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17/06/2022

Dear Standards Management,

Proposal P1028 Infant Formula – 1st Call for Submissions

Fonterra is a global dairy nutrition company owned by 10,000 farmers and their families. With a can-do attitude and collaborative spirit, we are a world leading dairy exporter. We draw on generations of dairy expertise and are one of the world's largest investors in dairy research and innovation, to produce more than two million tonnes annually of value-added advanced dairy ingredients, foodservice and consumer products for over 140 markets.

Fonterra has a long history in the manufacture of paediatric nutrition, with more than 50 years of experience in producing world class infant formula and young child formulas globally. Fonterra produces formula and ingredients for large multinational and major regional paediatric companies and is one of the world's largest contract manufacturers of paediatric nutrition formula and ingredients.

Fonterra welcomes the opportunity to provide comments and information to FSANZ on **P1028 – Infant Formula, 1st Call for Submissions**. We thank FSANZ for the consideration of the comments outlined in this submission.

Fonterra supports the continued protection of breastfeeding noting the many benefits this has for both mothers and infants. For non-breast fed infants that are fed infant formula, Fonterra supports a regulatory approach that ensures the best possible nutrition for such infants. This includes measures to ensure appropriate food safety and protection of public health, while allowing for continued innovation including scientific and technical development of infant formula. Fonterra supports harmonization with relevant Codex standards as a means of reducing trade barriers, unless there is strong scientific justification for a different approach.

Fonterra supports the content and views of the Infant Nutrition Council (INC) P1028 submission. In conjunction with the Scientific and Technical INC working group, Fonterra have invested significant time in developing aligned industry positions on the key issues and questions through P1028 as summarized by the INC response. In light of this, and rather than repeat INC responses in full, Fonterra have selected key areas of P1028 where we are well placed from both our dairy and infant formula expertise to provide additional information or elaboration on certain topics.

We thank FSANZ for the consideration of the comments outlined in both ours and the INC submission. If there are any queries relating to this submission, please contact [redacted]

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2.0 REGULATORY FRAMEWORK

2.4.1 Infant Formula Products

FSANZ Preferred approach: *The regulatory framework for infant formula products for healthy infants is proposed to be retained.*

Fonterra Response:

- Fonterra supports maintaining the current regulatory framework for healthy infants.

3.0 DEFINITIONS

3.1.4 Preferred option – Definitions of infant formula products

FSANZ Preferred approach: *Retain the proposed definition from 2021 CP3 for infant formula and to include the existing definitions in the Code for infant formula products and follow-on formula.*

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 ~~[4 to]~~ 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.*

Fonterra Response:

- In relation to 'infant formula', we do not support the proposal to remove '4 to' from the definition as indicated in the preferred approach.
- We consider that this fails to reflect the policy guideline which requires consideration for "*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*." Currently, both Australian and New Zealand dietary guidelines suggest caregivers introduce complementary foods "around 6 months". It is not explicitly 6 months as suggested in the proposed definition.
- As covered in our response to CP3, evolving science demonstrates a link between the age to introduce complementary feeding and the likelihood of developing food allergy. To ensure the definition maintains relevance into the future FSANZ should consider if the below is more appropriate:
    - Infant formula means an infant formula product that:
        - Is represented as a breast milk substitute for infants; and
        - Satisfies by itself the nutritional requirements for infants for the first months of life up to the introduction of complementary food. [~~under the age of 4 to 6 months~~]."
- We support maintaining the existing definitions for infant formula products, infant and follow-on formula.

3.4.3 Preferred option – Medium chain triglycerides

FSANZ Preferred approach: *Remove the definition for MCTs from Standard 2.9.1.*

Fonterra Response:

- Fonterra support retention of the definition for MCT, to ensure its clear that this is defined as saturated fatty acids designated C8:0 and C10:0.

3.4.3 Preferred option – New definitions

FSANZ Preferred approach: *Not introduce any new definitions.*

Fonterra Response:

- Recommend a definition for "Guidance Upper Limit (GULs)" be considered to help provide clarity on the use of this term which is being proposed within the compositional requirements.
- Previous consultations have provided insight into FSANZ's intended use of this term however, we consider for consistency across industry and auditors, verifiers etc. that it would be helpful to include.
- While Codex do not provide a definition, Codex text does include a note to explain what the intended use of the term is, which could be simplified within a FSANZ standard to:
    - "*Guidance Upper Limits are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. The Guidance Upper Levels should usually not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons*."

4.0 NOVEL FOODS AND NUTRITIVE SUBSTANCES

4.1.4 Preferred option – Pre-market assessment requirements

FSANZ Preferred approach: *The preferred option is to retain the proposed approach from 2021 CP3, i.e. requirements for novel foods and nutritive substances in infant formula products are to be considered as part of the broader review of these substances for all food categories in P1024.*

Fonterra Response:

- We continue to support the proposed approach. Novel foods to be used within infant formula products should be reviewed under P1024. We support exclusion of pre-market assessments requirements in P1028 to ensure a consistent and comprehensive review under P1024.
- We recommend that priority be given to progression of P1024 to facilitate innovation within the food sector. Further clarity from FSANZ on next steps to keep this progressing would be greatly appreciated.
- FSANZ has suggested a proposed change to the definition of novel food to include "for the intended consumer population". While we in principle support this clarification, we note that the impact of this definition change extends beyond infant formula and should be more widely reviewed by other stakeholders. We can support a more infant specific definition, such as that proposed by the INC:
    - "*For infants, a novel food is defined as a non-traditional food for the intended infant consumer population*"
- The consultation paper noted that "*The ACNF no longer considers questions about substances to be added to infant formula products as such substances are subject to pre-market assessment*". Fonterra are not aware of any communication provided to industry that this was indeed the case. Currently the ACNF record of views provides commentary which includes 'infants' suggesting that the ACNF has previously considered the infant population within the scope of some ingredient reviews. For example, Beta palmitin vegetable oil and DHA from algae *Crypthecodinium cohnii*. We suggest a clear statement of scope of the ANCF is made publicly available.

