Nestlé Submission

Consultation Paper 2 2021

Proposal P1028 - Infant Formula

02 September 2021

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Consultation Paper 2 2021: Proposal P1028 - Infant Formula

This submission is made on behalf of Nestlé Australia Ltd and Nestlé New Zealand Limited.

Nestlé is a manufacturer and importer of a wide variety of foods for the Australian and New Zealand markets and is globally one of the largest manufacturers of infant formula and other foods. Nestlé currently imports and markets infant formula products which are regulated in section 2.9.1 of the Australia New Zealand Food Standards Code ('the Code').

Nestlé welcomes the opportunity to consider the issues and preliminary views proposed in the consultation paper for Proposal 1028 (P1028), and to provide comment and information to Food Standards Australia New Zealand (FSANZ) relating to the Consultation paper on the Regulation of Infant Formula. We thank FSANZ for its consideration of the comments, issues and views raised in this submission.

Introduction:

Breast milk is the best nutrition for infants. Nestlé fully supports this and optimal breastfeeding for optimal health outcomes for infants. We welcome the consultative effort of FSANZ to determine the best nutrition advice and outcomes for Australian and New Zealand infants.

In situations where the infant cannot receive breast milk, an infant formula is the only suitable and safe alternative, as a sole source of nutrition. Nestlé advocates a science–based approach to formulating products for the health and well-being of infants and young children. It is important that health recommendations and regulations focus on the best interests of the child and are based on the latest body of scientific evidence.

Comments and Responses to Questions

Section 3: Energy

Nestlé supports the FSANZ proposal to maintain the current energy minimum of 2500 kJ/L and lower the maximum energy to 2950kJ/L in line with Codex STAN 72-1981[1].

Section 4: Protein

4.1 Calculation of Protein Content

FSANZ has proposed two options:

> *Option 1: Adopt 6.25 as the NCF for all protein sources.*
>
> *Option 2: Adopt all three NCF (5.71, 6.25, 6.38) to enable manufacturers to choose the NCF value most aligned to their formulation.*

Nestlé supports the FSANZ proposal for Option 1. The advantages of this approach are that:

- practical to apply and enforce
- it aligns with approaches that have been used in the most recent international regulations (EU 2016/127[2]) and standards (Draft Codex Standard for Follow-up Formula for Older Infants[3])

[1] Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants CXS 72-1981

[2] Commission Delegated Regulation (EU) 1026/127 of 25 September 2015 supplementing Regulation (EU) No 609/213 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding

[3] Report of the Forty-First Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses. Düsseldorf, Germany. 24 – 29 November 2019

- it is a scientifically valid NCF for dairy-based infant formula (in the most recent report from the JEMNU Expert Panel[4], an NCF value of 6.25 would be the closest of the three options proposed by FSANZ to the holistic view of total protein rather than amino acids)
- this NCF can be applied to other proteins e.g. soy-based protein as long as the minimum protein amount is adjusted

4.2 Protein Range

4.2.1 Milk-based

Nestlé supports the FSANZ proposal for a protein range of 0.43 – 0.7 g/100kJ, aligned with recent International regulations[1,2]. However, we consider that it should not be limited to cows' milk-based formulas but also applied to goats' milk based infant formula products.

1.8g/100kcal represents the latest scientific evidence on low protein, with low protein infant formula recommended by the NHMRC Infant Feeding Guidelines[5] and most recently by FISPGHAN[6] as an effective obesity risk prevention measure globally. Also, it has recently been demonstrated to be cost-effective in reducing obesity risk[7]. Data now exists on reducing fat mass to 6 years of age[8] and equivalent mental performance at 8 years of follow-up[9].

The current FSANZ regulatory minimum of 0.45g/100kJ (1.88g/100kcal) would not allow harmonisation with Codex and EU at low protein levels. The aligned minimum would allow formulation closer to the levels clinically tested[10][11][12][13].

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[4] The Joint FAO/WHO Expert Meetings on Nutrition (JEMNU): nitrogen to protein conversion factors for soy-based and milk-based ingredients used in infant formula and follow-up formula. Report of the meeting of the expert panel, Geneva, Switzerland, 16–17 July 2019. Geneva: World Health Organization and Food and Agriculture Organization of the United Nations; 2020. Licence: CC BY-NC-SA 3.0 IGO

[5] National Health and Medical Research Council (2012) Infant Feeding Guidelines. Canberra: National Health and Medical Research Council.

