Submission – Consultation Paper 2 – Nutrient Composition

Proposal P1028 – Infant Formula

Comments from Public Health Services, Department of Health, Tasmania,
2 September 2021

Public Health Services, Department of Health, Tasmania (PHS) appreciates the opportunity to comment on Proposal P1028 – Infant Formula, Consultation Paper 2.

PHS recognises that breastfeeding is the normal and recommended way to feed an infant. For infants that rely on infant formula as the sole or principal source of nutrition up to 12 months of age, regulation is essential to ensure infant formula remains safe and that its nutrient composition supports normal growth and development.

Regulation of infant formula must also ensure that labelling and advertising of infant formula products does not undermine the promotion of breastfeeding. This is consistent with the World Health Organisation International Code of Breast Milk Substitutes.

There are a number of general comments that PHS would like FSANZ to consider as well as more detailed responses to questions and proposed approach of FSANZ throughout the consultation paper.

General comments

Prioritisation

FSANZ states in the paper the overarching goal of Proposal P1028 is to '*ensure that infant formula remains safe and suitable, takes account of current science, market developments, and the international regulatory context*'.

However, PHS is concerned that FSANZ have prioritised harmonisation with international regulations above the primary objective to protect infant health and safety. On numerous occasions FSANZ states '*the primary objective of P1028 is to align with international regulations unless safety or other concerns do not support alignment*'.

PHS does not support the primary objective of the review of P1028 being alignment with international standards. Whilst this is a consideration, the primary objective should be to consider the latest scientific evidence on infant nutrition and apply this first and foremost.

Standard 2.9.1 is over 20 years old and is unlikely to be reviewed again in the near future so it is essential that the latest scientific evidence is used.

Scope

PHS is concerned that P1028 and Consultation Paper 2 excludes follow-on formulas. The issues raised in this paper (as with Paper 1) are equally relevant to follow-on formulas. If the changes proposed by FSANZ in this consultation paper only apply to infant formula, then there will be two sets of nutrient composition standards without the scientific justification for these.

The NH&MRC Infant Feeding Guidelines (2012) state that '*follow-on formulas are not considered necessary and no studies have shown advantages over using infant formulas'*. Therefore, there is little need for different compositional requirements for infant formula and follow-on formula (FUF).

PHS supports consistent nutrient composition requirements in Standard 2.9.1 on both infant formula and follow-on formula based on the levels agreed as part of P1028. PHS is unclear why this had not been reviewed as part of P1028 particularly in relation to the higher protein and energy levels in follow-on formulas compared to infant formula.

PHS strongly supports follow-on formulas remaining in Standard 2.9.1 as these products (along with Infant formula) are the primary source of nutrition for infants from 6-12 months even with the introduction of solids.

3 Energy

PHS supports FSANZ proposed approach to retain the current minimum energy content (2500kJ/L) and lower the maximum to 2950kJ/L in line with Codex.

4 Protein

4.1 Calculation of protein content

PHS supports FSANZ proposed approach that option 1 (adopt 6.25 as the NCF for all protein sources) is the most practical option considering there is no consensus on this issue and that 6.25 has been used in the most recent international regulations (EU 2016/127) and Codex Draft Standards for FUF.

4.2 Protein range

Cow's milk based

PHS supports FSANZ proposed approach on the minimum protein content of 0.43g/100kJ for cows milk based formula. This is consistent with the EU 2016/127 and Codex standards.

PHS does not support FSANZ proposed approach for the maximum of 0.7g/100kJ and considers the EU maximum of 0.6g/100kJ more appropriate.

PHS agrees that there is not enough evidence at this stage to reduce the minimum protein content but there is no reason why the maximum cannot be lowered. The Childhood Obesity Project (Weber et al., 2014) was a randomised control trial that examined the effect of protein

intake in formula fed infants. This study found that those on a low protein (0.43g/100kJ) infant formula had a reduced BMI and obesity risk at school age compared to those on a high protein (0.7g/100kJ) infant formula. A study assessing the lifetime cost-effectiveness of low protein infant formula found that reducing protein content in infant formula was a cost effective obesity prevention strategy (Sonntag et al., 2019).

One of the key objectives of FSANZ is to protect infant health and safety. There is considerable evidence to suggest that higher protein intakes are associated with higher BMI in later childhood and adolescents (Stokes et al 2021). Whist it is still unknown if 0.6g/100kJ is too high to reduce the risk of obesity we do know that there is no physiological need for protein intake at 3g/100kcal (0.7g/100kJ) in infancy (EFSA 2014b). The NHMRC Infant Feeding Guidelines (2013) also state that '*it is preferable to use a formula with a lower protein level*'.

