Fonterra Co-operative Group Limited
[redacted]

07/07/2023

Dear Standards Management,

**Proposal P1028 Infant Formula — 2nd Call for Submissions**

Fonterra is a global dairy nutrition company owned by 9,000 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, 2nd 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.

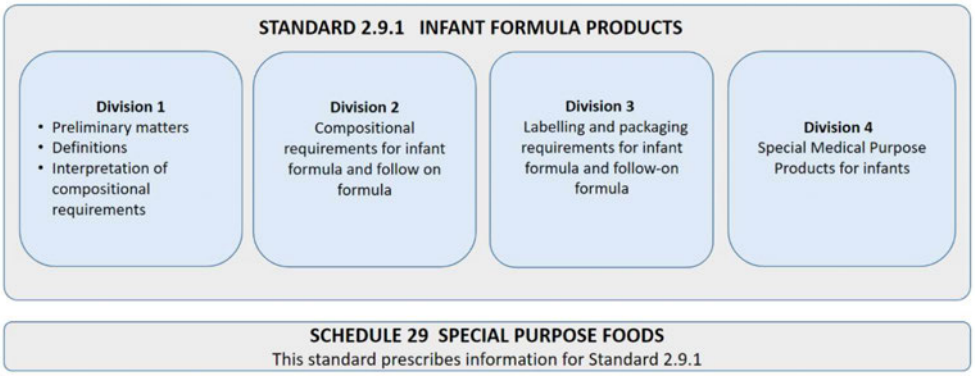
We thank FSANZ for the consideration of the comments outlined in both ours and the INC submission. If there are any queries relating to this submission, please contact Sarah Lochrie (sarah.lochrie@fonterra.com).

Yours Sincerely,

[redacted]

## 2.0 REGULATORY FRAMEWORK

***FSANZ Proposal:*** *In the 2nd Call for Submissions Document, the structure of Standard 2.9.1 for the regulation of infant formula products is proposed in figure 2.4 to be:*




***Fonterra Response:***

- Fonterra supports the proposed regulatory framework for infant formula products for healthy infants.

## 3.0 DEFINITIONS

### 3.1 Definitions of infant formula products and related terms

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

***Fonterra Response:***

- While Fonterra maintain that the current definition for infant formula with inclusion of '4 to' to be a more accurate reflection of policy guidelines feeding advice to caregivers (for reasons provided in response to 1CFS) we are not opposed to the proposed revised definition.
- Fonterra support maintenance of the existing definition for infant formula product, follow-on formula and infant.

## 4.0 NOVEL FOODS AND NUTRITIVE SUBSTANCES

### 4.1 Pre-market assessment requirements

***FSANZ Proposal:*** *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 review of requirements for novel foods and nutritive substances used within infant formula products as part of the broader review of these substances for all food categories in P1024. We support exclusion of these 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 on the timeline for FSANZ Act changes to facilitate this would be appreciated.
- Within the discussion paper FSANZ state: "*FSANZ is unaware of additional changes that would strengthen or clarify the existing requirements for nutritive substances added to infant formula products. FSANZ also considers that the increase in recent applications requesting to add nutritive substances to infant formula products, such as A1253 - Bovine lactoferrin in infant formula products (FSANZ 2022j),* ***demonstrates that the current regulation is clear and functioning effectively***."
- We do not believe an increase in the number of applications demonstrates that the nutritive substance definition and regulation is clear and functioning well. As stated in our response to A1253, Fonterra consider the Code's definition of Nutritive Substance is unclear, difficult to interpret and enforce while also being misaligned with other regulatory jurisdictions such as the EU where focus is on safety of an ingredient as part of a novel foods assessment. We also questioned FSANZ's rationale for bLf being 'used as a nutritive substance' rather than a novel food.

### 4.2. Standard 2.5.1 and Schedule 25 Permissions

***FSANZ Proposal:*** *To amend section 2.5.1-3 to state a novel food must not be added to infant formula products unless an express permission is listed in the table to section S25-2. And amend S25-2 so that use in infant formula is only appropriate for: (1) Oil derived from marine micro-algae* Schizochytrium *sp. (American Type Culture Collection (ATCC) PTA-9695) and (2) Trehalose.*

***Fonterra Response:***

- We support the draft variation proposal to clarify permissions in 2.5.1-3.
    - Query if there is a typo in 2.5.1-3(2) related to "…infant formula product food…". Recommend removal of 'food' from this statement to reflect the prescribed name in standard 2.9.1.
- Continue to support the conditions not being applied to formulated supplementary foods for young children.
- FSANZ comment that only two novel foods will have express permission to be added to infant formula products. This is misaligned to the previous proposal (CP3 and 1CFS) where FSANZ had proposed no conditions be set for dried marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA), oil derived from marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA), and oil derived from marine micro-algae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA), having given consideration to the risk assessments completed for marine algal oils. Further, there were no stakeholder objections to the continued permission for use of the DHA sources in infant formula products. We note FSANZ have commented in the living document that this was an omission and support the permission for the above listed DHA ingredients to be permitted in infant formula products aligned with the 1CFS proposal.

### 5.0 L(+) Lactic acid producing microorganisms (LAPM)

***FSANZ Proposal:*** *Retain current permissions.*

***Fonterra Response:***

- We support the proposal to retain the current permissions for addition of LAPM to infant formula products reflecting a risk-based approach and recognising the high level of due diligence applied by infant formula manufacturers. The status quo has been operating efficiently since the Code was enacted with no evidence of harm to public health and safety.
- We also agree with FSANZ's assessment which found:
    - *"No safety concerns*
    - *Long history of use and ubiquitous in products currently on market*
    - *Alignment with Codex*
    - *Removal of permission would cause large reformulation cost to industry (for minimal benefit), loss of products from the market (possibly permanently) and potentially a large influx of applications to FSANZ seeking permission to add LAPM to infant formula products."*
- As with any infant formula ingredient, industry premarket assessment is completed as part of our due diligence. This includes an internal safety assessment and review of external sources such as the EU qualified presumption of safety (QPS) list.
- We consider that the Code provides sufficient clarity on the permission to add LAPM to infant formula products similar to the approach taken in the EU.

- We support the view that novel LAPM will continue to require FSANZ pre-market approval, as they are captured by horizontal standards in the regulation (*e.g.*, Standard 1.5.1 Novel foods and Standard 1.5.2 Foods produced using gene technology *etc*).
- Science demonstrates that LAPM are commonly found in human breast milk and have been shown to support infant gut colonisation. The addition of LAPM to infant formula products aids in creating formula's that are closer to breast milk.

## 6.0 Food Technology for Infant Formula Products (SD1)

### 6.1 Food additives

***FSANZ Proposal:***

1. *Remove carry-over permissions for food additives.*
2. *Update food additive permissions for infant formula products to align as best as possible with relevant international regulations, especially Codex standards and EU regulations.*

***Fonterra Response:***

- Fonterra can accept the removal of the carry-over principle for infant formula products in alignment with the Codex position on this.
- Fonterra support the intent of FSANZ to update food additive permissions in alignment with Codex and EU. We appreciate that these changes will occur at the same time as the removal of the carry over principle.
- We do, however, note some exception's to achieving international alignment. As a result, Fonterra seek the below amendments and additions to the FSANZ proposal to maintain our current ability to operate:

#### INS 301 sodium ascorbate

- Fonterra supports the amended proposal as per the FSANZ living document, which is to add a new entry under Schedule 15-5 Table 13.1 for sodium ascorbate with the MPL of 75 mg/L with the condition for use only in coating of nutrient preparations containing polyunsaturated fatty acids.

#### INS 307c tocopherols, dl-alpha

- The current proposal does not provide for permission in Schedule 15-5 Table 13.1. Fonterra seeks an entry in S15—5 Table 13.1 that reads:
  - "*INS 307c dl alpha tocopherol 10 mg/L*".
- ***Technological justification****:* this additive is required as an antioxidant for nutrient preparations, which are added into infant formula products. Antioxidants prolong the shelf life of food and ingredients by preventing oxidation, such as in oils.
- Our ingredient supplier advises that DL-alpha-tocopherol specifically is added to the nutrient preparations to stabilize the active ingredient in the formulation and to increase the chemical stability of the active ingredient in various applications in which oxidative stress is high including premixed nutrient preparations. Tocopherol is chosen as an antioxidant due to its wide availability and using a synthetic (*i.e.*, INS 307c) over a natural ingredient has the advantage of less natural variation in the ingredient, which leads to a more consistent performance of the ingredient.
- ***Safety***: there are no safety concerns with this substance for infant formula products as this substance is already permitted at much higher levels as a nutrient fortifier. A much lower level is needed for antioxidant functionality.
- ***Alignment with international standards***: the EU permits the use of additive E 307 Alpha-tocopherol in infant formula products with an ML of 10 mg/kg and for use in nutrient preparations under the condition that the maximum level permitted in infant formula products is not exceeded. The Commission Regulation (EU) No 231/2012 provides specifications for E 307 and states that a synonym for alpha-tocopherol is dl-alpha-tocopherol which makes it equivalent to INS 307c. Therefore, the new entry would be aligned with EU regulations.
- ***Please refer to commercial in confidence for information on current use***.

### INS 340 Potassium phosphates

- The current proposal provides for permission only for infant formula but not for follow on formula. Fonterra seeks to extend the permission to follow on formula. The entry in S15—5 Table 13.1 would then read:
  - "*INS 340 Potassium phosphates 450 mg/L*"
- The same nutrient preparations may be used across both infant formula and follow-on formula. Given there is already permission for infant formula, the same additive should be permitted for both product types.
- **Technological justification:** this additive is used in nutrient preparations for functions such as acidity regulator to change or maintain pH of the formula during production. Phosphates represent a wide range of pH values and can each provide excellent buffering capacity as well as pH modification for stabilization of the formula matrix where necessary. The stabilization of the pH of the product preserves the nutritional quality of infant formula products by preventing the degradation of nutrients during processing as well as throughout product shelf life. Infant formula products are specially formulated to deliver specific nutrients that require stable storage conditions to maintain their efficacy.
- **Safety:** there are no safety concerns with this substance for follow on formula given it is already permitted for infant formula.
- **Alignment with international standards:** EU Regulation 1333/2008 permits potassium phosphates in both infant formula and follow-on formula with ML of 1000 mg/L expressed as $P_2O_5$. This translates to an ML of 450 mg/L. Therefore, the new entry would be aligned with EU regulations.
- ***Please refer to commercial in confidence for information on current use***.

### INS 414 Gum Arabic

- The current proposal does not provide for permission in Schedule 15-5 Table 13.1. Fonterra seeks an entry in S15—5 Table 13.1 that reads:
  - "*INS 414 Gum Arabic 150 000 mg/kg in the nutrient preparation and 10 mg/kg carry-over in final product*."
- Fonterra notes that this substance is permitted as a processing aid and therefore is already permitted as a carrier for nutrients. However, we seek to extend this permission to allow for other food additive functions in nutrient preparations.
- ***Technological justification:*** this additive is required as a stabiliser and carrier in nutrient preparations, which are added to infant formula products. Stabilisers are used to maintain a uniform dispersion of components within the nutrient preparation.
- ***Safety:*** EFSA re-evaluated the safety of gum arabic for infants below 16 weeks of age in 2019 and concluded that there was no reason for health concern (EFSA Journal 2019;17(12):5922, 23 pp https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2019.5922)
- ***Alignment with international standards:*** EU Regulation 1333/2008 permits gum arabic to be added as an additive in all nutrients for foods for infants and young children, at 150 000 mg/kg in the nutrient preparation and 10 mg/kg carry-over in final product. Therefore, the new entry would be aligned with EU regulations.
- ***Please refer to commercial in confidence for information on current use***.

## 6.2 Contaminants

***FSANZ Proposal:***

- *FSANZ's preferred option for MLs is 'as consumed' form in mg/kg.*
- *Proposed MLs per Table 6.2:*
  - *Retain single ML for aluminium (0.5 mg/kg) and move to Standard 1.4.1 and Schedule 19.*
  - *Lower ML for lead from 0.02 mg/kg to 0.01 mg/kg.*
  - *No change in MLs for: acrylonitrile (0.02 mg/kg), tin and inorganic tin (250 mg/kg), vinyl chloride (0.01 mg/kg)*
  - *No MLs to be established for: arsenic; cadmium; melamine; aflatoxins $B_1$ and $M_1$; ochratoxin A; polycyclic aromatic hydrocarbons (PAH); perchlorate; chloropropanol, glycidol and their esters.*

***Fonterra Response:***

- Fonterra can support FSANZ's proposed contaminant approaches outlined in the 2CFS.
- While we continue to consider a ML for aluminium in dairy formula to be unnecessary, and not internationally aligned with Codex/EU and US which does not set limits for aluminium in infant formula, we can comply with this approach.

### 6.3 Processing aids

***FSANZ Proposal:***

- *No change to the Code related to processing aids.*

***Fonterra Response:***

- Continue to support current regulatory approach as it relates to use of processing aids.

## 7.0 NUTRIENT COMPOSITION FOR INFANT FORMULA PRODUCTS (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 Proposal:*** *Set the maximum permitted amount of phospholipids (PL) at 72 mg/100 kJ.*

***Fonterra Response:***

- Fonterra maintains its view that a limit on total phospholipids is unnecessary based on the absence of safety concerns or evidence of adverse effects in infants 0–12 months, and existing controls requiring pre-market assessment on novel formula ingredients. We can, however, support the proposed phospholipid limit of 72 mg/100kJ which aligns with both EU and Codex limits.
- We continue to recommend that this is presented as a GUL rather than a maximum for the following reasons summarised below and outlined in further detail in our earlier response to 1CFS Consultation;
    - 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 0–12 months. We also note that older infants safely consume phospholipids from complementary foods in amounts that significantly exceed the proposed upper limit *e.g.*, 3.5 g of phospholipids in a hen's egg (Koletzko *et al.*, 2012).

### Nitrogen Conversion Factor

***FSANZ Proposal:*** Retain a single NCF of 6.25.

Draft Variation: *S29-2A Infant formula products — calculation of protein content*

*For paragraph 2.9.1—4(2)(b), the protein content of infant formula product must be calculated by multiplying the nitrogen content of the product by a nitrogen-to-protein conversion factor of 6.25.*

***Fonterra Response:***

- We continue to be disappointed at the move away from the option of a science-based NCF for dairy formula (6.38), and our reasoning for this is detailed in earlier responses to Consultation Paper 2 in July 2021 and 2016.
- We note FSANZ's preferred option to adopt a single NCF of 6.25 for both dairy and soy-based formula in order to harmonise with Codex STAN 72-1981 and the Codex Standard for Follow-up Formula for Older Infants and Product for Young Children (FuFOI). It is important the drafting of the Infant Formula

Products Standard footnote is updated to reflect the full footnote text outlined in the Codex STAN 72-1981 or the recently revised Draft Follow Up Formula for Older Infants Standard as outlined below.

- "*For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products*."[1]

## Protein Range (cow's milk)

***FSANZ Proposal:*** *For cow's milk-based infant formula FSANZ prescribe a permitted protein range of 0.43–0.7 g/100 kJ and 0.38–0.72 g/100kJ for infant and follow on formula respectively.*

***Fonterra Response:***

- Fonterra supports the permitted protein ranges for milk-based infant and follow-on formula.

## Protein Source

***FSANZ Proposal:*** *That the protein sources in infant formula be specified to be cow's milk, goat's milk, sheep milk, soy protein isolate, protein hydrolysates of one or more proteins normally used in infant formula. 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:***

- While Fonterra do not agree with the need for a positive list of permitted protein sources, we agree that the prescribed protein sources are safe and suitable for use in infant and follow-on formula.

## Amino Acids

***FSANZ Proposal:*** *Update Schedule29-3 minimum amino acids as per the table below. And introduce a ratio for methionine to cysteine of no more than 3 to 1.*

**L-amino acids that must be present in infant formula and follow-on formula**

| *L-amino acid* | *Minimum amount per 100 kJ* |
|---|---|
| Cysteine | 9 mg |
| Histidine | 10 mg |
| Isoleucine | 22 mg |
| Leucine | 40 mg |
| Lysine | 27 mg |
| Methionine | 6 mg |
| Phenylalanine | 19 mg |
| Threonine | 18 mg |
| Tryptophan | 8 mg |
| Tyrosine | 18 mg |
| Valine | 22 mg |

***Fonterra Response:***

- Proposal removes the ability in the current code to sum 'cysteine & cysteine total'; 'cysteine, cystine & methionine total'; and 'phenylalanine & tyrosine total'. This has resulted in the net effect of increasing the minimum cysteine by 50% from 6 mg to 9 mg.

[1] Codex, (2023). Report of the forty-third session of the Codex Committee on nutrition and foods for special dietary uses. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-43%252FFinal%252520Report%252FREP23_NFSDUe.pdf

- While we support FSANZ's approach in aligning with Codex, the lack of inclusion of the ability to calculate amino acids together has not been included in the FSANZ draft variation. Specifically, Codex states:
    - "*For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I); nevertheless for calculation purposes, the concentrations of tyrosine and phenylalanine may be added together. The concentrations of methionine and cysteine may be added together if the ratio is less than 2:1; in the case that the ratio is between 2:1 and 3:1 the suitability of the formula has to be demonstrated by clinical testing*."
- The ability to sum is also reflected in other global regulations including the EU:
    - "*For an equal energy value, infant formula manufactured from cows' milk or goats' milk proteins must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine:cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cysteine and of tyrosine:phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).*"
- We disagree with FSANZ that introducing minimums for methionine and cysteine allows the removal of summed requirements because having the ability to sum amino acids supports manufacturing where products are formulated to a 'sum' amount, while the ratio is used to confirm compliance.
- The use of the ratio provides manufacturers with enough confidence that conversion of indispensable to dispensable essential amino acids can occur (*e.g.*, *in vivo* conversion of phenylalanine to tyrosine).
- We recognise that FSANZ notes in SD2 that for "*calculation purposes cysteine and methionine can be added together, however the minimum requirement for each amino acid will be prescribed separately in Schedule 29*." The draft variation is unclear on our ability to sum since it states amino acids should be '*at a level no less than the corresponding minimum'* and further, FSANZ fails to comment in SD2 on the ability to sum phenylalanine and tyrosine.
- It's important to recognise that EU and Codex amino acid values are the mean population value for breastmilk. As such, Codex and EU do not specify their amino acids strictly as minimums rather they are described as 'at least equal to' such that manufacturers have flexibility to meet the summed figure without the need to fortify with additional amino acids to meet the minimums. Using FSANZ draft amino acids requirements as an example:
    - Cysteine is 9 mg/100 kJ, Methionine is 6 mg/100 kJ. Sum = 15 mg/100 kJ.
    - Naturally occurring amino acids in cows' milk produces a profile whereby cysteine is slightly below the minimum and methionine is slightly above. On balance using the ability to sum cows' milk will typically meet the summed requirement without the need to fortify with additional amino acids that would be required to meet a minimum. The use of the ratio helps ensure there is sufficient methionine to act a precursor to be converted into cysteine.
- The ability to sum and account for the *in vivo* conversion of amino acids helps to support compliance to 2.9.1-6(6) which requires amino acids "*must only be added to infant formula or follow-on formula in an amount necessary to improve protein quality*." While also supporting trade through harmonisation with international regulations.
- Fonterra could support alignment with the EU with a methionine cysteine ratio of 2 to 1. Appropriate justification should be provided if products were to approach a higher ratio of 3 to 1.
- To summarise, the ability to sum these amino acids simplifies the formulation development and minimises the need to fortify with additional amino acids while continuing to meet international regulations.
- On the above basis, we propose the below addition to the Standard to clarify intent of application and align with how amino acid requirements are set internationally:
    - *2.9.1-6 Protein Requirements*
        4) *The L-amino acids listed in the table to section S29-3 must be present in infant formula and follow-on formula at a level [equal to] ~~no less than~~ the corresponding minimum specified in the table. [For calculation purposes concentrations of 'tyrosine and phenylalanine' and 'methionine and cysteine' may be added together].*
        5) *Infant formula must have a ratio of methionine to cysteine of no more than 3 to 1.*

## Carbohydrate Source

***FSANZ Proposal:*** *Prohibit the presence of added fructose and/or added sucrose in infant and follow-on formula (except for hydrolysed protein containing formulas).*

*Draft variation: 2.9.1-5(2) Subject to subsection (3), infant formula and follow-on formula must not contain added fructose and/or added sucrose.*

***Fonterra Response:***

- Fonterra support the intent of clause to restrict direct addition of fructose and sucrose in infant formula products.
- However we consider that the proposed draft variation sets a higher standard than the Codex guidance though its use of 'must not contain' language compared to 'should not' in Codex.
- Sucrose is a common carrier used in minor amounts in vitamins, for example, used in infant formulas. Its use in this context is as a processing aid. These sugars may be present in low levels in other ingredients, for example fructo-oligosaccharides contains fructose.
- We do not consider that the intent of the regulation is to prohibit indirectly added or naturally occuring sugars, rather it is to prohibit their use as a carbohydrate source in products. Therefore,
- Fonterra recommends the following text modification for consideration:
    - *"2.9.1-5(2) Subject to subsection (3), infant formula and follow-on formula must not contain [directly] added fructose and/or added sucrose [as a carbohydrate source]."*

## Guidance Upper Limits

***FSANZ Proposal:***

- *Include the following Note within the composition drafting "An amount specified in Column 3 is a Guidance Upper Level and is a recommended upper level for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels <u>should not be</u> exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons."*

***Fonterra Response:***

- Fonterra generally support the use of GULs as a mechanism to allow for natural variation in dairy ingredients, while supporting manufacturing flexibility and also facilitating formulations compliant to multiple markets.
- The proposed note differs from that in Codex. The term 'usually' is included in the Codex text ('...<u>should usually not be</u>...') and this appears to have been omitted from the FSANZ note.
- We consider the inclusion of 'usually' to be important to include for providing flexibility. On this basis, we consider the note for GULs in the standard should be:
    - "*An amount specified in Column 3 is a Guidance Upper Level and is a recommended upper level for nutrients which pose no significant risks on the basis of current scientific knowledge. These 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 formula and follow-on formula or due to technological reasons*."

## Docosahexaenoic acid

***FSANZ Proposal:***

- *Maintain voluntary permissions for DHA in infant formula products.*
- *Specify a GUL for infant and follow-on formula (7 mg/100 kJ).*

***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 mg/100 kJ) proposed by FSANZ as being equivalent to 0.5% TFA.
- Fonterra support 12 mg/100 kJ, 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 important export markets such as China.
- While we support the use of GULs, when they are much lower than export market requirements (as is the case for the proposed DHA), they do not provide the necessary flexibility for manufacturers.

Therefore, a compromise on a higher maximum for DHA of 12 mg/100 kJ is preferred as this provides greater flexibility and alignment with international regulations.

## Vitamin D

***FSANZ Proposal:***

- *Maintain the existing range for infant and follow-on formula (0.24–0.63 µg/100kJ).*

***Fonterra Response:***

- Fonterra do not support maintaining the existing vitamin D ranges. We encourage FSANZ to future proof the code by aligning both infant and follow-on formula with the revised Codex Standard for Follow-up Formula for Older Infants and Product for Young Children (FuFOI) which 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.
- 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 recommendation at 10 µg/day — double the existing ANZ NHMRC value and the current FSANZ RDI for infants in Schedule 1. On this basis we may expect the vitamin D value to be increased in ANZ under the future NHMRC NRV review.
- 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 as highlighted in our submission to 1CFS. And further supports that the ANZ NRV may be increased in the future.
- 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 0.72 µg/100 kJ in follow-on formula. EFSA stated (2018):
    - "*For infants aged 4–12 months, the 95$^{th}$ 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 as the Australian NHMRC of 25 µg/day determined there was no safety concerns for older infants even after considering vitamin D intake from foods, containing naturally occurring sources or fortified with vitamin D.
- From a technical perspective, the current range on vitamin D presents challenges to manufacture paediatric formulations that align to both ANZ and international regulations.
- We would support a maximum of 0.72 µg/100 kJ per the revised Codex draft Standard for FuFOI for both infant formula and follow-on formula. We can compromise on 0.72 µg/100 kJ for follow-on until the ANZ NRV for vitamin D is reviewed.

## L-Carnitine

***FSANZ Proposal:***

- *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 do not believe a GUL or maximum is required for infant formula because the 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 can however support a GUL if this is increased to acknowledge inherent baseline levels in dairy-based infant formula products. Formula L-carnitine levels are variable due to the natural seasonal variation in dairy ingredients and in particular that attributed by the whey portion of dairy.
- L-Carnitine naturally occurs in milk and whey ingredients with content varying throughout the milking season. L-Carnitine is retained in whey during cheese making and manufacturing process to make whey. Therefore, natural variability from milk is carried over to whey protein ingredients. In addition, the L-Carnitine content of local and imported whey differs across suppliers due to variations in the milk supply and farming practices, as well as the manufacturing process used.
- A GUL is important in maintaining our ability to formulate due to the natural seasonal variation in L-carnitine content of dairy and in particular that attributed by the high content of L-Carnitine in the whey portion of dairy. Infant formulas are whey dominant and levels for some formulas would regularly exceed the proposed GUL and if a GUL was to be included, a higher GUL would be more appropriate.

### 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.

## 8.0 Labelling for Infant Formula Products (SD3)

Fonterra is generally supportive of the wide range of proposals related to labelling. We support the INC submission and highlight key areas for comment below.

### Product differentiation

***FSANZ Proposal:***

- *Update 2.9.1-6 to include a new provision requiring that a food represented as infant formula or follow-on formula must not be also represented as another food.*

**Fonterra Response:**

Fonterra supports the new provision recognising that FSANZ comments on companies having the flexibility to choose colours, text or images. To ensure sufficient product differentiation, Fonterra considers that mandatory prescribed names, age information and voluntary stage labelling are useful tools in differentiating products.

### Statement about age to offer food in addition to formula

***FSANZ Proposal:***

- *2.9.1-22(2)(c) for infant formula and follow-on formula — it is recommended that infants from the age of 6 months should be offered foods in addition to the infant formula or follow-on formula.*

**Fonterra Response:**

- Fonterra continues to support “from around the age” 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 FSANZ’s view that the standards are legislative instruments that must be clearly drafted, but we also consider it important to ensure caregivers are not provided with contradictory information across different platforms.

- The term 'around' is commonly used in current labelling practices and to our knowledge there is demonstrable consumer confusion to indicate that a need for change is necessary.
- 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".
- We therefore, recommend the below text:
    - "*2.9.1-22(2)(c) for infant formula and follow-on formula — it is recommended that infants from [around] the age of 6 months should be offered foods in addition to the infant formula or follow-on formula*."

### Nutrition Information Statement

***FSANZ Proposal:***

- *Draft Variation: 2.9.1-25 prescribes the declaration of nutrition information*
    - *2.9.1-25(2) If one of the following substances is present in the infant formula or follow-on formula, the statement required by subsection (1) may include the average quantity of that substance (including any naturally-occurring amount), expressed in milligrams or grams:*
        - *(a) docosahexaenoic acid; and*
        - *(b) eicosapentaenoic acid; and*
        - *(c) arachidonic acid; and*
        - *(d) whey; and*
        - *(e) casein.*
    - *2.9.1-26 outlines the required form for the declaration of nutrition information*

**Fonterra Response:**

- While Fonterra can accept the general aspects of the prescribed NIS, we do not support the high level of prescription on voluntary nutrients that may be listed in the NIS. Nor the prohibition on the use of common language and acronyms. We consider that this limits the ability of manufacturers to provide adequate information to enable consumers to make informed choices.
- Whilst Fonterra supports a specific order of nutrients to support consumers, 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 without the high level of prescription outlined in 2.9.1-25(2).
- Fonterra is concerned about the inability to use language commonly used by the consumer, specifically:
    - Folic acid:
        - We are concerned that declaring 'folate' in the NIS rather than 'folic acid' risks misrepresenting the ingredient being added. We see no evidence of folate being more commonly recognised than folic acid. We consider that caregivers are familiar with this term for example, pregnant women are instructed to take 'folic acid' during pregnancy suggesting this term would be known to most caregivers. Advice on supplementation (*e.g.*, FSANZ[2] and the NZ Ministry of Health[3]) talks specifically to micrograms of folic acid, not as folate. It is also common in other food products to declare 'folic acid' rather than folate, for example in labels for formulated supplementary foods for young children and those breads fortified with folic acid. These activities have heightened public awareness of folic acid.
        - We therefore recommend 'folic acid' rather than 'folate' be declared in the NIS.
    - Acronyms:

[2] FSANZ. (2016). Folic acid/folate and pregnancy https://www.foodstandards.gov.au/consumer/generalissues/pregnancy/folic/pages/default.aspx

[3] NZ Ministry of Health. (2018). Folic acid, iodine and vitamin D. https://www.health.govt.nz/your-health/pregnancy-and-kids/pregnancy/helpful-advice-during-pregnancy/folic-acid-iodine-and-vitamin-d

- Restricting permitted wording to 'Docosahexaenoic acid', 'Eicosapentaenoic acid' and 'Arachidonic acid' in the NIS limits the ability of manufacturers to provide consumers with the acronyms (DHA, EPA, ARA) that are more commonly used by consumers and healthcare professionals to communicate what nutrients to look for in a formula.
- There is no evidence to suggest that acronyms should not be used on labels, and we would suggest that consumers are increasingly aware of acronyms used in day to day life (DHA, HIV, COVID) and that an acronym is a useful way to simplify technical language.
- It is important to provide caregivers with the opportunity to identify with the word or acronyms that they understand. This will ensure that provision of information meets their individual needs to enable informed choice.
- Fonterra recommend that acronyms be permitted in addition to scientific names. *E.g.*, docosahexaenoic acid (DHA).

- Should FSANZ progress with the proposal to prescribed permitted optional nutrients, as outlined in 2.9.1-25(2):
  - Fonterra support the ability to declare protein fractions such as whey and casein within the NIS.
  - Fonterra currently list linoleic acid (LA) and alpha linoleic acid (ALA) on our products, we would like to be able to provide consumers with continuity of labelling and therefore request these be permitted to be labelled through addition to the list under 2.9.1-25(2).
  - Fonterra recommends that acronyms be permitted in addition to scientific names. *E.g.*, docosahexaenoic acid (DHA).
  - Fonterra supports acronyms for vitamins to be voluntarily permitted in addition to scientific names (E.g. Niacin (B3).
- We therefore support the below amendments to the draft variation:

*2.9.1-25(2) If one of the following substances is present in the infant formula or follow-on formula, the statement required by subsection (1) may include the average quantity of that substance (including any naturally-occurring amount), expressed in milligrams or grams:*

*a) docosahexaenoic acid (DHA); and*
*b) eicosapentaenoic acid (EPA); and*
*c) arachidonic acid (ARA); and*
*d) [linoleic acid (LA); and*
*e) alpha linoleic acid (ALA); and]*
*f) whey;*
*g) casein;*
*h) [Niacin (B3);*
*i) Pantothenic Acid (B5);*
*j) Riboflavin (B2); and*
*k) Thiamin (B1)]*

## Stage labelling

**FSANZ Proposal:** *To voluntarily permit stage labelling with specific requirements around use.*

- *Draft Variation: 2.9.1—28 Requirements for use of stage numbers*
  1) *The following numbers may be used on the label on a package of infant formula or follow-on formula to identify for consumers that product is infant formula or follow-on formula:*
     *(a) if the product is infant formula—the number '1'; and*
     *(b) if the product is follow-on formula—the number '2'.*
  2) *A number used in accordance with subsection (1) must appear:*
     *a) on the front of the package of the product; and*
     *b) immediately adjacent to:*
        *(i) for infant formula—the statement required by paragraph 2.9.1—22(2)(a); and*
        (ii) *for follow-on formula—the statement required by paragraph 2.9.1—22(2)(b).*

**Fonterra Response:**

- Fonterra supports the use of stage numbers as an important tool in helping consumers identify infant formula and follow-on formula.
- The numbers '1' and '2' are well recognised and understood by consumers. Further, this nomenclature is used globally to identify infant formula products.

## Prohibited Representations: Information related to other products

**FSANZ Proposal:** *To add new provisions related to prohibited representations.*

- *Draft Variation: 2.9.1—29 Prohibited representations*
  1) *The label on a package of infant formula or follow-on formula must not contain:*
     c) *information relating to another product; or*

        *Example The label on a package of infant formula must not refer to, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children.*

**Fonterra Response:**

- Fonterra support FSANZ's proposal to not permit information related to other products.

### Prohibited Representations: Restriction on 'ingredient claims'

**FSANZ Proposal:**

- *Draft Variation: 2.9.1—29 Prohibited representations*
  1) *The label on a package of infant formula or follow-on formula must not contain:*
     j) *information relating to ingredients, except for a reference in:*
        i. *a statement of ingredients; or*
        ii. *a declaration or statement expressly permitted or required by this Code; or*

**Fonterra Response:**

- Fonterra does not support the intent to prohibit 'ingredient claims'.
- 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. Further FSANZ are proposing a new note to 2.9.1-29 which further clarifies the requirements within the Standard. We consider such a note would address FSANZ's concern around implied nutrition and health claims, without the need for a prohibition on ingredient statements.
  - "*Note Standard 1.2.7 prescribes requirements for making health claims and nutrition content claims, including in relation to infant formula products. Section 1.2.7—4 provides that a nutrition content claim or *health claim must not be made about an infant formula product. Section 1.2.7—8 provides that a claim – including a claim about an infant formula product - must not be therapeutic in nature*."
- Provenance statements such as 'made with New Zealand milk' could inadvertently be captured by the proposed drafting by FSANZ. We challenge if this was the intent of the proposal given original concerns outlined in the 2016 consultation paper appeared more focussed on addressing implied nutrition and health claims:
  - *"FSANZ noted it had observed claims about specific ingredients (for example, 'fish oil', 'unique prebiotics', 'fish oil to help support brain and eye development'), or specific health effects (for example, 'unique ingredients to help promote comfortable digestion') on IFP labels. FSANZ suggested there may be confusion about how nutrition content and health claim definitions and provisions contained in Standard 1.2.7 apply to claims about ingredients made on IFP labels*" (FSANZ 1CFS SD3).
- This was interpreted in the 1CFS to indicate that provenance statements were not the intended target of the proposed restriction. However, the draft variation is non-specific, and its general nature means any reference to an ingredient regardless of context is captured by the clause.
- The inability to state "made with NZ milk" on packaging will have substantial implications for the competitiveness of the NZ infant formula industry. It is one of the few statements that is permitted on pack to help differentiate our NZ products in a global marketplace.
- Increasing restrictions on ANZ products impacts our ability to commercially compete in cross border e-commerce (CBEC) since other markets don't have these same restrictions.
- Further, because of the unique NZ export requirements for infant formula products the prohibition has the potential for a knock-on impact to exported products.
- Fonterra have previously raised concerns about the restriction inadvertently impacting the provision of information to consumers to make informed choices and differentiate between products.
- We request the removal of clause 2.9.1-29(j) to ensure infant formula products can continue to make provenance claims on key ingredients.
- Should FSANZ progress with this clause, Fonterra has sought clarification from FSANZ and understands that this does not preclude a general statement about ingredients, for example "high quality ingredients" or "sustainably sourced ingredients". This is not clear from the drafting and could

raise interpretation issues between different jurisdictions. We would appreciate comment in the approval report to clarify the intent of this requirement.

### Prohibited Representations: Restriction on name, numbers, pictures, images and words

**FSANZ Proposal:** Limit to duplication of protein source to front of pack.

- *Draft Variation: 2.9.1—29 Prohibited representations*
  1) *The label on a package of infant formula or follow-on formula must not contain:*
     *….*
     *(c) information relating to another product; or*
     *….*
     *(h) information relating to the nutritional content of human milk; or*
     *(i) information relating to the presence of a substance listed in subsection (3), except for a reference in…*
     *(j) information relating to ingredients, except for a reference in…*
     *(k) information relating to the animal or plant source or sources of protein in the infant formula or follow-on formula, except…*
  2) *For the purposes of subsection (1), 'information' includes a reference by means of a name, a number, a picture, an image, a word or words.*

**Fonterra Response:**

- Fonterra do not support the clause 2.9.1-29(2) to define information related to topics beyond information related to another products.
- Based on commentary within the discussion paper, Fonterra do not believe the intent was to prohibit "*name, numbers, pictures, images and words*" related to ingredients or protein source (E.g. images of cows, goats, sheep). FSANZ comments on images only within section 9 of SD3 which indicates both the Codex Draft Standard for FuFOI and the EU regulations (Page 60 of 2CFS SD3) focus on the prohibition of proxy advertising. We support the prohibition of information related to another product on infant formula product labels.
- Numbers, pictures and images are important to enable easy identification of products. These are used to support other statements made on the label and enable caregivers to make an informed choice. Imagery in particular can be an important tool in communicating this information, particularly where caregivers have low literacy and/or English is not their first language.
- We propose the clause is updated to reflect the intent of the discussion paper
  - *2.9.1-29(2) For the purposes of subsection [(1)(c), 'information relating to another product'] includes a reference by means of a name, a number, a picture, an image, a word or words*.

### Prohibited Representations: Restriction on protein source to front of pack only

**FSANZ Proposal:** Limit to duplication of protein source to front of pack.

- *Draft Variation: 2.9.1—29 Prohibited representations*
  1) *The label on a package of infant formula or follow-on formula must not contain:*
     *k) information relating to the animal or plant source or sources of protein in the infant formula or follow-on formula, except:*
        *(i) in a statement of ingredients; or*
        *(ii) where required by subsection 2.9.1—20(1);*

**Fonterra Response:**

- We do not consider it appropriate to restrict declaration of protein source to the front of pack only as this limit's important product information. Declaration of protein source as prescribed information on the label is not considered a claim~~. It~~ is a statement about an inherent property of the food which is important in helping consumers select the right product for their infant.
- Retaining permission to repeat these prescribed requirements or terms elsewhere on pack helps to ensure adequate information for consumers. We understand that the requirement to have these statements front of pack is to clearly communicate the information to consumers and ensure informed choice. While we continue to support their use on front of pack, prohibiting the terms elsewhere on pack is counter intuitive to the provision of information to consumers to make an informed choice. We note duplication can be an important driver for consumer awareness as well recognised during the plain English allergen labelling discussion which now requires allergens to be labelled multiple times within the ingredients list in addition to the summary statement.
- We support removal of this express prohibition.

### Prohibited Representations: Restriction on stage labelling to front of pack only

**FSANZ Proposal:** Limit the ability to declare protein source statements to front of pack only.

- *Draft Variation: 2.9.1—29 Prohibited representations*
  1) *The label on a package of infant formula or follow-on formula must not contain:*
     n) *a number used to identify for consumers that the product is infant formula or follow-on formula, except where required by section 2.9.1—28.*

**Fonterra Response:**

- Fonterra do not support the restriction on stage labelling only appearing on front of pack as discussed above in the section on the new stage labelling provision.
- We consider this to be information that supports consumers in differentiating between products and therefore, this information is relevant to other parts of the product packaging.
- Fonterra's own Anmum brand in ANZ uses the numbers '1' and '2' to differentiate between our two infant and follow-on formula products which are both named "Anmum NeoPro™". Information additionally provided on the back of pack via stage numbers is important to appropriately differentiate between these products. In this situation, removal of stage numbers, risks misleading consumers on the true nature of the product and the suitability for their infant.
- The cost and benefit analysis states that the stage labelling requirement is "*intended to reduce the risk of consumers purchasing a similarly packaged products that may not be suitable for their infant*". When a caregiver has made the decision to purchase infant formula products, we consider consumers do not make purchasing decisions solely on information provided on front of pack. For this reason, we consider it important that this information is also permitted elsewhere on the label.
- Retaining permission to repeat these prescribed requirements or terms elsewhere on pack helps to ensure adequate information for consumers. We understand that the requirement to have these statements front of pack is to clearly communicate the information to consumers and ensure informed choice. While we support their use on front of pack, prohibiting the terms elsewhere on pack is counter intuitive to the provision of information to consumers to make an informed choice. We note duplication can be an important driver for consumer awareness as well recognised during the plain English allergen labelling discussion which now requires allergens to be labelled multiple times within the ingredients list in addition to the summary statement.
- We request FSANZ remove the requirement that the use of stage labelling must appear on the front of pack only.

## 10 FSANZ Act Requirements

Please refer to commercial in confidence submission.

## 11 IMPLEMENTATION

### 11.1 Transitional Arrangement

***FSANZ Proposal:***

- *Five-year transition for infant formula products that will take effect on the date of gazettal.*

**Fonterra Response:**

- Support the proposal for a five-year transition period. We consider this provides adequate time for reformulation and sell through of infant formula products compliant to the current standard.

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