4.2.4 Preferred option – Novel foods – Schedule 25

FSANZ Preferred approach: *The preferred option is to amend Schedule 25 to include conditions for α-cyclodextrin, γ- cyclodextrin, diacylglycerol oil (DAG oil), isomaltulose, D-tagatose, and trehalose that restricts these substances from being used in infant formula products (i.e. infant formula and follow-on formula). The conditions will not be applied to FSFYC.*

Fonterra Response:

- Support clarifications to schedule 25 to reflect the lack of risk assessments undertaken for the infant population.
- Support the conditions not being applied to formulated supplementary foods for young children.

5.0 SAFETY AND FOOD TECHNOLOGY (SD1)

5.1. Proposed options – Food additives

FSANZ Proposed approach:

1. *Proposed only two food categories in the Code for food additive permissions, being 13.1.1 Infant formula products and 13.1.2 SMPPi.*
2. *Maintained earlier proposal to remove carry-over permissions for food additives.*

Fonterra Response:

- Fonterra support the proposal for the two food additive categories in the Code. We note that a number of additives from the draft Codex FuF Standard have not been included within the revised Code proposal. We encourage FSANZ to review and add these in the next Consultations.
- In specific regards to carry-over, Fonterra would prefer to maintain the status quo but can accept the removal of the carry-over principle for infant formula products in alignment with the Codex position on this.
- However, we would urge that if FSANZ proceed in removing the carry-over principle for infant formula product additives, there needs to be new permissions for infant formula products added to FSANZ which would allow for the continuation of use of certain substances that may be carried over into infant formula products. These include permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants and food for special medical purposes listed in Schedule 29—7.
- Fonterra notes that some limited food additive permissions in nutrient preparation have been adopted from the EU. Where the food additive in the nutrient preparation is either functioning as a carrier, or is on the permitted forms of vitamins, minerals and electrolytes listed in Schedule 29—7, we do not believe it is necessary to also directly permit that food additive in the final infant formula product for its use in the nutrient preparation. This is because if the food additive serves as a carrier, then it is a processing aid as per the FSANZ position; where the food additive is a permitted form in Schedule 29—7, then it is already directly permitted in the final infant formula product and should be already allowed to be carried over.
- Additionally, we urge that these new permissions be included in the second call for submissions so that the removal of the carry-over principle occurs concurrently with the addition of the necessary new additive permissions to enable a smooth transition for industry.

5.2 Preferred option – Contaminants

FSANZ Preferred approach:

- *FSANZ's preferred option for MLs is 'as consumed' form in mg/kg.*
- *Proposed maximum permitted levels in table 5.2.*

Fonterra Response:

- While ML's applied to a powder basis are more practical for implementation, we can align with Codex for mg/kg as consumed.
- Fonterra can support FSANZ's proposed contaminant approaches with the exception of Aluminium.
- We do not support the retention of the ML for Aluminium and reaffirm our previous position to align with Codex which does not set limits for aluminium in infant formula. This approach also aligns with the EU and US regulations.

5.4 Preferred option – L(+) lactic acid producing microorganisms

FSANZ Preferred approach: *retain the existing permission, however clarify that L(+) lactic acid producing microorganisms may only be added for acidification purposes. FSANZ also proposes to clarify the permission that only non pathogenic or non-toxigenic microorganisms may be used.*

Fonterra Response:

- Fonterra supports retention of the current permission for L(+) lactic acid producing microorganisms without any amendments.
- Fonterra do not consider that L(+) lactic acid producing microorganisms requires clarification to specify 'non-pathogenic' or 'non-toxigenic'. This is because there is an overarching requirement in the code

for all food to be safe and suitable. If there is a strong preference by other stakeholders, Fonterra is not opposed to the inclusion of 'non-pathogenic' and 'non-toxigenic' in the code.

- Fonterra does not agree with the FSANZ proposal for retrospective change. To summarise, this is because:
    - L(+) lactic acid producing microorganisms are generally considered as safe and traditional for infants. This is evidenced by their inclusion within regulations globally, scientific literature and the outcome of FSANZ's own risk assessment. The FSANZ proposal to change status quo does not appear to be based on risk analysis using the best available scientific evidence.
    - L(+) lactic acid producing microorganisms have a demonstrated history of safe use within Australia and New Zealand as a result of current permissions for addition in conjunction with overarching requirements for ensuring foods are safe. There has been no evidence of harm to public health and safety.
    - The proposal lacks international regulatory alignment and creates barriers for creating an internationally competitive food industry.
    - Twenty two years has passed since the Code was written with no indication by guidance or enforcement that the intent was to limit addition of L(+) lactic acid producing microorganisms for acidification purposes only. Given the length of time passed, industry practice that has been developed in line with international and scientific practice should also be given weight rather than a sole focus on the original intent of the regulation.
    - The microbiological testing requirements at the time the Code was written anticipate the presence of live bacteria, this is inconsistent with an intent to have no viable microorganisms present.
    - The horizontal novel and GM standards are the *appropriate* level of regulation to manage exceptions that require FSANZ pre-market assessment prior to addition.

- L(+) lactic acid producing microorganisms are generally considered safe, traditional and common substances for infants (i.e. not novel); *Lactobacilli* and *Bifidobacterium* genera abundantly populate the infant gut, and can be found on the EU Qualified Presumption of Safety (QPS) list.
    - The science on the infant gut colonisation demonstrates that infants have high exposure to L(+) lactic acid producing microorganisms, including *Lactobacillus* or *Bifidobacterium*. "*Species of both genera can be found in human breast milk, are common gut commensals in humans and other animals, and are commonly isolated from dairy and other foods. Lactobacilli are also considered ubiquitous in the environment. Thus, exposure of infants to lactic acid bacterial such as Lactobacilli and Bifidobacterium can be regarded as a natural event*." (Dekker et al. 2009). This demonstrates that a number of L(+) lactic acid producing microorganisms, specifically of the *Lactobacillus* and *Bifidobacterium* genera may be considered not-novel in infants.
    - The EU operates a QPS list to support food manufacturers in determining if a further pre-market safety assessment is required. To be granted QPS status, the taxonomic identity must be well defined, the available body of knowledge must be sufficient to establish its safety, a lack of pathogenic properties must be established and substantiated and its intended use must be clearly described. Many *Lactobacilli* and *Bifidobacterium* have QPS Status.

