4 April 2022
196-22

Supporting document 6

Assessment against Ministerial Policy Guidelines

Proposal P1028 – Infant formula

FSANZ has had regard to two Ministerial Policy Guidelines relevant to Proposal P1028, as required under subsection 18(2) of the FSANZ Act:

- Regulation of Infant Formula Products
- Intent of Part 2.9 - Special Purpose Foods

The tables below summarise our assessment against the specific policy principles of these policy guidelines.

1 Regulation of Infant Formula Products

FSANZ has had regard to the policy guideline on the Regulation of Infant Formula Products in our assessment of this proposal. The policy guideline includes specific policy principles relating to composition, labelling and advertising, as well as overarching principles. The table below summarises our assessment against these specific policy principles for the proposed changes to Standard 2.9.1 and Schedule 29.

Table 1: P1028 assessment against specific policy principles

Specific Policy Principles	Assessment
Overarching principles	
(a) The regulation of infant formula products should recognise that breastfeeding is the normal and recommended way to feed an infant.	FSANZ acknowledges in the 1st Call for Submissions (CFS) report that breastfeeding is the recommended way to feed an infant.
(b) The regulation of infant formula products should not be inconsistent with the national nutrition policies and guidelines of Australia and New Zealand that are relevant to infant feeding.	In reviewing the requirements for infant formula products in Standard 2.9.1 and Schedule 29, FSANZ has had regard to: - Australian Infant Feeding Guidelines - Healthy Eating Guidelines for New Zealand Babies and Toddlers Australian - Australian and New Zealand Nutrient Reference Values These documents are cited where relevant in the CFS and relevant Supporting Documents (SD).
(c) The regulation of infant formula products should be based on risk analysis, taking into account the vulnerability of the population for whom they are intended and the importance of these products in the diets of formula fed infants.	Infants are recognised as a vulnerable population group, hence infant formula is tightly regulated in the Code. FSANZ has used the internationally accepted risk analysis framework in our decision making, this takes into account the importance of the role of formula as a potential sole source of nutrients and the vulnerability of the formula-fed infant population. The risk analysis approach for Proposal P1028 comprised of: (i) a food additive safety assessment, which included evaluation against Joint FAO/WHO Expert Committee on Food Additives (JECFA) recommendations, food additive permissions in Codex and the EU regulation (ii) a microbiology risk assessment of L(+) lactic acid producing microorganisms, which evaluated relevant, appropriately designed studies, including clinical trials, case reports, other relevant epidemiological studies and studies evaluating safety (iii) a microbiological safety assessment of powdered infant formula which used the risk assessment model developed by the Food and Agriculture Organization/World Health Organization (FAO/WHO) to estimate the relative risk that the main microbiological hazard identified—Cronobacter spp. (formerly

Specific Policy Principles	Assessment
	known as Enterobacter sakazakii)—poses to infants from intrinsically contaminated powdered infant formula (iv) a consumer research evidence review that focused on the safe preparation and use of infant formula (v) consumer research on infant formula labelling (vi) a comparative nutrition assessment of compositional requirements in the Code and Codex Alimentarius Standard 72-1981 Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex STAN 72-1981; Codex 1981) (vii) a comparative nutrition assessment of compositional requirements in the Code and set by the European Commission Delegated Regulation (EU) 2016/127 (EU 2016/127) (viii) a comparative nutrition composition assessment of the Code, Codex STAN 72-1981 and EU 2016/127 against substances naturally present in human milk. The risk management component comprised: (i) consideration of risk assessment conclusions (ii) nutrient composition requirements to provide infants with all essential nutrients (iii) labelling for safe preparation and use and provision of information to enable informed choice.
Composition	
(d) The composition of infant formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole source of nutrition up to six months of age. AND (e) The composition of follow-on formula must be safe,	FSANZ 2016 Nutrition Assessment evaluated the best available scientific evidence on physiological, metabolic, and biochemical processes that underlie normal growth and development in infants. This included evidence obtained from reports published by key review panels, published primary research and other vitro evidence and infant trials relevant to the Australian and New Zealand (ANZ) population. The 2016 Nutrition Assessment also evaluated the Codex STAN 72-1981 provisions for each nutrient against a set of criteria. The assessment criteria was as follows: - origin of the current standards

