Imported food risk statement

Infant formula products

Scope: All requirements for infant formula products, as defined in Standard 1.1.2—3 of the Australia New Zealand Food Standards Code, which includes infant formula (0-6 months), follow-on formula (6-12 months) and special medical purpose product for infants (used under medical supervision).

Recommendation and rationale

Do infant formula products present a potential medium or high risk to public health:

☑ *Yes*

☐ *No*

Rationale:

- Infants are the most vulnerable population in our society, and it is critical to ensure appropriate safeguards are in place.
- The first year of life offers a critical window to shape the trajectory of their health and future development. A vital factor influencing infant health and safety is the nutrition they receive.
- Where infants cannot be breastfed, infant formula products are the only safe and nutritious alternative. Infant formula products provide the sole or principal source of nutrition and therefore a prescriptive approach to protecting infant health and safety is essential.
- Infant formula products that are prepared incorrectly, have inadequate nutrition or are inappropriate for the infant population (such as in the case of a special medical purpose product for infants or formula containing unapproved substances) can cause irreversible harm and serious health consequences such as failure to thrive[1] and death.
    - Incorrect preparation of infant formula products can lead to malnutrition, bacterial infections, choking, diarrhoea and constipation.
    - Inadequate nutrition composition of infant formula products can put developing infants at risk of malnutrition. Malnutrition encompasses deficiencies or excesses in nutrition intake, and imbalances in essential nutrients. In infants this can result in deficits in growth, developmental delays (e.g. cognitive, motor) and diseases later in life.
- The revised infant formula product requirements include substantial changes to the nutrition composition that are reflective of the best available scientific evidence and bring infant formula products more closely in line with breast milk. The improvements made to macronutrients, micronutrients, reducing levels of contaminants and mandating several new ingredients provides a significant benefit to the health of infants.
- The key risk factors identified in this risk statement are cases where infants (from birth to 12 months) are consuming infant formula products, which are not compliant with the revised Standard 2.9.1, as the sole or principal source of nutrition.
- The revised infant formula product requirements provide an interconnected risk management approach for the composition, labelling, category definitions and representation of infant formula products. Products that do not comply with the new regulatory changes in their entirety would not be adequately managing the risks considered during the revision of the infant formula product standard. This poses a medium to high risk to the public health of infants.

General description

Nature of the risk

Although breastfeeding is the recommended way to feed infants, a safe and nutritious substitute for breast milk is essential for infants who are not breastfed. Infant formula products are the only safe and suitable alternative to breast milk. Infant

[1] 'Failure to thrive' in paediatrics refers to slow physical development characterised by insufficient weight gain and absence of growth in infants and young children.

