[redacted]

2/09/2021

Dear Standards Management,

Proposal P1028 – Infant Formula Consultation Paper 2 – Nutrient Composition

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, Consultation Paper 2 – Nutrient Composition**. 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 information or elaboration on certain topics.

Our submission focuses on protein, fat, phospholipids, carbohydrate sources, iodine, selenium, fluoride and L-carnitine. We have utilised the same numbered headings for our response to selected questions on these 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 us.

Yours Sincerely,

[redacted]

4. Protein

4.1 Calculation of Protein Content (Nitrogen Conversion Factor)

FSANZ Proposed approach: *Based on the arguments presented above, FSANZ proposes that Option 1 is the most practical option and should be adopted into Standard 2.9.1.*

Fonterra Response:

- FSANZ proposed adopting the Codex NCF as Option One, with Option two comprising all three NCF (5.71, 6.25, 6.38).
- Fonterra appreciate that FSANZ has attempted to find a flexible approach in accommodating previous industry and stakeholder feedback in Option 2. This approach allows choice for industry to harmonise with international standards which use a NCF of 6.25 for infant formula, or to utilise science-based conversion factors i.e. 5.71 for soy based infant formula, or 6.38 for dairy-based infant formula, the latter also reflecting FSANZ status quo for dairy based infant formula.
- However, while Fonterra can support 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, Fonterra does not support that whey-based infant formula is distinguished from other dairy infant formula in the choice of NCFs as the Option 2 proposal currently outlines.
- The rationale FSANZ has applied in distinguishing NCFs in whey-based from other dairy formula is not clear. Such an approach was not outlined in the 2019 JEMNU Expert Panel recommendations. We refer to a recent publication by Elgar et al (2020) with a specific focus on a range of commercial whey products using different methods for protein determination. This continues to highlight that an NCF for whey ingredients is similar to other dairy products. Fonterra considers if this Option 2 is to be further progressed, that 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.
- Furthermore, Fonterra considers the FSANZ summary of the 2019 JEMNU Report recommendations incomplete as two Options were proposed by JEMNU, with the same NCF for soy regardless of which Option was selected. Report recommendations were dependent on the definition of protein for infant formula, and consideration of protein in infant formula was defined only as amino acids, or a more holistic view of total protein. INC continues to support a holistic view of total protein, acknowledging that dairy protein has total nutritional benefits not just its protein components individually.
- In summary, Fonterra considers there is insufficient scientific basis to support FSANZ's approach of distinguishing whey based from other dairy formula in the choice of NCF. If FSANZ was to proceed with Option 2, Fonterra would only be supportive of this approach if whey vs other dairy formula NCFs were not distinguished. Labelling and minimum protein levels would need to be worked through. Thus, at this stage as currently drafted Fonterra considers Option 1 more appropriate. We recommend Option 1 is updated to fully reflect the Codex IF Std NCF footnote.

4.2 Protein Range

FSANZ Proposed Approach: *Based on absence of evidence noting harm to infant health for this range, submitter comments to the 2016 Consultation paper, consistency with the EU 2016/127 regulations (minimum), FSANZ proposes to prescribe a permitted protein range of 0.43–0.7g/100 kJ for cow's milk-based infant formula. FSANZ also notes that the recently reviewed Codex Draft Standard for FUF (FAO/WHO 2018) is also aligned with this range.*

Fonterra Response:

- Fonterra support the proposed protein range of 0.43-0.72g/100kJ (corrected to 2 significant figures) in cow's milk based infant formula, aligned with recent international regulations. The technical correction of the FSANZ minimum allows harmonisation with Codex and EU recipes, particularly for low protein products. Furthermore, Fonterra recommends that this range is applied to all milk based infant formula products.
- Fonterra understand FSANZ will include consideration of follow-on formula composition in future P1028 Consultations. We note the protein minimum for follow-on formula was recently considered by

FSANZ in Application 1173, however the protein maximum was beyond the scope of this review. The Codex FUF Standard recently adopted a revised protein maximum of 3g/100kcal, however many respondents including both Australia and New Zealand had supported Codex to instead adopt a maximum of 3.5g/100kcal, and Countries such as China have recently adopted this maximum in Regulations. We note alignment with 3.5g/100kcal (expressed on a per 100kJ basis) would provide flexibility for manufacturers and facilitate trade.

