Comments from the Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions.

Due date of submission – 17 June 2022

Executive Summary

The Victorian Departments of Health and Jobs, Precincts and Regions (the departments) welcome the opportunity to provide further input into this Proposal to review Standard 2.9.1 of the Australia New Zealand Food Standards Code (the Code). Proposal P1028 Infant Formula reviews the regulatory requirements for infant formula products to update and clarify standards for the regulatory framework, composition, labelling, category definitions, representation of infant formula products and consider application of the Ministerial Policy Guideline on the Regulation of Infant Formula Products (the Policy Guideline).

The departments recognise that breastfeeding is the normal and recommended way of feeding infants and that formula fed infants have a higher risk of adverse health outcomes. Regulation of infant formula is necessary because infants are a particularly vulnerable population and infant formula composition, labelling and marketing have implications for breastfeeding rates as well as the health outcomes of formula-fed infants. The importance of the first 1000 days of life is well established and infant feeding has implications for both short term and life-long health. The WHO has recently published reports that highlight the growth in infant formula and exploitative practices that undermine breastfeeding, including labelling and cross promotion[1,2,3]. With the infant formula industry comprising the majority of submitters to FSANZ's consultations on P1028, care needs to be taken to ensure that infants' health and interests are the primary focus of regulatory decisions and that a 'majority of submitters support' approach is not used to justify a proposed position.

Key areas of concern

This is the seventh consultation on the review of infant formula regulations since 2012. While certain proposed regulatory approaches are supported, the departments are concerned with the direction of P1028 in a number of key areas and that concerns raised in previous responses have not been resolved:

1. **Inadequate prioritisation of protection of infant health and safety.** In determining the proposed regulatory approach for specific provisions (particularly nutrients), the purpose of P1028 is reported by FSANZ to be to align with Codex (a trade objective) rather than providing optimal nutrition based on the latest scientific evidence to protect infant health and safety. Members of the Food Ministers' Meeting have previously made it clear that, in the FSANZ Act, the primacy of public health and safety should remain the overarching priority. This is strengthened further by the ministerial policy guideline for the regulation of infant formula products that sets out the expectations of food ministers and the importance of infant health in reviewing P1028. This has not been reflected in proposed approaches for certain nutrients where proposed levels do not meet the physiological needs of infants, do not adequately reflect breastmilk composition, exceed

[1] 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), Licence: CC BY-NC-SA 3.0 IGO

[2] World Health Organization 2022. Scope and impact of digital marketing strategies for promoting breast-milk substitutes. Geneva:; 2022. Licence: CC BY-NC-SA 3.0 IGO

[3] World Health Organisation 2022. It's time to stop infant formula marketing practices that endanger our children. https://www.who.int/news-room/commentaries/detail/it-s-time-to-stop-infant-formula-marketing-practices-that-endanger-our-children. Accessed 6 June 2022.

Upper Levels, or where maximum limits are replaced with voluntary maximums, or allowing new permissions for food additives despite FSANZ's acknowledgment there is no apparent technological need for the additive in the infant formula product.

2. **Reduction in the risk management of medical purpose products and protections for infants.** FSANZ is proposing creating a two-tiered system where 'high risk' specialist medical purpose products (Special Medical Purpose Products for infants, SMPPi) will now be able to be sold for any purported medical condition (instead of the ones currently defined), will be able to add any new substance without requiring a pre-market assessment of safety and suitability, will no longer be subject to prohibited representations on labels designed to protect breastfeeding and will no longer need to have a prescribed name. There will be an increase in regulation that limits access to these products to pharmacies and medical centres, but these products are generally currently only accessed via prescription and pharmacies and in real terms the access restrictions will have little to no impact on product availability. Overall, there will be significantly reduced regulation and protections for the most vulnerable infants.
3. **Areas of regulatory uncertainty and enforcement concerns**. Failure to address and/ or create areas of regulatory uncertainty for example by not clarifying in the Code that pre-market assessment of any new substance is required (not just substances used as nutritive substances or food additives) and by not having sufficiently clear delineation between some SMPPis and modified formula (particularly those containing hydrolysed protein). FSANZ's proposed approach to defer the consideration of novel foods and nutritive substances, including pre-market assessment requirements in infant formula products under P1028 is at variance with a clear Ministerial Policy direction. The Policy Guideline states that pre-market assessment is required for any new substance that does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or 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.
4. **Trade objectives and alignment with international standards.** The departments are aware of the need for consistency and alignment with international standards where possible. However, there are multiple, overlapping regulations for infant formula across the EU, US and China which all differ from Codex standards. Alignment with Codex Alimentarius does not result in universal alignment or necessarily meet the import requirements for major export markets. Further, Australia and New Zealand have an important reputation for high quality infant formula to maintain. Regulations that require optimal levels of nutrients, avoid unnecessary substances that might burden infants' systems; and adequately control for contaminants support this reputation. The departments support additional work from FSANZ to map the potential trade implications of P1028 and to reflect this in the cost benefit analysis. This could include:
    - a clear articulation of the regulatory requirements for current and future export markets (including China, the European Union, the United States, Japan); and
    - analysis of the economic impact of alignment with Codex rather than other standards.

    The departments are aware of industry support for flexibility in nutritional formula composition to meet market access requirements for specific countries. We support additional work to map the need for such flexibility, in order that this can be weighed against the domestic public health objectives.

Given the significant number of issues covered in this First Call for Submissions, the departments have focused on areas of concern, noting only briefly where we support FSANZ's proposed approach. Our concerns for each section are summarised in the following table, with more detailed explanation provided in the body of the document:

Sections	Victorian departments' concerns
Regulatory framework	Does not set out adequate regulatory requirements for infant formula products and should: • Ensure all infant formulas (including special purpose products) are retained under the umbrella term infant formula products • Ensure the regulations recognise breastfeeding is the preferred way to feed infants by actively limiting the development of unnecessary formulas and associated marketing that undermine breastfeeding. • Ensure pre-market assessment requirements for any new substance in infant formula products is clear in the regulations • Make it clear infant formula is suitable for infants 0 to 12 months • Phase out follow-on formula • Address the imbalanced regulatory framework for optional ingredients • Ensure standard formula (and that with permitted optional ingredients) can be clearly delineated from valid special formula for the dietary management of medical conditions.
Definitions	• The infant formula definition does not adequately indicate it is appropriate for infants aged 0 to 12 months. • Wording in the definition for special medical purpose formulas that ensures these formulas are valid and effective formulas for the dietary management of medically determined conditions has been removed and needs clarifying.
Novel foods and nutritive substances	• The proposed approach does not make it clear that pre-market assessment is required for any new substance added to infant formula products and leaves areas of ambiguity for enforcement. • Clarification of pre-existing conditions on some novel food permissions should be applied for all relevant products (infant foods and Formulated Foods for Young Children).
Safety and food technology	• Food additives: of the 21 food additives discussed, do not support FSANZ's proposed approach for 7 of these. Support for others is based on proposed condition statements also being applied. • Contaminants: Do not support the proposed approach for 4 of the 11 contaminants. • Processing aids: further work is required to determine appropriate controls and assessment of processing aids for use in infant formula. • Lactic acid-producing bacteria: clarification needed that viable bacteria are not permitted in final product and that the permission cannot be used to produce fermentation by-products (such as postbiotics, GOS that are similar to ones in human milk, isoflavones) that are created for a health-related purpose without undergoing pre-market assessment for safety and suitability.
Nutrient composition	• Concerns with 29 of the 48 nutrients or nutritional issues, ranging from clarifications required to alternative levels to ensure protection of infant health and safety.
Labelling	• A more prescriptive approach for directions for use in line with the evidence FSANZ provided and a standardised ratio of water for reconstitution (of 1 scoop to 30ml) are needed. • For provision of information, do not support voluntary grouping of vitamins and minerals, do not support macro-nutrient subgroup listing, or any different wording for partially hydrolysed protein or labelling separate to the ingredients' list.
Special medical purpose products for infants (SMPPi)	• There are insufficient regulatory controls being proposed in relation to composition and pre-market assessment requirements, requirements to be evidence based, prohibited representations and a prescribed name.
Costs and benefits	• Gives no consideration to the costs and benefits to infants' health, including the impact on breastfeeding of regulatory changes. • The alignment with the Australian and New Zealand regulatory settings for infant formula and the removal (or creation) of any trade barriers for Australia and New Zealand companies can and should be quantified, with reference to the relevant trade figures and market access arrangements.

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Section 2 – Regulatory Framework

The departments support some elements of FSANZ's proposed framework (such as including general infant formula products, special purpose infant formula and supplements in Standard 2.9.1) but continue to have significant concerns about others. Currently, Standard 2.9.1 sets out the regulatory requirements for infant formula products which includes infant formula (suitable for 0 to 12 months), follow-on formula (designed for 6 to 12 months) and infant formula products for special dietary uses (IFPSDU), which permits products designed for the management of certain medical conditions (pre-term, metabolic, renal, hepatic or malabsorptive conditions) or those based on a protein substitute. Compositional requirements (including the need for pre-market assessment) and labelling requirements apply across all products, with certain adaptations for IFPSDU.

FSANZ is proposing that IFPSDU will be divided into 'high risk' products, called Special Medical Purpose Products for infants (SMPPi), which will no longer be considered infant formula products and will be broadened to allow products for any medical condition, and 'low risk' special purpose products, which will be newly captured as regular infant formula products. FSANZ has also proposed exempting SMPPi from the labelling requirements of Standard 2.9.1 that implement parts of the WHO International Code of Marketing of Breastmilk Substitutes. Low risk special purpose products will be available and sold alongside standard formula but will be unable to make nutrition and health claims (noting FSANZ is considering labelling options for partially hydrolysed formulas).

What should be considered in establishing a new regulatory framework for infant formula products

Infant formula products are not regular commercial foods. Regulations are needed to ensure products are as safe as possible, are designed to meet infant requirements and feeding guidelines, with primary reference to breastmilk, and only deviate where necessary to manage a valid medical condition where breastmilk or standard formula cannot be used. The departments consider there are two clear product types: 'standard formula', which includes infant and follow-on formula based on the essential composition with or without optional ingredients, and 'special or medical purpose formula' which has been specifically modified for the valid dietary management of a medical condition. Formulas which are modified to improve a purported condition that are not supported by science or recommended by health professionals should not be permitted. Regulations should facilitate industry innovation where this serves to bring formula fed infant health outcomes closer to breast fed infant health outcomes, but restrict broad innovation which does not reduce adverse health effects in formula-fed infants, promotes unnecessary consumption of infant formula products and impacts on breastfeeding rates. This existing issue has been raised recently by the WHO, which stated: the infant formula industry claims its products can solve common infant problems, distort science and medicine to legitimize their claims and make false and incomplete scientific claims and position formula as close to, equivalent or superior to breast milk. The cynical marketing tactics used to push milk formula drives over-consumption, discourages breastfeeding, undermines mothers' confidence, and exploits parents' instinct to do the best for their children[4].

The departments are concerned with FSANZ's risk-based approach to infant formula products and special purpose products. A narrow definition of risk has been applied in creating the SMPPi category and is limited to the risk of a healthy infant consuming the product. It does not consider the risk of

[4] World Health Organisation 2022. It's time to stop infant formula marketing practices that endanger our children. https://www.who.int/news-room/commentaries/detail/it-s-time-to-stop-infant-formula-marketing-practices-that-endanger-our-children. Accessed 6 June 2022.

misleading parents with products that are marketed with a non-evidence-based health purpose, the risk of longer term adverse effects (such a reduced calcium absorption with lactose free formula), or the risk of special purpose products marketed as solutions to normal infant behaviours negatively impacting breastfeeding rates. In considering the best way to regulate standard infant formula products and 'high' and 'low' risk special purpose formulas, a broader consideration of risk is required for the protection of infant health and safety.

The ministerial policy guideline sets out the overarching principles of the regulation of infant formula products, which reflect the need for regulation of infant formula products to ensure breastfeeding is not undermined by infant formula products and to prioritise infant health:

The specific overarching policy principles applying to all infant formula products are:

a) The regulation of infant formula products should recognise that breastfeeding is the normal and 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.)
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.

To this end, the regulatory framework should:

1. Retain all infant formulas as infant formula products, including SMPPIs, and ensure adequate protections (such as prohibited representations) are applied across all products to restrict inappropriate marketing and representations, and limit unnecessary consumption. *(to meet overarching principles a and c).*
2. Ensure the regulations recognise breastfeeding is the preferred way to feed infants by actively limiting the development of unnecessary formulas and associated marketing that undermine breastfeeding. *(to meet overarching principle a).*
3. Ensure the regulations clarify pre-market assessment of any new substance is required for all infant formula products (including special purpose formula). Certain ambiguities were introduced in the P1025 Code Revision work that need to be resolved in P1028 (such as substances that are food additives or nutritive substances being prohibited unless permitted across all infant formula products to only being prohibited if the substance is 'used as a food additive/nutritive substance). *(to meet overarching principle c)*
4. Make it clear that infant formula is suitable for infants 0 to 12 months (in line with national infant feeding guidelines, which state follow-on formula is not necessary and has no advantage over infant formula)[5]. It is the departments' view that the current definition for infant formula appears to suggest it is only suitable until 6 months and that follow-on formula is required after 6 months. *(to meet overarching principle b)*
5. Phase out follow-on formula as this is not a necessary or recommended product in national infant feeding guidelines, or in the scientific opinion on 'follow-on formula' that underpins the new Codex Follow-up Formula for Older Infants (FUFOI), which notes, infants unable to breastfeed should have infant formula until 12 months (not follow-up formula)[6] . This would also help solve

[5] NHMRC, Infant Feeding Guidelines: information for health workers. 2013

[6] The Compositional requirements of follow-up formula for use in infancy recommendations note: *Infants who cannot be fed at the breast, or should not receive breast milk for medical reasons (e.g. due to galactosaemia), or for whom breast milk is not available should receive **infant formula**. **Infant formula** can continue to serve as*

the issue of line marketing by removing step 2 and allowing infant formula to be clearly differentiated from other products. Until follow-on formula can be phased out, the nutrient composition should align with the updated composition for infant formula. With infant health and formula's role as a breastmilk substitute at the centre for nutrient composition, there is no rationale for having a different nutrient compositional requirement for follow-on formula. The departments note that the U.S. regulates formula from 0 to 12 months and follow-on formula does not exist there, supporting that it is not a necessary product. (*to meet overarching principle b)*

6. Find a better balance between industry innovation and infant health that focuses more on infant health. Support innovation that improves health outcomes of infants by permitting optional ingredients, with a period of use of 5 years to allow recuperation of R&D costs, followed by a review to determine whether they should be added to all infant formula, thereby improving infant health outcomes from the innovation, or removing the permission to avoid burdening infant systems with unnecessary ingredients and misleading carers to believe there is a benefit to choosing these 'premium' formulas with the optional substance. See more details below. *(to meet overarching principles a and c)*.
7. Clearly delineate standard formula (and that with permitted optional ingredients) from formula required for the valid dietary management of medical conditions. The regulations should minimise the potential for modified formula which is designed to manage a medical issue, but not supported by evidence, or recommended by health professionals, to protect carers from being misled by pseudo-medical formulas and associated impacts on breastfeeding (*to meet overarching principles a and c)*.

Optional ingredients

The departments have previously requested that FSANZ considers optional ingredients in its review of the regulatory framework in responses to consultations conducted in 2012, 2016 and 2021. FSANZ has not provided an assessment, nor consulted on this issue, and is proposing maintaining the current approach. The departments acknowledge the intention of permitting optional ingredients is to encourage industry to innovate to improve infant formula and reduce the well-established adverse health outcomes experienced by formula-fed infants. This is reflected in the Infant Nutrition Council's previous submission that stated, *It is important that scientific advances in infant nutrition are captured and incorporated into these products to ensure the best possible outcome for infants who do not receive breast milk.* **However, the current regulatory framework for optional ingredients in Standard 2.9.1, which permits substances to be optional indefinitely without review (or remain optional on the basis there is no evidence of toxicity) is predisposed towards supporting broad industry innovation for the purposes of product differentiation (and associated misleading marketing) rather than ensuring infants are the beneficiaries of industry innovation.**

Public health stakeholders have informed us they are strongly opposed to optional ingredients in infant formula on the basis that it creates inequity of access to these infant formula products (which are an essential replacement where breastmilk is not available), creates confusion for carers, misleads carers about the benefits of these ingredients marketed in formulas and leads mothers to consider these premium products as a benign or superior choice over breastfeeding, reducing breastfeeding

a breast milk substitute for the entire duration of the first year of life and even beyond, although cow's milk (or other suitable milks) can also be used in the second year of life' Koletzko B, et al. Compositional requirements of follow-up formula for use in infancy: recommendations of an international expert group coordinated by the Early Nutrition Academy. Ann Nutr Metab. 2013;62(1):44-54. doi: 10.1159/000345906. Epub 2012 Dec 13. PMID: 23258234.

rates. The issue of undesirable marketing of optional substances that are permitted simply because they are 'safe' and present in human milk is not a new issue and was raised by FSANZ's predecessor in 2000 in P93 Review of infant formula, with the comment that *any promotion of infant formula is regarded as being at the expense of breastfeeding*. The issue has grown since then. Premium infant formulas with optional ingredients can also cost two to four times more than standard formula. Assuming optional ingredients are beneficial in moving health outcomes of formula-fed infants towards that of breastfed infants, this results in infants in lower socio-economic populations (who already have a greater risk of poorer health outcomes) being unable to obtain the same quality formula and associated health outcomes as infants in higher socio-economic populations.

Industry stakeholders consider optional ingredients enable innovation to improve infant formula and move health outcomes closer to breastfed infants. Presumably it also assists with product differentiation and sales. The departments have been advised by industry that the higher cost associated with premium formula is an important incentive which helps recover product research and development investments.

A more balanced and agile regulatory framework is needed for optional ingredients. This framework could involve:

- a review by FSANZ of the evidence supporting an optional ingredient (for example three to five years after gazettal, noting this goes beyond usual periods of exclusivity of 18 months).
- If there is sufficient evidence that a substance contributes to optimal growth and development in line with breastfed infants, then a proposal should be raised to mandate it in infant formula products to benefit all formula-fed infants.
- Alternatively, if the evidence does not demonstrate a role in growth and development, then a Proposal should be raised to remove the voluntary permission to prevent overburdening infants' systems and the marketing of substances which do not benefit infants.

This framework would:

- allow industry to recuperate R&D costs
- enable more equitable access so all formula fed infants requiring these essential products can ultimately benefit from industry innovation, improve safety, reduce confusion and minimise carers being misled, potentially at the expense of breastfeeding.

Under this approach the following optional ingredients (which have been permitted for 10 to 20+ years) should be reviewed: DHA, lutein, taurine, nucleotides .

Modified formulas and Special Medical Purpose Products for infants (SMPPi)

FSANZ has changed its position since 2021, returning to a position similar to that of 2017, and will allow some modified formulas (low lactose, lactose free and partially hydrolysed) to be captured as standard formula. Nutrition and health claims will continue to be prohibited on these products, preventing the claims which are made on some non-evidence based, 'pseudo-medical' formulas. The departments previously supported FSANZ's approach to include these products under medical purpose formula, with adequate risk management controls, but appreciate that including them with SMPPi, with the proposed requirement to label the intended medical purpose and the broadening of the category to include any medical condition with reduced regulatory prescription, is likely to provide more latitude to inappropriately market these pseudo-medical formulas. **While it is not ideal to present a modified formula as a standard infant formula**, **the departments agree to including lactose free and any partially hydrolysed protein products as standard formula** as this would prevent claims made on some pseudo-medical formulas. In order for this to be an effective way to manage the risk

of pseudo-medical formulas, **there need to be adequate restrictions to prevent the marketing of these as a special purpose formula including clear prohibition on nutrition and health claims** as these are not 'low risk' formulas as indicated by FSANZ (more details below)**. The departments:**

- Do not agree to these being referred to in the standard as 'modified formula' or 'formula for transient gastrointestinal conditions' or any words to that effect.
- Support prescribed criteria for lactose free (specifying no detectable lactose) and a nutrient claim specifying 'lactose free'.
- Do not support criteria for 'low lactose' or a low lactose claim in the absence of clear scientific evidence that reduced lactose formula is required by some infants, or clear evidence of how low lactose in infant formula should be defined (given lactose usually provides 40% of energy in infants).
- Support reference to partially hydrolysed proteins in the statement of ingredients only, but not a nutrition content claim, or any reference on the front of the tin, given partially hydrolysed formulas are not recommended by health professionals and generally accepted science does not support their use for infants. There should also be no wording or naming permitted that implies there is a benefit to these formulas or an associated physiological or health effect, such as one relating to digestion.
- Request FSANZ proposes how to address the issue of infant formula companies circumventing claim prohibitions through the use of trademarks. This is a real issue that currently undermines health claim prohibitions in Standard 1.2.7 and as such, the departments do not agree that it should be out of scope in this Proposal. Even if FSANZ could propose a process such as notifying IP Australia of the regulations and seeking advice on what to do with existing trademarks that have been registered that constitute health claims and would not comply with the Code.

Evidence for concern around these 'low risk' special purpose products

Strict regulation is required around these modified products to discourage their production to prevent them being represented as a solution to common infant problems. FSANZ has proposed these will not be deemed 'medical purpose products' and will not be required to be labelled 'for use under medical supervision'. Some infant formulas medicalise and claim to provide solutions to common infant behaviours, such as crying, frequent waking and variable bowel habits. For example, some formulas claim to help babies sleep better at night, improve colic, help hungry babies, improve constipation and reflux. As indicated in the previously referenced WHO reports, these undermine breastfeeding. Other examples in the literature include:

- Australian babies may be unnecessarily weaned from breastmilk to a lactose-free formula because their irritability is wrongly assumed to be lactose intolerance[7].
- A study looking at participants' views on advertisements of special purpose formulas that would fall into the transient gastroenterological conditions/modified formula subcategory. It found these decrease mothers' confidence in their ability to breastfeed; the advertisements conveyed an expectation of failure with breastfeeding, and that formula is a solution to fussiness, spitting up, and other normal infant behaviours[8]. It is important to note that while the voluntary Marketing in Australia of Infant Formulas (MAIF) Agreement reduces the formal advertising of infant formula in Australia, online marketing occurs through a range of platforms and through cross promotion

[7] Douglas P & Hiscock H. The unsettled baby: crying out for an integrated, multi-disciplinary primary care approach. MJA 2010; 193 (09): 533-536.

[8] Parry, K. et al. Understanding Women's Interpretations of Infant Formula Advertising. Birth. 2013, 40: 115–124

with toddler milks continues. Labelling that highlights these modified formulas supports that marketing.

- Other literature discussed how these formulas for transient conditions encourage those parents who perceive their infants to be fussy, gassy, or colicky to purchase lactose-reduced, protein hydrolysate, soy, or pre-/probiotic containing formulas as a remedy, contrary to the currently available research as summarized by the highest quality systematic reviews[9]
- Another discusses how low lactose and lactose-free formulas can be misused for functional lactose overload and cause premature weaning from breastfeeding[10].
- A review discusses that partially hydrolysed protein formulas are not recommended for allergy prevention in healthy infants and have been overused, in the absence of data on metabolic consequences and long-term outcomes of these products[11]. The Australasian Society of Clinical Immunology and Allergy state that partially hydrolysed formula should not be used in allergy prevention or management, but these products are still named 'HA' for 'hypoallergenic'.
- Anecdotal evidence from Victorian health professionals includes maternal and child health nurses, lactation consultants and paediatric dietitians reporting that some healthy infants are inappropriately using special purpose products, and in some cases, weaning from breastmilk to do so. This is predominantly related to special purpose formulas marketed as helping typical infant issues such as colic, constipation, lactose-free formulas available on supermarket shelves.
- A consumer survey by the infant formula industry[12] indicated carers are confused by the numerous infant formula products on shelves, and that 40% of carers do not decide which formula product they will buy until they are standing at the supermarket shelf. Almost 30% of carers were interested in formulas that helped their child settle best, allergies and other health concerns. Ensuring regulations effectively restrict pseudo-medical formulas is vital to avoid misleading carers and for protecting breastfeeding rates.
- The recently updated Commission Delegated Regulation (EU) 2016/128 on Foods for Special Medical Purposes, which covers special purpose infant products, includes in its introduction a commentary on the recent rise in special purpose formula for infants and raises concerns about potential abuses, the inappropriate targeting of consumers, consumer confusion about the nature of products, and misclassification of products as the basis for the need for greater restrictions on the labelling, presentation, advertising, and promotional and commercial practices. This supports our view that inadequate regulatory controls will lead to an undesirable proliferation and marketing of modified infant formulas.

Human milk fortifiers and pre-term supplementary products

FSANZ now proposes that bovine human milk fortifiers and pre-term supplementary products that are added to other milk feeds and to provide supplementary nutrition will be captured under SMPPi. This enables provisions that protect infants to be applied, where relevant, to these products (such as food additives that have been assessed as safe for infants). **The departments support this approach.**

[9] Belamarich, P. F. et al. A critical review of the marketing claims of infant formula products in the United States. Clinical Pediatrics, 2016 55(5), 437-442

[10] Douglas, P. S. Diagnosing gastro-oesophageal reflux disease or lactose intolerance in babies who cry alot in the first few months overlooks feeding problems. J Paediatr Child Health, 2013 49: E252–E256.

[11] Vandenplas et al. Should Partial Hydrolysates Be Used As Starter Infant Formula? A Working Group Consensus. Journal of Pediatric Gastroenterology and Nutrition. Jan 2016, 62(1), p22-35

[12] Informed Choice for Consumers Jigsaw, March 2015. Commissioned by the Infant Nutrition Council.

Section 3 – Definitions

3.1 Infant formula product, infant formula and follow-on formula definitions

FSANZ now proposes 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. FSANZ preferred options for the definitions of infant formula product, infant formula and follow-on formula are:

> **Infant formula product** means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.
> **Infant formula** means an infant formula product that:
>
> a. is represented as a breast milk substitute for infants; and
> b. satisfies by itself the nutritional requirements of infants under the age of 6 months.

Infant means a person under the age of 12 months.

Follow-on formula means an infant formula product that:

a. is represented as either a breast milk substitute or replacement for infant formula; and
b. is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.

Infant formula product

The departments support re-introducing the base ingredients into the definition of infant formula product to ensure it could not be interpreted to include human **milk but continue to support a slight amendment so that the definition includes *partial* source of nourishment and is therefore able to capture all SMPPi's, including fortifiers**. All products serving to substitute for breastmilk should be captured under 'infant formula products' to ensure protective regulatory elements are applied across all products, with exemptions only where necessary. The definition for infant formula product could therefore be:

> *An infant formula product means a product that based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants depending on the age or **medical nutrition requirements** of the infant',* alternatively:
>
> *An infant formula product means a product that is based on milk or other edible food constituents of animal or plant origin which **serves as a partial or sole liquid source** of nourishment for infants depending on the age or **medical nutrition requirements** of the infant'*

Infant formula

As previously raised, t**he departments are concerned that the definition of infant formula does not clearly reflect its purpose as a breastmilk substitute, that is, suitable for use by infants up until 12 months of age**.

In 2016, FSANZ considered the additional wording for infant formula b): *satisfies by itself the nutritional requirements of infants under the age of 6 months and, as part of a progressively diversified diet, of infants from 6 months of age*. The departments supported this addition to clarify that infant formula is appropriate for use as a breastmilk substitute from birth to 12 months of age. This is consistent with the advice in the National Health and Medical Research Council's Infant Feeding Guidelines.

FSANZ has not discussed this further but noted previously that including a statement that an infant means a person under the age of 12 months indicates the total period for which infant formula is suitable. **The departments do not agree that the definition makes it clear that infant formula is an appropriate breastmilk substitute for birth to 12 months** and the proposed definition could be interpreted to mean that infant formula is only appropriate up until 6 months. **This could create a regulatory requirement for follow-on formula, a product not supported by national guidelines and evidence and therefore not consistent with the Policy Guideline**.

The departments agree that the definition must 'set out the regulatory identity and purpose of infant formula, which then determines the appropriate compositional requirements and labelling to guide safe and intended use' and **that this is best achieved by the addition of the wording '*and, as part of a progressively diversified diet, of infants from 6 months of age*' to the proposed definition of Infant formula product**

Follow-on formula

The departments support retaining the current definition for follow-on formula, noting it should be phased out as it is not supported by national infant guidelines or the scientific literature and therefore not consistent with the Policy Guideline. The National Health and Medical Research Council's Infant Feeding Guidelines states that the use of 'follow-on formula' for infants aged 6–12 months is not considered necessary and no studies have shown advantages over using infant formula'[13].

3.2 Special Medical Purpose Product for infants

In 2021, FSANZ proposed the following definition for the proposed category, then named Infant Formula Product for Special Medical Purposes: is a food that:

- serves as a substitute for human milk, and replacement of infant formula and follow on formula
- is specially formulated for the dietary management of infants based on appropriate scientific evidence
- is for infants:
  - who have special medically determined nutrient requirements, or
  - who have limited or impaired capacity to take, digest, absorb, metabolise other IFPs or excrete the metabolites of other IFPs, and
  - whose dietary management cannot be completely achieved without the use of IFPSMP
- is a food that must be used under medical supervision.

FSANZ now proposes:

A Special Medical Purpose Product for infants means a food that is

a. specially formulated for the dietary management of infants
   (i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and
   (ii) whose dietary management cannot be completely achieved without the use of the food; and
b. intended to be used under medical supervision; and
c. represented as being

[13]NHMRC, Infant Feeding Guidelines: information for health workers. 2013.

(i) a food for special medical purposes intended for infants; or
(ii) for the dietary management of a disease, disorder or medical condition in infants.

Based on our previous response, **the departments consider the proposed definition is a good start to capture the elements needed for these very specialised products but improvements are required** to ensure adequate risk management strategies are in place given the increasingly broad category and the lack of compositional requirements for specific conditions, to ensure certainty in product identity for compliance and enforcement purposes and to improve alignment with EU as the vast majority of these products are imported from the EU. The departments suggest the definition is amended to incorporate these elements as follows (amendments in bold):

A Special Medical Purpose Product for infants means a food that is

a. specially formulated ***to be safe, beneficial and effective*** for the dietary management of ***the specified condition in infants based on generally accepted scientific data***
[It is essential to specify that these products are 'formulated…for the dietary management of the specified condition' rather than just of infants. This ensures the products must be formulated for their specific purpose rather than just to meet infant nutritional requirements [the words 'safe, beneficial and effective' are taken from EU regulations and ensure products captured by SMPPi are legitimate medical purpose products.]
[Since 2021 FSANZ has removed 'based on generally accepted scientific data' from the definition. While this element taken in isolation may be difficult to prove in court, this reasoning could be applied to multiple elements. The definition is to be read as a whole and the reference to accepted scientific data is an important risk management strategy given the broadening of the category, the reduced prescriptiveness of compositional requirements, the particular vulnerability of this infant population and their reliance on these products as a significant source of nutrition]

(i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements ~~or~~ **and** whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and

[the purpose of this category is to limit medical purpose products to valid products for the dietary management of a diagnosed medical condition. 'or' allows the medically determined component to be voluntary. If 'or' is to remain, must insert 'medically determined' into second part of sentence ie whose capacity has been medically determined to be limited*.]*

(ii) whose dietary management cannot be completely achieved without the use of the food; and

b. intended to be used under medical supervision; and
c. represented as being
(i) a food for special medical purposes intended for infants; or
(ii) for the dietary management of a disease, disorder or medical condition in infants.

3.3 Protein substitutes

The departments previously supported removing definitions for protein substitutes (referring to products based on amino acids or hydrolysed proteins). Now that these products will sit across two categories, with very different regulatory requirements, **the departments request FSANZ provides more information for enforcement purposes on how formulas containing partially hydrolysed proteins (to be regulated as standard formulas and subject to a prohibition on health claims) will be differentiated from extensively hydrolysed proteins** (which form the basis of certain proposed SMPPi's and are permitted to indicate the relevant medical condition).

FSANZ is proposing to continue with its previous approach from last consultation to remove the definition for "protein substitute". The departments previously supported this approach but enforcement has now been complicated by the proposal to regulate products with hydrolysed proteins differently depending on the extent of the hydrolysation. The CFS report notes that the literature indicates that while some differentiation between partially and extensively hydrolysed infant formulas is possible, there would be considerable overlap in these cut-offs as well as differences resulting from methodology, protein source and manufacturing processes. **Products with hydrolysed proteins need to be able to be clearly differentiated in the regulations, either through retaining and expanding on the definition, or through other means.**

3.4 Soy-based formula and Medium Chain Triglycerides (MCT)

FSANZ proposed to remove definitions for soy-based formula and MCT and to rely on standard science definitions where required, noting the presence of soy and MCT will be apparent from labels. The departments support this approach in line with previous responses.

Pre-term formula

The departments previously supported removing individual classes or conditions being managed (in the dietary context) by special purpose formula and their associated definitions, provided sufficient risk management strategies are put in place. These included:

- the product clearly stating the purpose or condition it is managing and the modifications made that make it suitable for example, 'not for general use, suitable only for X condition under medical supervision'.
- **A semi-prescribed name for infant formula products for medical purposes to clearly identify these products and their purpose both for consumers and for regulators, allowing for variations for imported products**
- **the requirement in the definition for these products to be effective in their purpose for the dietary management of the proposed condition (in line with EU regulations)**
- **semi-prescribed labelling for 'use under medical supervision is required'**
- access limits in line with Standard 2.9.5.
- provisions to manage prohibition of nutrition and health claims within the above requirements to declare the intended condition and modifications.

This would address the current labelling requirements for pre-term formula that include a prescribed name and the advisory statement 'suitable only for pre-term infants under specialist medical supervision'.

The departments note that important risk management strategies (bolded above) are not being included to address the broadening of medical purpose products and associated reduced regulation. **If these elements in bold are not incorporated into the regulations, it is the view of the departments that the proposed SMPPi category will be inadequate to regulate these products and a limited number of specified conditions may be preferable**.

New definitions

FSANZ's preferred option is to not introduce new definitions on terms such as gastrointestinal reflux, gastrointestinal disorders or impairment of the gastrointestinal tract, inborn errors of metabolism or related. The basis for this conclusion is that additional definitions are unlikely to add regulatory clarity, medical professionals are best placed to understand the range of severity of conditions that may be included, and such definitions are inappropriate to include in the Code. The departments note some food additives are only permitted for use in products for gastrointestinal disorders. **The departments consider determining regulatory compliance for use of these food additives could be determined via the labelled purpose of the product and the standard medical definition.**

Section 4 – Novel Foods and Nutritive Substances

4.1 Pre-market assessment requirements

The departments have not previously supported FSANZ's proposed approach to defer the consideration of novel foods and nutritive substances in infant formula to the wider review as part of Proposal P1024 on the basis that it does not provide regulatory certainty for infant formula products, P1024 is developing a risk based framework that would not be relevant or appropriate for infants, P1024 is currently on hold indefinitely and it would add complexity to P1024, which has struggled to find resolution.

FSANZ has stated that consideration of novel foods and nutritive substances has been removed from P1028 to ensure that inconsistencies and regulatory ambiguity are not introduced into the Code, and that novel foods and nutritive substances requirements for infant formula products would effectively treat these products differently to all other food categories. However, the departments are of the view that **infant formula products are distinctly different from other foods and have a different regulatory framework**, as indicated by their dedicated standard within Part 2.9 of the Code and associated Policy Guideline and require dedicated consideration of novel foods and nutritive substances.

We note FSANZ has proposed to amend the definition of a novel food so that a novel food is defined as a non-traditional food for the intended consumer population, which is intended to address concerns about the use of protein sources that do not have an established history of use in infant formula products. FSANZ also notes that the definition of 'used as a nutritive substance' could similarly be amended to indicate 'for the intended population' as a safeguard that the nutritive purpose must be appropriate, safe & beneficial for the infant population. **The departments do not believe the proposed amendments sufficiently address current regulatory ambiguities and themselves may introduce uncertainty**.

Given there is no clarity on P1024 and what it will achieve, there may be some elements of P1024 that are relevant to infant formula products and could be amended at the time. **However it is essential that, at a minimum, pre-market assessment requirements for any new substances in infant formula must be clarified under P1028 on the basis that**:

1. There is clear ministerial policy direction that was given for P1028 and must be incorporated. The Policy Guideline sets out that that pre-market assessment is required for any new substance 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.

    As described in previous responses, the departments are of the view that subclause 6(1)(b) which automatically permits substances naturally present in an ingredient of the infant formula product is clear in its intention to prevent the unintentional requirement that the individual components of milk would need to undergo pre-market assessment, even though milk itself is a permitted ingredient. It does not mean that a substance that occurs naturally in milk can be extracted, purified and separately added to formula, either at the level naturally found or at higher levels for a nutritive or health purpose without seeking pre-

market approval. However, if FSANZ is advised that industry requires clarity on this, this should also be provided.

2. The regulatory ambiguity about pre-market assessment needs to be resolved. There has been a history of issues with pre-market assessment requirements for infant formula products. There are 2 key issues to resolve:
   - **i.** **The regulatory gap for pre-market assessment of bioactive substances or substances with a health effect**. Standard 2.9.1 previously stated that vitamins, minerals, nutritive substances and food additives were prohibited unless expressly permitted. At the time the Standard was originally written, this was intended to cover any substance that might be added and could impact on infant health. When a company added fructo-oligosaccharides and galacto-oligosaccharides for gut health without pre-market assessment with the rationale they weren't technically nutritive substances, this exposed this gap and they were taken to court. When the Policy Guideline was developed the overarching term 'substance' was intentionally used to capture all substances added. **The Code needs to clarify that for Standard 2.9.1 any new substance (not just food additives and nutritive substances) requires pre-market assessment.**

     Processing aids. The departments note historically Standard 2.9.1 has required pre-market assessment for food additives but has remained silent on processing aids. FSANZ proposes to not require pre-market assessment for processing aids in infant formula. While processing aids have no technical function in the final product, they can be present and can theoretically have safety implications for infants. A brief review of recent applications for processing aids indicates FSANZ risk assessments do not seem to include specific safety considerations for infants. It is unclear from a risk management point of view why these would not be subject to pre-market assessment for safety in infant formula products when they can be present in the final product (even if they no longer have a technological function). **The departments would like to see FSANZ provide scientific justification for why processing aids do not pose a safety risk to infants and do not require pre-market assessment.**
   - ii. **More recent regulatory ambiguities were created with the P1025 Code Revision**. This proposal was intended to clarify the Code; changes to the intent of standards was out of scope. Standard 1.1.1 – 10(6), which states '*unless expressly permitted by this Code, foods for sale must not have as an ingredient or component a substance* ***used as a*** *food additive/nutritive substance*'. The effect of this change in wording is that where previously it was clear that a nutritive substance of food additive could not be added unless permitted, it appears a substance that can provide a food additive or nutritive substance function, can be added without express permission as long as it is added for an alternative function, for example a health effect. By clarifying pre-market assessment for all substances outlined in (i) should resolve both of these issues simultaneously.

4.2 Novel foods – Schedule 25

FSANZ notes a number of novel foods currently listed in Schedule 25 that were not specifically assessed for addition to infant formula, infant foods and Formulated Supplementary Foods for Young Children (FSFYC), do not have conditions restricting their use in these products. FSANZ considers that the status of these novel substances as either clearly permitted or prohibited in IFP, infant food and FSFYC should be clarified according to their original assessments. FSANZ proposed to add conditions to achieve the original intention of the assessments for these novel foods which is to restrict them

from use in infant formula, infant foods, and FSFYC. **The departments previously supported this approach.**

FSANZ has changed its position and will now amend schedule 25 to only clarify the original intention of the novel foods for infant formula products and not for infant foods or FSFYC. This is on the basis of one industry submitter suggesting FSFYC products were out of scope of P1028 and despite FSANZ's comment that the status of these novel substances as either clearly permitted or prohibited needs to be clarified according to their original assessments.

While there may be other mechanisms to amend Schedule 25 to clarify the conditions for the relevant novel foods for FSFYC**, FSANZ will be making changes to Schedule 25 as part of P1028 and including all three products in the conditions amendments would be the most efficient way to do it. Omission of FSFYC and infant foods from the clarification is an example of the current inefficiencies the Food Regulation System modernisation work needs to address.**

The departments support the conditions being clarified for infant formula, infant foods and FSFYC as originally intended. Given these are not new conditions being introduced, but clarifications of the original assessments that were omitted from the schedule, the departments would hope that industry would not risk using these substances from a compliance, enforcement and safety point of view and therefore there should be no impact on current products. If industry has been using these ingredients despite the lack of safety assessment, this highlights the need for this condition to be clarified across all products as soon as possible.

Section 5 – Safety and Food Technology

5.1 Food additives

As noted in our comments to Consultation Paper 1 (CP1) in 2021, the departments support FSANZ's risk management framework for food additive permissions for infant formula products which is defined by three principles: 1) Protection of infant health and safety; 2) The number of food additives used in infant formula should be the least number necessary to achieve the required technological functions; and 3) Consideration of harmonisation with international standards. **The departments reiterate that the protection of infant health and safety is paramount and any consideration of trade implications should be secondary.** This is the basis for the departments' preferred food additive permissions, which are summarised and discussed below.

Table 1 - Summary of the departments preferred approach to food additive permissions

	Proposed MPL (mg/L) in Infant Formula Products (as per Table 5.1 in the CFS)	**Proposed MPL (mg/L) in SMPPi (as per Table 5.1 in the CFS)**	**Victorian departments' comments**
Calcium carbonates (INS 170)	Not permitted	GMP	**Support**, noting the substance is already permitted to be added to infant formula under S29 – 7 and is unlikely to pose safety concerns. The departments continue to support FSANZ's previous proposal that a condition statement be applied requiring that the use of these acidity regulators must be within maximum limits

	Proposed MPL (mg/L) in Infant Formula Products (as per Table 5.1 in the CFS)	**Proposed MPL (mg/L) in SMPPi (as per Table 5.1 in the CFS)**	**Victorian departments' comments**
			and ratios set in section S29—9, in line with Codex and EU.
Calcium citrates (INS 333)	Not permitted	GMP	**Support**, noting the substance is already permitted to be added to infant formula under S29 – 7 and is unlikely to pose safety concerns.
	Permit as carrier in nutrient preparations, consistent with EU MPL and with condition statement		
Calcium Hydroxide (INS 526)	2000mg/L (with limits for sodium, potassium and calcium)		**Support**, noting these substances are already permitted to be added to infant formula under S29 – 7, and are unlikely to pose safety concerns. **Strongly support a condition statement** that requires use as a food additive to comply with limits set in S29-9.
Calcium carbonates (INS 500)	2000mg/L (with limits for sodium, potassium and calcium)		
Sodium hydroxide (INS 524)	2000mg/L (with limits for sodium, potassium and calcium). Addition also needed to Schedule 8.		
Potassium carbonates (INS 501)	2000mg/L (with limits for potassium)		
Potassium hydroxide (INS 525)	2000mg/L (with limits for potassium). Addition also needed to Schedule 8.		
Phosphoric acid (INS 338)	450mg/L (as phosphorus). Additional condition statements on ions	450mg/L (as phosphorus). Only for pH adjustment	**Support the proposed permission in SMPPi** which is aligned with safety data and EU regulations. **We seek information on the technical need in standard infant formula** given phosphoric acid is not permitted as a food additive or a nutrient source in infant formula in either Codex or the Code. The benefits over other currently permitted acidulants would be particularly useful in understanding alignment with the principle to minimise food additive use.
Calcium phosphates (INS 341)	Specific permission for tricalcium phosphate (INS 341(iii)) in nutrient preparations added to products (MPL in nutrient preparation 70 mg/L as phosphate).		**Support**
Sodium phosphates (INS 339) Potassium phosphates (INS 340)	450mg/L (as phosphorus). Additional condition statements relating to calcium/phosphorous ratio.		**Support**, noting these substances are already permitted to be added to infant formula as a form of sodium, potassium and

	Proposed MPL (mg/L) in Infant Formula Products (as per Table 5.1 in the CFS)	**Proposed MPL (mg/L) in SMPPi (as per Table 5.1 in the CFS)**	**Victorian departments' comments**
			phosphorus under S29 – 7, and is unlikely to pose safety concerns. **We strongly support a condition statement** that requires usage as a food additive to comply with limits set in S29-9 and calcium/phosphorus ratio outlined in Standard 2.9.1-12.
Citric and fatty acid esters of glycerol (CITREM) (INS 472c)	9000 (liquid products) 7500 (powdered products)		**Support,** based on safety data and aligns with Codex and EU regulations.
Starch sodium octenylsuccinate (INS 1450)	Not permitted	20,000 for extensively hydrolysed protein formulas, with condition statement.	**Support,** based on safety data and aligns with Codex and EU regulations.
Locust bean (carob bean) gum (INS 410)	1000	5000 for gastro-oesophageal formulas, with condition statement.	**Support the proposed permission in gastro-oesophageal formula at a revised MPL of 5000mg/L**, which is aligned with safety data. We note FSANZ is also seeking information from industry on a MPL of 10,000mg/L. We would not support this higher permission given relevant scientific studies only provide evidence of tolerance up to 6,000mg/L. The technological need in standard infant formula remains unclear**. The departments are unable to support permission in standard infant formula unless a clear technical justification is provided.** Further details below.
Pectins (INS 440)	Not permitted	2000 for extensively hydrolysed protein formulas, with condition statement. 5000 for gastro-intestinal disorder	**Do not support a MPL of 5000mg/L in any infant formula products.** Assessments by both FSANZ and JECFA only provide evidence of safety up to 2,000mg/L. Additionally,

	Proposed MPL (mg/L) in Infant Formula Products (as per Table 5.1 in the CFS)	**Proposed MPL (mg/L) in SMPPi (as per Table 5.1 in the CFS)**	**Victorian departments' comments**
		formulas, with condition statement.	JECFA raised concerns with a high MPL of 5,000mg/L.
Xanthan gum (INS 415)	Not permitted	1000 for extensively hydrolysed protein formulas, with condition statement. 1200 for gastrointestinal, protein mal-adsorption, or inborn errors of metabolism formulas, with condition	**Do not support** a MPL of 1200mg/L for gastrointestinal, protein mal-adsorption, or inborn errors of metabolism formulas without evidence of actual use and safety at this level in the EU. We are also concerned overlap between the two proposed permission categories may create area of regulatory uncertainty. **Prefer a MPL of 1000mg/L in SMPPi, where there is a technological and trade harmonisation requirement.** Further details below.
Guar gum (INS 412)	1000, with condition statement	10,000 for extensively hydrolysed protein formulas, with condition statement.	**In the absence of appropriate safety data or industry evidence of technological need for a MPL of 10,00mg/L, do not support the proposed permission** in extensively hydrolysed protein formulas. The technological need in standard infant formula remains unclear**. Do not support permission in standard infant formula unless a clear technical justification is provided.** Further details below.
Sodium alginate (INS 401)	Not permitted	1000 for metabolic disorders and for general tube-feeding with condition statement.	**In the absence of appropriate safety data or industry evidence of technological need, do not support the proposed permission in selected SMPPi.** Further details below.

	Proposed MPL (mg/L) in Infant Formula Products (as per Table 5.1 in the CFS)	**Proposed MPL (mg/L) in SMPPi (as per Table 5.1 in the CFS)**	**Victorian departments' comments**
Sodium carboxymethylcellulose (INS 466)	Proposing not to permit but seeking information from stakeholders on current use		**Support the proposed approach not to permit this additive** based on the absence of safety data for young infants and evidence of technological need.
Sucrose esters of fatty acids (INS 473)	Not permitted	120 for extensively hydrolysed protein formulas, with condition statement.	**Do not support the proposed permission** based on the absence of appropriate safety data or medical justification. Further details below.
Diacyltartaric and fatty acid esters of glycerol (INS 472e)	Not permitted		**Support the proposed approach to remove permissions in infant formula products.** This is consistent with Codex and EU regulations and absence of evidence of technological need.

Locust bean (carob bean) gum (INS 410)

While the departments recognise that locust bean gum serves a technical function as a thickener in special medical formulas for the treatment of gastro-oesophageal reflux, the function (and proposed retained permission) in standard infant formula products remains unclear. FSANZ concluded that the proposed MPL of 1000mg/L in standard infant formula is unlikely to pose toxicological concern and is consistent with risk management principle 3, due to alignment with Codex. However, as noted earlier, the departments are of the view that harmonising with international regulations should be secondary to the protection of infant health and safety, which includes minimising unnecessary food additive use. Consistent with this view, we do not support retaining the permission in standard infant formula unless evidence of a technological justification is presented.

The departments note that specialised products are dependent on imports from the EU and recognise the importance of harmonisation. However, in line with the risk management principles, regulations must firstly protect infant health and safety. We note that safety assessment by FSANZ, JECFA and EFSA do not support addition of this food additive up to 10,000 mg/L and that the studies presented only tested tolerance up to 6,000 mg/L. **Based on this safety data, the departments strongly oppose permissions at a MPL of 10,000mg/L, even if industry indicates a desire to permit it at this level.**

Xanthan gum

FSANZ has proposed two MPLs for xanthan gum in SMPPi; 1000mg/L in extensively hydrolysed protein formulas (to align with Codex) and 1200mg/L in gastrointestinal, protein malabsorption, or inborn errors of metabolism formulas (to align with EU). While the proposed MPL for gastrointestinal, protein malabsorption, or inborn errors of metabolism formulas has been permitted in the EU for some years, it is not known whether companies have been using this additive at this maximum level to be able to establish a history of safe use at this level. Additionally, JECFA has concluded safety only at a maximum use of 1000mg/L for infants 0-12 weeks of age. The departments are reluctant to support the higher

MPL of 1200mg/L given the gaps in safety data. We are also concerned the dual permission may create regulatory ambiguity due to the crossover between the two import categories, with many products for protein malabsorption based on extensively hydrolysed protein. **The departments support a MPL of 1000mg/L in SMPPi if this slightly lower level does not impact of existing SMPPi.**

Guar gum

We note the proposed permission for guar gum in standard infant formula changed between 2017 (where it was proposed to remove the permission) and 2021 (where it was proposed to maintain a MPL of 1000mg/L) without any explanation. As noted earlier, the departments are of the view that harmonising with international regulations should be secondary to the protection of infant health and safety, which includes minimising unnecessary food additive use. **The departments do not support retaining the permission in standard infant formula unless evidence of a technological justification is presented.**

Sodium alginate

The departments note sodium alginate is not currently permitted in infant formula in the Code or in Codex, but there is a very limited permission in the EU in certain specialised products after four months of age. In its 2017 reassessment, EFSA concluded that the available data did not allow an adequate assessment of the safety of alginic acid and its salts in infants and young children consuming foods from these food categories. Neither FSANZ nor JECFA has assessed the safety of sodium alginate in infant formula. Despite these gaps in safety data, FSANZ has proposed to permit sodium alginate at a MPL of 1000mg/L in products for dietary management of metabolic disorders and for general tube-feeding, with a condition of use being from four months onwards. **The departments note this is not consistent with the protection of infant health and safety and do not support the proposed permission.**

Sucrose esters of fatty acids (INS 473)

We understand the importance of harmonising regulations for specialised infant formula products, particularly with the EU, which is a major supplier of SMPPi in Australia. However, we are not aware of any current supply or trade barrier issues, despite this additive not currently being permitted under the Code. We also note that FSANZ has not established a current medical need among health professionals. Given the current gaps in safety data, the departments believe it is inappropriate to grant permission until further risk assessment is completed and there is a demonstrated medical need.

5.2 Contaminants

The departments support FSANZ's proposed approach for the following contaminants in infant formula based on their alignment with exposure and risk data, and international regulations:

Table 2: Proposed contaminant MLs supported by the departments

Contaminant	FSANZ proposed ML
Acrylonitrile	No change to the current ML of 0.02 mg/L.
Aluminium	Move ML from Standard 2.9.1 to Standard 1.4.1 and Schedule 19. Retain single ML of 0.05 mg/100mL for aluminium for IFP including soy-based.
Arsenic	No ML for infant formula products. Monitor and review.
Lead	Lower ML from 0.02 mg/L to 0.01

	mg/L in IFP and apply to infant formula on a ready to-feed basis.
Melamine	No ML to be established.
Tin	No change to the current ML of 250 mg/L.
Vinyl chloride	No change to the current ML of 0.01 mg/L.

FSANZ has proposed not to establish MLs for aflatoxins B1 and B2, ochratoxin A, polycyclic aromatic hydrocarbons and perchlorate based on either a lack of data on current presence in infant formula, or recent survey results that did not identify their presence in infant formula in Australia. The departments note that fit-for-purpose regulation should respond to not only the current environment but also anticipate future challenges, and the departments are concerned that not setting MLs for these contaminants does not address emerging safety concerns. For example, there is strong evidence that rising temperatures linked to climate change are associated with greater levels of aflatoxin contamination[14]. The rise in interest in plant proteins also increases the risk of mycotoxins. Given the EU has set MLs for these contaminants, **the departments support setting MLs for these substances in line with EU limits.** FSANZ has also proposed not to set a ML for chloropropanol, glucidol and their esters despite the risk assessment identifying exposure among 3 month olds were in the range of concern of JECFA for glycidyl esters in powdered infant formula sampled. For the protection of infant health and safety, **the departments support aligning with the EU ML in liquid formula and considering MLs for powdered products for glycidyl esters based on FSANZ's analytical findings**.

The departments support FSANZ's preferred approach that MLs for infant formula apply to an as consumed form in mg/kg for the reasons outlined by FSANZ, including that it is consistent with international requirements.

The departments are not aware of any regulatory or safety issues with the current analyte definition. **We support FSANZ's preferred position not to make any definitional changes at the present time**, particularly as many analytes are common to both infant formula and general foods and require consideration of broader implications.

5.3 Processing aids

FSANZ has proposed to maintain current permissions for processing aids in infant formula, without any risk assessment or consideration of the Policy Guideline. Currently the Code does not specify processing aids that can only be used in the manufacture of infant formula products, meaning all generally permitted processing foods for all foods as defined in Standard 1.3.3-4 may be added to infant formula. We note that in assessing applications to permit new processing aids, FSANZ does not typically consider specific risks in infants. **The departments believe the current treatment of processing aids for infant formula has previously been overlooked and is not consistent with the intent of the policy guideline, which states that any substance that does not have a history of use in infant formula should be subject to pre-market assessment. The departments request further work is undertaken to determine appropriate controls and assessment of processing aids for use in infant formula**. This is also discussed under Section 4 Novel foods and nutritive substances.

[14] Van der Fels-Klerx, H.J., Vermeulen, L.C., Gavai, A.K. and Liu, C., 2019. Climate change impacts on aflatoxin B1 in maize and aflatoxin M1 in milk: A case study of maize grown in Eastern Europe and imported to the Netherlands. *PLoS One*, *14*(6), p.e0218956.

5.4 L(+) lactic acid producing microorganisms

FSANZ has proposed to retain the blanket permission for L(+) lactic acid producing microorganisms with clarification that only non-pathogenic and non-toxigenic microorganisms may be used, and that addition must be for acidification purposes only, in line with the original intended permission. This is based on FSANZ's conclusion that the use of non-toxigenic L(+) lactic acid producing bacteria in the production of fermented infant formula, where no viable bacteria are present in the final product, does not present a risk to public health and safety. FSANZ appears to have omitted from its proposed position that no viable bacteria are to be present in the final product. **The departments have two main concerns with the proposed approach:**

Presence of viable bacteria

The departments are concerned that **FSANZ's approach does not provide sufficient regulatory clarity to prevent the addition of novel probiotic microorganisms that have not undergone premarket assessment and does not address the safety risks we raised last consultation (including safety, purity and contamination concerns and transferable antibiotic resistance genes, refer to CP1 2021 response for details)**. Many probiotic microorganisms are lactic acid producing, including several species of lactobacillus and Bifidobacterium. Thus, in the case where a manufacturer adds a lactic acid producing probiotic, it would be challenging to prove the primary purpose of addition. We note this is currently common practice and that market products almost exclusively contain lactic acid microorganisms that are also well established as probiotics, including *Lactobacillus reuteri*, *Bifidobacterium breve* M-16V, *Bifidobacterium lactis*, *Bifidobacterium longum* BB536 and *Lactobacillus Fermentum* (CECT5716). While FSANZ has stated that any fermented infant formula product would require premarket assessment, it is unclear under what provisions this would be enforced.

For protection of infant health and to provide regulatory clarity, **FSANZ must also specify that no live bacteria may be present in infant formula products for sale**.

Postbiotics

Even if FSANZ were to specify that only non-pathogenic and non-toxigenic bacteria could be added for acidification purposes and no live bacteria could be present, these restrictions may not prevent novel practices such as the use of lactic acid bacteria to supplement infant formula with fermentation-produced metabolites (known as postbiotics), which can include human milk oligosaccharides. The departments seek information on **how the proposed drafting will also ensure the safety of any fermentation by-products and that the permission is not used to bypass pre-market assessment requirements to add novel substances to infant formula, such as human milk oligosaccharides.**

The departments also note acidification by means of lactic acid producing bacteria is time consuming and inefficient, particularly compared to the addition of food acids, many which are permitted to be added to infant formula and would achieve acidification. **The regulation of lactic acid producing micro-organisms must ensure these cannot be added for purposes other than acidification**.

The departments are aware that some manufacturers have been adding these organisms for a probiotic purpose with associated marketing and support a broad permission that allows the addition of non-specific probiotics without any requirement for assessment of safety and consideration of whether these benefit infants. **The departments would like to emphasize the vulnerability of this population, the need for regulations that protect both formula-fed and breastfed infants and the importance of not creating a broad permission to add a range of substances to achieve a health purpose simply because some in the industry have been adding them in this unintended way.** Any changes required to formulas as a result of P1028 will likely be given an appropriate transition period and therefore are unlikely to create supply issues.

Section 6 – Nutrient Composition

The departments have not previously commented on individual nutrient levels for follow-on formula, however **maintain their previously stated view that follow-on formula is not a necessary product and that infants who are not able to have breastmilk should be fed infant formula from birth to 12 months of age** (consistent with national infant guidelines and expert published positions[15,16]). As detailed above under Regulatory Framework, regulations would better protect infant health and recognise the importance of breastfeeding if follow-on formula was phased out of use. Until this can be done, the nutrient composition should align with that of infant formula, given both infant and follow-on formulas are breastmilk substitutes and should be based on breastmilk as the primary reference**. In terms of the proposed individual nutrients, the departments do not support different levels, or a voluntary status in follow-on formula for calcium, choline, myo-inositol, and L-carnitine for the reasons above.**

The departments have reconsidered FSANZ's proposed approach for the following nutritional composition requirements for infant formula products in line with the primary objective of protecting infant health and safety. While the departments previously supported, in some instances, alternative levels than those provided below, **we support the following levels proposed by FSANZ on the basis that they are similar and a reasonable compromise**:

	Unit	**Infant formula**		**Follow-on formula**	
		Min	Max	Min	Max
Energy	kJ/L	2500	2950	2500	2950
Carbohydrates	g/100 kJ	NS	NS	NS	NS
Total fat	g/100 kJ	1.05	1.4	1.05	1.4
α-Linolenic acid (ALA)	mg/100 kJ	12	NS	12	NS
Erucic Acid^	% total fatty acid	NS	1	NS	1
Vitamin D	µg /100 kJ	0.25	0.63	0.25	0.63
Vitamin E	mg α-TE/100 kJ	0.12	1.2 (GUL)	0.12	1.2 (GUL)
Vitamin K	µg /100 kJ	0.24	6.5 (GUL)	0.24	6.5 (GUL)
Magnesium	mg/100 kJ	1.2	3.6 (GUL)	1.2	3.6 (GUL)
Sodium	mg/100 kJ	5	14	5	14
Chloride	mg/100 kJ	12	38	12	38
Potassium	mg/100 kJ	14	43	14	43
Pantothenic acid	µg /100 kJ	96	478 (GUL)	96	478 (GUL)
Manganese	µg /100 kJ	0.25	24 (GUL)	0.25	24
L-Carnitine	mg/100 kJ	0.3	0.8	0.3	
Fluoride	µg /100 kJ	NS	24	NS	24
2'-O-fucosyllactose	mg / 100 kJ	NS	96[1]	NS	96[1]
LA:ALA	ratio	5:1	15:1	5:1	15:1
Vitamin E : fatty acids	ratio	0.5mg : 1g	NS	0.5mg : 1g	NS

The departments also support FSANZ's proposed approaches for protein quality, amino acid requirements, nitrogen conversion factor, which have not changed since the 2021 consultation.