[6] Koletzko B, Fishbein M, Lee WS, Moreno L, Mouane N, Mouzaki M, Verduci E. Prevention of Childhood Obesity: A Position Paper of the Global Federation of International Societies of Paediatric Gastroenterology, Hepatology and Nutrition (FISPGHAN). J Pediatr Gastroenterol Nutr. 2020 May;70(5):702-710.

[7] Sonntag D, De Bock F, Totzauer M, Koletzko B. Assessing the Lifetime Cost-Effectiveness of Low-Protein Infant Formula as Early Obesity Prevention Strategy: The CHOP Randomized Trial. Nutrients. 2019 Jul 19;11(7):1653.

[8] Totzauer M, Luque V, Escribano J, Closa-Monasterolo R, Verduci E, ReDionigi A, Hoyos J, Langhendries J-P, Gruszfeld D, Socha P, Koletzko B, Grote V for The European Childhood Obesity Trial Study Group. Effect of Lower Versus Higher Protein Content in Infant Formula Through the First Year on Body Composition from 1 to 6 Years: Follow-Up of a Randomized Clinical Trial. Obesity (2018) 26, 1203–1210.

[9] Escribano J, Luque V, Canals-Sans J, Ferré N, Koletzko B, Grote V, Weber M, Gruszfeld D, Szott K, Verduci E, Riva E, Brasselle G, Poncelet P, Closa-Monasterolo R; EU Childhood Obesity Project Group. Mental performance in 8-year-old children fed reduced protein content formula during the 1st year of life: safety analysis of a randomised clinical trial. Br J Nutr. 2019 Sep;122(s1):S22-S30.

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[11] Räihä NCR; Fazzolari-Nesci A; Cajozzo C; Puccio G; Monestier A; Moro G, Minoli I, Haschke-Becher E, Bachmann C; Van't Hof M, Carrié Fässler A.-L, Haschke F. Whey Predominant, Whey Modified Infant Formula with Protein/energy Ratio of 1.8 g/100 kcal: Adequate and Safe for Term Infants From Birth to Four Months. Journal of Pediatric Gastroenterology and Nutrition (2002) 35(3):275-281

[12] Turck D, Grillon C, Lachambre E, Robiliard P, Beck L, Maurin JL, Kempf C, Bernet JP, Marx J, Lebrun F, Van Egroo LD. Adequacy and safety of an infant formula with a protein/energy ratio of 1.8 g/100 kcal and enhanced protein efficiency for term infants during the first 4 months of life. J Pediatr Gastroenterol Nutr. (2006) Sep;43(3):364-71.

[13] Alexander DD, Yan J, Bylsma LC, Northington RS, Grathwohl D, Steenhout P, Erdmann P, Spivey-Krobath E, Haschke F.(2016) Growth of infants consuming whey-predominant term infant formulas with a protein content of 1.8 g/100 kcal: a multicenter pooled analysis of individual participant data. Am J Clin Nutr. Oct;104(4):1083-1092.

4.2.2 Soy-based

Nestlé supports the FSANZ proposal for a protein minimum of 0.54 g/100kJ, based on using an NCF of 6.25.

In addition, we suggest that consideration is given to the potential for future innovation using other plant proteins, demonstrated safe and suitable for infants. FSANZ may wish to consider adding a footnote similar to footnote 5 from Codex STAN 72-1981[1] which highlights that other minimum values may need to apply for formulas based on other non-milk proteins.

4.3 Protein Source

Nestlé does not agree with FSANZ's proposed approach to prescribing a positive list of permitted protein sources. Protein sources used in the manufacture of infant formula should be demonstrated safe and suitable for use in infant formula products.

The proposal for changes to the Code should consider future innovation, including new protein. However, there are safeguards in place to ensure safety and suitability of new protein sources. For example, novel foods are already required to undergo pre-market assessment, and this would include

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

Novel sources of protein are already required to be approved through the pre-market assessment process.

4.4 Protein Quality

Nestlé agrees with the FSANZ proposal that protein quality remain based on minimum amino acid amounts.

Nestlé notes that the CCNFSDU propose protein quality for Follow-up formula for older infants 6 – 12 months is based on minimum amino acid amounts. Whereas PDCAAS is the preferred measure of the protein quality for Follow-up formula for young children[3].