4.3 Protein Source

FSANZ Proposed Approach: *The recent focus on new proteins to be used in foods, and the potential safety issues associated with their use in infant formulas, has increased concerns about these sources if not approved through the pre-market assessment process. Therefore, FSANZ proposes that the protein source 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.*

Fonterra Response:

- Fonterra do not consider that the specific protein source needs to be further prescribed in the Infant Formula Standard. There are already a range of safeguards in place to ensure safety and suitability of protein source, including that covered by horizontal standards e.g. Novel Food Standards. We note that adoption of such an approach would not be aligned to Codex, 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.
- FSANZ's outline concerns regarding new plant proteins used in foods, and potential safety issues if these protein sources have not gone through pre-market assessment for use in infant formula. However, new sources of protein are already required to undergo a FSANZ pre-market assessment as outlined in the Novel Food Standard[1]. We support continuation of the P1024 proposal to provide greater clarity around novel/ nutritive substances. In the interim, we would also suggest that the current ACNF novel/ not-novel food opinions are dated, and it is made clear the intended population for which the Opinion relates to. For example, certain plant proteins have been assessed by the ACNF as non-traditional, not novel foods, however the intended population the Opinion related to was not explicitly stated.
- FSANZ propose that cows milk protein, goats milk protein, their protein hydrolysates, and soy protein be specified as permitted protein source within the Infant Formula Standard. While Fonterra agrees with FSANZ that these protein sources are safe and suitable for use in formula and do not require FSANZ pre-market assessment, we also consider a more general statement that recognises mammalian milk protein sufficient. If FSANZ continue to propose to stipulate protein source, we do not object to specific permissions for different plant protein sources (e.g. soy) being listed in light of their differences in amino acid digestibility and absorption, and structural differences to mammalian milk, at least until P1024 is progressed. This would provide further clarity that other plant protein sources require FSANZ pre-market assessment.

4.4 Protein Quality

FSANZ Proposed Approach: *Because current methods for measuring protein quality have yet to be established for regulatory purposes, FSANZ proposes to maintain the current requirements for protein quality by mandating minimum amino acid amounts (see section 4.5).*

[1] *"...foods produced from new sources, or by a process not previously applied to food".*

Fonterra Response:

- Fonterra agrees that the amino acid (aa) breast milk reference pattern should remain within the FSANZ Infant Formula Std 2.9.1 (S29-6) to regulate protein quality. This approach is consistent with EU 2016/127, Codex STAN 72-1981 and the draft revised Codex Standard for FuF for older infants 6-12 months.
- FSANZ summarise that both Standard 2.9.1 and Codex STAN 72-1981 regulate the protein quality through mandating minimum amounts of the amino acids considered essential (and semi essential) for infants. The FSANZ nutrition risk assessment considered that the DIAAS and PDCAAS methods for protein quality assessment are ideal methods, however PDCAAS as written is not suitable for use in 0-12 months as it was originally intended for use in 2 years plus (FAO 1991), and the evidence base for DIAAS is incomplete. PDCAAS was modified for use in protein quality assessment for FUF for young children aged 12 months plus (FAO, 2017). However, Fonterra also notes that it is possible to adapt PDCAAS for use in 0-12 months but the amino acid scoring pattern would need to be updated with the breastmilk amino acid reference pattern.
- Fonterra notes that CP2 (p25) states that the draft revised Codex Standard for FuF does not use breastmilk amino acid composition as the reference protein but rather has adopted PDCAAS. This statement is not fully correct. The draft Codex Standard for FuF for Older Infants retains use of breastmilk amino acids as the reference protein but PDCAAS is adopted for Young Children formula.