[15] National Health and Medical Research Council, Infant Feeding Guidelines. 2013, NHRMC: Canberra

[16] Koletzko B, Bhutta ZA, Cai W, Cruchet S, El Guindi M, Fuchs GJ, Goddard EA, van Goudoever JB, Quak SH, Kulkarni B, Makrides M, Ribeiro H, Walker A. Compositional requirements of follow-up formula for use in infancy: recommendations of an international expert group coordinated by the Early Nutrition Academy. Ann Nutr Metab. 2013;62(1):44-54. doi: 10.1159/000345906. Epub 2012 Dec 13. PMID: 23258234.

For the remaining nutrients, the departments do not support the proposed approaches on the basis that they do not prioritise the protection of public health and safety for infants. The departments are concerned that FSANZ has had little consideration for the optimal levels of nutrients for infants (based on infant requirements and breastmilk levels) and instead has made the priority to align with Codex levels, purely based on evidence of harm to infants. This fundamentally prioritises trade over infant health (noting Codex levels take into account issues such as developing countries' infrastructure and supply chains that may not be relevant to Australia and New Zealand). Apart from not considering the optimal nutrient levels for infants, another significant limitation to basing levels on risk is that there is often a lack of specific research on the risks or harm of providing a certain nutrient level. This often leads to a false conclusion that the lack of evidence means there is a low risk of harm. Further, a minimum or maximum level may not actually be added by manufacturers and so cannot be assumed to have a history of safe use.

For maximum levels, FSANZ states the European Food Safety Authority (EFSA) did not assign levels for most nutrients and set an arbitrary level three to five times higher than the minimum. The setting of maximum levels has been discussed by a number of experts, who indicate that '*The guiding principle is that infant formulas should contain components only in such amounts that serve a nutritional purpose, provide another benefit, or are necessary for technological reasons. The inclusion of unnecessary components, or unnecessary amounts of components, may put a burden on metabolic and other physiological functions of the infant and will reduce the margin of safety. These maximum values should be based on available scientific data on infants' requirements and the absence of adverse effects. For some water soluble vitamins acceptable daily intakes for infants and young children have not been established.* ***If these vitamins are supplied in amounts that cannot be used or stored by the body they must be excreted, and excessive intakes will reduce the margin of safety. This is particularly the case under conditions of stress such as during fever or diarrhoea or especially during weight loss.*** **Therefore, the scientific expert report to Codex recommended *that contents of water soluble vitamins in infant formulas generally should not exceed five times the minimum level without clear evidence to justify an alternative***.[17] **The departments would like FSANZ to provide scientific justifications for the maximum levels they propose, with clear justification and consideration of infant health, when the proposed levels exceed five times the minimum level.**

The following table outlines the nutrient levels of concern (highlighted red) and the departments' rationale.

[17] Koletzko B, Shamir R. Standards for infant formula milk. Commercial interests may be the strongest driver of what goes into formula milk BMJ. 2006;332(7542):621-622. doi:10.1136/bmj.332.7542.621

Table 3: Nutrient composition not supported by the departments

Micronutrients	VIC Departments' view
FSANZ proposed level	
Protein (cow) 0.43 – 0.7 g/100 kJ for IF and FOF	**Do not support a maximum of 0.7g/100kJ. Instead support 0.6g/100kJ (aligned with EU).** There is no evidence of a physiological need for protein intakes at 0.7g/100kJ[18]. FSANZ states there is an absence of evidence of harm at 0.7g/100kJ, however high protein intake in infants is a recognised risk factor for obesity and in the large, multi-centre, randomised control trial (The European Childhood Obesity Trial) it was found that infants fed a formula with 0.7g protein/100kJ had a significantly higher weight at 3, 6 and 12 months of age than infants fed a formula at the lower permitted level (0.43g/100kJ) and breastfed infants[19]. A follow-up of these children at 6 years of age found a significantly higher risk of obesity in those children fed the formula with 0.7g/100kJ of protein[20]. While the departments note that, in its scientific assessment of infant formula composition in 2014, EFSA stated 'there are no scientific data available which allow the establishment of precise cut-off values for the maximum protein content in infant formula[21] , it would be prudent, and consistent with FSANZ's objectives, to select a lower maximum than one that is associated with adverse health outcomes. This would also be consistent with the 2013 Infant Feeding Guidelines which recommend that it is preferable to use a formula with a lower protein level[22]. While it is unclear at this stage whether protein levels of 0.6g/100kJ may also increase the risk of obesity, the risk is likely to be lower than that of the current level and has the benefit of harmonising with EU regulations (where many formulas are made). In its infant formula label survey from the 2016 consultation, FSANZ indicated protein levels ranged from 0.46-0.63g/100kJ. A desktop review of the brands currently available in supermarkets indicates that all products reviewed range from 0.44-0.52g/100kJ protein and therefore are already beneath the EU lower maximum level of 0.6g/100kJ and would not require reformulation[23].
Protein (soy) 0.54 – 0.7 g/100 kJ For IF and FOF	**Support a maximum of 0.6g/100kJ as above**.

[18] EFSA (EFSA Panel on Dietetic Products Nutrition and Allergies), Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 2014.12(7): p. 3760-3866

[19] European Childhood Obesity Trial Study Group, Lower protein in infant formula is associated with lower weight up to age 2 y: a randomized clinical trial, The American Journal of Clinical Nutrition, Volume 89, Issue 6, June 2009, Pages 1836–1845, https://doi.org/10.3945/ajcn.2008.27091

[20] Martina Weber, Veit Grote, Ricardo Closa-Monasterolo, Joaquín Escribano, Jean-Paul Langhendries, Elena Dain, Marcello Giovannini, Elvira Verduci, Dariusz Gruszfeld, Piotr Socha, Berthold Koletzko, for The European Childhood Obesity Trial Study Group, Lower protein content in infant formula reduces BMI and obesity risk at school age: follow-up of a randomized trial, The American Journal of Clinical Nutrition, Volume 99, Issue 5, May 2014, Pages 1041–1051

[21] EFSA (EFSA Panel on Dietetic Products Nutrition and Allergies), Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 2014.12(7): p. 3760-3866

[22] National Health and Medical Research Council, Infant Feeding Guidelines. 2013, NHRMC: Canberra

[23] Brands reviewed: Nan Optipro, A2 Platinum, Bellamy's Organic, Bub's Goat, Aptamil Gold, Karicare, S26 Premium

Micronutrients	VIC Departments' view
FSANZ proposed level	
Linoleic acid (LA) 90 – 330 (GUL) mg/100 kJ For IF and FOF	FSANZ states: Comments raised in previous consultation have been addressed in FSANZ 2021 CP2 Section 5.3, with no new information to add. FSANZ's preferred option is to retain the approach of CP2 as it addresses stability and palatability concerns while ensuring nutritional adequacy and safety within the ANZ infant population. **The departments' concerns have not been addressed**. The proposed levels do not protect infant health and safety, do not meet the policy guidelines (f and h), and FSANZ's concerns regarding palatability issues at higher levels and trade issues appear unfounded. The proposed minimum of 90mg/100kJ is not consistent with FSANZ's risk assessment which concluded *the risk of harm to infants' health due to inadequate LA or ALA intake would be low if FSANZ adopted a minimum LA amount between 110 and 140 mg/100 kJ*. **The departments support a range of 120-300mg/100kJ (consistent with EU). 110mg/100kJ would be the lowest acceptable minimum.** ***Minimum:*** While the National Health and Medical Research Council (NHMRC) Nutrient Reference Values do not set a specific Adequate Intake for LA, EFSA established an Adequate Intake of 4% of energy for infants (equivalent to ~110mg/100kJ), which was based on the lowest estimated mean intake in various European countries that was not associated with LA deficiency symptoms and was consistent with levels in breastmilk. FSANZ's nutritional assessment confirmed the lowest reported average content in breastmilk is also equivalent to~110mg/100kJ, with 140mg/100kJ considered to be the average amount found in Australian and New Zealand women's breastmilk (142 mg/100 kJ in Australian women and 139 and 138mg/100 kJ in New Zealanders). A proposal to provide less than the minimum requirement for infants of an essential nutrient is not consistent with FSANZ's primary objective to protect health and safety. FSANZ suggests issues with stability and palatability of infant formula when LA levels are increased. FSANZ's label survey found the LA content of current market products was 146 – 267mg/100kJ, **indicating no apparent issues with stability and palatability** at higher levels. FSANZ also suggests that adopting a higher minimum LA level may create some trade barriers as Codex STAN 72-1981 sets a lower minimum LA requirement. However FSANZ has stated the much lower Codex minimum of 70mg/100kJ is not suitable and its proposed level will still not align with Codex. Australian and European products currently have levels above 120mg/100kJ and Australian exports to countries with lower minimums would still meet compositional requirements so it is unclear specifically what trade barriers FSANZ is concerned about. However, **the protection of health and safety, particularly for the very vulnerable population of infants, must always be the primary consideration.** ***Maximum (GUL)*** There is no apparent physiological or technical justification to set a higher upper level of 330mg/100kJ when the highest levels found in human milk are 300mg/100kJ[24] (and FSANZ suggests stability and palatability issues at higher levels). There is also evidence that higher levels of LA may affect

[24] EFSA (EFSA Panel on Dietetic Products Nutrition and Allergies), Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 2014.12(7): p. 3760-3866

Micronutrients	VIC Departments' view
FSANZ proposed level	
	LCPUFA status and impact immune, neural, and adipose tissue development[25] Based on ensuring the composition of infant formula meets the requirements of infants and does not overburden their systems[26], **the departments consider there should be a set maximum no higher than 300mg/100kJ, and ideally lower. The departments request FSANZ specifically reconsider a lower maximum level and whether this would better protect infant health based on current evidence.** FSANZ's market survey indicates LA content ranged between 146 – 267mg/100kJ.
Docosahexaenoic acid (DHA) NS – 7.2 mg/100 kJ in IF and FOF (optional)	***Voluntary status*** **Do not support FSANZ's proposed approach to retain the current voluntary permission for DHA or the rationale** being there is: (1) a long standing permission and no sound evidence of safety concerns, (2) consistency with international regulations (including recent discussions on the revision of the proposed Codex Draft Standard for FuFOI), (3) no lack of regulatory certainty and (4) assessment against the Ministerial Policy Guideline on the Regulation of Infant Formula (ANZ FRMC, 2011) only applies to new ingredients or substances. The policy guidelines were specifically developed for P1028 to guide regulatory decisions. **The departments request FSANZ provide advice on whether DHA is a partially essential nutrient and therefore should be mandated in all infant formula on this basis. If DHA is not required (because infants synthesise sufficient amounts), the permission for DHA should be removed.** In our 2016 comments, the departments supported specifying a mandatory minimum level for DHA in all infant formula, in line with the EU 2016/127 regulations and rationale that DHA should be present in infant formula based on its structural role in the nervous tissue and the retina and its involvement in normal brain and visual development, the need of the developing brain to accumulate large amounts of DHA in the first two years of life and the consideration that the intake of pre-formed DHA generally results in an erythrocyte DHA status more closely resembling that of a breast-fed infant than is achieved with ALA alone[27]. In its assessment in 2016, we note FSANZ acknowledged that DHA is an essential component of nerve and retinal cells, is involved in normal brain and visual function; and it accumulates in brain cells in the first two years of life.

[25] Susan E Carlson, Lidewij Schipper, J Thomas Brenna, Carlo Agostoni, Philip C Calder, Stewart Forsyth, Philippe Legrand, Marieke Abrahamse-Berkeveld, Bert J M van de Heijning, Eline M van der Beek, Berthold V Koletzko, Beverly Muhlhausler, Perspective: Moving Toward Desirable Linoleic Acid Content in Infant Formula, Advances in Nutrition, Volume 12, Issue 6, November 2021, Pages 2085–2098, https://doi.org/10.1093/advances/nmab07

[26] The International Expert Group position statement on the composition of infant formula states: 'infant formulae should only contain components in such amounts that serve a nutritional purpose or provide another benefit. The inclusion of unnecessary components, or unnecessary amounts of components, may put a burden on metabolic and other physiologic functions of the infant. Those components taken in the diet, which are not utilized or stored by the body, have to be excreted, often as solutes in the urine. Since water available to form urine is limited and the infant's ability to concentrate urine is not fully developed during the first months of life, the need to excrete any additional solutes will reduce the margin of safety, especially under conditions of stress, such as fever, diarrhea or during weight loss'. Koletzko, B., et al., Global standard for the composition of infant formula: recommendations of an ESPGHAN coordinated international expert group. Journal of Pediatric Gastroenterology and Nutrition, 2005. 41(5): p. 584-599.

[27] EFSA (EFSA Panel on Dietetic Products Nutrition and Allergies), Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 2014.12(7): p. 3760-3866

Micronutrients	VIC Departments' view
FSANZ proposed level	
	Given DHA is already considered to be an essential component for infant development, **the question is whether it is a partially essential nutrient**; that is, whether all infants can synthesise enough to meet requirements or whether infants partially rely on the amounts provided in breastmilk or formula to meet their requirements (similar to niacin and inositol). The departments note a number of papers suggest that although infants are able to synthesize DHA from essential fatty acids the conversion rate may not be sufficient to meet requirements and can vary by individuals, and that brain DHA content mainly relies on dietary supply, so it is important for infants to obtain an adequate amount of DHA from dietary sources (breastmilk or formula)[28,29,30,31, 32]. **The departments consider that, if there is evidence that infants are not always able to synthesize enough DHA, then it should be made available in all formula in the levels present in breastmilk. An essential nutrient that is permitted to remain optional and available only in more expensive premium products results in inequality of access and does not benefit all formula fed infants.** **Levels:** The departments note the concerns raised in a recent position paper published by the European Academy of Pediatrics and the Child Health Foundation about the EU regulatory decision to require DHA without a concomitant requirement for arachidonic acid (AA), but also note that this position paper recommended infant formula should provide *both* DHA and AA and that the DHA minimum should be at least 0.3% of FA (equal to the mean content in breastmilk), but preferably 0.5% of FA (equal to mean + 1 SD content in breastmilk) to cover higher needs of some groups[33]. **The departments note FSANZ has proposed that the content of DHA does not exceed the AA amount and support this proposal but that the GUL should be 0.5% total fatty acids,** which is not consistent with the expert position. **If mandated, the departments recommend aligning levels with the recent, published, expert positions rather than with EU 2016/127.**

[28] nnis SM. Impact of maternal diet on human milk composition and neurological development of infants. Am J Clin Nutr. 2014 Mar;99(3):734S-41S. doi:

[29] Gao C, Liu G, Whitfield KC, et al. Comparison of Human Milk Fatty Acid Composition of Women From Cambodia and Australia. Journal of Human Lactation. 2018;34(3):585-591.

[30] Koletzko B et al (2020) Should formula for infants provide arachidonic acid along with DHA? A position paper of the European Academy of Paediatrics and the Child Health Foundation. Am. J Clin. Nutr. 2020, 111, 10–16.

[31] Tounian P, Bellaïche M, Legrand P. ARA or no ARA in infant formulae, that is the question. Arch Pediatr. 2021 Jan;28(1):69-74. doi: 10.1016/j.arcped.2020.10.001. Epub 2020 Oct 22. PMID: 33268182.

[32] Susan E Carlson, Lidewij Schipper, J Thomas Brenna, Carlo Agostoni, Philip C Calder, Stewart Forsyth, Philippe Legrand, Marieke Abrahamse-Berkeveld, Bert J M van de Heijning, Eline M van der Beek, Berthold V Koletzko, Beverly Muhlhausler, Perspective: Moving Toward Desirable Linoleic Acid Content in Infant Formula, Advances in Nutrition, Volume 12, Issue 6, November 2021, Pages 2085–2098, https://doi.org/10.1093/advances/nmab07

[33] Koletzko B et al (2020) Should formula for infants provide arachidonic acid along with DHA? A position paper of the European Academy of Paediatrics and the Child Health Foundation. Am. J Clin. Nutr. 2020, 111, 10–16.

Micronutrients	**VIC Departments' view**
FSANZ proposed level	
Trans fatty acid NS to 4 % total FA In IF and FOF (optional)	**Do not support FSANZ's proposed approach.** The departments note no further nutrition risk assessment was considered on this issue. Codex, the EU and China set a maximum of 3% for trans fatty acids (TFA), with Codex further specifying that commercially hydrogenated oils that may contain industrial TFA are not permitted in infant formula. Given the increased understanding of the deleterious effects of industrial trans fats over the past 20 years, **the departments support a prohibition on commercially hydrogenated oils that may contain industrial TFA, in line with Codex and request FSANZ provides more information on the remaining percentage of naturally occurring dairy trans fats likely in formula to determine whether a 4% of total fatty acids limit is required.**
Phospholipids NS to 2 g/L in IF and FOF (optional)	**Support 1g/L limit for lecithin as food additive**. The departments note that phospholipids are added as a source of long chain-PUFA (i.e. as a nutritive substance) and also as a component of lecithin which is a processing aid or food additive emulsifier. In 2016 FSANZ considered that the amount of phospholipids in infant formula should not exceed that which normally occurs in breast or cow's milk (approximately 0.25g/L), due to their potential bioactivity, a lack of safety data, and insufficient evidence of their benefit. FSANZ now proposes to set the maximum permitted amount of phospholipids as 2 g/L (72 mg/100 kJ) and the maximum lecithin amount to 1 g/L, in line with Codex. FSANZ has not provided a rationale for the permission for phospholipids to be added as a nutritive substance, or at a level which is eight times that found in breastmilk. The departments note that EFSA's scientific assessment concluded that there is no need to add LCPUFAs as Phospholipids: 'Taking into account the lack of convincing evidence for a beneficial effect of LCPUFAs supplied as PLs instead of TAG in IF or FOF, the Panel considers that there is no necessity to use phospholipids as a source of LCPUFAs instead of TAG in IF and FOF'. ' **At this stage, the departments cannot support the proposed approach to retain a permission for phospholipids as a nutritive substance and set a limit of 2g/L**. In order to be consistent with the policy guidelines, **FSANZ should provide further scientific assessment to justify adding phospholipids as a nutritive substance** together with justification for the levels permitted (relative to the amounts found in breastmilk).
Vitamin A 14 – 43 µg RE/100 kJ In IF and FOF	**Do not support proposed maximum level**. **Support a maximum limit of 27.2 µg RE/ 100kJ which prioritises the protection of public health and safety.** FSANZ has not addressed concerns raised by government responses and has retained the industry-preferred levels. FSANZ states this was based on the absence of data indicating that the current maximum of 43 µg/100 kJ is associated with adverse health effects in infants, the uncertainty around the basis for EU 2016/127 maximum, and the objective of this proposal to align with Codex CXS 72 1981 where possible. The primary objective should be the protection of public health and safety, clarified by further guidance from ministers highlighting the vulnerable nature of infants and need for levels to be based on infant requirements, levels in breastmilk and consistent with infant feeding guidelines and policies.

Micronutrients	VIC Departments' view
FSANZ proposed level	
	Reviews of vitamin A note that the safety margin between the Tolerable Upper Intake Level (UL) and the 95th percentile of intake as well as the dietary reference intake is very small.[34,35]. The NHMRC UL for infants of 600 µg RE/day is based on reports of hypervitaminosis A in infants (rather than being extrapolated from the UL for older children or adults, as for some nutrients). The maximum level provided by the EU 2016/127 provides an amount just under this UL of 593 µg/day. FSANZ in its assessments indicates that higher maximum levels are justified as breastmilk can contain up to 38.3 µg RE/100 kJ (1044 µg RE/ L), and states two studies, cited by EFSA, record levels as high as 50–54 µg RE/100 kJ (1363-1472 µg RE/ L) which are higher than the maximum amount set under Codex STAN 72-1981 and section S29—9. The departments have reviewed the references provided by FSANZ and cannot find references to breastmilk levels above 773 µg RE/ L (or 28 µg/100kJ). **The EU 2016/126 maximum of 27.2 µg/100kJ appears more in line with maximum breastmilk concentrations and is therefore supported by the departments**. The departments request that FSANZ reviews the references it provided to clarify where the figures of 50–54 µg RE/100 kJ (1363-1472 µg RE/ L) came from. FSANZ also suggests there is an absence of data indicating that the current maximum of 43 µg/100 kJ is associated with adverse health effects, however EFSA's scientific assessment stated, in relation to maximum nutrient levels that exceed ULs, that '*while there may be no reports of adverse effects associated with the use of formula at these levels, there are no studies available which were designed to investigate the short- or long-term health consequences of consumption of formulae containing the currently permitted maximum amounts of micronutrients*'. This is supported by FSANZ's 2016 market survey which indicated the higher range of vitamin A present in products was below this at 33 µg RE/100kJ. FSANZ also concluded the lower EU maximum of 27.2 µg/100kJ resulted in an estimated slight exceedance of the UL for infants aged 6-12 months, including food intake, but was within the range considered to pose low risk to infant health (≤15% greater than the UL). This would not be the case if the current maximum was retained.
Vitamin B6 8..5 – 45 (GUL) µg /100 kJ In IF and FOF	**Do not support. Support Aligning with EU 4.8 µg/100 kJ minimum and retaining current maximum 36 µg/100 kJ.** EFSA provides the most recent review of vitamin B6 levels were directly linked to infant requirements based on breastmilk. Reported breastmilk concentrations are 2.6-11.4 µg/100 kJ (equal to 57 - 248 µg/day, based on 800mL of breastmilk) with an average concentration cited as 4.8 µg/100kJ by EFSA (equal to 104 µg /day)[36,37].

[34] German Federal Institute for Risk Assessment 2021. Updated recommended maximum levels for the addition of vitamins and minerals to food supplements and conventional foods

[35] SCF (Scientific Committee on Food), 2002. Opinion on the Tolerable Upper Intake Level of preformed vitamin A (retinol and retinyl esters).

[36] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal 2013;11(10):3408, 103 pp. doi:10.2903/j.efsa.2013.3408

[37] EFSA (EFSA Panel on Dietetic Products Nutrition and Allergies), Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 2014. 12(7): p. 3760-3866.

Micronutrients	VIC Departments' view
FSANZ proposed level	
	Minimum FSANZ's previous nutrition assessment found that the minimum EU level met the requirements of infants aged 0-6 months, however it may not meet the vitamin B6 requirements for infants aged 7-12 months on the basis that it does not meet 50% of the NHMRC Adequate Intake of 300 µg/day (assuming 600mL of formula is consumed and 50% is met via food). In contrast the Codex minimum level provides 62% of requirements of 7-12 months old. **The departments question whether formula is required to meet 50% of vitamin B6 requirements for 7-12 month olds, noting that vitamin B6 is widely available in first foods (meat, vegetables and fruit).** We note that in the NHMRC Australian and New Zealand Nutrient Reference Values, many requirements set for infants of 7-12 months **are based on a calculation where breastmilk provides less than 50%.** A rough example meal plan typical of an infant's diet from fresh (not fortified infant foods) indicated more than two thirds of vitamin B6 requirements could easily be met by foods, with the AI met by a combination of food and formula with 4.8 µg/100kJ, noting most companies also add above the minimum level. ***Maximum*** In terms of the maximum limits, the departments note these are very similar in both Codex and the EU (45 versus 41.8 µg/ 100kJ) and are four times the upper levels found in breastmilk. These would result in a daily intake of 911 -981 µg/day. **The departments question why such high maximum levels are required,** considering the principle identified by FSANZ from EFSA's scientific assessment of infant formula composition: that nutrients which are not used or stored have to be excreted and this may put a burden on the infant's metabolism. FSANZ has indicated current products on the market contain vitamin B6 up to 28.11 µg/ 100kJ, which is well below the proposed maximum level (GUL). The departments note that while an UL has not been set in Australia, the maximum is well below the UL set in the EU of 5000 µg/day. **The departments support aligning with the minimum levels assessed by EFSA and implemented in EU 2016/127 on the basis this best reflects the levels in breastmilk**. **The departments request that FSANZ determine a maximum guideline upper level that better reflects the upper levels in breastmilk, or consider retaining the current maximum of 36 µg/100 kJ, with scientific justification for the level.**
Vitamin B12 0.025 – 0.36 (GUL) µg /100 kJ In IF and FOF	**Do not support maximum levels. Support retaining current maximum of 0.17 µg /100 kJ (GUL) as this better reflects levels found in breastmilk**. EFSA reported on studies of breastmilk from Californian women and again of Danish women at 2 weeks, 4 months and 9 months post partum. Most women in both studies took vitamins containing vitamin B12, indicating breastmilk levels would likely be elevated. The maximum level in breastmilk from Californian women was 0.18 µg /100 kJ and in Danish women was 0.1 µg /100 kJ (at 9 months). The proposed Codex level of 0.36 µg /100 kJ is well above these maximum levels in breastmilk. The maximum vitamin B12 content of products currently on the market is 0.16 µg /100 kJ, indicating no reformulation will be required if the current level was retained. **If FSANZ intends to proceed with increasing the maximum to 0.36 µg /100 kJ to align with Codex, the departments request FSANZ provide a health based rationale for why such high maximum levels should be set**, when unnecessary levels of substances can burden infants' systems.

Micronutrients **FSANZ proposed level**	VIC Departments' view
Niacin 70 – 360 (GUL) µg /100 kJ In IF and FOF	**Do not support reducing the minimum from 130 µg /100 kJ to 70 µg /100 kJ to align with Codex. Support level of 100 µg /100 kJ** (consistent with EU 2016/127), which is based on the EFSA scientific opinion on the levels sufficient to meet infant requirements of 2mg/day and reflects levels in breastmilk[38,39]. The current products on the market contain 130.1–272.7 µg /100 kJ and would not need to be reformulated.
Riboflavin 14.3 – 119 (GUL) µg /100 kJ In IF and FOF	FSANZ previously proposed increasing the maximum level from the current 86 µg /100 kJ to **95.6 µg /100 kJ to align with EU, which we supported**. It is now proposing increasing it further to 119 µg /100 kJ to align with Codex. No nutrition or health based rationale has been provided for why the level should be raised to being more than eight times the minimum, noting breastmilk ranges from 9.8 – 22 µg /100 kJ. In line with the expert opinion that informed the Codex levels, the departments support a maximum level that is not more than five times the minimum amount, unless scientific justification for why it is required can be provided.[40]
Vitamin C 1.7 – 17(GUL) mg/100 kJ In IF and FOF	**Support a range of 2.5 – 7.2 mg/100kJ.** ***Minimum*** FSANZ indicates it previously proposed retaining the current minimum of 1.7 mg/100kJ but increasing the maximum for vitamin C from 5.4mg/100kJ to 17 mg/100kJ to align with Codex. The departments had misunderstood the proposed minimum, understanding that FSANZ was proposing to align the **minimum level with Codex at 2.5mg/100kJ. The departments supported this minimum based on meeting nutrient requirements and aligning with Codex.** The departments note that FSANZ justifies significantly increasing the maximum based on shelf-life losses but does not apply this same rationale to the minimum. Previously, we noted that EFSA set a minimum of 0.96/100kJ (a level that is 3 times the amount needed to prevent scurvy). At the Codex minimum of 2.5 mg/100kJ the upper end of typical losses of 50% would result in a level of 1.25mg/100kJ, which is still above the minimum set by EFSA. However, 50% losses at the current minimum of 1.7 mg/100kJ would result in 0.85mg/100kJ vitamin C. The departments note that industry submitters supported retaining the current level of 1.7mg/100kJ to avoid having to reformulate some products. **The departments continue to support a minimum level of 2.5mg/100kJ to allow for shelf life losses**. ***Maximum*** FSANZ's rationale for such a high maximum level is not clear.

[38] EFSA (EFSA Panel on Dietetic Products Nutrition and Allergies), Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 2014. 12(7): p. 3760-3866

[39] NHMRC, Nutrient Reference Values for Australia and New Zealand, Commonwealth of Australia, Editor. 2006: Canberra

[40] Koletzko, Berthold et al Global Standard for the Composition of Infant Formula: Recommendations of an ESPGHAN Coordinated International Expert Group, Journal of Pediatric Gastroenterology and Nutrition: November 2005 - Volume 41 - Issue 5 - p 584-599 doi: 10.1097/01.mpg.0000187817.38836.42

Micronutrients	VIC Departments' view
FSANZ proposed level	
	The departments previously supported a level of 7.2mg/100kJ (which aligned with the EU) on the basis of avoiding unnecessary excess of water soluble vitamins[41], minimising the risk of nutrient interactions (such as with copper and iron), allowing for shelf life losses and then aligning with international regulations where possible. FSANZ indicates the reason to increase the maximum to 17mg/100kJ in line with Codex is because of shelf-life losses. FSANZ do not note that the higher maximum in Codex is accompanied by the footnote: "this GUL has been set to account for possible high losses over shelf-life in liquid formulas; for powdered products *lower upper limits should be aimed for*". While it is important to ensure sufficient amounts of vitamin C in liquid formula, only powdered formula are currently available for retail sale in Australia therefore providing unnecessarily high amounts (when the lower level would be sufficient) is not ideal. FSANZ has also not considered that the current maximum of 5.4mg/100kJ has not been reportedly associated with vitamin C inadequacy resulting from shelf life losses. In terms of actual losses and future proofing the standard to cover ready-to-feed formulas, **could FSANZ explain why 17mg/100kJ is required**? As we previously noted, at the current maximum of 5.4mg/100kJ if the upper end of typical losses of 50% occurred, this would leave a vitamin C content of 2.7mg/100kJ, which is still above the minimum requirement of 0.96mg/100KJ established by EFSA. If a loss of 75% of vitamin C occurred in a liquid formula, the resulting vitamin C content would still be 1.35mg/100kJ which remains well above the level that EFSA considered as sufficient for the majority of infants. Given most infant formula available is in powdered form, losses would be expected to be less than this.
Calcium 12 – 35 (GUL) mg/100 kJ in IF 12 – 43 (GUL) mg/100 kJ in FOF	**Do not support the rationale provided for setting a higher calcium maximum level for follow-on formula.** FSANZ indicates a higher maximum was suggested by industry to align with the Codex draft standard for FuFOI. The reasons for the higher level were based on the increase in calcium requirements for this age group, reduced intakes of follow-up formula at this age, and noting that calcium intakes are often limited in the diets of this age group. Follow-on formula is a breastmilk substitute, not a treatment modality, and should use breastmilk from healthy mothers and breastfed infants as the primary reference (taking into account differences in absorption efficiency), consistent with the Policy Guideline. The literature indicates that the concentration of calcium in mature breastmilk gradually declines over the duration of lactation[42], with the NHMRC Nutrient Reference Values for calcium noting the average content of calcium in breastmilk is slightly lower in the second six months of lactation and

[41] Koletzko, Berthold et al Global Standard for the Composition of Infant Formula: Recommendations of an ESPGHAN Coordinated International Expert Group, Journal of Pediatric Gastroenterology and Nutrition: November 2005 - Volume 41 - Issue 5 - p 584-599 doi: 10.1097/01.mpg.0000187817.38836.42

[42] The increased GUL was based on the increase in calcium requirements for this age group, reduced intakes of follow-up formula at this age, and noting that calcium intakes are often limited in the diets of this age group.

Micronutrients	VIC Departments' view
FSANZ proposed level	
	other studies noting a 25% reduction in calcium content between 4 and 12 months[43]. **Calcium levels in follow-on formula should therefore not be higher than those for infant formula.**
Phosphorous 6 – 24 mg/100kJ For all IF and FOF	**Do not support one range to cover both cow's milk and soy containing formula**. In line with the EU, the departments **support separating out regulatory requirements to:** **6 – 21.5 mg/100kJ for cow or goat based formulas** and **7.2 – 24 mg/100kJ for formula containing soy** This is consistent with our approach for other nutrients where lower bioavailability in soy products exists (and aligns with the EU approach). This ensures sufficient amounts of nutrients are provided through soy formula and also serves to indicate to manufacturers and formula developers the difference in bioavailability that needs to be considered when adding these nutrients.
Iron 0.2 – 0.5 mg/100 kJ In IF and FOF	**Do not support FSANZ's proposed approach to retain the current iron levels of 0.2-0.5mg/100kJ,** noting this is above the ranges set by Codex and in the EU. **Support a range of 0.14-0.31 mg/100kJ in cow's milk-based formula and 0.2-0.5 mg/100kJ for soy-based formula to allow for reduced absorption from phytic acid content.** As soy-based formulas represent a very small minority of the infant formulas on the market, separate ranges for soy formulas should be provided. Separate provisions make it clear to regulators and manufacturers that soy products have lower bioavailability of nutrients and therefore require higher levels. *Cow's milk formula levels:* **The departments support a lower minimum iron level of 0.14mg/100kJ for cow's milk-based infant formula for 0-12 months, in line with EFSA's recommendations and a maximum of 0.31mg/100kJ, to avoid excess iron.** Other recent regulations, such as those in China also have lower maximums (China: 0.1-0.36mg/100kJ). Support for these lower levels is based on: • Relatively recent assessments of infant iron requirements indicate that in the EU, infant formulas have contained 0.15 to 0.29mg/100kJ with very low prevalence of iron deficiency at 6 months . In EFSA's scientific assessment, it recommended a minimum of 0.14mg/100kJ for follow-on formula and formula designed to cover 0-12 months, recognising food provides more than 50% of iron requirements for older infants.

[43] LASKEY, M.A., PRENTICE, A., SHAW, J., ZACHOU, T., CEESAY, S.M., VASQUEZ-VELASQUEZ, L. and FRASER, D.R. (1990), Breast-Milk Calcium Concentrations during Prolonged Lactation in British and Rural Gambian Mothers. Acta Pædiatrica, 79: 507-512. https://doi.org/10.1111/j.1651-2227.1990.tb11504.x

Micronutrients	VIC Departments' view
FSANZ proposed level	
	• Evidence that excess iron intake in iron replete infants is associated with poorer long term developmental outcomes, infection risk and status of trace minerals[44,45,46,47]. The proposed maximum level of 0.5mg/100kJ is greater than levels associated with poorer outcomes. • From FSANZ's market survey, products on the market currently contain up to 0.44mg/100kJ, approaching the levels associated with poorer developmental outcomes in iron replete infants. • Studies that show while low iron status occurs in some Australian infants and young children, the vast majority of infants are iron replete (76% of 9-24 months olds replete, with 5.4% with iron deficiency in a Sydney population and similar levels in an Adelaide population) and therefore the majority of infants may be disadvantaged by the levels proposed at the upper end of the proposed range[48,49]. • Iron levels are kept within a narrow range in breastmilk 0.007-0.014mg/100kJ (with an average of 0.01mg/100kJ), with absorption shown to be 25 to 50%[50]. • The estimated iron *absorbed* from infant formula when using the Code's minimum level is well above the amount absorbed from breastmilk (0.44mg/day from formula, based on a 10% absorption vs 0.11mg/day from human milk, based on a 50% absorption) and therefore not in line with the Policy Guideline. • Follow-on formula is a breastmilk substitute, not a treatment modality, and should use breastmilk from healthy mothers and breastfed infants as the primary reference (taking into account differences in absorption efficiency), consistent with the Policy Guideline. FSANZ's rationale is that iron levels in follow-on formula should meet 50% of the NHMRC EAR of 7mg/day for 7 to 12month olds, of which 10% would be bioavailable. This no longer uses the relative bioavailable amounts in breastmilk as a reference. EFSA also noted literature from the U.S and U.K. indicating

[44] Koletzko, B., et al., Global standard for the composition of infant formula: recommendations of an ESPGHAN coordinated international expert group. Journal of Pediatric Gastroenterology and Nutrition, 2005. 41(5): p. 584-599.

[45] Lozoff B, Castillo M, Clark KM, Smith JB. Iron-Fortified vs Low-Iron Infant Formula: Developmental Outcome at 10 Years. Arch Pediatr Adolesc Med. 2012;166(3):208–215. doi:10.1001/archpediatrics.2011.197

[46] Hare DJ, Cardoso BR, Szymlek-Gay EA, Biggs BA. Neurological effects of iron supplementation in infancy: finding the balance between health and harm in iron-replete infants. Lancet Child Adolesc Health. 2018 Feb;2(2):144-156. doi: 10.1016/S2352-4642(17)30159-1. Epub 2017 Dec 6. PMID: 30169236.

[47] Lönnerdal B, Excess iron intake as a factor in growth, infections, and development of infants and young children, The American Journal of Clinical Nutrition, Volume 106, Issue suppl_6, December 2017, Pages 1681S–1687S, https://doi.org/10.3945/ajcn.117.156042

[48] Oti-Boateng P, Seshadri R, Petrick S, Gibson RA, Simmer K. Iron status and dietary iron intake of 6-24-month-old children in Adelaide. J Paediatr Child Health. 1998 Jun;34(3):250-3. doi: 10.1046/j.1440-1754.1998.00205.x. PMID: 9633972.

[49] Karr M, Alperstein G, Causer J, Mira M, Lammi A, Fett MJ. Iron status and anaemia in preschool children in Sydney. Aust N Z J Public Health. 1996 Dec;20(6):618-22. doi: 10.1111/j.1467-842x.1996.tb01076.x. PMID: 9117969.

[50] EFSA (EFSA Panel on Dietetic Products Nutrition and Allergies), Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 2014. 12(7): p. 3760-3866

Micronutrients	VIC Departments' view
FSANZ proposed level	
	that food provides the majority of iron in the second six months and can feasibly make up the difference if formula contains 0.14mg/100kJ[51]. This indicates it is not necessary for formula to meet 50% of iron requirements of this age group. • **Supplementing infant formula well above the nutritional reference of breastmilk and breastfed infants to reduce iron deficiency anaemia in a minority of infant populations risks undermining breastmilk** as the ideal and preferred source of nutrition and may not be in the best interests of infant health. Breastmilk has sufficient iron to meet the needs of infants until around 6 months of age, and as part of a progressive diversified diet that includes solid foods rich in iron, until 12 months and beyond.
Folic acid 2.5 – 12 (GUL) µg /100 kJ In IF and FOF	**Do not support FSANZ's proposed approach**. **Support use of Dietary Folate Equivalents, including all sources of folate and a permitted range of 3.6 – 11.4 µg/100 kJ, in line with the EU.** **The departments do not support FSANZ's proposed approach** to regulate folate only as µg folic acid/100 kJ on the basis that it is not consistent with consideration of infant's nutritional requirements nor current accepted understanding and use of Dietary Folate Equivalents in Australia. The departments note no further nutrition risk assessment was considered on this issue. Infants have no requirement for folic acid *per se* and excluding any naturally occurring folate from calculations of total folate and the representation of folic acid as being equivalent to folate is misleading. **The departments instead support the use of Dietary Folate Equivalents (DFEs) and including all forms of folate present**. The 2006 Nutrient Reference Values for Australia and New Zealand recognise the difference in bioavailability between folic acid and folate adopts the use of DFEs. The use of DFEs has also been adopted by health professionals. The EU has changed its regulations, using DFEs, and there have been recent discussions about the US Food and Nutrition Board's 2016 decision to adopt DFEs into food and supplements[52]. FSANZ indicates excluding folate from ingredients is justified on the basis that a 2018 study, looking at testing methods, found that in 10 infant formula samples, folic acid was the major contributor of folates with only small amounts contributed by folate from the ingredients[53]. This is in contrast to the 2010 study that looked at 21,388 batches of formula and found up to 40% of folate is provided from folate containing ingredients[54]. Given the lack of consistency in results, lack of evidence that infant formula manufacturers use consistent processing methods that remove folate, together with the

[51] EFSA (EFSA Panel on Dietetic Products Nutrition and Allergies), Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 2014. 12(7): p. 3760-3866

[52] Leila G Saldanha, Johanna T Dwyer, Carol J Haggans, James L Mills, Nancy Potischman, Perspective: Time to Resolve Confusion on Folate Amounts, Units, and Forms in Prenatal Supplements, Advances in Nutrition, Volume 11, Issue 4, July 2020, Pages 753–759, https://doi.org/10.1093/advances/nmaa017

[53] Campos-Giménez E, Bénet S, Oguey Y, Martin F, Redeuil K (2018) The contribution of minor folates to the total vitamin B9 content of Infant formula and clinical nutrition products. Food Chem. 249: 91-97. https://doi.org/10.1016/j.foodchem.2017.12.061.

[54] MacLean J, Van Dael P, Clemens R, Davies J, Underwood E, Risky L, Rooney D, Schrijver J (2010) Upper levels of nutrients in infant formulas: Comparison of analytical data with the revised Codex infant formula standard. J. Food Comp. Anal. 23(1):44–53.

Micronutrients **FSANZ proposed level**	VIC Departments' view
	reasons listed above, all sources of folate should be included and represented as Dietary Folate Equivalents. Changing the units to take into account the relative activities of the natural and synthetic forms of folate is also consistent with the approach FSANZ has taken for vitamin E. *Permitted levels* The Code currently requires 2 – 8 µg folate /100 kJ (not specifying whether DFEs) which is equivalent to 44-174 µg folate/day, the minimum being below the NHMRC Adequate Intake of 65 µg folate/day. In comparison Codex permissions are 2.5-12 µg/100 kJ folic acid and EU: 3.6 – 11.4 µg DFE/100 kJ. **The departments support a range of 3.6 – 11.4 µg DFE/100 kJ which aligns with the EU.** This better reflects infant requirements (equivalent to 3 µg DFE/100 kJ) without providing excessive amounts.
Zinc 0.12 – 0.36 (GUL) mg/100 kJ In IF and FOF	**Do not support aligning the maximum with Codex and instead support aligning with the EU maximum of 0.24mg/100kJ**. The departments also **support setting different levels for cow's milk and soy formula (0.18-0.3mg/100kJ for soy),** consistent with the approach for other nutrients where lower bioavailability in soy products exists. This ensures sufficient amounts of nutrients are provided through soy formula and also serves to indicate to manufacturers and formula developers the difference in bioavailability that needs to be considered. Choosing a maximum zinc for infant formula because it is the level proposed in a draft Codex standard for formula for 6 to 12 month olds does not provide sufficient scientific rationale for how infant health and safety is being considered in updating these regulations. The proposed maximum level results in a daily intake of 7.8mg/day compared to the UL of 4mg/day for infants aged 0 to 6 months. Our preferred EU level (which was reduced from the Codex level) is much closer to the UL at 5.2 mg/day, compared to an UL of 4mg/day for infants aged 0 to 6 months. While the bioavailability of zinc from formula is lower and note that FSANZ's review of the study underpinning the 4 mg/day UL had a number of limitations which indicate an overly conservative basis for this level, FSANZ has equally not provided evidence suggesting it is safe to provide double the UL on a regular basis. As previously mentioned, EFSA noted there are no studies available which were designed to investigate the short- or long-term health consequences of consumption of formulae containing the currently permitted maximum amounts of micronutrients in infant or follow-on formula[55]. For this reason, the **departments support retaining a set maximum limit for zinc rather than a voluntary GUL maximum**. We also note from the FSANZ's 2016 market label survey that the highest level being added to formula was 0.25mg/100kJ, which is close to our preferred maximum. *Zinc: copper ratio* In our 2016 response, the departments did not have a position on whether the Zn:CU ratio should be retained but noted that breastmilk has a Zn:Cu ratio of 10:1 and supported the principle that infant formula should be primarily based on the composition of breastmilk, noting the ratio was initially created to manage the potential impact of zinc intakes on copper bioavailability. **We requested more information on how the proposed**

[55] EFSA (EFSA Panel on Dietetic Products Nutrition and Allergies), Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 2014. 12(7): p. 3760-3866.

Micronutrients	VIC Departments' view
FSANZ proposed level	
	changes for zinc and copper levels impacted on the ratio of Zn:Cu to help determine whether a set ratio was required. FSANZ provided no further assessment on this. At the minimum proposed copper level (which does not meet infant requirements for ready-to-feed formula), the minimum Zn:Cu ratio would be 14:1. This would be higher if levels of zinc above the minimum were added. Presumably this presents a risk for meeting infant copper requirements, particularly in liquid products which may not meet requirements for copper. This supports 'future-proofing' the standard and ensuring copper compositional requirements are sufficient to meet requirements. If the Zn: Cu ratio requirement is removed and guidance is not to be provided on maintaining a zinc and copper in a ratio as close to 10:1 ratio as possible, **could FSANZ explain how the zinc to copper ratio will be maintained to reflect levels in breastmilk and how copper levels in formula (particularly ready to feed, which is currently used in hospital settings) will be sufficient**.
Thiamin 10 – 72 (GUL) µg /100 kJ In IF and FOF	**Do not support proposed maximum.** FSANZ is proposing retaining the current minimum for thiamin of 10 µg /100 kJ (compared to the Codex minimum of 14 µg /100 kJ) but increasing the maximum from its current level of 48 µg /100 kJ to the Codex level of 72 µg /100 kJ. **The departments support retaining the current range of 10- 48 µg /100kJ** for thiamin on the basis that this best supports infant requirements and limits the provision of unnecessary amounts of thiamine to less than five times the minimum. If FSANZ intends to proceed with a level of 72 µg /100 kJ, clear evidence to justify this level needs to be provided. Thiamin in breastmilk have been reported by EFSA as ranging from 150-330 µg/L (equivalent to 5.5-12 µg /100kJ). This is consistent with levels reported in other studies in different populations[56]. The current Codex maximum of 72 µg /100 kJ provides 1962 µg/L (approximately 6 times higher than upper levels in breastmilk). Products on the ANZ market are currently within our preferred range and therefore reformulation would not be required.
Biotin 0.24 – 2.4 (GUL)µg /100 kJ In IF and FOF	**Do not support proposed maximum**. FSANZ is proposing to lower the minimum level of biotin from 0.36 µg /100 kJ to align with the EU minimum of 0.24 µg /100 kJ but align the maximum with the Codex level of 2.4 µg /100 kJ . **The departments continue to support aligning the maximum with the EU Level of 1.8 µg/100 kJ.** Formula currently on the market are in this range and would not need to reformulate. FSANZ indicates the higher level (which is ten times the minimum) does not pose a safety risk to ANZ infants however has not provided scientific justification for why the level needs to be so high. While the supported 1.8 µg /100 kJ level exceeds the recommended 5 times the minimum level, this is less than Codex and provides alignment with the EU, which is a major supplier of formula to Australia.

[56] Allen LH. B vitamins in breast milk: relative importance of maternal status and intake, and effects on infant status and function. *Adv Nutr*. 2012;3(3):362-369. Published 2012 May 1. doi:10.3945/an.111.001172

Micronutrients **FSANZ proposed level**	VIC Departments' view
Copper 8.5 – 29 (GUL) µg /100 kJ In IF and FOF	**Do not support reducing the minimum copper levels from 14 to 8.5 µg /100 kJ to align with Codex and instead consider that the compositional requirements should first and foremost be based on meeting infants' requirements**. FSANZ's comment that EFSA 2014 reported a higher range of copper in breast milk which is the basis for the EU 2016/127 minimum is noted. The EU minimum at 14.3 µg /100 kJ is not being requested; t**he departments suggest the minimum should be at least at 9.2 µg/100 kJ,** based on the minimum required to meet the NHMRC AI. This is particularly the case given FSANZ is also proposing higher zinc levels and removing the Zinc: Copper ratio, which may impact on the amount of copper available to infants. While the deficit might be made up with the copper content of potable water, ready-to-feed formula are for retail sale overseas and it is important to ensure the standards are 'future proof' in case this market develops in Australia. **Maximum** The departments do not support aligning the maximum (GUL) with Codex and instead support aligning it with the EU max of 24 µg /100kJ (GUL) as this best reflects breastmilk levels. Compared to the upper levels found in breastmilk (400 µg /L), 24 µg /100kJ provides 654 µg /L, while the Codex maximum provides 790 µg /L. The EU levels are less likely to create a burden on infants' systems from unnecessary amounts.
Iodine 2.5-14 (GUL) µg /100 kJ In IF and FOF	**Do not support the proposed levels. Support 3.6 to 6.9 µg /100 kJ** FSANZ has changed its position since last consultation. Instead of a minimum of 3.6 µg /100 kJ (which aligned with EU) and retaining a maximum of 10 µg /100 kJ, FSANZ is proposing a lower minimum of 2.5 µg /100 kJ and a higher maximum of 14 µg /100 kJ to align with Codex. This rationale appears to have prioritised aligning with Codex over consideration of meeting infants' requirements (as per the NHMRC and EFSA opinions). FSANZ notes this is unlikely to pose a risk to infant health **but has not responded to our previous comments that a level of 3.6 µg /100 kJ better meets infant requirements and that the Huynh study quoted based on South Australia cannot be extrapolated to the rest of the Australian population given South Australia was in the minority for being iodine replete (likely due to higher soil and water levels).** **The departments continue to support a minimum EU min of 3.6 µg/100 kJ in order to meet infant requirements**. ***Maximum*** **The departments continue supporting aligning with the EU maximum of 6.9 µg /100 kJ,** previously noting the current maximum of 10 µg /100 kJ exceeds the UL. FSANZ is now proposing setting the maximum higher still to 14 µg /100 kJ, to align with Codex. While there may be a lack of studies specifically looking at the effects of feeding infants formula at 14 µg /100 kJ iodine, consideration of the maximum should consider an approach based on health-based principles and expert advice that unnecessary excesses of nutrients should be avoided. The current 10 µg /100 kJ provides infant intakes of 218 µg/day (226-258µg/day with water), which is above the UL of 200µg/day for one to three year olds set by NHMRC (and consistent with the EU UL, which is based on thyroid stimulating hormone levels)[57]. The proposed Codex maximum of 14 µg /100 kJ would provide 305 µg/day (313 – 345 µg/day with water). The departments note that the EU reduced the maximum limit for iodine on the basis that it resulted in intakes that exceed the UL. The EU maximum of 6.9 µg/100kJ was considered by FSANZ not to pose a risk and results in intakes of 150 µg/day (158-190 µg/day with water), which meets infant requirements. Consideration of the Australian and New Zealand context

[57] NHMRC, Nutrient Reference Values for Australia and New Zealand, Commonwealth of Australia, Editor. 2006: Canberra.

Micronutrients **FSANZ proposed level**	VIC Departments' view
	which now has iodine fortified bread (often consumed in later infancy) needs to be also taken into account before automatically adopting a level proposed in the draft Codex standard for FUFOI.
Selenium 0.48 – 2.2 (GUL) µg /100 kJ in IF and FOF	**Do not support maximum level or the voluntary level** FSANZ is proposing increasing selenium levels from 0.25-1.19 µg/100 kJ to 0.48 – 2.2 µg/100 kJ. ***Minimum*** The proposed minimum is higher than the Codex minimum and **supported by the departments** as described in our previous responses based on infant requirements and breastmilk content. ***Maximum*** FSANZ appears to have changed its approach and instead of a maximum of 2 µg /100 kJ (which aligns with EU) is now proposing aligning the maximum with Codex and changing it to a voluntary GUL. Its proposed approach does not prioritise the protection of infant health and safety. The departments supported a level of 2 µg /100 kJ (44 µg/day) as this resulted in intakes that fell just below the ANZ UL of 45µg/day, whereas the Codex level results in infant intakes above the UL (48 µg/day). **The maximum set should be based on a level that results in intakes of selenium that are below the Australia and New Zealand UL**. FSANZ (2016) also concluded that the Codex STAN 72-1981 maximum amount (specified as a GUL) could pose a risk to infant health due to the lack of international consensus on the appropriate maximum, and estimated intake calculated using the Codex maximum exceeding the ANZ UL. **Given the proposed levels are close to the UL, the maximum should be retained as a set maximum rather than a GUL.**
Taurine 0.8 – 3 mg/100 kJ in IF (optional) NS – 3 mg/100 kJ in FOF (optional)	Not previously assessed by FSANZ. **An assessment is needed on the essentiality of taurine**. As in our previous responses, taurine (as an optional ingredient) should be assessed as to whether it is an essential nutrient and of benefit to infants (and made mandatory) or after extensive use (20+ years) it appears it is not essential (and so should be removed from permissions). Retaining optional ingredients indefinitely despite a lack of evidence as to their benefit does not reflect innovation that intends to produce the best possible outcomes for infants who do not have breastmilk. The departments note that EFSA's position was that taurine is not necessary in IF or FOF due to a lack of convincing evidence for a benefit, but that it is also present in breastmilk in levels of 1.12 up to 2.9mg/100kJ
Choline 1.7 – 12 (GUL) mg/100 kJ in IF NS – 12 mg/100 kJ in FOF (optional)	**Support FSANZ's proposed approach to mandate choline, with a maximum level of 12mg/100kJ.** **Do not support retaining the current minimum level and instead support a level of 6mg/100kJ, in line with EU 2016/127.** **Do not support a voluntary permission for follow-on formula**. Choline is considered an essential nutrient for infants throughout infancy (and beyond) and is present in breastmilk throughout the first 12 months. Given FOF is a breastmilk substitute it should contain choline as a mandatory nutrient.

Micronutrients	VIC Departments' view
FSANZ proposed level	
	Minimum The minimum level of choline being proposed is well below infant requirements. The departments consider that the total choline in infant formula should meet infant requirements of at least 125mg/day and should encompass both free choline added as an ingredient as well as the free choline and other forms naturally present from cow's milk, in line with the total nutrient content of the final product for other nutrients. Given the essential nature of choline, the water-soluble nature of free choline and the presence of other forms of choline in infant formula, the departments consider it prudent to align the minimum with the EU 2016/127 level of 6mg/100kJ of total choline to meet infants' total choline requirements. The EU 2016/127 requires 6mg/100kJ, based on all sources of choline; i.e. choline, phosphocholine, glycerophosphocholine, phosphatidylcholine and sphingomyelin. Chinese infant formula standards appear to be proposing a minimum closer to the EU of 4.8mg/100kJ[58]. The EU raised its minimum from the Codex level in 2016 in order to meet infant requirements it established to be 130mg/day, which is similar to the NHMRC Adequate Intake of 125mg/day[59]. The current proposed minimum of 1.7mg/100kJ would provide 37mg/day, which is significantly lower than accepted infant requirements. This is also significantly lower than levels found in breastmilk, which are on average 160mg/L or ~6mg/100kJ.. The departments note that FSANZ states there are multiple forms of choline in breastmilk, but only free choline is permitted to be added to infant formula, therefore the minimum level would not be based on the total choline content or infant requirement. This is not consistent with FSANZ's approach to other nutrients with multiple forms and does not ensure that infants' choline requirements are being met. **The departments support setting a limit that meets total choline requirements.** Choline is an essential nutrient, with accumulating evidence for its importance in early neurodevelopment during the first 1000 days of life. Infants can synthesize choline but not in sufficient amounts to meet requirements[60]. Strong evidence from animal studies have demonstrated that deficiency in infancy leads to cognitive impairments such as permanent long term impaired memory function[61],[62]. It is also critical for maintaining structural integrity of cells, is a precursor for neurotransmitters, is involved in lipid and cholesterol transport and metabolism and is a source of methyl groups for many metabolic processes,

[58] USDA Foreign Agricultural Service Global Agricultrural Information 2018 China Notifies Measure on Infant Formula for Young Infants (as SPS 1082)
[59] EFSA (EFSA Panel on Dietetic Products Nutrition and Allergies), Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 2014. 12(7): p. 3760-3866
[60] Mun JG, Legette LL, Ikonte CJ, Mitmesser SH. Choline and DHA in Maternal and Infant Nutrition: Synergistic Implications in Brain and Eye Health. Nutrients. 2019;11(5):1125. Published 2019 May 21. doi:10.3390/nu11051125
[61] Schwarzenberg, S.J.; Georgieff, M.K. Advocacy for improving nutrition in the first 1000 days to support childhood development and adult health. *Pediatrics* 2018, *141*, doi:10.1542/peds.2017-3716.
[62] Zeisel, S.H.; Carolina, N.; Hill, C.; Carolina, N.; Blusztajn, J.K. Choline and human nutrition. Annu Rev Nutr 1994, 14, 269–96.

Micronutrients	VIC Departments' view
FSANZ proposed level	
	including folate-dependent one-carbon metabolism[63]. Neonates and infants require large amounts of choline to support a rapid growth rate and optimal development[64]. Choline exists in both water-soluble (e.g., free choline, phosphocholine, and glycerophosphocholine) and lipid-soluble (e.g., phosphatidylcholine and sphingomyelin). In infancy, the predominant forms of choline via breastmilk are the water-soluble forms, including free choline, which are more readily absorbed than the lipid-soluble forms of choline (phosphatidylcholine and sphingomyelin), which are mainly present as a minor component of the milk fat globule membrane, and thus make up a relatively small fraction of the total choline in human milk[65], [66]. Free choline is converted to these other forms. The provision of free choline therefore may be sufficient to meet total choline requirements. The departments also note that cow's milk is a source of all forms of choline and studies indicate it is possible to manufacture infant formula that more closely matches these metabolites' profile in human milk[67, 68]. Therefore while other forms of choline are not permitted to be added to infant formula at this time, they are permitted to be present from cow's milk and will contribute to total choline content.
Myo-inositol 1.0– 9.5 (GUL) mg/100 kJ in IF and FOF (optional in FOF)	**Support mandating myo- inositol in infant formula products, including IF and FOF** given the primary function of these products is as a breastmilk substitute and there is no evidence that breastmilk ceases to contain myo-inositol after 6 months. The departments previously requested FSANZ to review the minimum, which is approximately 5 times below breastmilk levels. FSANZ has indicated that a level of 1 mg/100kcal still appears sufficient because endogenous *de novo* synthesis of inositol appears to be efficient in newborn infants. **Further evidence of this should be provided given there is a much higher level in breastmilk despite *de novo* synthesis of inositol**.
L-Carnitine 0.3-0.8 mg/100 kJ in IF	**Support FSANZ's proposed approach to mandate L-carnitine with a range of 0.3 to 0.8 (GUL)mg/100kJ** on the basis that this best meets infant requirements, is similar to the range found in breastmilk.

[63] Zeisel, S.H.; Klatt, K.C.; Caudill, M.A. Choline. *Adv. Nutr.* 2018, *9*, 58–60, doi:10.1093/advances/nmx004.
[64] *Zeisel SH, Wurtman RJ* Developmental changes in rat blood choline concentration. *Biochem J. 1981 Sep 15; 198(3):565-70.*
[65] Zeisel S.H., Char D., Sheard N.F. Choline, phosphatidylcholine and sphingomyelin in human and bovine milk and infant formulas. *J. Nutr.* 1986;116:50–58. doi: 10.1093/jn/116.1.50.
[66] Wiedeman, A.M.; Barr, S.I.; Green, T.J.; Xu, Z.; Innis, S.M.; Kitts, D.D. Dietary choline intake: Current state of knowledge across the life cycle. *Nutrients* 2018, *10*, doi:10.3390/nu10101513.
[67] Artegoitia VM, Middleton JL, Harte FM, Campagna SR, de Veth MJ. Choline and choline metabolite patterns and associations in blood and milk during lactation in dairy cows. *PLoS One*. 2014;9(8):e103412. Published 2014 Aug 26. doi:10.1371/journal.pone.0103412
[68] Zeisel S.H., Char D., Sheard N.F. Choline, phosphatidylcholine and sphingomyelin in human and bovine milk and infant formulas. *J. Nutr.* 1986;116:50–58. doi: 10.1093/jn/116.1.50.

Micronutrients	**VIC Departments' view**
FSANZ proposed level	
0.3 – NS in FOF (optional)	**Do not support an optional status in FOF,** as these products are a breastmilk substitute, noting that in breastmilk carnitine levels reduce in the first 2 months but then stay constant up to 12 months[69] .
Nucleotides (optional): Adenosine-5'-monophosphate^ NS – 0.38 mg/100 kJ Cytidine-5'-monophosphate^ NS – 0.6 mg/100 kJ Guanosine-5'-monophosphate^ NS- 0.12 mg/100 kJ Inosine-5'-monophosphate^ NS- 0.24 mg/100 kJ Uridine-5'-monophosphate^ NS-0.42 mg/100 kJ	**Do not support maintaining an indefinite optional status for nucleotides**, that has continued for 20 + years already. FSANZ should determine whether these are an important component in a breastmilk substitute for optimal growth and development and make them available in all infant formula products, or remove the permission to avoid burdening infant systems with unnecessary ingredients. Further assessment is required on whether a source of nucleotides in breastmilk substitutes is required for optimal infant growth. EFSA (2014) noted that *the presence of nucleotides and nucleosides in human milk does not necessarily indicate a specific benefit for the infants as they may also be by-products of milk formation that reflect metabolic activity of the mammary gland tissue, shedding of somatic cells and occurrence of microorganisms, without having a specific function for the infant. Taking into account the lack of convincing evidence for a benefit of the addition of nucleotides to IF and/or FOF, the Panel considers that there is no necessity to add nucleotides to IF or FOF.*

[69] Rovamo LM, Salmenperä L, Arjomaa P, Raivio KO. Carnitine during prolonged breast feeding. Pediatr Res. 1986 Aug;20(8):806-9. doi: 10.1203/00006450-198608000-00022. PMID: 3737295.

Micronutrients	VIC Departments' view
FSANZ proposed level	
Total free nucleotide 5'-monophosphates^ NS-3.8 mg/100 kJ	
Protein source	**Support the proposal for the Standard to clearly state the protein sources that have undergone pre-market assessment and are permitted in infant formula products (including special medical purpose products)**. This aligns with the Ministerial Policy Guideline on Infant Formula Products, which specifies that all new substances used in infant formula in Australia and New Zealand should undergo pre-market assessment. This will ensure that permitted protein sources are suitable and issues such as bioavailability of the protein and the presence of anti-nutritive factors (such as trypsin inhibitors, lectins and phytic acid found in soy), and relevant contaminants (such as mycotoxins, arsenic), are accounted for and kept as low as possible. The departments note that this is consistent with the EU and with the draft Codex approach for 'follow-up formula'. **The departments have also been made aware that sheep milk is used in NZ as a basis for infant formula products. If it is considered nutritionally comparable to cow and goat, with no additional issues or contaminants, the departments support this being included**. Plant-based proteins are more likely to have significant variation in factors (such as anti-nutritive factors and contaminants) that need to be closely considered and managed. In terms of enforceability, **the departments requested FSANZ reconsider the following proposed wording, which could be ambiguous in terms of what might be considered 'normally used in formula'**: '*cow's milk protein, goat's milk protein, protein hydrolysates of one or more proteins* ***normally used in infant formula****, and soy protein isolate*'. Could this, for example, permit proteins used in formula overseas that are not permitted in Australia and New Zealand?
Carbohydrate source	**Do not support proposed approach**. **Support restricting glucose in addition to sucrose and fructose, in line with the EU.** FSANZ is proposing adopting limits on sucrose and fructose to align with Codex CXS 72-1981, indicating this option is supported by safety concerns cited in previous consultations, FSANZ's safety assessment conducted in 2002 and by international requirements that come into place in 2020 that are in line with Codex CXS 72-1981. **Could FSANZ provide clear evidence why glucose should not also be restricted to protect infant health and safety?** Both EFSA and the European Society for Paediatric Gastroenterology Hepatology and Nutrition's Medical Position Statement on infant formula composition (which informed Codex) indicated that sucrose, glucose and fructose should not be added to infant formula. Sucrose and fructose do not have any advantage over lactose, pose a serious risk to infants with hereditary fructose intolerance and saccharase deficiency and may, because of their greater sweetness, increase the preference for sweet tastes in infants. Glucose is considered unsuitable as it may form Maillard products, is

Micronutrients	VIC Departments' view
FSANZ proposed level	
	rapidly absorbed with a rapid rise in blood glucose and increases the osmolality of infant formula[70,71]. These should only be added where necessary, such as to specialised formula based on protein hydrolysates (to mask bitterness).
Permitted forms of micronutrients	β **-carotene:** **Do not support proposed approach to permit β -carotene as a form of vitamin A** FSANZ is proposing to continue to allow β -carotene as a form of vitamin A while simultaneously prohibiting it from being counted as a form of vitamin A due to a lack of evidence about its bioconversion to vitamin A in infants. This lacks logic and a lack of safety concern with β -carotene is inadequate to justify continuing to add a substance for a nutritive purpose that has no role. This is also contrary to the Policy Guidelines in that substances added to infant formula should have a specific role, either technological or health based.

[70] Koletzko, B., et al., Global standard for the composition of infant formula: recommendations of an ESPGHAN coordinated international expert group. Journal of Pediatric Gastroenterology and Nutrition, 2005. 41(5): p. 584-599.
[71] EFSA (EFSA Panel on Dietetic Products Nutrition and Allergies), Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 2014. 12(7): p. 3760-3866.

Section 7 – Labelling

7.1 Safety and technology

Directions for preparation and use

The departments support FSANZ's proposed requirements for directions for preparation and use, including:

- maintain without change the mandatory requirement for directions:
  - to prepare bottles individually, and
  - instructing that if a bottle of made up formula is to be stored before use, it must be refrigerated and used within 24 hours.
  - instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used.
- revise the directions:
  - for water used to reconstitute powdered formula to include the word 'cooled'.
  - instructing to discard unfinished formula to include the text 'within 2 hours'.

We note FSANZ has assessed the microbiological safety of various preparation temperatures and feeding times and all examined scenarios did not present heighted risk of illness, including up to 2 hours feeding time.

We also support not applying selected directions to ready-to-drink formula due to their limited relevance, including:

- that each bottle to be prepared individually
- to refrigerate formula and use within 24 hours if it is made up and stored prior to use
- to use potable, previously boiled water
- to not apply the direction to only use the enclosed scoop to concentrated and ready-to-drink formula.

Standardised wording or pictures for directions for preparation and use

As per our comments to Consultation Paper 1 in 2021, **the departments support a more prescriptive approach** for directions based on FSANZ's consumer research that shows that a significant proportion of test subjects misunderstood certain instructions (for example, after reading the instructions, 32% of participants thought left over formula could be put in the fridge and reheated, 28% believed flavourings and other food could be added to made up formula and 28% believed any scoop could be used). When the wording was improved, there was a statistically significant increase in participants understanding the instructions around not adding other foods or flavourings to the formula, ensuring water is added first when making up formula and not keeping remaining formula after feeding. This study was also supported by the Malek (2017) research quoted by FSANZ that found a lack of understanding of instructions was one reason some caregivers were preparing or using infant formula incorrectly.

While we supported flexibility for manufacturers, we noted the primary aim of providing directions for preparation is to ensure all caregivers can safely prepare formula using the instructions on the tin and that if consumers found instructions unclear then these should be clarified, which may include prescribed wording. FSANZ has now presented consumer research which shows that a large proportion of participants did not understand current wording, which could be significantly improved with changes to wording. **This provides clear evidence that instructions**

need a greater level of prescription, even if it is to include a greater number of prescribed elements, rather than prescribing the entire phrasing. The elements from FSANZ's research which showed a larger proportion of participants misunderstood instructions should be the starting point for prescribing of elements. Proposed changes for adding 'cooled' and a time to discard unused formula will help address some, but not all of the issues identified. Prescribing information could address manufacturers that present inappropriate information and confusing instructions such as the instruction that qualified cooling to lukewarm as being 40◦C (when this temperature was shown to increase the microbiological risk).

Date marking

The departments support the proposed approach to continue the requirement for a date mark due to deterioration in nutrient content over time. FSANZ proposes to provide flexibility in the use of a use-by or a best-before date noting that a use-by must be used if the formula should not be consumed past the date for health or safety reasons (which includes nutrient deterioration). It is unclear what would trigger a use-by date in terms of nutrient deterioration (for example if any levels fall below minimum) and **FSANZ should provide written guidance on the expectation for use of the use-by date.**

Storage instructions

The departments support FSANZ's proposed approach to maintain the existing requirements for storage instructions, which includes a specific requirement for an opened tin, on the basis that consumers appear to understand this instruction and it is consistent with Codex.

Legibility requirements for warning statements

The departments support FSANZ's proposed approach to retain the existing legibility requirements for generic or specific warning statements noting industry practice is to emphasise warning statements through the use of bolding or capitalisation.

Warning statements about following directions exactly

The departments support FSANZ revised proposal to require the preparation directions to instruct:

- For powdered and concentrated infant formula products - not to change proportions of [powder/concentrate] or add other food except on medical advice
- For ready-to-drink infant formula products - not to dilute or add anything except on medical advice.

We note while FSANZ previously proposed these instructions form part of the warning statement about following instruction exactly, consumer research indicated slightly more caregivers identified the preparation instructions of greater importance compared to warning statements. Locating the additional guidance on following directions exactly in the preparation instructions is therefore likely to have an equal or greater reach among caregivers.

Based on the relocation of some directions to the preparation instructions, **the departments support a consolidated single warning statement that reads:**

'Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill'.

'Breast milk is best for babies' warning statement

In line with our previous comments, **the departments support the ongoing 'breast is best' statement** rather than a risk-based statement, given no research has been provided on the relative merits of gain-framed versus loss/risk-framed statements and the impacts on intention to breastfeed or use formula.

Prescribed name

The departments support the proposed approach to retain the prescribed names 'infant formula' and 'follow-on formula' (until follow-on formula is phased out) to ensure the true nature of the product is clear and can be clearly differentiated from other similar-looking products on the market for children of different age. As noted earlier, follow-on formula is not a recommended or necessary product in the national infant feeding guidelines and the departments do not see any value in a prescribed name for follow-on formula when infant formula is suitable for infants up to 12 months.

Statement that infant formula may be used from birth

The departments support the proposed approach to continue the requirement that infant formula states it may be used from birth. This provides clear information about appropriate use for caregivers and is consistent with Codex.

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

The departments support the proposed approach to continue the requirement that follow-on formula indicating that should not be used for infants aged under the age of 6 months. This provides clear information about appropriate use for caregivers and is consistent with Codex.

Statement about age to offer foods in addition to formula

FSANZ has proposed to maintain the current requirement for a statement that recommends that infants **from the age of 6 months** should be offered food in addition to infant formula. While the departments preferred approach would be to align with the infant feeding guidelines that recommend **around the age of 6 months**, we note maintaining the current wording is unlikely to raise health or safety concerns.

Statement on protein source

The departments support FSANZ's proposed approach to retain the requirement for the label to state the specific source of protein, and clarify this means the origin of the protein and not protein fraction, such as casein or whey. This enables caregivers of infants with allergies or intolerances to correctly identify suitable products. In addition to clarifying the origin of the protein, there should also be an explicit prohibition against labelling protein fractions in the protein source to ensure the information is simple and more easily identified by caregivers. **The departments note and support the proposed approach to mandate a list of permitted protein sources. See further details under Nutrient Composition.**

Co-location of protein source statement with the name of the food

The departments support FSANZ's proposed approach to retain the requirement for the co-location of the protein source statement and the name of the product. The departments note that the 'name of the product' will be clarified as the prescribed name, which will mean the protein source will not necessarily be located next to the brand name and that it will not be required every time the prescribed name appears on the label. Given the prescribed name can appear on different areas of the label and not always in a prominent position, **the departments also support aligning with section 8.1.4 of the Codex General Standard for the Labelling of Pre-packaged Foods that requires the name of the food to appear in a prominent position**.

Standardised ratio of water for preparation

FSANZ considered in 2021 standardised ratios for preparation (for example, 1 scoop of formula powder per 30ml water across all products, regardless of scoop size) and noted there are few benefits to requiring a consistent reconstitution ratio of formula to water across all brands and that it has not identified any evidence to indicate incorrect usage. FSANZ's proposed approach is to not standardise reconstitution ratios. **The departments do not agree with FSANZ's rationale or proposed approach for reconstitution ratios. The departments support a standardised ratio of 1 scoop to 30 ml on the basis that:**

- FSANZ's consumer research shows that the majority of people (59%) did not recheck instructions when they changed the brand of formula. If most people do not read the instructions, it is more than likely that they do not realise that different brands use different ratios of water, even if they are using the correct scoop in the tin. There is also some published literature of case studies where changes in water ratios from different brands have resulted in errors and hypernatremic dehydration in infants[72].
- Different reconstitution ratios are problematic for groups with lower literacy or English language skills. From discussions with our stakeholders, health professionals indicated that in some indigenous communities for example, caregivers are instructed to use only one brand of formula and are verbally taught how to prepare this formula by maternal health nurses due to the variation in recipes. However, it was noted problems often arise when caregivers change the formula and are unable to read the tin to determine that a different ratio of water is required. Discussions with the Victorian Maternal and Child Health service also indicated that some caregivers, particularly those with financial difficulties, frequently take advantage of infant formula brands that are on sale and as such are more likely to switch brands. Recent fluctuations in formula availability due to exports may also increase the risk of this practice.

[72] Leung C, Chang WC, Yeh SJ. Hypernatremic dehydration due to concentrated infant formula: report of two cases. Pediatr Neonatol. 2009 Apr;50(2):70-3. doi: 10.1016/S1875-9572(09)60036-X. PMID: 19453082.

- Standardised reconstitution ratios are possible because they have been the norm in the U.K for over 20 years (noting a standard ratio of 1 scoop to 30ml was also requested by a health organisation for P93 20 years ago, noting the UK example).
- A review of supermarket brands in Australia shows that of the main seven brands, two use a water ratio of 30ml per scoop, two use 60ml and three use 50ml, creating a risk of over or under concentration of feeds which presents health risks for infants. The departments note that health professionals, such as the Australian College of Midwives, also advocated for standardised water ratios and recommended 1 scoop to 30ml to allow smaller increments to support reducing overfeeding.
- Advice from the Victorian Maternal and Child Health Nurse service is that larger reconstitution ratios, which produce more wastage when increasing volume of formula provided as infants grow contribute to carers keeping unused formula, which has safety implications.
- The departments also note an industry submitter indicated that a standard reconstitution ratio can be applied, even though a standard scoop size would not be possible.
- Despite the practice in overseas jurisdictions, the Australian market has not adopted this safety measure, indicating a need to regulate this aspect.

7.2 Provision of information

Labelling of ingredients

The departments support in principle the grouping of vitamins and minerals in the ingredient list. This approach would simplify the presentation of ingredients and may assist caregivers that have reported difficulty in understand ingredient names and lists. It is also noted that grouping of vitamins and minerals was also supported by caregivers in consumer research conducted by FSANZ. However, the departments **do not support the proposal to permit grouping optionally and not require grouped vitamins and minerals to be listed in descending order**. This approach will create inconsistency in how ingredient information is presented among products, making label use and comparison much more difficult for both caregivers and health professionals.

Prescribing the requirement to group vitamins and minerals and list these ingredients in descending order would have minimal impact on label flexibility since the only additional information that would be required would be the term ‘vitamins’ or ‘minerals’ before listing the grouped ingredients. The departments believe the benefit of clear and consistent ingredient labelling outweighs the minor impost on manufacturers and therefore **support prescribing the requirement for vitamins and minerals to be grouped and listed in descending order**.

Format of the nutrition information statement

The departments note consumer research presented by FSANZ in 2021 and 2022 indicates that caregivers struggle to use the current nutrition information statement (NIS), suggesting the current format is not optimal for supporting informed choice among caregivers. **On this basis the departments support several changes to the NIS proposed by FSANZ that aim to simplify and standardise information provided, including:**

- to prescribe the format of the nutrition information statement (NIS) in accordance with the recommended format in the existing guideline in Schedule 29 of the Code with additional subheadings ‘Vitamins’, ‘Minerals’ to group the micronutrients and the subheading ‘Additional’ to group optional substances.
- only permit the base unit of expression (per 100 mL as reconstituted) in the NIS

- require nutrition information (excepting energy) to be expressed as the 'average quantity' in the NIS
- maintain the requirements for the weight of one scoop to be declared (if a powdered product), and the proportion of powder or concentrate required to reconstitute the formula according to directions to be declared (if a powdered or concentrated form of infant formula) and clarify this nutrition information must not be located in the NIS.

Q1 Do you agree with FSANZ's preferred option to prescribe the format of the NIS as shown in Figure 1? Please provide the reasons for your views

As noted above, the departments support a prescribed NIS format as it will ensure nutrition information is presented consistently which may support caregivers in understanding and comparing labels. We note the format shown in Figure 1 is logical and in a similar format currently used by many manufacturers.

Q2 How should the subheadings for 'Vitamins', 'Minerals' and 'Additional' be separated from other text (e.g. using lines, bolding)?

The departments are not aware of evidence to inform best practice design of the proposed subheadings. However, we note it is common practice among current market products to use a contrasting background colour behind the text of subheadings, and this approach appears to be effective in clearly separating the nutrient sections.

Macronutrient sub-group nutrients in the nutrition information statement

FSANZ proposes to permit the voluntary listing (with prescribed wording and format) of the following macronutrient subgroups in the NIS:

- 'Whey' and 'Casein', indented under the macronutrient 'Protein'
- 'Docosahexaenoic acid', 'Eicosapentaenoic acid' and 'Arachidonic acid', indented under the sub-group nutrient heading 'Long chain polyunsaturated fatty acids', which is indented under the macronutrient 'Fat'.

As per our comments in 2016, **the departments do not believe there is a clear need to provide information on macronutrient subgroup composition and are concerned that this information may be more detrimental than beneficial**. The vast majority of caregivers are unlikely to have the skills to interpret this information, and the provision of unnecessary and overly complex information may result in confusion or decisions made on an incorrect and uninformed basis. Additionally, paediatric dietitians have also indicated that the information on infant formula tins is not commonly used to make clinical decisions. Infant formula companies provide detailed reference nutrition information to paediatric dietitians; this would provide any relevant information on macronutrient subgroups. **The departments therefore question what additional benefit is provided by providing detailed nutrition information (in terms of breakdown of macronutrient subgroups) on labels**.

The departments are particularly concerned that casein and whey protein subgroup labelling may lead to undesirable product innovation that deviates from the intended breastmilk reference. The intention of innovation with infant formula is to improve infant formula to achieve health outcomes closer to breastfed infants. It is therefore unclear how the infant formula industry is achieving this intention if it markets a variety of different compositions of infant formula, with no

active monitoring of infant populations consuming the various formulations to determine which achieve health outcomes are most similar to breastmilk. It would appear that such innovation is purely for marketing and business purposes, and not for the overall improvement of infant formula for infants.

Interrelationship between declarations in the nutrition information statement and the statement of ingredients

The departments note there is no evidence that there is confusion between the differences in ingredient declarations and nutrition information declarations. On this basis, **we support FSANZ's proposed approach to maintain the status quo and not align the declaration of ingredient names in the statement of ingredients and nutrient names in the NIS.**

Partially hydrolysed formula

Q3 Without referencing specific conditions, how should partially hydrolysed formula be labelled to inform caregivers of the nature of the modification from other IFP?

As described under the Regulatory Framework section for modified formulas and SMPPi, the departments support reference to partially hydrolysed proteins in the statement of ingredients only. A nutrient content claim or reference to partially hydrolysed formula should not be permitted elsewhere on the tin, given partially hydrolysed formulas are not recommended by health professionals and generally accepted science does not support their use for infants. Highlighting this aspect would promote this point of difference implying it is important and of benefit to infants. **There should also be no claims permitted that imply there is an associated physiological or health effect, such as one relating to digestion**.

Nutrition, health and ingredient claims

The departments continue to support FSANZ's proposed approach to maintain existing prohibitions on nutrient content and health claims. We also support the proposed approach to continue to only permit information about ingredients in the statement of ingredients (except for nutrients that are required to be declared in the NIS). We note the current regulatory approach is consistent with the principles outlined in the Ministerial Policy Guidelines for Nutrient, Health and Related Claims, and for the Regulation of Infant Formula Products and remains appropriate to ensure caregivers are not misled about the quality or effectiveness of infant formula.

Line marketing

The departments strongly support addressing the issue of line marketing to ensure infant formula is sufficiently differentiated from other products. Phasing out follow-on formula (step 2) on the basis that it is not recommended by national feeding guidelines, would help address the issue of line marketing by removing 'step 2' of infant formula.

The departments note that the Code does not currently regulate so called 'line marketing'. This is where the packaging design for the same brand of infant formula, follow-on formula and toddler milk are almost identical, with the major difference being labelling as stage 1, 2 and 3, respectively. Research shows upon quick viewing, many caregivers do not distinguish between products targeted

at different age groups[73,74,75,76] . This is relevant to parents of infants, who are often time-poor and fatigued, and presents a safety risk if infants are accidently given the wrong product with an inappropriate composition, particularly toddler milks and pregnancy supplements, which are compositionally distinct from infant formula and pose the greatest safety risk.

Further, we note the difficulties in differentiating the stages of formula products may also have implications for caregivers understanding of labelling claims and benefits of infant formula products. Australian research has shown that caregivers conceptualise Stage 3 formula (commonly known as 'toddler milk') advertisements as being for the infant formula range, rather than the specific Stage 3 product. As toddler milks are not subject to the same nutrition and health claim prohibitions as infant formula and follow-on formula, claims commonly made on the labels and in advertisement for toddler milk products are presumably being interpreted for the entire range, including infant formula, which is contradictory to the intent set out in the Policy Guideline. We also note in reauthorising the Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement (MAIF Agreement) in 2021, the Australian Competition and Consumer Commission (ACCC) noted the rise in marketing of toddler milks and concerns that this was being used as a proxy to market infant formula[77].