4.5 Amino Acid Content

Nestlé strongly supports the FSANZ proposal to align the minimum amounts of all amino acids with Codex STAN 72-1981[1] and to define the ratio of methionine to cysteine and for tyrosine to phenylalanine in Schedule 29. This approach ensures regulations do not inadvertently lead to the unnecessary addition of individual amino acids.

In addition, the wording of the additional note regarding the methionine to cysteine ratio should include the option for clinical evaluation of the suitability for formulas with methionine to cysteine ratios greater than 2. This is consistent with both Codex STAN 72-1981[1] and EU Regulation 2016/127[2].

We note that manufacturers (both local and imported) may need to amend recipes that are currently supplementing with L-methionine to meet regulatory minimums and suggest consideration of an appropriate transition period.

Section 5: Fat

5.1 Fat Content

Nestlé supports the FSANZ proposal for alignment with International regulations however a rounding correction should be applied such that the fat range is 1.05 – **1.44** g/100kJ.

5.2 Units of Expression

Nestlé supports the FSANZ proposal to align the units of expression with Codex and EU. Limits for linoleic acid (LA), alpha-linolenic acid (ALA) and docosahexaenoic acid (DHA) should be expressed per 100kJ.

5.3 Essential Fatty Acid Composition LA and ALA

FSANZ has proposed two options for LA minimum:

> ***Option 1:*** *Adopt EU 2016/127 minimum LA level of 120 mg/100 kJ. This option supports alignment with the most recently updated regulation standards and alignment with the minimum LA levels noted within breast milk of the ANZ population.*
>
> ***Option 2:*** *Retain the current minimum LA level of 90 mg/100 kJ within Standard 2.9.1 (S29—8). This option migrates risks surrounding infant formula stability and palatability when LA levels are increased. It also represents the best available option for alignment with Codex and would mitigate risk of reformulation or trade implications*.

Question 3. Do you support retaining the current minimum requirement for LA (9% total fatty acids) in infant formula? Please provide your rationale and any supporting evidence.

Nestlé can support Option 2 to retain the current minimum expressed as mg/100kJ. FSANZ risk assessment along with many years of no market failure confirm this approach is safe and suitable for infants. It is more feasible to align this option with the proposed approach for the maximum for linoleic which is that of Codex STAN 72-1981. Also the ratio of LA : ALA is retained in alignment to Codex STAN 1981.

5.4 Long Chain Polysaturated Fatty Acid and Other LC-PUFA, Ratio and Sources

Nestlé supports the FSANZ proposal to retain the current voluntary permission for DHA and AA provided the content of DHA does not exceed the AA amount. We understand that it is FSANZ intent to set a guideline upper limit (GUL) for DHA in the units mg/100kJ (Section 5.2).

Nestlé does not agree with the proposal to set the GUL as 7.2 mg/100kJ in alignment with Codex STAN 72-1981). Instead, we suggest consideration of 12 mg/100kJ (GUL) as in EU Regulation 2016/127. This would allow DHA addition towards the recommendation of Koletzko *et al*., 2020[6] where preferably DHA reaches 0.5% fatty acids.

The content of LC PUFA should not exceed 2 % of the total fat content for n-6 LC PUFAs and 1 % of the total fat content for arachidonic acid.

In addition, that EPA should be no more than DHA where LC-PUFAs are present.

5.5 Fat Source

Nestlé agrees with the Option 1: Retain current approach which restricts specific fats and no further definition of fat source. This aligns to the FSANZ preferred approach and is consistent with international regulations.

5.6 Restrictions of Certain Fats

5.6.1 Medium Chain Triglycerides

Nestlé notes that the FSANZ proposal is not in line with international regulations that do not include a restriction on medium chain triglycerides however we can accept the status quo.

5.6.2 Trans Fatty Acids

Nestlé supports the FSANZ proposal to retain the status quo given that the definition for trans fatty acids differs between the Food Standards Code and that in the Codex Standards.

5.6.3 Phospholipids

FSANZ proposed three options for phospholipid permissions:

Option 1 - Restricting the phospholipid content to 2g/L
Option 2 - Restricting the lecithin content to 1 g/L
Option 3 - Both (1) and (2)

Nestlé supports Option 1, to include a maximum permitted amount of phospholipid at 2 g/L (72 mg/100kJ) in alignment with Codex STAN 72-1981 and EU 2016/127. We do not view it to be necessary to amend the maximum permitted limit for lecithin from 5g/L to 1g/L, as any concerns relating to phospholipids from lecithin would be directly addressed by a restriction to the phospholipid content.

