AUSTRALIAN FOOD & GROCERY COUNCIL

2 September 2021

FSANZ

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Dear Standards Management

Proposal P1028– Infant Formula Products Consultation paper 2 – Nutrient Composition

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, drink and grocery manufacturing industry. The membership of AFGC comprises more than 180 companies, subsidiaries and associates which constitutes in the order of 80 per cent of the gross dollar value of the processed food, beverage and grocery products sectors in Australia.

The AFGC appreciates the opportunity to provide comments on Proposal P1028– Infant Formula Products Consultation paper 2 – Nutrient Composition: the focus of which is nutrient composition for macronutrients and energy, vitamins and minerals, permitted forms and other nutritive substances.

The consultation documents have been reviewed and the comments below relate to these specific documents.

The AFGC supports government policies for the protection and promotion of breastfeeding and recognises the role of scientifically-developed infant formula product as the only suitable and safe alternative when breast milk is unavailable for an infant.

In response to the consultation, the AFGC has had the opportunity to review the submission to this consultation by the **Infant Nutrition Council of Australia and New Zealand** (**INC**).

The AFGC strongly supports the INC's positions as stated in its submission and shares the concerns that the INC has described in detail.

COMMENTS

The AFGC wishes to make a few specific comments, as tabled below, in relation to this Proposal.

Section	AFGC Comments
Scope (section 2)	• Notes that FSANZ has advised that the scope of P1028 will be expanded to include **Follow-on Formula**. • Supports that Follow-on Formula be included in the scope of P1028 in its response to P1028 CP1 2021. • Recommends that the term 'GUL' (Guidance Upper Limits**)** is used and defined (as described in CP2) within the Food Standards Code replacing the use of guideline maximum amounts.
Energy (section 3)	• Supports the **lowering the maximum energy** content to 2950 kJ/L in line with Codex STAN 72-1981.

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Section	AFGC Comments
Protein (section 4) 4.1 Calculation of protein content	• Supports **Option 1 Adopt 6.25** as the nitrogen conversion factor (**NCF**) for all protein sources for calculation of protein content such that it be updated to align with the full Codex STAN 72-1981 NCF footnote. • However, it does **not** support that whey-based infant formula is distinguished from other dairy infant formula in the choice of NCFs. • If FSANZ was to proceed with **Option 2** Adopt all three NCF (5.71, 6.25, 6.38), the AFGC would only support this approach if whey vs. other dairy formula NCFs were not distinguished. The AFGC would in this case support 6.38 or 6.25 to be used for all dairy formula, regardless of whether whey-based or other dairy formula.
4.2 Protein range	• Supports FSANZ proposal to **prescribe a permitted protein range of 0.43 – 0.7g/100 kJ** for cows' milk-based infant formula. • However, it recommends that this range is applied for all milk based infant formula products. • Supports to retain the protein maximum aligned with Codex STAN 72-1981.
4.3 Protein source	• Does **not** support proposed approach to prescribing permitted protein sources as this is not aligned with the Codex approach. • Supports Codex STAN 72-1981 definition of infant formula as a product based on: *'milk of cows or other animals or mixture thereof and other ingredients proven to be suitable for infant feeding'* • If FSANZ was to proceed with a prescribed list, further consideration needs to be given to protein sources in products already on the market, such as plant-based proteins e.g. rice.
4.4 Protein quality	• Supports protein quality for infant formula should continue to be regulated by mandating minimum amino acid amounts comparable to those found in breastmilk. • This is consistent with EU Regulation 2016/127 and Codex STAN 72-1981.
4.5 Amino acid content	• Supports the approach to align the minimum amounts of all amino acids with Codex STAN 72-1981, including combined totals and ratio for SAA, methionine and cysteine, and the AAA, tyrosine and phenylalanine. • Inclusion of a combined total and ratio is important to avoid unnecessary fortification. • Note: the change for cysteine and methionine means any manufacturers with a cysteine level between 6 and 9 who are fortifying with methionine will need to change the formulations concerned.
Fat (section 5) 5.1 Fat content	• Supports the **proposed levels** to align with Codex STAN 72-1981 and further recommends three significant places be applied to support a rounding to 1.44 g/100kJ.
5.2 Units of expression	• Supports the alignment with Codex fatty acid units as proposed.
5.3 Essential fatty acid composition: LA and ALA	• Supports **Option 2** and the **retention** of the current minimum requirement for LA within Standard 2.9.1 (Schedule 29—8) which equates to 90 mg/100kJ which allows for the lower end of the LA:α linolenic acid (**ALA**) ratio of 5:1 to be achieved.