- There is an absence of market failure or safety concern for L(+) lactic acid producing microorganisms addition to infant formula products in Australia and New Zealand.
    - FSANZ in CP1 identified "*no public health and safety concerns, there is no scientific or technical basis to restrict addition of L(+) lactic acid producing microorganisms*" AND "*From published clinical trial data on the safety of a range of L-lactic acid producing microorganisms - including species of Bifidobacterium, Propionibacterium and Lactobacillus - FSANZ has not identified any risks for healthy, full term infants. Infant formulas supplemented with L-lactic acid producing bacteria were well tolerated, and no adverse events associated with the lactic acid producing bacteria were noted in the clinical trials assessed. FSANZ concludes that infant formula supplemented with non-pathogenic, non-toxigenic L-lactic acid producing microorganisms does not present a risk to public health and safety for healthy, full term infants*." (FSANZ, CP1, 2021).

- We consider that the proposed update to restrict L(+) lactic acid producing microorganisms addition for an acidification only purpose is misaligned with Codex and EU.

- The Codex Infant Formula (CXS72-1981) standard provides "*Only L(+)lactic acid producing cultures may be used*" as optional ingredients as well as recognising use as an acidity regulator. The revised Codex Follow-Up Standard provides text to support L(+)lactic acid producing cultures and others that provide for physiological effects to be included.
- The EU permits optional ingredients provided safety and suitability is demonstrated. In practice, this means companies are required to hold safety and suitability substantiation for the specific L(+) lactic acid producing microorganisms strain used for strains that are considered to be not-novel, and this does not require a regulator pre-market assessment.
  - Like the EU who also operate horizontal novel and GM standards, Fonterra consider that this is the appropriate level of regulation to manage exceptions to the permission that do require FSANZ pre-market assessment prior to addition.

- The original drafting within the Code is inconsistent with FSANZ reported intent in the 1st call for submission consultation documents. The microbiological testing requirements at the time the Code was written anticipated the presence of live microorganisms, this is inconsistent with an intent to have no viable microorganisms present in infant formula products.
  - This suggests that at the time of drafting the scope of L(+) lactic acid producing microorganisms permission in infant formula products was not solely for acidification purposes.

- If the proposal proceeds, Fonterra believes FSANZ should consider:
  - If it is appropriate to restrict permissions for follow-on formula when infants are consuming complementary foods which contain naturally occurring L(+) lactic acid producing microorganisms, such as cheese and yoghurt.
  - Their ability to resource the number of pre-market assessments that may need to be conducted based on their view that these ingredients may be novel.
  - Potential reputational impacts to the Australian and New Zealand food industry being efficient and internationally competitive.
- Fonterra also takes this opportunity to provide FSANZ with commercial in confidence information related to L(+) producing lactic acid microorganisms used by Fonterra. Please refer to supplementary commercial in confidence paper.

6.0 NUTRIENT COMPOSITION (SD2)

A range of topics are covered in P1028 for composition. Fonterra supports the INC submission on nutrient composition for infant and follow-on formula and have selected key areas on composition where we are well placed from both our dairy and infant formula expertise to provide information or elaboration on certain topics. Please see these topics outlined below.

Phospholipids

FSANZ Proposed approach: *Set the maximum permitted amount of phospholipids (PL) at at 2 g/L (72 mg/100 kJ) and the maximum lecithin amount to 1 g/L*

Fonterra Response:

Phospholipids

- Fonterra considers a total phospholipid (PL) limit as unnecessary in the absence of specific safety concerns or market failure with the current approach. However, noting FSANZ's continued preference for an Upper (UL) Limit, Fonterra can support the proposed phospholipid limit of 72mg/100kJ (2.1g/L) which aligns with both EU and Codex limits. We recommend this is presented as a GUL rather than a maximum for the following reasons;
  - Use of a GUL would align with the general principles for the selection of GULs or maximum amounts for vitamin and mineral addition. As highlighted in Section 7.1 of CP2 in 2021, absolute maximum amounts are only prescribed for vitamins and minerals considered to pose a significant risk to infants if consumed in excess. GULs may instead be used for nutrients where the risk is "*not of significance on the basis of current scientific knowledge (ANZFA 1999a IN CP2)*".
  - There is an absence of specific safety concerns or evidence of adverse effects of phospholipid intake in infants 0-12months. We also note that older infants safely consume phospholipids from complementary foods in amounts that significantly exceed the proposed upper limit e.g. 3.5g of phospholipids in a hen's egg (Koletzko et al 2012).

Lecithin

- Fonterra do not support FSANZ's proposal to reduce the permitted lecithin level to 1g/L and consider the maximum for lecithin should remain at 5000 mg/kg (approximately equivalent to 5 g/L) in alignment with Codex levels. As per our response to CP2 in 2021 we note that lecithin was not addressed in CP1 which looked at food additives, and we believe it would have been more appropriate to consider lecithin within this scope. It remains unclear why FSANZ consulted on this in CP2 (nutrient composition) and not CP1 (food additive) given lecithin is used as a processing aid/ food additive in formulations. Lecithin has not been listed in Table 6.3 of the 1st call for submission's (1stCFS) consultation paper, but a limit of 1g/L is proposed in SD2 of the 1stCFS. Fonterra considers that the current proposal would introduce contradictions to the Code.
- Manufacturers add lecithin for technological purposes including instantising dry infant formula powders for easier dispersion in water and/or adding to the oil blend during the manufacture of infant formula to stabilise the oil by emulsifying it to avoid fat separation in the final formula.
- This needs to be accommodated for and we are concerned the reduced limit of 1g/L may be unnecessarily restrictive. This may not allow for sufficient flexibility during manufacture, particularly for formulations that may be targeting higher fat levels with lower protein as well as for formulations with higher melting fractions in the oil such as OPO or palm stearic.
- In the 2021 consultation paper 2 (CP2) FSANZ highlighted the significantly reduced 1g/L limit was aligned with the 'most recently reviewed international regulations i.e. EU 2016/127. This limit was in turn based on the EFSA 2020 opinion on the re-evaluation of lecithin as a food additive in infants <16weeks of age, a limit that has been in place in the EU since 1997. However, the EFSA opinion details the substantial toxicological data on lecithin that highlights an absence of adverse effects in animal models at high dose and does not set an ADI. EFSA 2020 instead, and in line with the earlier Scientific Committee on Food (SCF) 1997 assessment, based the safety assessment for lecithin on choline levels in human milk compared to existing levels in infant formula, a 'different' approach for a food additive technological assessment noting the small amount of choline to total formula that lecithin contributes. We consider there is insufficient evidence in the EFSA 2020 report to justify FSANZ adopting a lecithin maximum that is lower than that of Codex (0.5 g per 100 mL) and the existing FSANZ additive permission for use in infant formula products.