We do not consider there to be an inconsistency in the Code if Option 1 were to be implemented. The limit for phospholipids would apply to the total phospholipid content, which would include phospholipids from lecithin as well as other sources (e.g. LC-PUFA, vegetable oils, milk fat), whereas the existing limit in Schedule 15 is specific to lecithin as a food additive. Manufacturers would need to comply to both limits.

Section 6: Carbohydrate

6.1 Definitions and Calculations Relevant to Carbohydrate Identity

Nestlé supports the FSANZ proposal to retain the status quo and continue with the definitions for ‘carbohydrate’, ‘available carbohydrate’ and ‘carbohydrate by difference’ set out Standard 1.1.2.

6.2 Dietary Fibre

Nestlé supports the FSANZ proposal to make no change to the existing requirements. The Code is aligned with Codex STAN 72-1981 and EU 2016/127 in not prescribing methods of analysis for dietary fibre.

6.3 Carbohydrate Source

FSANZ proposed three options regarding provisions for the source of carbohydrate:

Option 1: Retain current Standard 2.9.1 (no restrictions on carbohydrate source)

Option 2: Adopt limits on sucrose and fructose that are aligned with Codex STAN 72-1981 guidance

Option 3: Adopt guidelines from EU 2016/127 and set a list of permitted carbohydrates

Nestlé supports the FSANZ proposal to accept Option 2 and align limits on sucrose and fructose with Codex *STAN 72-1981*. Imposing limits on other carbohydrate sources, as per Option 3 and EU 2016/127, could potentially create a trade barrier, particularly for IFPSDU which share formulations with non-EU aligned markets.

6.4 Permitted range for total carbohydrate content

Nestlé supports the FSANZ proposal to retain the current approach in Standard 2.9.1. which does not specify a permitted range for carbohydrate content.

Section 7: Micronutrients

7.1 Guideline and Maximum Amounts

Nestlé supports the FSANZ proposal to maintain maximums for vitamins A and D, iron and electrolytes chloride, sodium and potassium. We suggest that GULs are set for selenium and

iodine are which would be aligned to Codex STAN 72-91981 and the revised draft Codex Standard for Follow-up Formula for Older Infants.

We support the FSANZ proposal to maintain GULs for vitamins B_{12}, C and K, niacin, thiamin, riboflavin, pantothenic acid, folic acid and biotin and for calcium.

We support the FSANZ proposal outline in Section 7.3.7 to remove the GUL for chromium and molybdenum for infant formula.

Also, we support the FSANZ proposal to change maximums to GULs for vitamin B_6 and E and for minerals copper, magnesium, manganese, phosphorous and zinc.

7.2 Vitamin Equivalents and Conversion Factors

Nestlé supports the FSANZ proposals for:

- vitamin A to be expressed as µg RE/100kJ and exclude β-carotene from the vitamin A calculation
- folic acid to be expressed as µg folic acid/100kJ
- the adoption of α-TE as the units for vitamin E
- maintaining the status quo for preformed niacin

7.3 Permitted Ranges for Micronutrients

Permitted range is aligned with Codex

Nestlé supports the FSANZ proposal to maintain the vitamin A range of 14 – 43 µg/100kJ.

Nestlé supports the FSANZ proposal to maintain the vitamin D range of **0.24** – 0.6µg/100kJ, amended to align with Codex value per 100 kcal. We agree that the current minimum is unlikely to pose a risk to infant health and that the range allows for product formulation and manufacture in compliance with these requirements.

Permitted range is not aligned with Codex

Nestlé supports the FSANZ proposals to align the ranges set out in Codex STAN 72-1981 for each of the following vitamins, minerals and electrolytes: vitamin B_{12}, vitamin E, niacin, pantothenic acid, folic acid, magnesium, zinc, manganese, calcium, sodium, potassium, and chloride. Where appropriate revised based upon the conversion from 100 kcal.