4.5 Amino Acid Content

FSANZ Proposed approach: *FSANZ proposes to align the minimum amounts of all amino acids with Codex STAN 72- 1981. Regarding SAA and AAA, the added requirements to define ratios of methionine to cysteine and tyrosine to phenylalanine is proposed to be included in Schedule 29 as a condition (for example, see EU 2016/127 above).*

Fonterra Response:

- Fonterra supports the FSANZ proposal to align the minimum amounts of all amino acids with Codex STAN 72-1981, including combined totals and ratio for sulphur amino acids (SAA) methionine and cysteine, and the aromatic amino acids (AAA) tyrosine and phenylalanine.
- Fonterra agrees that the SAA and AAA combined totals and ratios be defined in Schedule 29 in alignment with Codex STAN 72-1981. In addition to the proposals put forward by FSANZ in CP2 , this should include the option for clinical evaluation of the suitability for formula with methionine to cysteine ratios greater than 2 as is included in both Codex STAN 72-1981 and EU Regulation 2016/127

5.0 Fat

5.1 Fat Content

FSANZ Proposed approach*: Based on the conclusions of the 2016 nutrition risk assessment, alignment with Codex STAN 72-1981, EU 2016/127 and fat content levels found in human milk, FSANZ proposes to retain the current minimum level and lower the maximum to 1.4g/100 kJ.*

- Fonterra supports the FSANZ Proposal to retain the current minimum and revision of the maximum to 1.4g/100kJ to align with Codex STAN 72-1981.

5.2 Units of Expression

FSANZ Proposed approach*: Based on alignment with Codex STAN 72-1981 and the Codex Draft Standard for FUF, FSANZ proposes to express the amounts of fatty acids in terms of mg/100 kJ. This applies to LA, ALA and DHA. Limits on lauric acid, myristic acid, and erucic acid will still be prescribed as a percentage of fatty acids.*

- Fonterra supports the FSANZ proposal to express the amounts of fatty acids for LA, ALA and DHA in mg/100kJ in order to align with Codex and support regulatory harmonisation. While retaining lauric acid, myristic acid, and erucic acid as percentage of fatty acids.

5.5 Fat Source

***FSANZ Proposed approach**: FSANZ considers that retaining the current approach is appropriate based on the number of submissions which supported this view. This conclusion has been factored into consideration on restrictions of certain fats, discussed in following sections.*

- Fonterra supports the FSANZ proposal to retain the current approach which restricts specific fats and no further definition of fat source. As is noted in CP2, this is aligned internationally and with the current Food Standards Code.

5.6 Restrictions on certain fats

5.6.2 Trans Fat

***FSANZ Proposed approach**: Aligning with Codex STAN 72-1981 for TFA would require a change in the definition of TFA in the Code. FSANZ considers this to be out of scope for this proposal. The proposed option is to retain the current restriction for TFA at 4% of total fatty acids.*

- Fonterra supports retention of the current TFA restriction of 4% total fatty acids. Fonterra also recommends future consideration of the Code TFA definition to align with Codex.

5.6.3 Phospholipids

***FSANZ Proposed approach**: FSANZ proposes to set the maximum permitted amount of PL as 2 g/L (72 mg/100 kJ) and the maximum lecithin amount to 1 g/L (Option 3). This approach provides alignment with the most recently reviewed international regulations (EU 2016/127) and provides the most clarity for PL amounts in the Code. We request information (including quantitative evidence) about this approach, particularly from manufacturers that may be disproportionately impacted by these restrictions.*

Fonterra Response:

- **Phospholipids**: In earlier submissions Fonterra and industry have outlined we consider a UL for total PL is unnecessarily prescriptive, and there is an absence of market failure with the current approach. We note FSANZ continue to pursues an upper limit for total PL. Fonterra thus can support Option 1 in alignment with Codex, but with the limit being a GUL of 2g/L. Our preference for a GUL as opposed to a maximum is outlined in General Comments. We similarly prefer alignment with Codex units which expresses total phospholipids on a mg/100kcal basis

- **Lecithin**: Fonterra notes that lecithin is a food additive but was not covered in CP1. Fonterra has reservations about the proposal to restrict its use as food additive from the limit currently applied to its use in infant and follow-up formulas in Codex STAN 192-1995 and FSANZ (5g/L) to that stipulated in EU Regulations (1g/L).