Specific Policy Principles	Assessment
suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical or functional outcomes) of healthy full term breastfed infants at the appropriate age when follow-on formula used as the principal source of liquid nourishment in a progressively diversified diet.	- recommendations of key expert bodies - comparison with human milk concentrations - estimation of intakes and comparison with ANZ Nutrient Reference Values (NRVs) for adequate and excess intakes - physiological, biochemical or functional outcomes - identification of new or emerging scientific evidence. The 2021 Nutrition Assessment built on the 2016 Nutrition Assessment and evaluated the EU 2016/17 provisions for each nutrient against a set of criteria. The assessment criteria was as follows: - outline of the scientific basis of the current standards - comparison with human milk concentrations, focusing on ANZ populations - comparison with EFSA (2014) recommendations and FSANZ (2016) proposed levels - estimation of intakes and comparison with ANZ NRVs for adequate and excess intakes (non-ANZ NRVs were used in circumstances when an ANZ value was not available) - other relevant factors unique to the nutrient of interest such as the impact of manufacturing or other nutrients on the nutrient's bioavailability, history of apparent safe use, or the ANZ infant or maternal population - when a potential risk was identified based on comparisons to human milk concentrations and NRVs, a review of scientific evidence which focused on primary research published after the FSANZ 2016 assessment and on ANZ populations - if a potential risk was identified, a comparative assessment of the risk associated with the compositional requirements of the Code and Codex STAN 72-1981 was conducted. Both Nutrition Assessments evaluated evidence based on infants aged 0-12 months. Normal growth and development was considered through the FSANZ 2016 and 2021 Nutrition Assessments, noting measures of growth relate to both safety and favourable health effects. Given the complexities and ethical challenges in infant feeding research, FSANZ notes that comparisons of anthropometric measures (length, weight, head circumference)

Specific Policy Principles	Assessment
	should consider: control and intervention groups as well as intervention groups and breastfed reference group. The assessment included infant studies which assessed growth concluding that there are no negative impacts on physical growth throughout infancy. The above assessments concluded that the proposed composition for infant formula products is safe, suitable for the intended purpose and will achieve as closely as possible the normal growth and development of healthy full term exclusively breastfed infants when infant formula is used as the sole source of nutrition for up to six months of age and continued use for up to 12 months of age alongside complementary feeding.
(f) The essential composition of infant formula and follow-on formula should be prescribed in regulation and must satisfy the nutritional requirements of infants.	Proposal P1028 – Infant Formula has reviewed and proposed updated essential composition and voluntary permissions for infant formula and follow-on formula. As noted above, the FSANZ 2016 and 2021 Nutrition Assessments concluded that the proposed composition satisfied the nutritional requirements of ANZ infants and ensures normal growth and development.
(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.	See comments for specific policy principles (d), (e) and (f).
(h) The composition of breast milk should be used as a primary reference for determining the composition of infant formula and follow-on formula.	FSANZ 2016 and 2021 Nutrition Assessments used breast milk as the primary reference for determining compositional requirements of infant formula products (FSANZ 2016, FSANZ 2021). Further to this, comparison of breast milk from Australian and New Zealand mothers was used where available.
(i) Pre-market assessment, relative to principles (d) and (e), should be required for any substance proposed to be used in infant formula and follow-on formula that: i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or ii. has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.	Policy principle (i) sets the requirements for pre-market assessment for any new substance proposed to be used in infant formula and follow on formula. FSANZ has reviewed the current compositional requirements and no new substances are proposed to be added.

Specific Policy Principles	Assessment
(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 breast milk. 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. Particular caution should be applied by the Authority where such links are less clear.	See comments for specific policy principle (i).
Labelling and advertising	
(k) The labelling and advertising of infant formula products should be consistent with the World Health Organization International Code of Marketing of Breast Milk Substitutes (*WHO Marketing Code*) as implemented in Australia and New Zealand.	FSANZ has reviewed existing generic requirements in Part 1.2 of the Code (e.g. labelling of ingredients, lot identification) and specific requirements in Standard 2.9.1 (e.g. directions for preparation and use, prohibited representations) that are consistent with the WHO Marketing Code. FSANZ is proposing: • these labelling requirements primarily remain unchanged • minor changes to some provisions to assist caregivers' understanding and use of infant formula products. Proposed changes for certain directions for preparation and use (including a new direction), a warning statement to follow instructions exactly and clarifications to the protein source statement are detailed in SD1. FSANZ is also proposing a consistent, prescribed format for declaring nutrition information, and clarifications for ingredient declarations and certain nutrient declarations to assist caregivers when making product choices and for regulatory certainty regarding prohibited representations (see SD3).
(l) The labelling and advertising of infant formula products should not represent those products as an equivalent to, or better than, breast milk.	Existing provisions in section 2.9.1—24 Prohibited representations are proposed to be retained.