Nutrient	Units	Proposed minimum	Proposed maximum/GUL
Vitamin B_{12}	µg/100kJ	0.024	0.36 (GUL)
Vitamin E (α-TE)	mg/100kJ	0.12	1.2
Niacin	µg/100kJ	72	360 (GUL)
Pantothenic acid	µg/100kJ	96	480 (GUL)
Folic acid	µg/100kJ	2.4	12 (GUL)
Magnesium	mg/100kJ	1.2	3.6 (GUL)
Zinc	mg/100kJ	0.12	0.36 (GUL)
Manganese	µg/100kJ	0.24	24 (GUL)
Calcium	mg/100kJ	12	33 (GUL)
Sodium	mg/100kJ	4.8	14
Potassium	mg/100kJ	14	43
Chloride	mg/100kJ	12	38

Vitamin K, thiamin, riboflavin, vitamin B_6 and biotin

Nestlé supports the FSANZ proposal to adopt a minimum for vitamin K of 0.24 µg/100kJ, aligned to EU regulation 2016/127. Nestlé continues to support the FSANZ proposal from 2016, to adopt the Codex GUL of 6.5 µg/100kJ from Codex STAN 72-1981 as FSANZ considered this was unlikely to pose risk to infant health.

Nestlé agrees with the FSANZ rationale to retain the current minimum for thiamin in Standard 2.9.1 of 10µg/100kJ. Nestlé continues to support the FSANZ proposal from 2016, to adopt the GUL from Codex STAN 72-1981of 72 µg/100kJ as FSANZ considered this was unlikely to pose risk to infant health. Also, this is aligned to EU Regulation 2016/127, Codex STAN 72-1981 and the draft Codex Follow-up Formula Standard for Older Infant.

Nestlé supports the FSANZ proposal to maintain the current riboflavin minimum level of 14µg/100kJ which is aligned with the EU regulation 2016/127. Nestlé does not agree with the FSANZ proposal to adopt the GUL from EU Regulation 2016/127. Instead, we support aligning with the GUL from Codex STAN 72-1981 at 120 µg/100kJ.

Nestlé supports the FSANZ proposal to adopt the minimum level for vitamin B_6 from Codex STAN 72-1981 of 8.4 µg/100kJ. Nestlé continues to support the FSANZ proposal from 2016, to adopt the GUL from Codex STAN 72-1981of 42 µg/100kJ as FSANZ considered this was unlikely to pose risk to infant health. of 42 µg/100kJ. Also, this aligns with EU Regulation 2016/127 and the draft Codex Standard for Follow-up Formula for Older Infants.

Nestlé supports the FSANZ proposal to adopt the EU Regulation 2016/127 minimum for biotin of 0.24 µg/100kJ. Nestlé continues to support the FSANZ proposal from 2016, to adopt the GUL from Codex STAN 72-1981 of 2.4 µg/100kJ as FSANZ considered this was unlikely to pose risk to infant health.

7.3.4-6 Phosphorus, Copper & Vitamin C

Nestlé supports the FSANZ proposal to maintain the minimum for phosphorus of 6 mg/100kJ This range is aligned to Codex STAN 72-1981 and EU Regulation 2016/127. Also, to change to a GUL of 24 mg/100kJ.

Nestlé supports the FSANZ proposal to adopt the range for copper of 8.4-29 µg/100kJ which is aligned to Codex STAN 72-1981.

Nestlé supports the FSANZ proposal to adopt a vitamin C GUL of mg/100 kJ, aligned with Codex STAN 72-1981.

7.3.7 Chromium and Molybdenum

Nestlé supports the FSANZ proposal to remove the GUL for chromium and molybdenum for infant formula.

Nestlé does not support the FSANZ proposal to retain the current requirements for chromium and molybdenum, noting that FSANZ has not yet set out its preliminary approach to categories of IFPSDU.

Regulation (EU) 2016/128 did not set minimum amounts. Codex STAN 72-1981 Part B specifies a minimum for chromium and molybdenum in section 3.1.4, ‘where appropriate’.

Regarding the maximum, the NHMRC noted that there is insufficient information to establish an estimate UL in infants for chromium and molybdenum.

If FSANZ does retain a GUL for chromium and molybdenum, then Nestlé suggests alignment of with the GUL in Codex STAN 72-1981 Part B and EU Regulation 2016/128 of 2.4 µg/100kJ for chromium. For molybdenum, a GUL of 3.3 µg/100kJ aligned to EU Regulation 2016/128

7.3.8 Iodine

Nestlé opposes the FSANZ proposal for an iodine range of 3.6 – 10 µg/100kJ.