- We note FSANZ's reference to the EFSA 2020 opinion on the re-evaluation of lecithin as a food additive in infants <16 weeks of age as justification for FSANZ to similarly adopt a reduced lecithin limit of 1g/L. This limit 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 doses, and does not set an ADI. EFSA 2020 instead, and in line with the earlier 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 recent EFSA 2020Report to justify FSANZ adopting a lower lecithin maximum.

6. Carbohydrate

6.2 Dietary Fibre

***FSANZ Proposed approach**: The primary objective of the P1028 proposal is to align with international regulations unless safety or other concerns do not support alignment. FSANZ is unaware of safety issues associated with addition of permitted oligosaccharides to infant formula without a prescribed method of analysis for that substance. Currently the Code is aligned with Codex STAN 72- 1981 and EU 2016/127 in not prescribing methods of analysis for dietary fibre. Therefore no change to the existing requirements is proposed.*

Fonterra Response:

- Fonterra support not prescribing methods of analysis for dietary fibre in the Food Standards Code in line with proposal 6.2.
- The FSANZ Dietary fibre definition is inconsistent with Codex/ other Country regulations due to inclusion of 'plant' and the specific list of benefits within the definition. We support a wider FSANZ review of fibre definition.

6.3 Carbohydrate Source

***FSANZ Proposed approach**: FSANZ proposes to adopt limits on sucrose and fructose that are aligned with Codex STAN 72-1981. This option is supported by safety concerns cited by government submitters, by FSANZ's safety assessment conducted in 2002, and by international requirements that come into place in 2020 that are in line with Codex STAN 72-1981.*

Fonterra Response:

- Fonterra do not support adoption of limits on sucrose and fructose. Our preference is to maintain the current approach which does not include specific provisions relating to carbohydrate source (Option 1).
- If the proposals for adoption of limits on sucrose and fructose is progressed, we recommend alignment with Codex STAN 72-1981 in that these are guidance and that there are no specific limits prescribed. as outlined in Option 2. However, we recommend modification of Codex STAN 72-1981 guidance statement as follows:
    - "*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*".
- Modification is recommended to ensure there is clarity of the rationale and purpose for restriction on sucrose and fructose addition, and avoid any inference or confusion that no sucrose or fructose is permissible in these products, noting that these sugars can be present at low levels from indirect presence in other ingredients, for example fructo-oligosaccharides.

7 Micronutrients

7.3.8 Iodine

***FSANZ Proposed approach**: To ensure infants meet their requirements for iodine, the proposed approach is to align the minimum amount with EU 2016/127 (3.6 µg/100 kJ). FSANZ proposes to retain the existing section S29—9 maximum as this amount is comparable to expert recommendations and is an amount that manufacturers are able to meet already.*

Fonterra Response:

- Fonterra does not support the FSANZ proposal for iodine i.e. to raise the minimum to 3.6ug/100kJ and retain the maximum of 10ug/100KJ. Fonterra strongly supports aligning the iodine minimum and GUL to that of the Codex STAN 72-1981 levels i.e. a range 2.5 to 14 µg/100kJ.

- Nutritional reasons detailing our support for minimum and GUL iodine levels aligned with Codex STAN 72-1981 are detailed in the INC submission. We note there is no UL established for infants 0-12 months of age and FSANZ's conclusion in 2016 was that the Codex GUL of 14 µg/100kJ would be unlikely to pose a risk to infant health. Furthermore, the iodine content in raw materials (e.g. milk) can be variable and the proposed higher iodine minimum outlined by FSANZ further reduces the manufacturing range which can already pose challenge. Alignment with the Codex range also supports trade harmonisation with Countries following Codex, including facilitation of trade with China.