Section	AFGC Comments
5.4 Long chain polyunsaturated fatty acids & other LC-PUFA, ratios & sources	• Supports docosahexaenoic acid (**DHA**) **remaining optional** together with the requirement of DHA being no higher than arachidonic acid (**AA**) when added. • However, the guidance upper limit (**GUL**) should be increased from 0.5 to 1.0% of fat to 14 mg/100kJ.
5.5 Fat Source	• Supports **Option 1**, to maintain the current approach, which restricts specific fats and no further definition of fat source.
5.6 Restriction of certain fats	• Does not support the maintenance of the current restriction on medium chain triglycerides (**MCT**) as is not aligned to Codex or EU. • Recommends that if the restriction on **MCTs** is to remain, the definition of MCT be clarified to include 'oil'. "*medium chain triglyceride oil means oil containing triacyglycerols that contain predominantly the saturated fatty acids designated by 8:0 and 10:0*." • Supports the proposed approach of maintaining the current restriction of 4% total fatty acids (**TFA**) for TFA. • Supports **Option 1**, if FSANZ pursues a UL for total **phospholipids** but with the limit being a GUL of 2g/L. • Supports maintaining the status quo for **myristic, lauric and erucic acids.**
Carbohydrate (section 6) 6.2 Dietary fibre	• Supports the recently approved new method of analysis of fibre (A1178) as the preferred voluntary method. This new method (AOAC 2017.16) detects non-digestible oligosaccharides, galacto-oligosaccharides (GOS) and isomalto-oligosaccharides (IMO). At present there is no single method of analysis that can comprehensively measure all low and high molecular weight dietary fibre. AOAC 2017.16 is the most comprehensive method FSANZ has assessed to date. • Recommends **a review of the definition of dietary fibre** to align internationally and to consider other physiological effects such as are included in the EU definition. For example, galacto-oligosaccharides (**GOS**) have beneficial physiological effects that are not included under the current Code definition.
6.3 Carbohydrate source	• Supports **Option 1**, **maintaining the current approach** in Standard 2.9.1 and not to include provisions relating to carbohydrate source. • Strongly opposed to a positive list of permitted carbohydrates because it is counter to the approach of minimum effective regulation.
6.4 Permitted range for total carbohydrate content	• Supports **retention of the current approach** of not specifying a permitted range for carbohydrate content.
Micronutrients (section 7) 7.1 Guideline &maximum amounts	• Supports maintaining maximums for vitamins **A and D** and minerals **chloride, sodium, potassium and iron**. • Recommends GULs for **selenium and iodine** that are aligned to Codex and the draft revised Codex Standard for Follow-up Formula (**FuF**). • Supports maintaining GULs for **vitamins K and C, niacin, thiamine, riboflavin, pantothenic acid, folic acid, vitamin B12, biotin and calcium.** • Supports removal of GULs for **chromium and molybdenum** for infant formula. • Supports changing maximums to GULs for **vitamins E and B6** and minerals **phosphorus, magnesium, copper, zinc and manganese** as well as **selenium and iodine,** as noted above.
7.2 Vitamin equivalents & conversion factors	• Supports **vitamin A** being expressed as mg RE/100kJ and the exclusion of β-carotene from the vitamin A calculation. • Supports the proposal to express **folic acid** as mg folic acid/100kJ only and supports the non-inclusion of naturally occurring folate. • Supports the adoption of **α-TE** as the units for vitamin E to indicate the relative activities of natural and synthetic forms of α-tocopherol. • Supports maintaining the current requirement of preformed **niacin**.

Section	AFGC Comments
7.3 Permitted ranges for micronutrients	• Supports maintaining the **vitamin A** maximum and therefore maintaining the current levels for vitamin A. • Supports maintaining the current range for **vitamin** D for infant formula • Recommends reviewing the maximum level of vitamin D for older infants and increasing in line with these international standards - Codex Standard for FUF is 0.72 mg/100kJ. • Supports the alignment of **niacin, pantothenic acid, folic acid, B12 magnesium, sodium, potassium, manganese, calcium and chloride** to Codex STAN 72—1981 • Supports alignment of **Vitamin E** range to Codex but set a slightly higher minimum of 0.14 mg/100kJ (0.60 mg/100kcal) with no additional vitamin E PUFA requirement. • Supports alignment with higher GUL for **calcium** for the older age group for older infants - 43 mg/100kJ - in the draft revised Codex Standard for FuF. • Supports adopting the EU minimum for **vitamin K** and the Codex GUL to provide a range of 0.24-6.5 mg/100kJ • Supports retention of the current minimum for **thiamin** in Standard 2.9.1 of 10 mg/100kJ, and recommends a GUL of 72 mg/100kJ aligned to EU Regulation 2016/127, Codex STAN 72-1981 and the draft Codex Follow-up Formula Standard for Older Infants. • Supports maintaining the current **riboflavin** minimum level of 14 mg/100kJ, and aligning the GUL to Codex at 120 mg/100kJ rather than EU 95.6 mg/100kJ. • Supports adoption of the Codex minimum level for **vitamin B6** to provide a range of 8.4 – 42 mg/100kJ, and that the GUL is 42mg/100kJ (175 mg/100kcal) rather than 45 mg/100kJ. • Supports the adoption of the EU minimum for **biotin** and alignment with the Codex GUL to provide a range of 0.24 – 2.4 mg/100kJ. • Supports these proposals for **phosphorous** (Codex aligned minimum and a GUL). • Supports the adoption of the Codex range for **copper.** • Supports the approach of maintaining the **Vitamin C** current levels in the Food Standards Code of 1.7 mg/100kJ and not increasing to align with Codex STAN72-1981. • Supports the approach proposed to increase the GUL of vitamin C from 5.4 mg/100kJ to the level in Codex STAN 72-1981 of 17 mg/100kJ. • Supports the removal of the current GUL for **chromium and molybdenum** in alignment with Codex STAN 72-1981 for infant formula. • Recommends adopting an **iodine** minimum of 2.5 µg/100kJ and GUL of 14 µg/100kJ (not as a maximum) as to align with the Codex STAN 72-1981 level. • A GUL instead of a maximum level for iodine best accommodates for natural and extensive variation and manufacturing capability. • Supports alignment with the permitted range in Codex STAN 72-1981 which includes a maximum that accommodates the higher concentration of **zinc** in soy-based formula, it supports removal of the prescribed Zn:Cu ratio for infant formula. • Supports the retention of the maximum for **iron** in infant formula but it does not agree that retention of the current range allows manufacturers to meet both FSANZ and EU ranges. • Requests that FSANZ widen the iron range for infant formula to include the Codex minimum (0.11 mg/100kJ) to give flexibility for recipe harmonisation. There is a lack of international alignment with the proposed minimum which creates a barrier to trade. • Agrees that the current levels of iron account for older infants and soy-based formula products and that therefore it is unnecessary to set different levels for soy-based formula. • Supports increasing the **selenium** minimum to 0.48 mg/100kJ which aligns with the revised Codex Follow-up Formula (FuF) for Older Infants provision. • Supports **selenium** to align with the GUL in the recent draft revised Codex Standard for FUF (i.e. 2.2 µg/100kJ) and not set a maximum as currently proposed at 2.0 µg/100kJ.

Section	AFGC Comments
7.4 Other ratios, equivalents & nutrient interactions	• Supports changing from the **current Ca:P minimum ratio** of 1.2:1 to the Codex minimum for the Ca:P ratio of 1:1, whilst maintaining the existing maximum Ca:P ratio of 2:1. • Supports adjusting the **current phosphorus maximum** of 25 mg/100kJ to a GUL of 24 mg/100kJ. • Supports the FSANZ proposal to not adopt Codex **vitamin E** requirements in relation to PUFA. However, preferred is the EU approach to set a slightly higher minimum of 0.14 mg/100kJ (0.60mg/100kcal) with no additional vitamin E PUFA requirement. • Supports removal of the prescribed **Zn:Cu ratio** for infant formula.
7.5 Permitted forms of vitamins, minerals & electrolytes	• Supports **alignment with the permitted forms** in Codex STAN 72-1981 and the approach proposed under Table 7.17 17 'Submitter comments on permitted forms' (p96 of CP2), Row 1. • Does not support the non-alignment with Codex with **nicotinic acid and DL-panthenol.** • Supports retaining permission for **β-carotene** as a permitted form of provitamin A, and it proposes to not include β-carotene in the calculation of vitamin A content. • Supports retention of both **vitamin D2 and vitamin D3** as permitted forms of vitamin D. • Supports **calcium-L-methylfolate** as a permitted form of folate and its inclusion in the Food Standards Code.
7.6 Fluoride	• Supports the increase to 24 µg/100kJ of **fluoride** and removal of the labelling requirements on dental fluorosis, and would recommend removing the statement "*when reconstituted and prepared ready for consumption"* • The main contributor to the fluoride content is water, which manufacturers have no control over, therefore difficult to interpret.
Other optional substances (section 8)	• Supports **choline** being 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. • Supports an increase in the permitted forms of choline listed in Schedule 29 such that in addition to already permitted forms choline chloride and choline bitartate, choline, choline citrate and choline hydrogen citrate be added. • Recommends reviewing choline for older infants and supports aligning to Codex and maintaining choline as optional for 6 to 12 months. • Supports that **L-carnitine** should be mandatory in infant formula and should align with the Codex and EU mandatory minimum. • Supports the additional inclusion in Schedule 29 of the permitted forms L-carnitine hydrochloride and L-carnitine tartrate. • Supports the listing of **inositol** as a mandatory substance in infant formula and a GUL of 9.5 mg per 100kJ • Recommends a review of the minimum level to align with Codex based on the per 100kcal values - 0.96 mg/100kJ and GUL of 9.6 mg/100kJ. This also aligns with EU Regulation 2016/127 • Recommends reviewing inositol for older infants and supports maintaining it as optional for 6 to 12 months. Aligned with Codex STAN 72-1981. • Supports no changes to the current voluntary addition permissions for **taurine and lutein.** • Supports the continued inclusion of **nucleotide-5′-monophosphates** as optional ingredients but does not support retention of minimums for nucleotides. No minimums are set by the US, Canada or the EU reflecting that nucleotides are not considered essential nutrients.
Transition period	• Recommends a **minimum transition period of 5 years** followed by a **stock-in-trade period**. • There is a significant amount of change proposed for companies to implement.

In summary, the AFGC supports the submission to this consultation by the Infant Nutrition Council of Australia and New Zealand (INC) and shares the concerns that the INC has described.

Yours sincerely

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