Nestlé suggests that further consideration is given to adopting an iodine range of 2.4-14µg/100kJ, aligned with Codex STAN 72-1981.

FSANZ proposes a reduction in the iodine range, which is an issue for manufacturers. The iodine content of raw materials, particularly dairy ingredients, is very variable due to seasonal, hygiene and agricultural practices. Manufacturers do not target the minimum or maximum due the need to allow for variance, hence the levels in most products will not be near either the minimum or maximum on a continuous basis.

Nestlé notes that in 2016, FSANZ determined that Codex range would be unlikely to pose a risk to health.

7.3.9 Zinc and Zinc: Copper Ratio

Nestlé supports the FSANZ proposal to adopt the range of 0.12-0.36 mg/100kJ for zinc which is aligned to Codex STAN 72-1981 and the removal of the prescribed Zn:Cu ratio for infant formula.

7.3.10 Iron

Nestlé has reservations regarding the FSANZ proposal to retain the current iron range. The proposed range does not allow for harmonisation of recipes with EU. This is of particular concern for IFPSDU required in small volume to meet the specific requirements of certain infants. For example, a product designed under both EU and Food Standards Code requirements would have to meet an iron range of 0.20–0.31mg/100kJ. Manufacturers do not target the minimum to allow for variation during manufacture and analysis. The recent review of EFSA[14] allowed for a greater proportion of the iron requirements of older infants to come from complementary feeding.

Also, we note the recent review of EFSA[14] and the ESPGHAN Committee on Nutrition[15] that have indicated further study of the optimal levels of iron fortification between 6 and 12 months are warranted. This follows some emerging evidence where higher iron intakes in iron replete individuals have been associated with increased risk of infection, reduced growth and poorer cognitive outcomes.

We request that FSANZ consider widening the range to include, as a minimum, the EU minimum for infant formula products for infants 0-12 months (0.14 – 0.5 mg/100kJ) to give flexibility for recipe harmonisation with Codex and EU, particularly for IFPSDU.

7.3.11 Selenium

Nestlé could accept the FSANZ proposal to adopt the selenium minimum of 0.48µg/100kJ for infant formula for healthy infants. However, the proposed selenium minimum could prevent supply of some IFPSDU where the recipes are aligned to the Codex Standard which has a minimum of 2.4ug/100kJ. In addition, we would request further consideration of adopting a GUL of 2.2µg/100kJ aligned with Codex STAN 72-1981.

We note that whilst there is a theoretical exceedance of the UL for young children, FSANZ found no evidence of excess intakes or associated adverse health effects. Manufacturers do not generally target the minimum or maximum/GUL. Aligning with to the Codex GUL of 2.2ug/100kJ facilitates ingredient and recipe harmonisation and better supports trade.

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[14] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760.

[15] Domellöf M, Braegger C, Campoy C, Colomb V, Decsi T, Fewtrell M, Hojsak I, Mihatsch W, Molgaard C, Shamir R, Turck D, van Goudoever J; ESPGHAN Committee on Nutrition. Iron requirements of infants and toddlers. J Pediatr Gastroenterol Nutr. 2014 Jan;58(1):119-29.

7.4 Other Ratios, Equivalents and Nutrient Interactions

Nestlé supports the FSANZ proposal to change the Ca:P minimum ratio of 1.2:1 to the Codex Ca:P minimum ratio of 1:1, whilst maintaining the existing maximum Ca:P ratio of 2:1.

Also, to retain the current Vitamin E ratio requirement and to remove the Zn:Cu ratio.

7.5 Permitted Forms of Vitamins, Minerals and Electrolytes

Nestlé supports the FSANZ proposals for further alignment with Codex and in addition the comments set out in the INC response.

7.6 Fluoride

Nestlé recommends that if a fluoride maximum is set based on infant formula prepared ready for consumption as recommended by the manufacturer, then the maximum should be aligned with Codex STAN 72-1981 of 24µg/100 kJ.

Section 8 Other Optional Substances

8.1 Choline

Nestlé supports the FSANZ proposal for choline to be listed as a mandatory substance in infant formula with a range of 1.7–12.0 mg/100 kJ, to align with the Codex STAN 72-1981.

8.2 L-Carnitine

Nestlé supports that L-carnitine should be mandatory in infant formula. We recommend that the minimum content is conversion corrected to 0.29 mg/100kJ (1.2 mg/100kcal).