General description
formula products are specifically regulated through Standard 2.9.1 – Infant formula products of the Australia New Zealand Food Standards Code (the Code) and have the most prescriptive requirements of any food category. In 2024, Food Standards Australia New Zealand (FSANZ) completed a review of the regulation of infant formula products through Proposal P1028 (FSANZ, 2024). Following a thorough evidence-based risk analysis and consultation process, a comprehensive suite of interconnected risk management measures inclusive of composition, labelling, category definitions and representation of infant formula products were developed. These were developed to ensure infant formula product regulations are based on the best available scientific evidence including: • Updated nutrient composition (including energy, macronutrients, micronutrients and permitted sources). • Revised permissions for food additives, contaminants and processing aids. • Revised labelling requirements (including safety-related labelling such as directions for use and storage, warning statements and age-related statements, and provision of information such as nutrition information, stage labelling and a prohibition on proxy advertising). • Requirements for special medical purpose product for infants (including a definition, nutrient composition, restriction on sale and standalone labelling permissions reflective of Standard 2.9.5 - Foods for Special Medial Purpose). • Clarified novel food permissions and pre-market assessment requirements.
Adverse health effects: The first year of life is a critical time for growth and development of an infant. Infant nutritional requirements are best met through breastfeeding, which provides appropriate nourishment as an infant's digestive and immune system matures to allow consumption of solid food. For infants who are not breastfed, infant formula products are the only safe and nutritious substitute for breast milk. The revised infant formula product requirements include substantial changes to the nutrition composition that are reflective of the best available scientific evidence and bring infant formula products more closely in line with breast milk. The improvements made provide significant benefit to the health of infants, these include: • Prescribed protein sources which ensure only proteins that have been assessed by FSANZ as safe and suitable will be present in infant formula products. • Prescribed carbohydrate sources which ensure carbohydrates that are naturally occurring in breast milk are present in infant formula products. • Updated macronutrient and micronutrient levels to better reflect nutrient reference values and breast milk composition. • Reduced levels for contaminants, such as lead, to avoid burdening immature and developing infant digestive and immune systems. • Mandated three essential ingredients that were previously voluntarily added. Under the revised regulations all infant formula products will be required to include L-carnitine, inositol and choline, which are all key components of breastmilk. Infant formula products that are prepared incorrectly, have inadequate nutrition or are inappropriate for the infant population (such as in the case of a special medical purpose product for infants or formula containing unapproved novel foods) can cause irreversible harm to infants. Incorrect preparation of infant formula products can lead to malnutrition, bacterial infections, choking, diarrhoea, constipation and in prolonged cases can have serious health consequences such as failure to thrive and death. Inadequate nutrition composition of infant formula products can put developing infants at risk of malnutrition. Malnutrition encompasses deficiencies or excesses in nutrition intake, and imbalances in essential nutrients. In infants this can result in deficits in growth, developmental delays (e.g. cognitive, motor), diseases later in life and increased risk of other serious health consequences such as failure to thrive and death. Special medical purpose product for infants (specialised formulas) are inappropriate for general use by the infant population and can also be misused by target populations. Both circumstances can result in serious health consequences for infants. Under revisions made to the infant formula product standard, the risk of unintentional misuse of specialised formulas is managed through multiple regulatory interventions to ensure these products are regulated consistently with all other foods for special medical purposes and are now required to state 'for use under medical supervision' on the label. The misuse of these products resulting from unclear labelling and misrepresentation, significantly risks infant health and safety. A common example is the misuse of low lactose and lactose free formulas in the treatment of cows milk protein

General description
allergy, which can cause damage to infants digestive tracts and can prolong diagnosing the allergy (Crittenden 2005, Di Constanzo 2018, Walsh 2016). The FSANZ literature and consumer evidence review (FSANZ, 2024) found that: • Caregivers often interpret normal unsettled infant behaviours as medical concerns which require use of specialised formulas. • Only 19% of caregivers seek medical advice prior to commencing formula feeding. • Self-reported food allergy overestimates prevalence relative to clinically diagnosed prevalence. • There has been rapid growth in the sale of specialised formulas that are marketed to address sensitivities and allergies, which is not aligned with international epidemiological prevalence data.
Consumption patterns: Infant formula products are the sole or principal source of nutrition consumed by formula-fed infants in the first year of life. As the most vulnerable population in our society, infants who are formula-fed rely on infant formula products to provide all essential nutrition for adequate growth and development.
Risk factors and risk mitigation Key risk factors identified in this risk statement concern infants (from birth to 12 months) consuming infant formula products which are not compliant with the revised requirements of Standard 2.9.1, as the sole or principal source of nutrition. A prescriptive and comprehensive regulatory approach is essential in protecting the health and safety of this vulnerable population. Products which do not comply with the revised requirements of Standard 2.9.1 in their entirety (inclusive of composition, labelling, category definitions and representation of infant formula products) do not adequately manage the risks addressed by Proposal P1028. The revised requirements for composition, labelling and sale under Standard 2.9.1 are based on the best available scientific evidence and were developed as an interconnected risk management approach. In addition to the amendments to the primary Standard 2.9.1, there are consequential amendments to the Code across 12 other standards and schedules.

Australian standards or guidelines
Policies, Codes of Practice and Guidelines The regulation of infant formula products complements broader public health policy by aligning where possible and extending consideration to the Australian Infant Feeding Guidelines (NHMRC, 2012), Healthy Eating Guidelines for New Zealand Babies and Toddlers (MoH, 2021), Nutrient Reference Values for Australia and New Zealand (NHMRC and MoH, 2006), the Marketing in Australia of Infant Formulas Agreement (MAIF agreement) (DOHA, 2022), Infant Nutrition Council Code of Practice for the Marketing of Infant Formula in New Zealand (INC, 2018) and the Ministerial Policy Guideline on the Regulation of Infant Formula Products (ANZFRMC, 2011). **Standards** Standard 2.9.1 of the Code regulates composition, labelling and sale of infant formula products. This regulation was recently reviewed and updated as part of Proposal P1028. The revised regulation for infant formula products came into effect on 13 September 2024 and applies in Australia only (i.e. it is not a bi-national food standard). The revised regulation extends across eight standards and five schedules in the Code, including: • Standard 2.9.1—Infant formula products Infant formula products • Standard 1.1.2—Definitions used throughout the Code • Standard 1.2.3—Information requirements – warning statements, advisory statements and declarations • Standard 1.3.1—Food additives • Standard 1.5.1—Novel foods • Standard 2.9.2—Food for infants • Standard 2.9.3—Formulated meal replacements and formulated supplementary foods • Standard 2.9.5—Food for special medical purposes • Schedule 8—Food additive names and code numbers (for statement of ingredients) • Schedule 15—Substances that may be used as food additives • Schedule 19—Maximum levels of contaminants and natural toxicants • Schedule 25—Permitted novel foods

Australian standards or guidelines
• Schedule 29—Special purpose foods. A summary of the regulatory changes made to each standard and schedule is detailed in Appendix 1. There is a five year transition period to allow companies to become compliant with the revised Standard 2.9.1, which ends on 13 September 2029. Due to the lengthy product shelf-life of infant formula products (18-24 months), and complexities in reformulation, it is expected that most products will be fully complaint with revised Standard 2.9.1 within three years. Infant formula products regulated under Standard 2.9.1 do not include supplementary or modular medical products for infants, toddler milks or foods for infants. These are regulated by Standard 2.9.5, Standard 2.9.3 and Standard 2.9.2 of the Code respectively.

Management approaches used by overseas countries
New Zealand New Zealand did not adopt Amendment No. 231 to Standard 2.9.1 of the Code, which were changes made by Proposal P1028. In New Zealand, infant formula products are regulated by the *New Zealand Food Act (2014)*. **European Union** In 2016 the European Commission Directive revised its regulation for Infant Formula and Follow-on Formulae (European Commission, 2016). The regulation follows a similar regulatory framework to that of the Code and prescribes requirements for labelling and composition. Where appropriate, based on the Australian and New Zealand nutrient reference values and breastmilk composition, compositional alignment was sought through Proposal P1028. Where possible, consistency between labelling requirements was also sought. Like Australia, the EU prohibits the use of nutrient and health claims on infant formula products. Products compliant with EU regulations are currently permitted to include a statement on the front of the pack that the product contains DHA (docosahexaenoic acid), however this is a transitional arrangement while the DHA composition becomes mandatory in infant formula products. After 22 February 2025, such claims will be prohibited and aligned with amendments made under Proposal P1028. The EU regulates special purpose infant formulas as food for special medical purposes specifically designed for infants. Specific compositional and information requirements for infant formula for special medical purposes are set out in Commission Delegated Regulation 2016/128 (European Commission, 2016). This includes a requirement for the nutritional composition to be based on that of infant and follow-on formula, except where necessary for the intended purpose of the product. Where appropriate, the revised Standard 2.9.1 considered the EU regulations to ensure specialised formula (predominantly imported from the EU) continue to be accessible for Australian infants. **Codex Alimentarius** Codex Alimentarius provides guidelines that international jurisdictions can chose to adopt and amend based on their populations needs. Codex Alimentarius, through the Codex Committee for Nutrition and Special Dietary Uses (CCNFSDU), updated its infant formula standard in 2007 to include new provisions in section B of that standard for formula for special medical purposes intended for infants. Section B sets out the composition, quality, labelling and safety requirements by referencing the requirements for infant formula in section A of that standard, where appropriate. It also draws on the Codex provisions for labelling of food for special medical purposes (FSMP) (Codex CXS 180-1991; Codex 1991). In recent years, the Codex Committee has revised the Codex Standard for Follow-up Formula for older infants and products for young children (Codex CXS 156-1987; Codex 1987; Codex 2023). Codex CXS 156-1987 was adopted by the Codex Alimentarius Committee (CAC) in late 2023 and the related food additive provisions were considered by the Codex Committee on Food Additives (CCFA) at the CCFA53 meeting held in March 2023. Where appropriate, the revised Standard 2.9.1 aligned with the Codex Standards to facilitate alignment with international regulations.