- Fonterra consider that consistent principles should be applied in determining whether a maximum or a GUL is appropriate for nutrients, noting maximum levels are generally set for nutrients that have documented adverse health effects and for which upper safety limits have been established. GUL's generally consider history of safe use and values derived on the basis of meeting nutritional requirements. In the case of iodine, Fonterra consider a GUL is more appropriate than a maximum given there is no UL established for iodine in infancy, and absence of any safety concern in the Codex STAN 72-1981 use of a GUL.

7.3.11 Selenium

FSANZ Proposed approach*: Based on the most recent information on selenium status of ANZ infants, FSANZ proposes to increase the minimum to 0.48 µg/100 kJ. This level is consistent with recent international regulations, would meet the ANZ AI, and is slightly higher than breast milk concentrations of ANZ mothers, a population that may not be selenium sufficient. FSANZ proposes to also increase the maximum level to 2.0 µg/100 kJ which would align with EU 2016/127 and is comparable to the Codex STAN 72-1981 maximum. This amount would result in estimated intakes that do not exceed UL. The proposed permitted range (0.48 – 2.0 µg/100 kJ) is broader than the current range in the Code and is more aligned with international regulations which should minimise the amount of reformulation that would be required by manufacturers. Consideration on the proposed approach regarding the GUL status of the selenium maximum is discussed in section 7.1.*

Fonterra Response:

- FSANZ proposes, to increase the minimum from 0.25 µg/100kJ to 0.48 µg/100 kJ and the maximum from 1.19 µg/100kJ to 2.0 µg/100kJ. FSANZ also proposes retention of a maximum, instead of changing to a GUL for selenium. While Fonterra can support the revised minimum

- We recommend that the Selenium upper limit is aligned with the Codex GUL (i.e. 2.2ug/100kJ) and not set a maximum as currently proposed by FSANZ at 2.0ug/100kJ. We note the Codex FUF review reconfirmed the appropriateness of a GUL for Selenium at 2.2ug/100kJ. It is understood that no electronic working group members raised issues with this GUL, highlighting lack of global safety concerns in infants at this level.

- FSANZ discusses the 2018 NZ total diet survey as a demonstration that dietary intakes were meeting the nutritional requirements for selenium in the NZ population. We agree with FSANZ that the report indicates 1) infant formula products are a key dietary source of selenium for infants and 2) infants did not have an estimated mean dietary intake in exceedance of the UL for selenium. This raises the question, what is the risk of exceedance of the UL in practical terms of extension to the Codex 2.2ug/100kJ GUL?

- FSANZ references in CP2 that alignment with Codex could (not would) exceed the UL and also made comment that there was no evidence of excess intakes or associated adverse health effects. Given the selenium range of breastmilk provided in CP2 can be much higher than the Codex GUL, and New Zealand Total Diet Survey estimates infants are achieving only 40% of the UL, an increase is not likely to cause adverse health effects. We therefore question the current relevance of the science used in the original development of the ANZ UL and recommend that these should be reviewed based on more recent evidence.

- Manufacturers do not generally target the minimum or maximum/GUL especially where overages for nutrient level maintenance over shelf life are not required, as is the case for Selenium. Increasing the maximum to 2.2ug/100kJ, and changing to a GUL facilitates trade and tailoring of formulations to suit populations who may require increased selenium intake.

7.4.2 Vitamin E and PUFA

***FSANZ Proposed approach**: Based on the 2016 nutrition risk assessment conclusions and stakeholder support, FSANZ's proposed approach is to retain the current permission for vitamin E requirements relating to the PUFA content of infant formula within Standard 2.9.1. It is not considered necessary to adopt the 'factors of equivalence' for α-TE to individual PUFA outlined in Codex STAN 72- 1981.*

- Fonterra can support proposal 7.4.2 however, we recognise that FSANZ are one of the few markets which prescribe a vitamin E PUFA requirement. We can therefore also support INC's alternative of increasing the minimum to 0.14 mg/100kJ if the PUFA requirement is removed. This supports harmonisation, reducing technical complexity while also meeting current minimum requirements.

7.6 Fluoride

***FSANZ Proposed approach**: Based on the above discussion, 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). This approach will still provide a mechanism to protect infant health and safety and will align with international regulations.*

Fonterra Response:

- On proposal 7.6 in relation to Fluoride, 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*".

- Fonterra therefore recommend that the level be provided as per the existing standard for powdered infant formula products 24 ug/100kJ prior to reconstitution.

8.2 L-Carnitine

***FSANZ Proposed approach**: Based on the above considerations, FSANZ proposes that L-carnitine be listed as a mandatory substance in infant formula and should align with the permitted Codex and EU mandatory minimum of 0.3g/100 kJ. FSANZ also proposes that the current maximum level within Schedule 29 (0.8 mg/100 kJ) should be retained, however presented as a GUL to account for the natural variability of L-carnitine content in differing milks, provide flexibility for manufacturers and avoid trade barriers. This is based on a lack of evidence specific to infants or children indicating consumption of excess carnitine being linked with adverse health outcomes and the absence of a UL. Based on the safety conclusions of Codex STAN 72-1981 and A1102 – L-carnitine in Food, FSANZ proposes that L-carnitine should be permitted as L-carnitine hydrochloride and L-carnitine tartrate in Schedule 29.*

Fonterra Response:

- Fonterra supports L-Carnitine as a mandatory substance to be present in infant formula and as a voluntary substance to be present in follow on formula, at a minimum level of 0.29mg/100kJ. We note this aligns to CODEX STAN 72-1981 & 156-1987 and EU 2016/127 Regulations which mandate a minimum level of L-Carnitine in infant formula and optional addition in follow on formula. Both the EU SCF (2003) and EFSA (2014) similarly recommend L-Carnitine is mandated to ensure appropriate levels are present in all infant formulas due to the temporary inability of infants to synthesise sufficient L-Carnitine, however that L-Carnitine should not be mandatory for follow on formula due to the addition of other complementary food sources of L-Carnitine and sufficient endogenous synthesis in older infants (EU SCF 2003, EFSA 2014).

- Fonterra however does not support the FSANZ proposal to include a GUL for L-Carnitine. This is not aligned with the above-mentioned regulations and expert opinions which do not recommend any

maximum or GULs in the absence of an UL. Further, there is no evidence of any untoward effects of higher intakes of L-Carnitine in infants (Koletzko et. al. 2005).

- The only source of L-carnitine for this age group would be breastmilk or infant formula thus it is important that sufficient is provided, allowing for natural variation and manufacturing capability. We note the natural content of some dairy ingredients when used in infant formula products is likely to result in the proposed FSANZ GUL being exceeded. In particular, some whey protein ingredients commonly used in infant formula to adjust whey:casein ratios can contain a concentrated level of L-Carnitine and therefore contribute a large proportion of L-Carnitine to the proposed GUL. As a result, common dairy ingredients used in export infant formula products and in other markets would be limited in Australian and New Zealand formulations.
- This is further evidenced by a study from Woollard, Indyk & Woollard (1999) which indicated the level of L-Carnitine in dairy based infant formula would commonly exceed the proposed GUL level, and by the number of MPI Exemptions related to the L-Carnitine maximum levels in infant formula products for export. This clearly demonstrates that dairy based infant formulas would commonly contain L-Carnitine in excess of the GUL and that the proposed GUL does not account for the natural variation of L-Carnitine content of dairy ingredients.
- In summary, we believe there is a strong case to remove the GUL based on the inherent natural and variable content in dairy ingredients; technical challenges and evidence industry may not be able to consistently meet the GUL, higher levels of intake showing no untoward effects in this age group, international alignment in the literature and regulatory approach, as well as supporting trade to CODEX-aligned, EU and GB markets all of which do not specify a maximum L-Carnitine level in infant formula or follow on formula.

Other Comments

- There is significant inconsistency in conversion factors used in the Codex Infant Formula Standard to convert from the limits set per 100kcal to per 100kJ. These are reflected in the Food Standards Code due to use of per kJ limits only. This review provides the opportunity to correct the limits intended to align to the Codex Infant Formula Standard such that they consistently align with the primary reference limits set per 100kcal. We support the extensive INC corrections and comments outlined on this point.

Optional Ingredients

- Given the holistic review of P1028 we see an opportunity to consider if the term ‘may be used as a nutritive substance’ remains appropriate. We note this currently creates confusion and removal and replacement with an ‘optional ingredient’ approach used by Codex would support harmonisation with Codex and other jurisdictions. We understand this may be covered in Consultation paper 3 and we recommend the continued review of P1024 to address this.

Follow-on Formula:

- Fonterra support FSANZ’s decision to reintroduce follow-on formula within scope of P1028 as Standard 2.9.1 covers products 0-12 months. We support that different requirements be considered as recommended by INC including:
  - Protein minimum
  - Protein maximum
  - Depending on protein maximum applied for Follow-on formula INC may recommend some mineral maximums are reconsidered
  - When DHA is added, requirement for DHA to be no less that ARA
  - Vitamin D maximum
  - Calcium GUL
  - Iron minimum
  - Phospholipid upper limit
  - Choline, L-carnitine and inositol retained as voluntary rather mandatory

Renal Solute Load:

- Fonterra recommends the removal of the current limit on potential renal solute load for follow-on formula at the same time as changes are introduced in relation to infant formula, implementing the outcomes of P1028. This would better align with the Codex infant formula standard, the Codex follow-up formula standard and EU requirements for follow-on formula, none of which set a limit for potential renal solute load.

- Potential renal solute load is mainly determined by the protein content. It is INC's view that the protein requirements for follow-on formula suffice without the need for an additional potential renal solute load requirement. Furthermore, Fomon et al. (2000) states that healthy infants consuming a predominantly liquid diet have a sufficient renal concentrating ability to maintain water balance even if the diet would provide a PRSL comparable to cow's milk (46 mOsm/100 kcal or 11 mOsm/100kJ).

- Follow-on formula is not introduced before 6 months of age, and evidence from the WHO states that from the age of 4 months infants have matured renal function and metabolic interconversion system which can manage a higher dietary protein content (WHO 2003). As such, none of the Codex Infant Formula Standard, the revised draft Codex FUF Standard or the EU formula regulation stipulate provisions for PRSL in their provisions (SCF 2003, EFSA 2012). The current FSANZ potential renal solute load requirement results in unnecessary compliance costs that are not justifiable from a risk management perspective.

Guidance Upper Limits (GULs)

- We support FSANZ in permitting broader use of Guidance Upper Limits (GUL) where appropriate for certain nutrients. We note that page 53 of CP2 states that these are, "*recommended maximum amounts," and, "are not binding and serve as guidance for industry in deriving formulations*." We recommend that a GUL definition be included within the Code, and the terminology of guideline maximum amounts replaced with GUL to align this interpretation with Codex for consistency in application of terminology internationally.

Rounding

- While we haven't commented on individual rounding of nutrients, we support INC's consistent approach to a set number of significant figures for macro- and micro- nutrients.

Transition

- Fonterra recommend a five-year period plus an additional stock in trade provision should considered for transition. This period is considered appropriate given the significand number, scope and complexity of changes proposed (from both CP1 and 2) and would permit sufficient time to allow for the necessary planning, reformulation, packaging implementation. and regulatory permissions (e.g., exemptions from New Zealand standards for export products).

- While we acknowledge that the New Zealand requirement for gazetted exemptions from the New Zealand Food Act 2014 (and therefore relevant sections of the Joint Food Standards Code) is both outside of the jurisdiction of FSANZ, and the scope of the P1028 review, this is another factor that highlights the need for a lengthy transition period. One of the impacts of this New Zealand regulatory requirement, is that additional time will be required, and cost incurred by New Zealand manufacturers, to transition to a revised Infant Formula Standard.

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