Given the vulnerability of infants where infant formula may be their sole source of nutrition, the departments believe it is necessary for FSANZ to **undertake further work to determine appropriate controls to ensure infant formula is sufficiently differentiated from other products** sold in a similar format. The outcome should aim to ensure that caregivers are able to quickly and easily identify the appropriate product, and that they are not misled about the quality or effectiveness of infant and follow-on formula.

Q4 What evidence can you provide of caregivers' understanding of stage labelling on infant formula products?

Q5 What evidence can you provide about caregivers' understanding and behaviours associated with proxy advertising appearing on the labels of infant formula or follow-on formula?

In addition to the studies noted above, there is growing published literature on the marketing practices of infant formula companies and the use of stage labelling and cross-promotion as a means of circumventing restrictions on the marketing of infant formula[78,79].

[73]Cattaneo, A., Pani, P., Carletti, C., Guidetti, M., Mutti, V., Guidetti, C., Knowles, A. and Follow-on Formula Research Group, 2015. Advertisements of follow-on formula and their perception by pregnant women and mothers in Italy. Archives of disease in childhood, 100(4), pp.323-328.

[74] Romo-Palafox, M.J., Pomeranz, J.L. and Harris, J.L., 2020. Infant formula and toddler milk marketing and caregiver's provision to young children. Maternal & child nutrition, 16(3), p.e12962.

[75] Berry, N. J., Jones, S., & Iverson, D. (2010). It's All Formula to Me: Women's Understandings of Toddler Milk Ads. Breastfeeding Review, 18(1), 21–30.

[76] Pereira C, Ford R, Feeley A. Cross-sectional survey shows that follow-up formula and growing-up milks are labelled similarly to infant formula in four low and middle income countries. Maternal Child Nutr. 2016;12:91–105.

[77] https://www.accc.gov.au/media-release/restrictions-on-marketing-of-infant-formula-reauthorised

[78] Becker, Genevieve E et al. "Global evidence of persistent violations of the International Code of Marketing of Breast-milk Substitutes: A systematic scoping review." Maternal & child nutrition vol. 18 Suppl 3,Suppl 3 (2022): e13335. doi:10.1111/mcn.13335

[79] Baker, P. et al 2021. Globalization, first-foods systems transformations and corporate power: a synthesis of literature and data on the market and political practices of the transnational baby food industry. Globalization and health, 17(1), 58. https://doi.org/10.1186/s12992-021-00708-1

Section 8 – Special Medical Purpose Products for Infants

8.1 Composition

FSANZ has proposed that Special Medical Purpose Products for infants (SMPPi) composition should meet the composition prescribed for infant formula products, except where deviation is required to address the specific disease, disorder or medical condition the product is intended for.

Deviation from infant formula compositional requirements

The departments supported in principle FSANZ's proposed approach to continue to allow compositional deviation from infant formula products for SMPPi with clarification that **deviation from essential IF product composition is only permitted for the specified condition of the SMPPi based on scientific evidence** (to prevent creating a nonspecific permission to deviate from infant formula composition).

FSANZ appears to incorporate this clarification with the following statements:

- FSANZ preferred option to allow deviation from the baseline composition to address the special medical purpose of the formula. *These deviations must also be supported by scientific evidence*
- For all SMPPi, use in accordance with the manufacturer's instructions, must be safe, beneficial and effective in meeting the special medical purpose for which the formula is intended, as demonstrated by generally accepted scientific data.

However FSANZ provides no indication of how this important aspect will be incorporated into the Standard.

The departments support the proposed approach provided the concepts in the above statements are clearly incorporated into the Standard for SMPPi.

Pre-market assessment

The departments do not support FSANZ's proposed approach to not require pre-market assessment of new and novel substances in SMPPi. FSANZ's rationale is that regulations should be flexible enough to accommodate new ingredients or future innovation for the specific disease, disorder or medical condition for which the food has been formulated.

The departments do not support removing this regulatory requirement for the following reasons:

- Infants that require SMPPi are even more vulnerable than other infants and a pre-market safety and suitability should equally apply to SMPPi and other infant formula products and be conducted by an independent party (FSANZ) rather than relying on the manufacturer's own assessment.
- In the vast majority of situations, dietary management of medical conditions requires modification of normal dietary components, such as lower protein, removing certain amino acids, lower potassium, higher fat etc. The addition of a single ingredient to help manage a medical condition borders on a therapeutic effect. Care needs to be taken to ensure these products remain a dietary management tool rather than a therapeutic product. It is for this reason essential that new substances should undergo pre-market assessment by FSANZ to ensure the line into therapeutics is not crossed. Given the nature of these special purpose products it is unlikely this will be a regular occurrence or pose a significant access barrier for infants that require SMPPi, but will ensure the protection of infant health and safety.
- It may also create a perverse incentive for companies to trial new substances in SMPPi in order to establish a history of safe use and potentially enable them to be used in standard formula without pre-market assessment.

Other compositional elements

FSANZ has also proposed other compositional requirements as follows:

- **Removal of the manganese guideline maximum for infant formula products specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.**

FSANZ has not responded to our comments and questions in our response from 2021:

The departments note that products for metabolic, immunological, renal, hepatic and malabsorptive conditions have a significantly lower guideline maximum amount for manganese than for standard infant formula (7.2 µg/100 kJ compared to 24 µg/100 kJ). FSANZ proposes to increase the maximum level to align with standard formula. FSANZ has not indicated why a lower level was originally set. **The departments consider it is important to understand why a lower limit was set and the risks of increasing the level.** Manganese is a trace element but there is growing recognition that it is also a toxicant, with excess levels resulting in neurotoxicity[80]. A number of studies have assessed this, with one finding that children consuming water containing >400 µg/L showed significant reductions in academic achievement (noting a maximum of 24 µg/100 kJ is equivalent to 654 µg/L and provides levels above this)[81]. Recent literature calls for a review of manganese regulations in infant formula and formulas for young children[82]. In infants requiring SMPPi impaired hepatic or renal function may result in a higher risk of manganese accumulation[83], noting higher manganese levels were measured in adults with chronic renal failure[84]. **The departments request further risk assessment is conducted to determine a guideline maximum amount for both standard and SMPPi that is not associated with increased risk of neurotoxicity**.

- **Permission for the addition of MCT to SMPPi, where required to address the products special medical purpose. Specific compositional limits have not been set and are to be determined based on the specific disease, disorder or medical condition, supported by generally accepted scientific data.**

The departments support this approach, specially to clarify permission to use MCT in SMPPi is only where necessary to manage the specified condition.

- **Permission for the addition of molybdenum and chromium to SMPPi, where required to address the product's special medical purpose. Specific compositional limits have not been set and are to be determined based on the specific disease, disorder or medical condition, supported by generally accepted scientific data.**

[80] Roels HA, Bowler RM, Kim Y, Claus Henn B, Mergler D, Hoet P, Gocheva VV, Bellinger DC, Wright RO, Harris MG, Chang Y, Bouchard MF, Riojas-Rodriguez H, Menezes-Filho JA, Téllez-Rojo MM. Manganese exposure and cognitive deficits: a growing concern for manganese neurotoxicity. Neurotoxicology. 2012 Aug;33(4):872-80. doi: 10.1016/j.neuro.2012.03.009. Epub 2012 Apr 3. PMID: 22498092; PMCID: PMC3839941.

[81] Khan K, Wasserman GA, Liu X, et al. Manganese exposure from drinking water and children's academic achievement. Neurotoxicology. 2012;33(1):91-97. doi:10.1016/j.neuro.2011.12.002

[82] Mitchell EJ, Frisbie SH, Roudeau S, Carmona A, Ortega R. How much manganese is safe for infants? A review of the scientific basis of intake guidelines and regulations relevant to the manganese content of infant formulas. J Trace Elem Med Biol. 2021 May;65:126710. doi: 10.1016/j.jtemb.2020.126710. Epub 2020 Dec 25. PMID: 33450552.

[83] Erikson KM, Thompson K, Aschner J, Aschner M. Manganese neurotoxicity: a focus on the neonate. Pharmacol Ther. 2007 Feb;113(2):369-77. doi: 10.1016/j.pharmthera.2006.09.002. Epub 2006 Sep 22. PMID: 17084903; PMCID: PMC1852452.

[84] Sánchez-González C, López-Chaves C, Gómez-Aracena J, Galindo P, Aranda P, Llopis J. Association of plasma manganese levels with chronic renal failure. J Trace Elem Med Biol. 2015;31:78-84. doi: 10.1016/j.jtemb.2015.04.001. Epub 2015 Apr 16. PMID: 26004896.

The departments support this approach.

- **Exemption from the measuring scoop requirements prescribed in Standard 2.9.1, where required to address the clinical nature and special medical purpose of the product.**

The departments support this approach given the inclusion of supplements which may be added to bottles, highlighting the importance of the clarification, '*where required*' so that formula that needs to be made up with a certain ratio of formula to water continues to include a scoop.

- **The addition of optional substances to SMPPi will require pre-market approval, unless the addition is made for the products special medical purpose. Any deviation from the baseline Infant Formula Product composition must be based on scientific evidence.**

The departments support this approach as per our previous responses, provided that the optional ingredient has pre-existing approval. The departments do not support adding a new substance to SMPPi without pre-market assessment.

8.2 Labelling

FSANZ has made changes to its approach since last consultation with the changes in SMPPi category. The departments support most of the proposed labelling provisions but retain concerns.

Despite SMPPi being for the most vulnerable infants, they have the lowest level of regulatory prescription to enable those children who rely on imported products to access them. This opens this product category to a greater risk of being exploited for commercial gain. Both the EU and WHO have raised concerns about the growth in special purpose formula, with the EU inserting into its introduction a commentary on the recent rise in special purpose formula for infants and raises concerns about *potential abuses, the inappropriate targeting of consumers, consumer confusion about the nature of products, and misclassification of products as the basis for the need for greater restrictions on the labelling, presentation, advertising, and promotional and commercial practices*. The WHO has this year released a similar comment raising concerns about pain point marketing: *a common but often subtle marketing scheme that aims to convince potential customers that they have a problem which can be solved by purchasing a product. There has been a rise in marketing for 'specialized' and 'comfort' milks that make bold claims to solve common infant ailments and behaviours such as colic, reflux and crying, despite insufficient evidence that they are effective*[85].

While SMPPi is intended for only very specialist, valid medical formulas, it is untested as to whether the industry will attempt to redirect formulas to be SMPPi's to take advantage of reduced compositional prescriptiveness and labelling permissions to declare medical conditions.

FSANZ is proposing the following labelling requirements for SMPPi:

- to label food as 'genetically modified' in line with current requirements
- FSMP labelling requirements for inner packages, transportation outers, mandatory labelling information, mandatory statements and declarations, nutrition information requirements (subparagraphs 2.9.5—13(b)(i) and (ii)), and
- a general requirement to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose.

The specific mandatory statements applying to FSMPs are provided in subsection 2.9.5—10(1) include:

[85] World Health Organisation 2022. It's time to stop infant formula marketing practices that endanger our children. https://www.who.int/news-room/commentaries/detail/it-s-time-to-stop-infant-formula-marketing-practices-that-endanger-our-children. Accessed 6 June 2022

- a statement to the effect that the food must be used under medical supervision
- a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food
- 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
- a statement describing the properties or characteristics which make the food appropriate for the medical purpose
- if the food has been formulated for a specific age group—a statement to the effect that the food is intended for persons within the specified age group
- a statement indicating whether or not the food is suitable for use as a sole source of nutrition
- for products represented as the sole source of nutrition, the statement to the effect that the food is not for parenteral use, and additional statements about the nutritional modifications made to the product.

The departments support all of the above, with clarification that the statement indicating the medical purpose of the food should be presented along the lines of 'not for general use, suitable only for X condition under medical supervision', to prevent the use of this provision to make health or therapeutic claims.

In addition, if FSANZ continues to propose that SMPPi will not be 'infant formula products' but a separate category under 2.9.1, then amendments will be needed to Standard 1.2.7 to ensure the prohibition on nutrition and health claims continues to apply to SMPPi. Currently Standard 1.2.7 states: *A nutrition content claim or *health claim must not be made about: (b) an infant formula product.* Other parts of the Code that reference 'infant formula products' will also need to be amended to include SMPPis.

FSANZ is proposing labelling requirements that would not apply to SMPPi, or where SMPPi are exempt are:

- the name of business address
- characterising ingredients and components
- prescribed names 'Infant formula' and 'Follow-on formula', a prescribed name for SMPPi, warning statements, directions for preparation and use, age-related statements, a protein source statement, prohibited representations, and
- FSMP labelling requirements for nutrition information (subparagraphs 2.9.5—13(b)(iii) or (iv)), requirements for claims in relation to lactose and gluten content (sections 2.9.5—14 and 15) and existing conditions for 'lactose free' and 'low lactose' for infant formula products (as discussed in Section 5.1 of SD3).

The departments support all but the point that exempts SMPPi's from requiring a prescribed name and exemption from prohibited representations.

Prohibited representations

The prohibited representations under clause 24(1) are for the protection of infants and breastfeeding by, for example, prohibiting pictures that idealise infant formula or words that humanise, maternalise or make references to human milk, including the recent prohibition on 'human milk oligosaccharide', or claims the formula is suitable for all infants. Given the very specific medical nature of SMPPi's there should be no justification for using these prohibited representations on products. Members of the Food Ministers' Meeting have also very recently declared that 'human

milk oligosaccharide' should not be permitted on infant formula products. Exempting certain products from this would go against this decision.

FSANZ considers prohibited representations on IFP should not apply to SMPPi because these are highly specialised products for use under medical supervision and which are not marketed to caregivers of healthy infants. This does not sufficiently explain why SMPPi's should need to make the above representations. The departments also refer to the above comments made in the EU regulations and by the WHO to counter that companies do not market these products to caregivers. This is supported by literature that discusses the extent of the influence of industry marketing of SMPPi type products and the overdiagnosis of cow's milk protein allergy in the UK, with prescriptions of specialist formula milks increasing by nearly 500% between 2006 and 2016, outstripping the epidemiological change in prevalence[86]. Of note is that much of the information available on cow's milk protein allergy online is industry sponsored, promoting non-specific symptoms that virtually every infant would have, indicating cow's milk allergy as a diagnosis in exclusively breastfed infants.

Restriction of access to pharmacies is also unlikely to prevent the marketing of and access to these specialised formula products given the nature of the large supermarket style pharmacies and online retail outlets.

Prescribed name for SMPPi

FSANZ is proposing no prescribed name for SMPPi in order to prevent this being a barrier to access products for medical needs. FSANZ has indicated adoption of certain existing Food for Special Medical Purpose (FSMP) statements would ensure SMPPi are distinguishable from general purpose formula and provide sufficient information about their medical purpose and characteristics to health professionals and caregivers. The proposal to restrict their sale would also address submitter concerns that caregivers of healthy infants may be confused by these products. Given large discount pharmacies can stock a range of general formula and medical purpose products, **the departments consider carers may still be confused between general and medical purpose formula (and potentially other FSMP) unless there is wording on the front of pack that clearly labels the formula as a formula for special medical purpose.** While restrictions on sale from pharmacies provide some safeguards, they are not sufficient on their own, particularly in light of the rise in online purchasing without access to pharmacist advice.

The departments also support a prescribed name for SMPPi for regulatory clarity and enforcement purposes. Given the broadening of the regulations with respect to the types of SMPPi permitted, a lack of prescription in compositional requirements for the intended condition, the lack of prescribed name could introduce sufficient uncertainty to make it difficult to enforce labelling and compositional provisions for a product that is not labelled as either an infant formula or an SMPPi and may not be packaged in a traditional infant formula type tin.

In order to clearly distinguish SMPPi from both standard formula and from other FSMP to ensure infant-specific provisions are applied, **the departments consider a semi-prescribed name could also be a possibility to reduce restrictions on imports, provided:**

- Includes prescribed elements of 'special medical purpose' for infants, such as infant formula for special medical purpose or food for special medical purpose for infants
- Must be placed on the front of the label, consistent with the approach in the EU.

[86] van Tulleken C. Overdiagnosis and industry influence: how cow's milk protein allergy is extending the reach of infant formula manufacturers BMJ 2018; 363 :k5056 doi:10.1136/bmj.k5056

- Similar to ingredients labelling, drafting of the standard that permits imported products that comply with certain international prescribed naming requirements, provided the labelling clearly includes prescribed elements such as food or formula for medical purpose for infants and clearly distinguishes them from standard formula and other FSMP.

This is consistent with the prescribed naming of these products in the EU and with Codex provisions, which indicate FSMP products should be labelled in such a way to avoid the risk of confusion between infant formula, follow-up formula and formula for special medical purposes.

Additional labelling consideration

The departments have been informed by clinical paediatric dietitians that infants with medical conditions often have different fluid tolerances and information about the potential renal solute load (PRSL) of SMPPi is essential. While a mandatory requirement for this information may create a trade barrier, the departments support provisions that state the PRSL should be included on labels where possible.

9 FSANZ Act assessment requirements

9.1.1 Consideration of costs and benefits

FSANZ currently concludes that the following unquantified benefits are likely to outweigh the costs of this Proposal:

- further ensuring that IFP and SMPPi remain safe and suitable into the foreseeable future for almost 3 million infants a decade
- regulatory clarity for producers and enforcement agencies
- greater international alignment and fewer trade barriers enabling longer-term production-cost savings, and improving sustainability of supply. Fewer trade barriers will particularly benefit the most vulnerable infants that depend on continued access to special formula products for high-risk health conditions.

FSANZ further indicates that 40-55% of infants under 6 months in Australia and New Zealand and greater than 80% of infants and toddlers over 6 months are fed formula. This staggering number alone **should prompt FSANZ to consider how the regulation of infant formula products could better assist in reducing the over-consumption of formula and the impact of formula and associated marketing on breastfeeding rates.**

Questions

1. **To what extent do you agree with FSANZ's conclusion on benefits outweighing the costs?**

Based on the current proposed approaches, the departments are not convinced that the benefits outweigh the costs. As described in our response, the focus on trade over infant health for nutrient levels and food additives, the continued lack of clarity on pre-market assessment for infant formula products and the proposal to remove pre-market assessment altogether for SMPPi's, the exempting of SMPPis from the WHO Code of Marketing of Breastmilk substitutes based representations, and the proposal to broaden SMPPis and reduce regulatory prescription and associated enforcement difficulties and failure to improve the regulatory framework for optional ingredients do not appear to result in real benefits for infants or governments.

2. **Do you agree with FSANZ's summary of industry costs and that the main costs will be:**
    a. **one-off product reformulation to meet new domestic standards**
    b. **processes to further reduce contaminant levels, and**
    c. **one-off product label changes to meet new standards?**

No comment

3. **Do you agree with FSANZ's current estimates of relabelling costs in SD5 (pg.4 - 6)?**

No comment

4. **Do you agree with FSANZ's current estimates of reformulation costs in SD5 (pg. 3 – 4)?**

No comment

5. **Do you agree that reformulation costs would be lower for multinational companies than domestic companies, if there is an adequate transition period?**

No Comment

6. **Do you have any further information on estimated numbers of products that:**
    a. **sell in Australia and New Zealand**
    b. **would need to reformulate?**

No comment

7. **Do you have any further information on the numbers of companies that would need to reformulate, or how many products your company would need to reformulate?**

No comment

Do you have any other comments on costs and benefits as presented in this section or in SD5?

Consideration of costs have been limited to costs born by industry. The costs of not prioritising infant health (both formula fed and breastfeeding rates) in proposed regulatory positions and the opportunity cost of not providing a more balanced regulatory framework for optional ingredients for the benefit of all formula-fed infants should be taken into account.

In addition, the underlying approach to align with Codex for trade purposes needs to be better justified. The removal (or creation) of any trade barriers for Australia and New Zealand companies can and should be quantified, with reference to the relevant trade figures and market access arrangements.

The departments support additional work from FSANZ to map the potential trade implications of P1028 and to reflect this in the cost benefit analysis. This could include:

- a clear articulation of the regulatory requirements for current and future export markets (including China, the European Union, the United States, Japan); and

analysis of the economic impact of alignment with Codex rather than other standards. The departments do not support FSANZ changing its position to permit carry-over food additive provisions to reduce costs for industry.