This risk statement was compiled in: December 2024

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Appendix 1 - Key changes made by Proposal P1028

Key changes made by the approved draft variations are summarised below.

Standard 2.9.1—Infant formula products

Division 1 Preliminary

- To take effect after a 60 month transition period during which a product may comply with either the Code in force without the variations or the Code as amended by the variations.
- Renamed the Infant Formula Products for Special Dietary Use (IFPSDU) category as Special Medical Purpose Product for infants (SMPPi) with a new definition for SMPPi.
- Amended the regulatory framework to clearly separate infant formula and follow-on formula requirements from SMPPi.
- Amended the definitions for infant formula products, infant formula and follow-on formula to ensure each definition captures the respective products they represent.

Division 2 Compositional requirements for infant formula and follow-on formula

- Amended Division 2 to prescribe compositional requirements for infant formula and follow-on formula.
- Amended general compositional requirements for infant formula and follow-on formula such as permissions relating to energy, macronutrients, minerals, vitamins, electrolytes and nutritive substances.
- Added compositional limits for fluoride content of powdered, concentrated and ready-to-drink formulas.
- Added a requirement that the protein source for infant formula and follow-on formula must only be derived from one or more of the following proteins - cow milk, goat milk, sheep milk, soy protein isolate or a partially hydrolysed protein of one or more of these.
- Added a requirement that infant formula and follow-on formula must not contain added fructose and/or added sucrose, unless manufactured from partially hydrolysed protein where the fructose or sucrose is added as a source of carbohydrate and does not exceed 20% of available carbohydrates in the formula.
- Follow-on formula and infant formula have the same compositional requirements except for the protein minimum, vitamin D maximum, calcium maximum, iron minimum, choline minimum, inositol minimum and L-carnitine maximum.

Division 3 Labelling and packaging requirements for infant formula and follow-on formula

- Amended Division 3 by modifying existing requirements and adding new requirements relating to the labelling of infant formula and follow-on formula.
- Retained most labelling requirements for infant formula and follow-on formula, such as the prescribed name, the warning statement about 'breast milk is best', required statements about age, print size of warning statements, storage instructions and the application of general labelling requirements in Part 1.2 of the Code.
- Introduced requirements for product differentiation to require infant formula and follow-on formula to be differentiated from each other and from other foods by the use of text, pictures and/or colour.
- Varied the statement of protein source to require the specific animal or plant source of protein to be included in the name of the food, on the front of the package.
- Introduced an optional format for declaring added vitamins and minerals in the statement of ingredients.
- Simplified separate 'follow instructions exactly' warning statements for powdered, concentrated and ready-to-drink formulas to a single warning statement applicable to all product types. Added new directions for preparation and use specifying not to change proportions of powder/concentrate or to dilute ready-to-drink formula or add other food to any product type.
- Amended requirements for the nutrition information statement including what must be provided in the statement and introduced a new requirement for a prescribed form of the statement.
- Introduced requirements for the voluntary use of stage numbers.
- Retained existing prohibited representations and added further prohibitions on information relating to other foods and ingredients, the protein source and the words 'partially hydrolysed'.
- Removed labelling permissions for making low lactose and lactose free representations on infant formula and follow-on formula labels.