Nestlé appreciates that FSANZ is now proposing a GUL however we do not consider that a GUL is necessary given the absence of an UL. Not specifying a maximum or GUL would be in line with other International regulations such as Codex STAN 72-1981 and EU 2016/127.

There are both nutritional and technical reasons for not setting a limit. In the absence of indications of any untoward effects of higher L-carnitine intakes in infants, ESPGHAN concluded that no maximum level needed to be set[16].

The only source of L-carnitine for this age group would be breast milk or infant formula thus it is important that sufficient is provided, allowing for natural variation and manufacturing capability. The GUL is likely to be exceeded because of natural and variable contribution of L-carnitine from cow or goat milk to the infant formula base. Wollard, Indyk & Wollard analysed the level of L-carnitine in a range of infant formulas[17]. Their survey indicated a range of values from 6.9-30.1mg/100g.

8.3 Inositol

Nestlé supports the FSANZ proposals for inositol to be listed as a mandatory substance in infant formula with a range of **0.96** – 9.5 mg/100 kJ, the latter being a GUL to align with the Codex STAN 72-1981. The recommended minimum being corrected value of the per 100kcal value.

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[16] Koletzko B, Baker S, Cleghorn G, Neto UF, Gopalan S, Hernell O, Hock QS, Jirapinyo P, Lonnerdal B, Pencharz P, Pzyrembel H, Ramirez-Mayans J, Shamir R, Turck D, Yamashiro Y, Zong-Yi D. Global standard for the composition of infant formula: recommendations of an ESPGHAN coordinated international expert group. J Pediatr Gastroenterol Nutr. 2005 Nov;41(5):584-99.

[17] Woollard DC, Indyk HE, Woollard GA. Enzymatic determination of carnitine in milk and infant formula. Food Chemistry (1997) 59 (3), 325-332

8.4 Nucleotides

Nestlé supports the FSANZ proposals for the continued inclusion of nucleotides as optional ingredients and to retain the status quo for both individual maximums and combined total.

We remain of the view expressed in 2016 that Australia and New Zealand are out of step globally in setting a minimum, when added, for nucleotides. No minimums are set by the US, Canada or the EU.

General question related to the Consultation paper

Question 1 In addition to your submissions from previous Consultations for this Proposal, do you have any further comments on how any of our proposed options in this paper would affect market opportunities for infant formula? Please provide evidence of practical barriers and quantify impacts where possible.

Nestlé urges FSANZ not to lose momentum with the revision to Food Standard 2.9.1 and Schedule 29. The ongoing delays result in re-work for both FSANZ and the industry, has the potential for products to be de-listed as recipes cannot remain harmonised with other markets and the uncertain timings delay bringing innovation to market. In particular, expanding the scope to include follow-on formula should not further delay gazettal.

<u>Transition Period</u>

Nestlé would like to highlight that compositional changes will require a suitable transition period to allow for reformulation, with some infant formula products having a 3-year shelf-life. Equally, it should be possible to move to a harmonised recipe immediately after gazettal where such a recipe is available. Also, some products may be listed in the Australian Pharmaceutical Benefits Scheme (PBS) or New Zealand Pharmac Pharmaceuticals Schedules which require notification of changes.

<u>IFPSDU Composition</u>

Nestlé requests consideration for the flexibility to align all nutritional compositional requirements for IFPSDU to Codex, EU or USA standards, if it otherwise prevents the sale of such products. These products are typically required in very small quantities and are used under medical supervision. The requirement for market specific reformulation limits availability and can add to the cost of the product for both consumers, and where publicly funded, to government.

<u>Follow-on Formula</u>

Nestlé provides some initial comment on considerations for follow-on formula, although further review is required.

Nestlé would like to highlight that FSANZ only recently assessed an application to vary the minimum protein requirement in follow-on formula. We would strongly support retaining the protein minimum for a milk-based follow-on formula as no less than 0.38 g/100 kJ.

Amending the maximum protein was beyond the scope of Application A1173. We suggest adopting the infant formula protein maximum (0.72 g/100kJ) which is aligned with the revised draft Codex Standard for FuF for Older Infants.

Vitamin and mineral ranges could be widened where appropriate to safety and to meet the nutritional needs of this older age group. Particularly this should be considered where it would increase the opportunity for harmonised recipes.

Choline, carnitine and inositol should be retained as voluntary additions.