The impact this would have on industry is minimal as our analysis of over 29 cow's milk infant formula products found only one that was greater than 0.6g/100kJ. As a result, it seems reasonable to conclude that a lower maximum of 0.6g/100kJ would have minimal impact on industry and lowers the risk of harm associated with higher protein formulas and obesity risk.

Soy-based

PHS supports FSANZ proposed approach to set the minimum at 0.54g/100kJ, only if the NCF of 6.25 is used. This higher level is based on the consideration that soy has a different amino acid profile than cows milk proteins and takes account of the NCF of 6.25 which is not as accurate for soy protein and potentially overestimates the true protein content. This value is consistent with the EU and Codex Draft Standard for FUF.

4.3 Protein source

PHS supports FSANZ proposed approach that protein source be specified. However, the current wording in the consultation paper is confusing and PHS is unclear what FSANZ means by 'protein hydrolysates of one or more protein normally used in infant formula'. Is this referring to cow's milk, goat's milk and soy protein isolates only? The wording in the EU regulations is clearer where it states, *'infant formula must be manufactured from cow's milk or goats milk proteins, soya protein isolates, alone or in a mixture with cow's milk or goat milk protein'*. It is important that the revised Standard be clear on what protein sources are allowed.

PHS does not support other plant based sources of protein being included without pre-market assessment. Some plant based sources of protein may contain anti-nutrient factors that can interfere with nutrient absorption which needs to be carefully considered before being added to infant formula. The *Ministerial Policy Guidelines on the Regulation of Infant Formula Products* clearly states that pre-market assessment should be required for any substance that does not have a history of safe use in Australia and New Zealand. Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated role in the normal growth and development.

4.4 Protein quality

PHS supports FSANZ proposed approach for measuring protein quality through mandating minimum amounts of amino acids based off the composition of breast milk. PHS also recommends the same approach to measuring protein quality by used for infant formula and follow-on formula.

4.5 Amino acid content

PHS supports FSANZ proposed approach to align the minimum amounts of all essential amino acids (and semi-essential amino acids) with Codex and to ensure the ratio of methionine to cysteine and tyrosine to phenylalanine must both be less that 2:1 to ensure the amino acid composition remains closely aligned with breast milk. This approach ensures consistency with international regulations.

5. Fat

5.1 Fat content

PHS supports FSANZ proposed approach to retain the current minimum of 1.05g/100kJ and lower the maximum to 1.4g/100kJ. These changes align with Codex STAN 72-1981 and EU regulations and is consistent with the average fat content in breast milk.

5.2 Units of expression

PHS supports FSANZ proposed approach to express the amounts of fatty acids in terms of mg/100kJ for LA, ALA and DHA. This is consistent with Codex Draft Standards for FUF and EU regulations.

5.3 Essential fatty acid composition: LA and ALA

PHS supports Option 1: Adopt EU 2016/127 minimum LA levels of 120mg/100kJ. PHS notes that there is no NRV for LA in Australia and New Zealand. However, ESFA AI for LA was derived from the lowest estimated mean intake that was not accompanied by deficiency symptoms which is approx. 110mg/100kJ. In addition, the best available data on breast milk LA in ANZ population suggests the mean intake is140mg/100kJ. FSANZ therefore concluded the use of a minimum amount of LA between 110mg/100kJ and 140mg/100kJ poses a low risk to infant health. PHS supports this conclusion.

PHS does not support retaining the current minimum LA level of 90mg/100kJ. This is below the levels found in breast milk and as stated in the *Ministerial Policy Guidelines on Infant Formula Products* that the composition of breastmilk should be used as a primary reference for determining the composition of infant formula and follow-on formula.

FSANZ technological concerns regarding a higher level and its impact on palatability and stability are unlikely to be a major issue for industry as LA content of infant formula products in ANZ are between 146 – 267mg/100kJ. This is well above the minimum of 120mg/100kJ. The higher level of 120mg/100kJ is unlikely to pose any more trade issues than 90mg/100kJ as both levels are above the Codex Standard (70mg/100kJ) and FSANZ 2021 label survey found the minimum is well above all of these levels.

PHS supports the proposed approach by FSANZ for the minimum amount of ALA of 12mg/100kJ and the LA:ALA ratio of 5:1 – 15:1. This is consistent with Codex and the EU.

