim.

Dietitians Australia does not support the use of stages on labelling and instead we recommend age ranges e.g. 0-6 months, 6-12 months. Using stages may be seen as promoting continued use. Ages should be prominently positioned on the front of packaging to avoid confusion and to indicate suitability of use.

Dietitians Australia believes that notifications of changes in product formulations can be seen as marketing. We recommend that such notifications only be permitted for a set period of time, e.g. 6 months. We do not support the use of transition guides as they are neither evidence-based nor medically necessary. These should be removed.

With reference to feeding volumes, Dietitians Australia recommends using language consistent with that in the NHMRC Infant Feeding Guidelines as a warning statement on feeding guides:

> "Bottle-feeding according to need is appropriate. Feeding guides are a guide only and may not suit every infant. Volumes are based on exclusively formula-fed babies."

We are concerned that leaving feeding volumes up to manufacturers' discretion can contribute to overfeeding of infants and confusion among parents and caregivers where guides differ across brands. We therefore recommend standardisation of feeding volumes across labels in line with the NHMRC Infant Feeding Guidelines Table 8.5.

We also reiterate that we strongly recommend standardised pictures and language for the preparation of infant formula. This will support consumers and industry. Instructions must align with the NHMRC Infant Feeding Guidelines and should use images and language similar to the World Health Organization guide on preparing infant formula.[1,37] Advice should be to discard formula after 1 hour rather than 2, as 1 hour is consistent with the NHMRC Infant Feeding Guidelines.[1] It is critical to provide this information in alignment with these guidelines as overfeeding is common and can lead to overweight and obesity.[38]

With regard to FSANZ's request for specific evidence around proxy advertising relating to infant formula products, studies have shown that proxy advertising does impact on product recognition and consumer choice.[39-41] With regard to advertisement of toddler milks for example, which share brand identities with infant formula, Berry *et al*. demonstrated that consumers were unable to distinguish between advertising for infant formula and that for toddler milk.[39] Other marketing practices on labels have also been shown to add to consumer confusion, influence choice and undermine breastfeeding.[42-44]

7.2 Provision of information

Dietitians Australia supports FSANZ's proposal to maintain existing requirements for most labelling elements (see sections 2.4.2 and 7.1 above) and we support the proposed prescribed format of the nutrition information statement.

We recommend that FSANZ mandate plain packaging for 'ready to drink' products. As the hospital system is a major distribution channel for ready to drink formulas, Dietitians Australia is of the view that parents and caregivers may see this as endorsement of products.

8 Special Medical Purpose Products for infants

Dietitians Australia supports the FSANZ's proposed approaches for the regulation of SMPPi.

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8.5 Storage instructions

Dietitians Australia recommends prescribed generic requirements for storage instructions for infant formula products to cover the period after the package is opened e.g. 4 weeks.

8.6 Legibility requirements for warning statements

Dietitians Australia supports maintenance of the existing legibility requirements.

8.7 Warning statements about following instructions exactly

Dietitians Australia supports the approach for a new direction for the preparation and use of infant formula products and consolidation of the warning statement into a single statement.

8.8 'Breast milk is best for babies' warning statement

Dietitians Australia supports the approach to retain the existing 'breast milk is best for babies' warning statement.

8.9 Prescribed name

Dietitians Australia supports maintenance of the current prescribed names.

8.10 Statement that infant formula product may be used from birth

Dietitians Australia supports the approach to maintain current requirements indicating infant formula may be used from birth.

8.11 Statement that FOF should not be used for infants under 6 months

Dietitians Australia supports maintenance of the current statement.

8.12 Statement about age to offer food in addition to formula.

Dietitians Australia recommends the addition of the term 'around' to align with the NHMRC Infant Feeding Guidelines.

8.13 Statement of protein source

Dietitians Australia supports FSANZ's approach. We agree that references to protein fractions in the protein source statement are not useful for caregivers and that they are used primarily for marketing purposes. We support clarification of protein fractions for medical purposes as per NHMRC Infant Feeding Guidelines and ASCIA guidelines, (eg complete hydrolysed formula, amino acid formula) where needed.

8. 14 Co-location of protein source statement with name of food

Dietitians Australia supports the maintenance of the current approach and recommendation.