Division 4 Special medical purpose product for infants

- Amended Division 4 to prescribe requirements for SMPPi including sale, nutrition composition and labelling.
- Added a restriction on sale that limits the sale of SMPPi to a medical practitioner, dietitian, medical practice, pharmacy, responsible institution or majority seller of that product.
- Introduced compositional requirements for SMPPi that replicate the baseline composition of infant formula. Retained existing Code provisions that allow deviation from the prescribed compositional requirements if necessary to achieve the product's intended medical purpose or if it would otherwise prevent the sale of the product.
- Introduced a new labelling framework for SMPPi that specifies:
    - applicable general labelling requirements in Parts 1.2 and 1.5 of the Code (for example a name or description to indicate the true nature of the food)
    - required statements and declarations (for example the product must be used under medical supervision, the medical purpose of the product).
    - new labelling requirements for ingredients, date marking and nutrition information, inner packages and transportation outers and for SMPPi to be differentiated from other products.
    - a specific prohibition on claims made about SMPPi, unless expressly permitted.
    - permitted a lactose free claim on SMPPi.
    - retained prohibited representations that apply to infant formula and follow-on formula.

Schedule 29—Special purpose foods

- Amended compositional requirements for infant formula, follow-on formula and SMPPi, such as associated maximums, minimums, permitted forms, quality scores, units of expression, conversion factors, equivalents, ratios and nutrient interactions for energy, macronutrients, minerals, vitamins, electrolytes and nutritive substances.
- Prescribes the required format of the nutrition information statement including headings, subheadings, order, names and acronyms, base units of expression, units of measurement and bold text.

Standard 1.1.2—Definitions used throughout the Code

- Amended definitions that were revised, repealed or inserted into Standard 2.9.1, to ensure definitions are consistently applied throughout the Code.

Standard 1.2.3—Information requirements – warning statements, advisory statements and declarations

- Amended requirements to refer to SMPPi as the new infant formula product category.

Standard 1.3.1—Food additives

- Amended the requirements for carry-over of food additives to apply to foods other than infant formula products.

Standard 1.5.1—Novel foods

- Amended the definition for novel foods to note that the presence of a food as a SMPPi or in a SMPPi does not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of this section.
- Amended the requirements for sale of a novel food to ensure that unless there is express permission a novel food must not be added to infant formula products.

Standard 2.9.2—Food for infants

- Amended references to Schedule 29 to ensure compositional requirements are correctly captured.

Standard 2.9.3—Formulated meal replacements and formulated supplementary foods

- Amended references to Schedule 29 to ensure compositional requirements are correctly captured.

Standard 2.9.5—Food for special medical purposes

- Amended references to Schedule 29 to ensure compositional requirements are correctly captured.

Schedule 8—Food additive names and code numbers (for statement of ingredients)

- Added dl-Alpha-tocopherol, potassium hydroxide and sodium hydroxide to the food additive names and code numbers listed in the Schedule.

Schedule 15—Substances that may be used as food additives

- Amended requirements for food additives, including revision of condition statements and variation to Maximum Permitted Levels for infant formula products.

Schedule 19—Maximum levels of contaminants and natural toxicants

- Added separate maximum levels for aluminium in the following groups: infant formula, follow-on formula and special medical purpose product for infants (other than special medical purpose product for infants formulated for pre-term infants), soy-based infant formula products and special medical purpose product for infants formulated for pre-term infants.
- Reduced the maximum level for lead in infant formula products.

Schedule 25—Permitted novel foods

- Amended the condition statements for dried marine micro-algae (Schizochytrium sp.) rich in docosahexaenoic acid (DHA), oil derived from marine micro-algae Schizochytrium sp. (American Type Culture Collection (ATCC) PTA-9695) and oil derived from marine micro-algae (Ulkenia sp.) rich in docosahexaenoic acid (DHA) to clarify they may be added to infant formula products in accordance with Standard 2.9.1.
- Amended the condition statements for oil derived from marine micro-algae (Schizochytrium sp.) rich in docosahexaenoic acid (DHA) to clarify it is only permitted for use in infant formula products in accordance with Standard 2.9.1.
- Amended condition statements for isomalto-oligosaccharide and rapeseed protein isolate to clarify that they must not be added to infant formula products.
- Added trehalose as a novel food with a condition that it may be added to infant formula products only as a cryo-preservative for L(+) lactic acid producing microorganisms.