Nitrogen Conversion Factor

FSANZ Proposed approach: to adopt a single nitrogen conversion factor (NCF) of 6.25 for dairy and soy formula as it aligns with the EU 2016/127 and the Codex draft Standard for FuFOI.

Fonterra Response:

- While Fonterra can support FSANZ's preferred option to adopt a single NCF of 6.25 for both dairy and soy-based formula to harmonise with Codex STAN 72-1981 and the draft Codex FUFOI Standard, from a science perspective we note our disappointment at the move away from the current use of a science based NCF for dairy formula (6.38).
- To reiterate our earlier comments, we appreciate in CP2 2021 that FSANZ had attempted to provide a flexible alternative Option 2, with a choice of three NCFs (5.71, 6.25, 6.38). Option 2 also had the potential to achieve harmonisation with Codex, and could have provided a valid, flexible approach with overlap with the existing use of NCFs in formula.
- However, while Fonterra could have supported the flexibility outlined for the use of 5.71 or 6.25 for soy based infant formula (with appropriate modification of the minimum protein level, and labelling consideration), and flexibility in the use of a NCF of 6.38 or 6.25 for any dairy formula including whey based formula, we did not support that whey-based infant formula was distinguished from other dairy infant formula in the choice of NCFs as the Option 2 proposal previously outlined.
- The rationale FSANZ had applied in distinguishing NCFs in whey-based from other dairy formula was not clear. Such an approach was not outlined in the 2019 JEMNU Expert Panel recommendations. We refer to a publication by Elgar et al (2020) with a specific focus on a range of commercial whey products using different methods for protein determination. This continued to highlight that an NCF for whey ingredients is similar to other dairy products. We thus consider either 6.38 or 6.25 should be able to be used for all dairy formula, regardless of if whey-based or other dairy formula.
- Noting FSANZ preference to align with the Codex NCF for formula, we recommend the Infant Formula Products Standard footnote is updated to reflect the text outlined in full in the Codex IF Standard.

Protein Range (cow's milk)

FSANZ Proposed approach: *Prescribe a permitted protein range of 0.43 – 0.7 g/100 kJ for cow's milk-based infant formula.*

Fonterra Response:

- **Infant Formula:** Fonterra supports the permitted protein range for infant formula based on milk protein, subject to the upper limit being reflected as 2 significant figures i.e., a range of 0.43 – 0.72g/100kJ. The technical correction of the FSANZ minimum and use of two significant figures is harmonised with Codex and supports trade.
- **Follow on Formula**: Fonterra disagrees with the proposed protein minimum of 0.43 g/100kJ for milk-based follow-on formula, this does not reflect the lower protein level for cow's milk formula that was permitted in the Code post gazettal of *A1173– Minimum protein in follow-on formula*. This should be updated to 0.38g/100kJ.
- Fonterra can support the proposed maximum for milk protein in follow-on formula, however again highlights this should be updated to two significant figures (0.72g/100kJ). We note this is a dramatic reduction in permitted protein levels, nearly half that of the existing protein maximum (1.3g/100kJ). While Fonterra considers a slightly higher protein maximum of 3.5g/100kcal would also have been appropriate because this;
    - Aligns with the positions Australia and NZ took as part of the Codex FUF Standard deliberations on protein maximum.
    - Enable greater flexibility for trade with China which similarly has a max of 3.5g/100kcal.
    - Provides a 'cross-over' with the existing protein levels of the current Codex FUF Standard (3-5.5g/100kcal) and greater cross-over with the existing FSANZ range.
- We can support the reduced maximum which aligns with the compromise now adopted in the draft Codex FOF Std.

Protein Source

FSANZ Proposed approach: *That the protein sources in infant formula be specified to be cow's milk protein, goat's milk protein, protein hydrolysates of one or more proteins normally used in infant formula and soy protein isolate. This does not include extensively hydrolysed proteins or proteins hydrolysed for other nutritive purposes. Any protein sources outside of those specified will need to undergo a premarket assessment through FSANZ.*

Fonterra Response:

- Fonterra agrees with FSANZ that cows, goats, protein hydrolysates and soy are all safe and suitable non-novel protein sources for use in infant and follow-on formula that do not require FSANZ pre-market assessment. Fonterra also agrees that plant protein sources, excluding soy isolates, when used in 'normal' infant formula require FSANZ pre-market assessment.
- However, Fonterra does not agree with FSANZ's proposed regulatory approach to include a positive list of permitted protein sources. We do not consider this is necessary, particularly for mammalian milks where retention of a more general statement on milk protein is sufficient and continues to be a risk proportionate approach.
- We note that adoption of a positive list of permitted protein sources would be misaligned in part to Codex IF and draft Codex FUFOI Standards, and maintenance of positive lists can be slow to update in line with innovation, are counter to the approach of minimum effective regulation and can take significant resources (time and human) to maintain currency.
- In addition to the FSANZ Infant Formula Products Standard and policy guidelines, manufacturers have regard to a range of horizontal Standards and Schedules in the Code, including the Novel Food Standard. This is the appropriate place to regulate new protein source addition to infant formula products, which includes the requirement for a FSANZ pre-market assessment. We do not consider it necessary to repeat specific protein source permissions within the Infant Formula Products Standard itself.
- With regards to mammalian milks, Codex STAN 72-1981 and Codex draft FUFOI clearly recognises that formula can be *based on milk of cows or other animals* (essential composition section 3.1), with the protein section(s) in the additionally recognising cow's milk, goat's milk, their hydrolysates and soy isolates.

- FSANZ propose to include only cow's and goat's milk as permitted mammalian milk sources on a positive list. While we consider reference to 'mammalian milk protein', or 'milk protein' suffice, if FSANZ proceed with listing permitted mammalian milk sources, in addition to cow and goat, sheep milk formula which has been sold in ANZ for a number of years should also be considered, as outlined in depth in the INC Standard.
- We note it appears FSANZ's focus in proposing to list permitted protein sources within the IF Standard is predominately to address concerns regarding new plant protein sources (excluding soy isolates which are recognised as not-novel for use in formula). However, such plant proteins are already required to undergo FSANZ pre-market assessment for use in formula as this would be covered within the horizontal novel food standard.
- If FSANZ continue to propose to stipulate protein source, while Fonterra do not consider positive lists necessary for the reasons stated earlier, we do not object to specific permissions for different plant protein sources (e.g. soy) being listed in light of their differences in structure, amino acid digestibility and absorption relative to mammalian milks that warrant a more in-depth pre-market safety assessment.

Carbohydrate Source

FSANZ Proposed approach: *Adopt limits on sucrose and fructose that are aligned with Codex CXS 72-1981.*

- ***Fonterra Response:***Fonterra can accept the proposal is to adopt limits on sucrose and fructose that are aligned with the guidance in Codex STAN 72-1981.
- Fonterra recommends that consideration is given to including the rationale from the Codex documents for guidance to avoid the use of sucrose and fructose.
- Fonterra also notes that it is important that there is no inference that no sucrose or fructose is permissible in these products as these sugars can be present in low levels in other ingredients, for example fructo-oligosaccharides.
- Fonterra suggests text along the following lines for consideration:
    - *"The use of sucrose, except where needed, and fructose, as direct ingredients should be avoided in infant formula products. This is to address potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance, limit sugars other than lactose and manage sweetness".*

Docosahexaenoic acid

FSANZ Proposed approach:

- *Maintain voluntary permissions for DHA.*
- *Specify a GUL for infant and follow-on formula (7.2ug/100kJ).*

Fonterra Response:

- Fonterra supports maintenance of voluntary permissions for DHA in infant and follow-on formula.
- Fonterra support a DHA GUL but do not support the lower GUL (7.2ug/100kJ) proposed by FSANZ as being equivalent to 0.5% TFA.
- Fonterra continue to support a GUL of 12mg/100kJ, as being within the range reported in breast milk of 0.06-1.4% (Brenna et al. 2007). This aligns with EU but also enables additional overlap with China who have a GUL of 9.6mg/100kJ.

Vitamin D

FSANZ Proposed approach:

- *Maintain the existing range for infant and follow-on formula (0.25-0.63 ug/100kJ).*

Fonterra Response:

- Fonterra do not support maintaining the existing vitamin D ranges.
- Fonterra's preference is for the maximum to be increased to 0.72ug/100kJ in line with the revised Codex Follow-up formula standard and EU. This limit is based on the most recent available science

and is appropriate for consideration at this time while full compositional changes are being reviewed and products are being reformulated. This recommendation helps future proof the Code.

- The NHMRC AI for vitamin D is based on outdated studies which are 2-3 decades old (1982-1995). These studies included a small number of infants and were not expressly based on the ANZ infant population. Data was based on infants from the US, Hong Kong and Europe. This suggests that more recent studies on infant vitamin D status from overseas populations could be used in the absence of data specific to the ANZ infant population. This is an approach supported in the previous NRV development:
    - The Nutrient Reference Value document published by NHMRC (National Health and Medical Research Council, 2006) includes agreed considerations for "*the review should build upon concurrent work being undertaken in the US and Canada, while also taking into consideration recommendations from the United Kingdom, Germany and the European Union, recent dietary survey data in Australia and New Zealand, scientific data and unique Australasian conditions*". This demonstrates the consideration of international NRVs can be considered within a review process and as such should be considered in future work where consistent approaches are taken.
- The Australian NHMRC are some of the longest standing dietary reference values, originally being set in 2005. Since then, the US (2010), Europe (2016), Canada (2010) and China (2014) have revised their recommended dietary reference values for vitamin D in infants. For 0-12 months, they all set the value at 10ug/day - double the existing ANZ NHMRC value and the current FSANZ RDI for infants in Schedule 1.
    - The NHMRC was directed in 2018 to continue its review of nutrients, including all adequate NRVs for infants however, this work has not yet been reported on since the phased approach in 2019 commenced with sodium and iodine (https://www.nrv.gov.au/). As yet, there doesn't appear to have been an infant working group membership established.
- With studies including serum 25OHD concentration of infants within ANZ lacking FSANZ should consider trends both locally and globally on the rates of vitamin D deficiency in the general population as this can be suggested to also be representative of infants. This information demonstrates that in the Australian population (2-71+ years) more than 95% of people had inadequate vitamin D intakes (compared to 10µg), with the authors suggesting that data driven nutrition policy is required to safely increase intakes of vitamin D and improve vitamin D status at the population level. This deficiency within the general population for Australia has been documented over a number of years, including 23% of the population is deficient (25(OH)D levels <50 nmol/L) (Australian Bureau of Statistics 2013). Furthermore, 20% of young Australian children (1-5 years) were recently found to be vitamin D deficient (25(OH)D <50 nmol/L) (Zhou et al 2015). Outside Australia, Research in the US, Europe and Canada demonstrates 25%, 40% and 37% of individuals respectively are vitamin D deficient (Amrein, et al. 2020).
- The Australian College of Dermatologists and Cancer Council Australia recommend that babies under 12 months are kept out of direct sunlight when the UV Index is three or higher, and the UV levels in Australia are more often than not above 3 (Cancer Council, 2020).
- The Ministry of Health in New Zealand "recommends that infants are not left in direct sunlight", considering guidelines around the world and research that infant's skin barrier remains immature throughout the first two years of life. In fact, Plunket in New Zealand, while recognising the role of sunlight in vitamin D production, notes this is only 10-15 minutes a day and suggests it is best to keep your child out of strong sunlight.
- As FSANZ does not permit vitamin D fortification in infant foods, the vitamin D contribution from other foods would be limited and should not be of concern. EU does allow the fortification of infant foods and 0.72µg/100kJ in follow-on formula. EFSA stated (2018):
    - "*For infants aged 4–12 months, the 95th percentile of vitamin D intake (high consumers) estimated from formulae and foods fortified or not with vitamin D does not exceed the ULs, without considering vitamin D supplemental intake*."
- Therefore, the EU assessment with the same Upper Limit of 25 µg/day determined there was no safety concerns for older infants even after considering fortification with food.

- From a technical perspective, the current range on vitamin D presents challenges for Fonterra to manufacture paediatric formulations that align to both ANZ and international regulations.

L-Carnitine

FSANZ Proposed approach:

- *List L-carnitine as a mandatory substance in infant formula and voluntary substance in follow-on formula with a minimum of 0.3mg/100kJ.*
- *Retain the current maximum within Schedule 29 (0.8mg/100kJ) but present as a GUL for infant formula and to not specify a maximum in follow on formula.*

Fonterra Response:

Infant Formula

- Fonterra supports that the presence of L-Carnitine should be mandatory in infant formula to align with international regulations (EU, Codex, GB) and scientific literature (SCF 2003, EFSA 2014, Koletzko 2005). Fonterra support the proposed minimum, however, we note the content conversion should be corrected to 0.29 mg/100kJ (1.2 mg/100kcal).
- Fonterra maintains that there should be no maximum or GUL for infant formula. FSANZ's proposed approach is not aligned with international regulations (EU, Codex, GB) or expert scientific opinions (SCF 2003, EFSA 2014, Koletzko 2005), which do not recommend any maximum or GUL.
- We note the Life Sciences Research Organisation ("LSRO") paper from 1998 suggests a maximum L-Carnitine level in infant formula, based on the upper end of the usual breast milk content (LSRO 1998). However, the LSRO paper was subsequently considered within the recommendations of the ESPHGAN international expert group paper on the global standard for infant formula and no maximum was set (Koletzko 2005). Further, the ESPHGAN paper outlines that using only minimum and maximum human milk content to inform levels in infant formula can be limited, and that other factors such as the source of nutrients, absence of adverse effects and an established history of safe use should also be taken into account (Koletzko 2005).
- Therefore, Fonterra would emphasise previous evidence provided (May 2016, September 2021) which demonstrates that dairy based infant formula products typically contain higher levels of L-Carnitine than the GUL currently proposed, due to the natural and variable content of L-Carnitine in dairy ingredients (Woollard 1999) and that there are no indications of any untoward effects of higher intakes of L-Carnitine in infants (Koletzko 2005), highlighting that no upper limit is required.
- Whilst Fonterra strongly supports no maximum or GUL for infant formula as outlined, if FSANZ continues to proceed with a GUL level in infant formula, there must be a clear definition for GUL to ensure consistency of interpretation which acknowledges technical challenges and nutrient source.
- Consideration should also be given to the natural L-Carnitine content in infant formula products when setting a GUL level, particularly given L-Carnitine is predominantly found in the whey portion of dairy and infant formulas are whey dominant.
- Please refer to supplementary commercial in confidence submission for further information.

Follow on Formula

- Fonterra supports the preferred option to retain the voluntary addition of L-Carnitine to follow-on formula and not specify an upper limit. Fonterra suggests that no minimum be specified, which would be more consistent with international regulations.

Fluoride

FSANZ Preferred approach: *FSANZ is proposing to set a compositional limit of 24 µg/100 kJ when prepared ready for consumption and to remove the labelling statements 101 relating to dental fluorosis in paragraph 2.9.1—23(1)(b).*
Fonterra Response:

- Fonterra do not support the proposal on an 'as prepared' basis and continue to recommend that the limit be applied on a powered basis.
- We recognise that apart from not adding any fluoride via the processing water that is used as an ingredient, as a manufacturer there is little, we can do to impact the reconstituted (ready for consumption) levels of fluoride. Given the fluoridation status of water is varied across regions both locally and internationally it becomes impossible to monitor and comply without also providing consumers with liquid formula or water for mixing in locations where the local drinking water has a high fluoride content.
- Codex stipulates "fluoride should not be added to infant formula. In any case its level should not exceed 100ug/100kcal (24ug/100kJ) in infant formula prepared ready for consumption as recommended by the manufacturer." While not explicitly stated in Codex, we would consider the Codex approach to copper is also relevant to fluoride, where copper has a note such that "adjustment may be needed in these levels for infant formula made in regions with a high content of copper in the water supply".

LABELLING: Safety and technology (SD1)

FSANZ Proposed approach:

FSANZ is proposing to maintain:

- *the current approach not to prescribe the exact wording or pictures to be used for the*
- *required directions for preparation and use*
- *existing requirements for date marking and storage instructions*
- *legibility requirements for generic or specific warning statements*
- *the existing 'breast milk is best' warning statement*
- *prescribed names 'Infant formula' and 'Follow-on formula'*
- ***age-related statements***
- *the requirement for the co-location of the protein source statement with the name of the food*

FSANZ is also proposing to maintain most safety-related labelling requirements. These include directions to:

- *prepare bottles individually*
- *instruct that if a bottle of made up formula is to be stored before use, it must be*
- *refrigerated and used within 24 hours, and*
- *instruct that, where a package contains a measuring scoop, only the enclosed scoop*
- *should be used.*

FSANZ is proposing to change the remaining safety related labelling requirements. The proposed changes include:

- *revised direction for water used to reconstitute powdered infant formula to include the word 'cooled' and for the discard unfinished formula direction to include the text 'within 2 hours'*
- *for ready-to-drink formula, to not apply directions that each bottle be prepared individually, that made up formula is refrigerated and used within 24 hours prior to use, to use potable, previously boiled water*
- *for concentrated and ready-to-drink formula, to not apply the direction to only use the enclosed scoop.*
- *consolidating the warning statements for powdered, concentrated and ready-to-drink infant formula products into a single prescribed warning statement applicable to all product types.*
- ***clarify the source of protein statement to ensure the origin of the protein is declared and that this statement needs to appear in a prominent position just once on the label.***

Fonterra Response:

- Fonterra supports the FSANZ proposals outlined above with the exception of:
  - Age related statements, specifically the age to offer food in addition to formula
  - Clarification of the protein source statement to protein origin
  - Addition of prominent requirement for the protein source statement location

Statement about age to offer food in addition to formula

*FSANZ's preferred option is to maintain, as it is currently worded, the statement indicating that infants **from** the age of 6 months should be offered foods in addition to the infant formula product in paragraph 2.9.1—19(4)(c)).*

- Fonterra continues to support use of the term "around" to align with both New Zealand and Australian Dietary Guidelines for Infants and Toddlers and the Australian Infant Feeding and Allergy Prevention Guidelines. This change would support the specific policy principle that the regulation of infant formula products should not be inconsistent with national nutrition guidelines.
- We recognise the timing of introduction to offered foods is subject to growth and development as noted by FSANZ and while we respect that the Code does not serve the same purpose as feeding guidelines, the Code directly impacts information provided to parents on the label. Infant formula labels are a key source of information for carers on infants. It is therefore important that there is consistency for parents by ensuring no contradictory information is provided.
- Continued use of "from the age of 6 months" is out of step with the evolving scientific literature and dietary guidelines which state "around the age of 6 months".

Statement on protein source

FSANZ's preferred option is to clarify that the 'source' of protein in section 2.9.1—23 refers to the origin of the protein (e.g. cow's milk) and not the protein fractions (e.g. whey or casein protein).

- Fonterra does not support this clarification. Providing adequate information about protein fraction proportions and/or processing methods is important to enable consumers to make informed choices. Flexibility to include this relevant information within the protein source statement (along with the protein origin), where caregivers are currently familiar its placement, should be maintained.
- As FSANZ notes, the original intent of the statement was to provide clarity for consumers to enable informed decisions. Further limiting the statement will in some cases limit the information and clarity that can be provided to consumers. There is currently no evidence of consumer confusion or issues with the status quo and there is anecdotal evidence that this information is sought out through consumer queries.
- Describing the true, complete, and accurate description of products is required under Consumer Law and companies consider how to do this clearly for each product label both on front and on back of label. Clarifying that additional information on protein fractions cannot be used could limit information required to meet these obligations. For example, without information on protein fractions or partially hydrolysed whey protein being permitted on labels, manufacturers could not provide a true, complete, and accurate product description. This information on protein is relevant and important for both consumers and healthcare professionals.

Co-location of protein source statement with name of food in a prominent location

FSANZ's preferred option is to maintain the requirement for the co-location of the protein source statement with the name of the food and clarify that the co-located protein source statement and name of the food needs to appear in a prominent position just once on the label.

- Fonterra does not support the inclusion of 'prominent' in relation to the position of the protein source statement. There is currently no requirement for the name of the food to be located in a prominent position on product packaging and no evidence of consumer confusion as to the type of product being purchased.
- Fonterra supports Division 3 of Standard 1.2.3 applying to infant formula products, as we believe this provides appropriate information on the allergens present in the product to help protect public health and safety. Requiring the protein source statement and name of the food to be in a prominent position for the reason of allergen management is not appropriate, as this statement is not a full and complete allergen statement. Further, the allergen declaration is not required to be prominent and therefore the protein source statement should not be given prominence over the allergen statement, as this may inadvertently risk public health and safety.
- The proposal for 'prominent' positioning of protein source information should be removed to allow manufacturers enough flexibility to ensure consumers take note of both protein source and allergen information within a similar field of view.

- Further, general legibility requirements in FSANZ Standard 1.2.1-24 already contains a requirement for wording to be "prominent so as to contrast distinctly with the background of the label" and any use of 'prominent' within the Code should be used with the same intent.
- Fonterra does support the requirement for co-location of the protein source statement with the name of the food, and the clarification that this only needs to appear once on the label (without the additional requirement for this to be 'prominent').

LABELLING: Provision of Information (SD3)

FSANZ Proposed approach:

FSANZ is proposing to maintain existing requirements for the following labelling elements:

- *for labelling of ingredients: generic requirements for a statement of ingredients,*
- *allergen declarations and genetically modified foods*
- *to not align the declaration of ingredient names in the statement of ingredients and nutrient names in the nutrition information statement (i.e. the status quo)*
- *specific labelling requirements for lactose free and low lactose infant formula products*
- *non-regulatory approach for the notification of changes to product formulations*

FSANZ is proposing a prescribed format for the nutrition information statement (NIS) to:

- *permit additional subheadings 'Vitamins', 'Minerals' to group the micronutrients and 'Additional' to group optional substances*
- *only permit the base unit of expression (per 100 mL as reconstituted)*
- *require nutrition information (excepting energy) to be expressed as the 'average quantity' and clarify the calculation methods for average quantity that will not apply to infant formula products*
- *clarify declarations for the weight of one scoop (if a powdered product)*
- *permit with **prescribed wording and format** the voluntary listing in the NIS of 'Whey', 'Casein', 'Docosahexaenoic acid', 'Eicosapentaenoic acid' and 'Arachidonic acid' as indicated in Section 3 of SD3.*
- *propose the proportion of powder or concentrate required to reconstitute the formula according to directions must not be located in the NIS*
- ***to only permit information about ingredients in the statement of ingredients (except for ingredients (e.g. nutritive substances) that are required to be declared in the NIS).***

FSANZ is also specifically seeking evidence and stakeholder comment to inform consideration on the format of the NIS, stage labelling and proxy advertising related only to infant formula products, and labelling of partially hydrolysed formula as a modified infant formula product.

Fonterra Response:

- Fonterra supports FSANZ proposals outlined above with the exception of:
  - Some elements of the prescribed format and wording of the NIS
  - Restriction of information about ingredients to the statement of ingredients (aside from nutrients required to be declared 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. *Refer section on "Prescribed NIS format and wording"*

Q2 How should the subheadings for 'Vitamins', 'Minerals' and 'Additional' be separated from other text (e.g. using lines, bolding)? *Refer section on "Prescribed NIS format and wording"*

Prescribed NIS format and wording

- Fonterra if of the opinion that the level of prescription proposed for the NIS limits the ability of manufacturers to provide adequate information to enable consumers to make informed choices.

- The flexibility of the current NIS allows for manufacturers to label for nutrients in an appropriate location within the NIS (e.g. listed with similar nutrients) and with appropriate contextual information (e.g. subheadings, common terms, acronyms and abbreviations) to assist both caregivers and healthcare professionals.
- Restricting the use of subheadings, common terms, acronyms and abbreviations does not provide flexibility to use more consumer-friendly language and commonly understood terminology which could reduce consumer understanding of the NIS. For example:
    - Permitting only an 'additional' subheading for optionally permitted substances would limit the ability of manufacturers to provide contextual information which may help consumers understand scientific names. For example, nucleotides as a subheading to group these substances would provide useful context for consumers. Further, there may be new ingredient applications in the future where the nutrient(s) provided may be better placed with similar nutrients to adequately inform consumers.
    - Restricting permitted wording to 'Docosahexaenoic acid', 'Eicosapentaenoic acid' and 'Arachidonic acid' in the NIS limits the ability of manufacturers to provide consumers with the abbreviated terms (DHA, EPA, ARA) which are more commonly used by consumers and healthcare professionals to communicate what nutrients to look for in a formula.
- A prescribed listing of macronutrient sub-groups does not align with Codex or the EU.
    - EU 2016/127 outlines requirements similar to the Food Standards Code. However, it also allows for the voluntary declaration of components of protein, carbohydrate or fat, the whey/casein ratio, and the amount of substances whose suitability has been established by generally accepted scientific data.
    - Codex STAN 72-1981 does not prescribe macronutrient sub-groups and is silent on voluntary declaration. Codex *Guidelines on Nutrition Labelling CXS 2-1985* recommends nutrients are declared in a specific order and should be consistent across food, however, it does not limit additional information or prescribe the nutrient names.
    - Whilst Fonterra supports a specific order of nutrients, we do not support explicitly permitting or limiting additional information that may be provided within that prescribed order. Fonterra therefore supports a similar approach to the EU labelling that allows more generally for the voluntary declaration of macronutrient components.
- Maintaining some flexibility in the NIS can support consumers to better understand the NIS, differentiate between products and therefore make informed decisions. It can also support consistency between domestic and international food standards. Additionally, it may help to future proof the standard by reducing the frequency of regulatory changes required to be made to the NIS format as a result of changing science and nutrients of interest, or due to certain new ingredient applications that provide macronutrients (which under the current proposal, we interpret could only be listed under the 'additional' heading without also applying to change the NIS format).
- Further, Fonterra does not support the NIS formatting being prescribed further by requiring the use of lines, bolding etc. This level of prescription is not aligned with Codex and not harmonised with other international jurisdictions. Companies are already required to meet the legibility provisions under Standard 1.2.1 Division 6, and these general provisions of food labelling should be sufficient as they are for all other foods. Manufacturers are also well placed to determine whether lines, bolding and other formatting tools are needed to provide for clear contrast and legibility in accordance with other considerations of the label (e.g. colours used, space constraints etc.).

Restriction of information about ingredients to the statement of ingredients

- Fonterra notes that ingredients are not defined in The Code and 'ingredients claims' have not been considered in any category except infant formula products. General information about ingredients outside of the ingredients list is common, because it allows food to be correctly described. Restrictions on ingredient information must be considered in the context of consumer law. A failure to provide clear information on what the product is could be perceived as misleading through omission. The proposed restriction creates many issues in the ability of companies to describe products accurately and trade fairly.
- The Code defines health claim as *"a claim which states, suggests or implies that a food or a property of food has, or may have, a health effect*" and defines nutrition content claims as *"the presence or absence of a biologically active substance, energy, micronutrients, macronutrients and macronutrient components".* General information about ingredients (e.g. organic) is not the same as nutrition content

and health claims as defined by FSANZ, and consideration should be given to whether restriction of 'ingredient claims' would inadvertently restrict the adequate provision of information to enable consumers to make informed choices and differentiate between products.

- Fonterra does not believe that the issues identified by FSANZ regarding ingredient-based claims could be resolved by generally restricting 'ingredient claims'. Further, the Ministerial Policy Guideline is clear and unambiguous on the types of claims that should be restricted *"prohibitions and restrictions on nutrient content, health, therapeutic, and prophylactic claims in the Food Standards Code are clear and effective for infant formula products"* indicating that consideration of the types of claims has been carefully given.
- FSANZ's proposal to restrict 'ingredient claims' is not internationally aligned to Codex, EU and US. The Food Standards Code already restricts nutrition and health claims for infant formula products which should be considered sufficient to allow enforcement.

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

- Fonterra recommends that information about partially hydrolysed protein should be labelled in the ingredient list and in the protein source statement. Please refer to our comments on protein source statement.

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

- Labelling of infant formula products currently has multiple references to age-appropriate text, numbers and symbols to provide multiple visual cues. Numbers are simple and easily-recalled label features and a useful tool for primary and secondary caregivers. They help reduce consumer confusion and minimise the likelihood of purchasing an incorrect product for the age of an infant. Numbers and symbols (in addition to text) can benefit tired caregivers making hurried purchases, and are also likely to benefit those with low proficiency in English.
- Many labels also contain information about the sequence of products intended to be used as a formula-fed infant grows. It relates to a sequence of products in the range suitable as a formula-fed infant grows, not "add on" products. Caregivers of formula-fed infants from 6 months will either continue using infant formula or decide to substitute it with follow-on formula, not both.
- In this sense, staging information on labels provides a factual, age-appropriate guide to carers and should not be seen as "promoting" additional products for purchase by infant formula users. Notably staging is used on a range of products for infants including, for example, nappies.

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