References

1. National Health and Medical Research Council (2012) Infant Feeding Guidelines. Canberra: National Health and Medical Research Council. Available from: https://www.nhmrc.gov.au/about-us/publications/infant-feeding-guidelines-information-health-workers#block-views-block-file-attachments-content-block-1. Accessed 16 June 2022.
2. Council of Australian Governments (2019) Australian National Breastfeeding Strategy: 2019 and beyond. Canberra: Australian Government Department of Health. (https://www.health.gov.au/sites/default/files/documents/2022/03/australian-national-breastfeeding-strategy-2019-and-beyond.pdf) Accessed 16 June 2022.
3. National Health and Medical Research Council (2012) Infant Feeding Guidelines: information for health workers. Canberra: National Health and Medical Research Council. (https://www.eatforhealth.gov.au/sites/default/files/files/the_guidelines/n56_infant_feeding_guidelines.pdf) Accessed 16 June 2022.
4. World Health Organization and the United Nations Children's Fund (UNICEF) (2022) How the marketing of formula milk influences our decisions on infant feeding. Geneva: World Health Organization and the United Nations Children's Fund (UNICEF). (https://www.who.int/teams/maternal-newborn-child-adolescent-health-and-ageing/formula-milk-industry) Accessed 16 June 2022.
5. Australasian Society of Clinical Immunology and Allergy (2020) Guide for Milk Substitutes in Cow's Milk Allergy. ASCIA. (https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Guide_CMA_Milk_Substitutes_2020.pdf.) Accessed 16 June 2022.
6. Parry K, Taylor E, Hall-Dardess P, Walker M, Labbok M. (2013) Understanding women's interpretations of infant formula advertising. Birth.40(2):115-24.
7. Koletzko B, Lapillonne A. (2021) Lipid Requirements of Preterm Infants. World Rev Nutr Diet. 2021;122:89-102. 10.1159/000514749
8. Perretta L, Ouldibbat L, Hagadorn JI, Brumberg HL.(2021) High versus low medium chain triglyceride content of formula for promoting short-term growth of preterm infants. Cochrane Database Syst Rev. 2021;2(2):Cd002777. 10.1002/14651858.CD002777.pub2
9. Łoś-Rycharska E, Kieraszewicz Z, Czerwionka-Szaflarska M. (2016) Medium chain triglycerides (MCT) formulas in paediatric and allergological practice. Prz Gastroenterol. 2016;11(4):226-31.10.5114/pg.2016.61374
10. Australia and New Zealand Food Regulation Ministerial Council. (2011) Regulation of Infant Formula Products. (https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-Infant-Formula-Products.) Accessed 16 June 2022.
11. Miles EA, Childs CE, Calder PC.(2021) Long-Chain Polyunsaturated Fatty Acids (LCPUFAs) and the Developing Immune System: A Narrative Review. Nutrients. 2021;13(1). 10.3390/nu13010247
12. Hoppenbrouwers T, Cvejić Hogervorst JH, Garssen J, Wichers HJ, Willemsen LEM. (2019) Long Chain Polyunsaturated Fatty Acids (LCPUFAs) in the Prevention of Food Allergy. Front Immunol. 2019;10:1118. 10.3389/fimmu.2019.01118

13. Foiles AM, Kerling EH, Wick JA, Scalabrin DM, Colombo J, Carlson SE. Formula with long-chain polyunsaturated fatty acids reduces incidence of allergy in early childhood. Pediatr Allergy Immunol. 2016;27(2):156-61. 10.1111/pai.12515
14. Lien EL, Richard C, Hoffman DR. DHA and ARA addition to infant formula: Current status and future research directions. Prostaglandins, Leukotrienes and Essential Fatty Acids. 2018;128:26-40. 10.1016/j.plefa.2017.09.005
15. Verfuerden ML, Dib S, Jerrim J, Fewtrell M, Gilbert RE. (2020) Effect of long-chain polyunsaturated fatty acids in infant formula on long-term cognitive function in childhood: A systematic review and meta-analysis of randomised controlled trials. PLOS ONE. 2020;15(11):e0241800.10.1371/journal.pone.0241800
16. Carlson SE, Schipper L, Brenna JT, Agostoni C, Calder PC, Forsyth S, et al. (2021) Perspective: Moving Toward Desirable Linoleic Acid Content in Infant Formula. Advances in Nutrition. 2021.10.1093/advances/nmab076
17. Jasani B, Simmer K, Patole SK, Rao SC. (2017) Long chain polyunsaturated fatty acid supplementation in infants born at term. Cochrane Database Syst Rev. 2017;3(3):Cd000376.10.1002/14651858.CD000376.pub4
18. Moon K, Rao SC, Schulzke SM, Patole SK, Simmer K. (2016) Longchain polyunsaturated fatty acid supplementation in preterm infants. Cochrane Database Syst Rev. 2016;12(12):Cd000375.10.1002/14651858.CD000375.pub5
19. Food Standards Australia New Zealand Act 1991 (Cth). (https://www.legislation.gov.au/Details/C2018C00243.) Accessed 16 June 2022.
20. Dupont C, Bocquet A, Tomé D, Bernard M, Campeotto F, Dumond P, et al. (2020) Hydrolyzed Rice Protein-Based Formulas, a Vegetal Alternative in Cow's Milk Allergy. Nutrients. 2020;12(9):2654. 10.3390/nu12092654
21. Vandenplas Y, De Greef E, Hauser B, Paradice Study G. (2014) An extensively hydrolysed rice protein-based formula in the management of infants with cow's milk protein allergy: preliminary results after 1 month. Arch Dis Child. 2014;99(10):933-6. 10.1136/archdischild-2013-304727
22. Fiocchi A, Dahda L, Dupont C, Campoy C, Fierro V, Nieto A. (2016) Cow's milk allergy: towards an update of DRACMA guidelines. World Allergy Organization Journal. 2016;9(1):35. 10.1186/s40413-016-0125-0
23. Llorente-Mirandes T, Calderón J, López-Sánchez JF, Centrich F, Rubio R. (2012) A fully validated method for the determination of arsenic species in rice and infant cereal products. Pure and Applied Chemistry. 2012;84(2):225-38.
24. Igweze ZN, Ekhator OC, Nwaogazie I, Orisakwe OE. (2020) Public Health and Paediatric Risk Assessment of Aluminium, Arsenic and Mercury in Infant Formulas Marketed in Nigeria. Sultan Qaboos Univ Med J. 2020;20(1):e63-e70. 10.18295/squmj.2020.20.01.009
25. Jackson BP, Taylor VF, Punshon T, Cottingham KL. Arsenic concentration and speciation in infant formulas and first foods. Pure Appl Chem. 2012;84(2):215-23. 10.1351/PAC-CON-11-09-17
26. Gu Z, de Silva S, Reichman SM. (2020) Arsenic Concentrations and Dietary Exposure in Rice-Based Infant Food in Australia. International journal of environmental research and public health. 2020;17(2):415. 10.3390/ijerph17020415