5.4 Long chain polyunsaturated fatty acids and other LC-PUFA, ratio and sources.

PHS does not support the proposed approach to retain the current voluntary permission for DHA without reviewing the evidence. FSANZ needs to review the evidence to either accept there is sufficient evidence for it to be a mandatory ingredient based on its essentiality or revoke its voluntary permission as a result of insufficient evidence for a need for pre-formed DHA in IF.

The EU has recently mandated DHA on the basis that (1) DHA is an essential structural component of the nervous tissue and retina and is involved in normal brain and visual development; (2) the developing brain has to accumulate large amounts of DHA in the first two years of life; (3) although DHA can be synthesised from ALA the intake of pre-formed DHA results in erythrocyte DHA status more closely resembling that of a breast fed infant than ALA alone; and (4) although there is no convincing evidence beyond infancy there is a lack of long term follow up data. Based on these factors combined ESFA supported pre-formed DHA to be mandatory in IF (ESFA 2014)

DHA has been permitted in infant formula as an optional ingredient in Australia and New Zealand for over 20 years. This is more than sufficient time for manufacturers to provide enough evidence for its role in infant growth and development. The food regulatory system in its current form is not fit for purpose for optional ingredients if there is not a mechanism to review the evidence after a certain number of years.

PHS supported the Food Ministers Meeting (formerly the Forum) in November 2020 where they agreed that A1155 be reviewed within five years of gazettal to determine if there is sufficient evidence of a '*substantiated beneficial role in normal growth and development*'. This same process needs to apply to DHA. Continuing to allow DHA to remain an optional ingredient increases inequity in IF products as many of these products are sold at a higher premium price. If it is deemed that there is no need for pre-formed DHA then retaining the permission could be considered misleading. If it is deemed that pre-formed DHA should be included in all infant formulas, then this would create a level playing field and ensure all consumers can obtain the benefits irrespective of purchasing standard formula or a premium one.

PHS acknowledges the findings from Koletzko et al (2020) regarding the safety of IF with relatively high concentrations of DHA without providing adequate AA. The international experts in the field of infant nutrition did, however, recommend that both DHA and AA should be included in IF. PHS supports FSANZ approach that DHA does not exceed the AA amount.

5.6 Restriction on certain fats

5.6.1 Medium chain Triglycerides

PHS supports FSANZ proposed approach to retain the current restrictions on MCTs'

5.6.2 Trans fatty acids

PHS supports the lowest level possible of TFA being present in IF.

PHS also supports alignment with Codex by prohibiting the use of hydrogenated fats in IF from any other source if they contain TFA. This is consistent with FSANZ review of the

relationships between dietary trans-fatty acids and adverse health outcomes (O'Sullivan et al., 2014). This review concluded that there is sufficient epidemiological and experimental evidence to recommended that industrial TFA be eliminated from the food supply. Infants are a vulnerable population and as a result all TFA should be as low as possible with hydrogenated fats prohibited in infant formula.

PHS requests FSANZ consider what the maximum level of TFA in IF is without restricting the amount of milk fat that could be used as a fat source. PHS supports either a maximum of 4% or lower if this is achievable (O'Sullivan et al., 2014).

5.6.3 Phospholipids

PHS supports FSANZ proposed approach to restrict the lecithin content to 1g/L for infant formula products. This level is consistent with the EU and supports ESFA re-evaluation of the safety of lecithin's as a food additive in foods for infants. PHS notes that FSANZ did not conduct a nutrition risk assessment of the use of lecithin and as a result must rely on the findings from ESFA.

PHS notes that PLs are added as a nutritive substance to IF, however ESFA states '*the lack of convincing evidence for a beneficial effect of LC PUFA supplied as PLs … there is no necessity to use PLs as a source of LC-PUFA' (ESFA 2014).*

PHS requests that FSANZ review the evidence on the need for PLs to be added to IF. This seems imperative considering in 2016 FSANZ nutrition assessment considered that given the bioactivity of PLs, the lack of adequate safety data and unknown biological activity of certain types of PL in infants the amount of PL in infant formula should not exceed the amount normally present in breast milk (0.25g/L). FSANZ proposed value of 2g/L is based on the alignment with Codex and the EU whilst also acknowledging that the justification for this amount was not clearly reported.

5.6.4 Other fatty acids: myristic, lauric and erucic acids

PHS supports FSANZ proposed approach for myristic, lauric and erucic acids to retain current restrictions in Standard 2.9.1 for these fatty acids.