Specific Policy Principles	Assessment
(m) The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products.	See comments for specific policy principle (k).
(n) The Authority should: i. ensure that the prohibitions and restrictions on nutrient content, health, therapeutic, and prophylactic claims in the Food Standards Code are clear and effective for infant formula products; and ii. consider whether the current labelling regime is leading to consumers being misled about the quality or effectiveness of an infant formula product.	The existing prohibition for nutrition content claims and health claims for infant formula products remains unchanged. Additional labelling considerations relevant to policy principle (n) include prescribing the format of the nutrition information statement to clearly indicate mandatory nutrition information and permitted optional nutrients and substances. FSANZ is also proposing whey and casein, and certain polyunsaturated fatty acids that are currently permitted by Standard 2.9.1 may be declared as additional nutrition information to assist health professionals, however the format of these declarations would be prescribed.
Infant formula products for special dietary uses	
(o) Infant formula products for special dietary use must be safe, suitable and meet the nutritional requirements to support the growth, development and dietary management of the infants for whom they are intended.	See comments for specific policy principle (d), (p) and (q).
(p) The composition of infant formula products for special dietary use should be based on appropriate scientific evidence.	FSANZ has proposed that infant formula products for special dietary uses (IFPSDU), now re-classified as Special Medical Purpose Products for infants (SMPPi), may deviate from the baseline composition, prescribed in Standard 2.9.1, to satisfy the particular disease, disorder or medical condition supported by generally accepted scientific evidence. Care is taken by food businesses to formulate products for specific dietary uses. Proposed changes are discussed in SD4.
(q) The labelling and advertising of infant formula products for special dietary use should clearly specify the special dietary or medical uses for which the product is intended.	FSANZ is proposing to mimic specific labelling requirements in Standard 2.9.5 Foods for Special Medical Purpose in the proposed drafting for SMPPi. These provisions include requirements for a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated. Proposed changes are discussed in SD4.
Expert Group	

Specific Policy Principles	Assessment
FSANZ should consider establishing an independent scientific expert group that may provide advise prior to pre-market assessment, based on scientific criteria established by the Authority, on whether: i. a substance proposed to be added to infant formula products has a history of safe use in infant formula or follow-on formula in Australia and New Zealand; and ii. there is evidence available that the substance has a substantiated beneficial role in the normal growth and development of infants or children.	FSANZ considers that an independent group is not necessary for our assessment of this proposal, noting that we have assessed the proposal using a risk analysis approach. Further, under this proposal FSANZ has reviewed the current compositional requirements and no new substances are proposed to be added. FSANZ will continue to consider if consultation with an Expert Group is required for all applications and/or proposals which require pre-market assessment of new substance permissions for use in infant formula products.
Relevant international agreements	
The regulation of infant formula products in Australia and New Zealand should be consistent to the greatest extent possible with: • relevant World Health Organization agreements; and • relevant World Trade Organization agreements, Codex standards and guidelines.	A primary purpose of the proposal is to align Standard 2.9.1 and Schedule 29 with international regulations, where appropriate and safe. Comparison with Codex standards and EU regulations has been described throughout the CFS and SDs and is cited where relevant.

2 Intent of Part 2.9 – Special Purpose Foods

FSANZ has had regard to the policy guideline on the Intent of Part 2.9 – Special Purpose Foods of the Code. The policy guideline includes specific policy principles for standards contained within Part 2.9 of the Code.

Specific Policy Principles	Assessment
a) Special purpose foods should be targeted to specific population groups who meet the criteria outlined in the policy guideline.	This proposal does not amend the range of special purpose foods in Part 2.9 of the Code. Special purpose foods relevant to this application are infant formula products (as assessed against the specific policy above) and SMPPi. SMPPi are highly specialised products, specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition for which standard infant formula or follow-on formula is not suitable.
b) The composition of special purpose food should be consistent with the intended purpose.	Compositional requirements are based on assumption of infant formula products being used as the sole source of nutrition. The composition of SMPPi is based on the essential composition of infant formula products, and only deviates where needed to satisfy the diagnosed disease, disorder or medical condition.
c) Adequate information should be provided, including through labelling and advertising of special purpose foods.	The proposed labelling requirements for infant formula products are detailed in SD1 and SD3. These requirements will enable consumers to make informed purchasing decisions. Labelling information provided on SMPPi must also facilitate the safe and effective use of these products with infants whose medical conditions make them more vulnerable than healthy infants. The proposed labelling requirements for SMPPi are detailed within SD4.
d) Consideration, where appropriate, should be given to application of controls to restrict access to a special purpose food on the basis of risk to public health and safety.	Access to infant formula products on the market is currently not restricted. In the proposed regulation SMPPi will be restricted by the persons whom, and the premises at which may be sold. SMPPi products are to be used under medical supervision and are primarily accessed via prescription. Proposed changes are discussed in SD4.

References

FSANZ (2016) Attachment A1.1 – Nutrition Assessment. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

FSANZ (2021) Consultation Paper 2 – Nutrient Composition. Supporting Document 1 – Nutrition Assessment. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx