

P1028 Paper 1 – Infant formula safety and food technology

**Response to consultation
July 2021**

Recipient

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About Dietitians Australia

Dietitians Australia is the national association of the dietetic profession with over 7500 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 safety and food technology.

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 Guidelines¹ and Australian National Breastfeeding Strategy.² When breastfeeding or breastmilk is not an option, infant formulas can be used under the guidance of appropriately qualified health professionals, particularly dietitians.

Dietitians Australia recommends:

1. A conservative approach is taken to contaminants and food additives in infant formula to protect infant health and safety, allowing only additives supported as safe and efficacious by strong human research.
2. Clearer restrictions for carry-over additives which should not be permitted in infant formulas.
3. FSANZ further investigate 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.
4. Standard directions for infant formula preparation and use are clarified.
5. Prescribed warning statements promoting breastmilk are maintained.
6. Standardised pictures and language for preparation of infant formula are introduced.
7. FSANZ consider how protein subfractions are used on infant formula labelling, potential confusion for carers, and carer attitudes to infant formulas of various protein sources.
8. FSANZ consider that several smaller firms use contract manufacturers so costs of implementing regulatory changes would likely be shared by companies.

Discussion

Food additives and contaminants

1. FSANZ has proposed two options in relation to the ML for cadmium (Section 3.3.4). FSANZ asks stakeholders for views on these options.

Option 1, to not establish a maximum limit for cadmium, is not acceptable. This could present risks to infant health and safety, as well as trade issues.

Dietitians Australia recommends Option 2 as more appropriate for infant safety, trade with the European Union and consistency across international jurisdictions.

2. FSANZ requests further information from health professionals about the need to permit food additives as proposed in Table 2.17.

LOCUST BEAN GUM

Dietitians Australia supports the assessment in Supporting Document 1 and recommends the status quo is maintained, with no increase to permitted levels locust bean gum in infant formulas. As stated in Supporting Document 1, there is insufficient evidence of the safety of increasing locust bean gum in infant formulas to the level (10,000mg/L) proposed in Table 2.17. Further research with stronger methodology is required if locust bean gum levels are to be increased in infant formulas.

PECTINS

Dietitians Australia recommends FSANZ consider the strength of evidence of the safety and efficacy of pectins in infant formula in human research. We acknowledge this food additive may have a role in specialised infant formula but are concerned with the lack of data on the safety for human infants.

XANTHAN GUM

Dietitians Australia recommends FSANZ consider the strength of evidence of the safety of xanthan gum in infant formula in human research. While animal studies and limited observational human studies indicate xanthan gum may not be unsafe for vulnerable infants, 22 case reports have potentially linked xanthan gum with necrotising enterocolitis (NEC). Vulnerable infants relying on formula to support their growth and development must be protected. We therefore advocate for a conservative approach to protect infant safety.

SODIUM ALGINATE

Dietitians Australia recommends the status quo is maintained so sodium alginate is not permitted in infant formula. There is a lack of safety data and no risk assessments for this food additive in infant formula. Future review may be appropriate once sufficient data is available.

SODIUM CARBOXYMETHYLCELLULOSE

Dietitians Australia supports the FSANZ assessment that sodium carboxymethylcellulose should not be a permitted food additive in infant formula.

SUCROSE ESTERS OF FATTY ACIDS

Dietitians Australia recommends FSANZ consider the strength of evidence of the safety of sucrose esters of fatty acids in human research. We acknowledge this food additive may have a role in specialised infant formula but are concerned with the lack of data on the safety for infants aged less than 12 weeks.

3. In addition to the above list, what new evidence (if any) do you have for the potential health impacts for infants of changing any of the current permissions for any other food additives, discussed in this paper?

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 infant 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 infant reflux and reduce the associated stress.

4. In addition to the list above, can you provide any further examples of lack of alignment with EU regulations delaying important formula from reaching vulnerable infants?

Dietitians Australia is not aware of examples of lack of alignment with EU regulations delaying access to infant formula. In consultation with paediatric dietitians in major paediatric hospitals across Australia, no infant formulas were identified as desired but delayed or blocked from import.

5. To what extent would proposed changes to current permissions and limits for Special formula address any perceived delays to vulnerable infants accessing the imported formula that they need?

Dietitians Australia is not aware of examples of lack of alignment with EU regulations delaying access to infant formula. In consultation with paediatric dietitians in major paediatric hospitals across Australia, no infant formulas were identified as desired but delayed or blocked from import.

6. Would there be any practical barriers to complying with new permissions and limits as proposed in this document for any formula products that have not yet been identified? How might such barriers be overcome?

We understand several smaller firms use contract manufacturers so costs may not be as large as estimated, as they would be shared by companies contracting the manufacturer.

7. What (if any) implications might overcoming any practical barriers have for production costs per product line?

We understand several smaller firms use contract manufacturers so costs may not be as large as estimated, as they would be shared by companies contracting the manufacturer.

8. Might smaller or else larger businesses be disproportionately impacted if a new permission does not align with international regulations or standards?

We understand several smaller firms use contract manufacturers so costs may not be as large as estimated, as they would be shared by companies contracting the manufacturer.

9. Are any food additive preparations (food category 0 in Schedule 15) used in infant formula products? If so, how?

Not applicable.

10. What would be the practical steps involved in ensuring compliance of your products with the carry over provisions proposed in this paper?

Not applicable.

11. Do you have any more information on how much ensuring compliance would cost per effected product?

Not applicable.

12. Would different sized businesses be generally equally impacted from our proposed changes to the carry-over principle?

No comment.

L(+) lactic acid producing microorganisms

13. Does the current permission for L(+) lactic acid producing microorganisms need to be clarified?

Dietitians Australia recommends the current permission for L(+) lactic acid producing microorganisms is clarified to include only non-pathogenic species. This will reduce any room for misinterpretation. There is a lack of data of safety of L(+) lactic acid producing microorganisms in pre-term infants, so a warning should be applied to infant formulas that contain this culture.

Labelling

14. Do you support the amendments proposed (section 5.7)?

SECTION 5.3.1 – DIRECTIONS FOR PREPARATION AND USE

Dietitians Australia supports revision of the direction for water used to reconstitute powdered infant formula to include the word ‘cooled’.

Dietitians Australia supports revision of the direction to discard unfinished formula to include a specific time frame but recommends this be 1 hour rather than 2, to align with the Infant Feeding Guidelines.¹

SECTION 5.3.2 – STANDARDISED WORDING OR PICTURES FOR DIRECTIONS FOR PREPARATION AND USE

Dietitians Australia opposes the approach proposed in the consultation paper.

We strongly support standardised pictures and language for preparation of infant formula. This will support consumers and industry. Instructions must align with the NHMRC Infant Feeding Guidelines¹ and should use images and language similar to the World Health Organization guide on preparing infant formula.³ Advice should be to discard formula after 1 hour rather than 2, as 1 hour is consistent with the NHMRC Infant Feeding Guidelines.¹

SECTION 5.5.2 – WARNING STATEMENTS ABOUT FOLLOWING INSTRUCTIONS EXACTLY

Dietitians Australia supports the proposed additions to the warning statement, to specify that nothing should be added to infant formula except on medical advice.

SECTION 5.5.3 – WARNING STATEMENT THAT ‘BREAST IS BEST’

Dietitians Australia supports prescribed warning statements on infant formula. We suggest the prescribed statement is referred to as the ‘breastmilk is best’ statement. While we acknowledge the full statement reads ‘Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice’, we advise this change as some parents who cannot breastfeed find the ‘breast is best’ phrase to be alienating and a barrier to engaging with the healthcare system, or socially with other parents.

SECTION 5.6.4 – STATEMENT ON PROTEIN SOURCE

Dietitians Australia supports the proposed approach to clarify the ‘source’ of protein as referring to the origin of the protein (eg cow’s milk, goat’s milk, soy).

Dietitians Australia recommends FSANZ consider how protein subfractions are used on infant formula labelling (content claims and product names eg A2). Protein subfractions could further confuse parents and carers into thinking that some infant formulas are better than others. Research into trends should be analysed, including infants on a vegan or vegetarian diets, infant allergies and carer attitudes to infant formulas based on cow’s milk as more alternatives (eg pea protein-, rice-, A2-based) come to market.

SECTION 5.6.5 – CO-LOCATION OF PROTEIN SOURCE STATEMENT WITH THE NAME OF THE FOOD

Dietitians Australia supports the proposed approach to maintain the requirement for the co-location of the protein source statement and the prescribed name of the product. We support that the protein source statement would not be required each time the prescribed name occurs on the label.

15. Are you aware of any further data on infant illnesses that can be attributed to incorrect preparation as a result of unclear labelling or warning statements on products?

Dietitians Australia does not have further data.

16. How often do you change labels on your products voluntarily for marketing or other purposes?

Not applicable.

17. If the proposed changes were made at the same time as a voluntary label change, how much extra would it cost to change each product’s labels (on average)?

Not applicable.

18. If the proposed changes could not be made at the same time as a voluntary change, how much extra would it cost to change each product’s labels (on average)?

Not applicable.

19. Apart from any costs, would there be any other practical challenges of changing your products’ labels as proposed?

Not applicable.

General comments

20. 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?

Dietitians Australia notes the introductory statement on page 7 of the consultation paper ‘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’ and recommends this be strengthened in upcoming consultation papers on P1028. The NHMRC Infant Feeding Guidelines Information for Health Workers¹ (page 1) has stronger language that FSANZ should consider adding so consultation paper introductory statements reads:

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 infant and young child feeding.

A safe and nutritious substitute for breast milk is needed for infants when breastfeeding is not possible.

Further, Dietitians Australia recommends FSANZ further investigate 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 Cows Milk Protein Allergy.⁴⁻⁷ Many commercial first foods are also rice-based and have been the subject of research into arsenic exposure in infants across the globe.⁸⁻¹³ 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.

References

1. National Health and Medical Research Council. Infant Feeding Guidelines. 2012 Available from: <https://www.nhmrc.gov.au/about-us/publications/infant-feeding-guidelines-information-health-workers#block-views-block-file-attachments-content-block-1>.
2. COAG Health Council. Australian National Breastfeeding Strategy: 2019 and Beyond. 2019 Available from: <http://www.coaghealthcouncil.gov.au/Publications/Reports>.
3. 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.
4. Dupont C, Bocquet A, Tomé D, Bernard M, Campeotto F, Dumond P, et al. Hydrolyzed Rice Protein-Based Formulas, a Vegetal Alternative in Cow's Milk Allergy. *Nutrients*. 2020;12(9):2654. 10.3390/nu12092654
5. Australasian Society of Clinical Immunology and Allergy. Guide for Milk Substitutes in Cow's Milk Allergy. ASCIA; 2020 Available from: https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Guide_CMA_Milk_Substitutes_2020.pdf.
6. Vandenplas Y, De Greef E, Hauser B, Paradise Study G, Paradise Study G. 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
7. Fiocchi A, Dahda L, Dupont C, Campoy C, Fierro V, Nieto A. Cow's milk allergy: towards an update of DRACMA guidelines. *World Allergy Organization Journal*. 2016;9(1):35. 10.1186/s40413-016-0125-0
8. Llorente-Mirandes T, Calderón J, López-Sánchez JF, Centrich F, Rubio R. 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.
9. Igweze ZN, Ekhaton OC, Nwaogazie I, Orisakwe OE. 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
10. 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
11. Gu Z, de Silva S, Reichman SM. 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
12. Shi Z, Carey M, Davidson E, Meharg C, Meharg AA. 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
13. Guillod-Magnin R, Brüscheweiler BJ, Aubert R, Haldimann M. 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