27. Shi Z, Carey M, Davidson E, Meharg C, Meharg AA. (2021) Avoiding Rice-Based Cadmium and Inorganic Arsenic in Infant Diets Through Selection of Products Low in Concentration of These Contaminants. Exposure and Health. 2021;13(2):229-35. 10.1007/s12403-020-00376-3
28. Guillod-Magnin R, Brüschweiler BJ, Aubert R, Haldimann M. (2018) Arsenic species in rice and rice-based products consumed by toddlers in Switzerland. Food Additives & Contaminants: Part A. 2018;35(6):1164-78. 10.1080/19440049.2018.1440641
29. Commission Delegated Regulation (EU) 2016/127 (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0127&qid=1629422693768&from=EN Accessed 16 June 2022.)
30. Food Standards Australia New Zealand. (2021) Consultation paper 2 – Nutrient Composition. Proposal P1028 – Infant Formula. (https://www.foodstandards.gov.au/code/applications/Documents/CP2%20P1028.pdf (page 34). Accessed 16 June 2022.)
31. National Health and Medical Research Council. (2006) Nutrient Reference Values for Australia and New Zealand - Fats: Total fat & fatty acids. (https://www.nrv.gov.au/nutrients/fats-total-fat-fatty-acids Accessed 16 June 2022.)
32. National Health and Medical Research Council. (2006) Nutrient Reference Values for Australia and New Zealand - Choline. (https://www.nrv.gov.au/nutrients/choline Accessed 16 June 2022.)
33. Ball HL, Tomori C, McKenna JJ. Toward an Integrated Anthropology of Infant Sleep. American Anthropologist 2019; 121(3): 595-612.
34. Victora CG, Bahl R, Barros AJ, et al. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. Lancet 2016; 387(10017): 475-90. (https://doi.org/10.1016/S0140-6736(15)01024-7 Accessed 16 June 2022.)
35. Chu W. Infant nutrition: The business of 'selling sleep' and 'peace of mind'. Available from https://www.nutraingredients.com/Article/2017/05/16/Infant-nutrition-The-business-of-selling-sleep-and-peace-of-mind.
36. Verfurden ML, Gilbert R, Lucas A, Jerrim J, Fewtrell M. Effect of nutritionally modified infant formula on academic performance: linkage of seven dormant randomised controlled trials to national education data. BMJ (Clinical research ed) 2021; 375: e065805.
37. World Health Organization. How to prepare formula for bottle-feeding at home. 2007 Available from: https://www.who.int/foodsafety/publications/micro/PIF_Bottle_en.pdf. Accessed 16 June 2022.
38. Appleton J, Russell CG, Laws R, Fowler C, Campbell K, Denney, Wilson E. Infant formula feeding practices associated with rapid weight gain: A systematic review. Maternal & child nutrition. 2018 Jul;14(3):e12602.
39. Berry NJ, Jones SC, Iverson D. Toddler milk advertising in Australia: Infant formula advertising in disguise?. Australasian Marketing Journal. 2012 Feb;20(1):24-7.
40. Dickinson R, Gunter B, Matthews J, Cole J. The impact of amended controls on the advertising of infant formula in the UK: findings from a before and after study. International Journal of Health Promotion and Education. 2013 Jan 1;51(1):11-22.
41. Hastings G, Angus K, Eadie D, Hunt K. Selling second best: how infant formula marketing works. Globalization and Health. 2020 Dec;16(1):1-2.

42. Pomeranz JL, Palafox MJ, Harris JL. Toddler drinks, formulas, and milks: Labeling practices and policy implications. Preventive Medicine. 2018 Apr 1;109:11-6.
43. Romo-Palafox MJ, Pomeranz JL, Harris JL. Infant formula and toddler milk marketing and caregiver's provision to young children. Maternal & child nutrition. 2020 Jul;16(3):e12962.
44. Malek, L., Fowler, H., Duffy, G., & Katzer, L. (2019). Informed choice or guessing game? understanding caregivers' perceptions and use of infant formula labelling. Public Health Nutrition, 22(2), 273-286. doi:https://doi.org/10.1017/S1368980018003178