6. Carbohydrate

PHS supports FSANZ proposed view that the definition in Standard 1.1.2 in the Code clarifies the definition of 'carbohydrate', 'available carbohydrate' and 'carbohydrate by difference'

6.3 Carbohydrate source

PHS supports FSANZ proposed approach to place restrictions on sugars permitted in infant formula and supports Option 3 to adopt EU guidelines 2016/127 that sets a list of permitted carbohydrates.

The EU regulations more clearly state that '*sucrose [and glucose] may only be added to infant formula manufactured from protein hydrolysates*'.

The ESFA (2014) paper also states that lactose should be the preferred carbohydrate in IF which is justified by the predominance in breast milk and the absence of advantages that other carbohydrates might have compared with lactose.

The panel concluded that sucrose, glucose and fructose should not be added to IF, as sucrose and fructose do not have any advantage over lactose but may pose a risk to infants with fructose intolerance and saccharase deficiency. Glucose may also increase the osmolarity of the formula which may lead to an increased incidence of diarrhoea. It does state however that small amounts of sucrose and glucose may help to mitigate the disagreeable taste of IF containing protein hydrolysates.

The Codex standards are not as clear when it states '*sucrose, when needed and the addition of fructose as an ingredient should be avoided in infant formula'*. The Codex standard also does not include glucose. Therefore, PHS supports Option 3 above Option 2.

6.4 Permitted range for total carbohydrate content

PHS supports FSANZ proposed approach to retain the current approach in Standard 2.9.1 which does not specify a permitted range for carbohydrate content. As stated, this is indirectly controlled by the regulations on protein, fat and energy content.

7 Micronutrients

7.2.1 Vitamin A, B-carotene and calculations of retinol equivalents

PHS supports FSANZ proposed approach to:

- express vitamin A requirements as ug RE/100kJ
- exclude B-carotene from the vitamin A calculation

PHS does not support retaining the permission for B carotene as a permitted form of vitamin A in section 29-7.

Food additive permissions under the Code (Schedule15) and Codex do not include B carotene. Therefore B-carotene is not permitted to be added for technological functions such as colour or anti-oxidant. If B-carotene is no longer going to included as part of the vitamin A calculations due to its uncertainty around its bioavailability, then there is no justification for its addition to infant formula.

7.2.2 Folic acid and folate equivalents

PHS does not support FSANZ approach to express the requirements for folic acid/folate as ug folic acid/100kJ.

PHS supports the use of DFE which is consistent with Australia's Nutrient Reference Values. The DFE takes into consideration the bioavailability of folates in food which is about 50-60% compared to folic acid which is about 85% (NH&MRC, 2006). Recent ESFA (2014) recommendations on the composition of infant formula also support the use of DFE. More recently the US FDA have issued guidance for using DFE in expressing folate amounts in conventional foods.

PHS notes that the study by Campos-Gimenez et al. (2018) on 10 cows milk and soy based formula suggests IF were low or below levels of detection for folate. This is in contrast to MacLean et al. (2010) study on over 21000 batches of cows milk formula and 9000 batches of soy milk formula where it was estimated that folate accounted for approx. 40% of folate.

Due to this uncertainty and the fact that both the NRV and the EU are now using DFE it seems prudent that this method is also used in the updated IF regulations. This approach would also be consistent with vitamin E below.

7.2.3 vitamin E and tocopherol equivalents

PHS supports FSANZ approach to adopt alpha-TE as the units for vitamin E to indicate the relative activities of natural and synthetic forms of alpha-tocopherol.

7.3 Permitted ranges of micronutrients

PHS supports where possible the minimum level needed to meet the requirements of virtually all healthy full term infants from 0-6 months of age. PHS also supports the lowest maximum possible to reduce the burden on infant's metabolism.

7.3.3 Vitamin K, thiamine, riboflavin, vitamin B6 and biotin

PHS supports in principle FSANZ proposed approach for vitamin K, thiamine, riboflavin, vitamin B6 and biotin. However, PHS questions whether the minimum needs to meet the AI for infants aged 7-12 months in IF. Around 6 months of age it is not expected that breast milk or infant formula will meet all the nutritional needs of an infant, especially iron and zinc. FSANZ notes that the EU minimum for vitamin B6 meets only half the AI value for infants aged 6 - < 12 months and concluded that the EU levels may pose a risk to infant health. However, vitamin B6 is found in a wide range of foods including muscle meats, breakfast cereals, vegetables and fruit which are all considered first foods for infants. In addition, vitamin B6 clinical deficiency is rare (NH&MRC, 2006). Revisiting the EU minimum for vitamin B6 which is more closely aligned with breastmilk may be worth reconsidering.

7.3.5 Copper

PHS acknowledges that Standard 2.9.1 needs to be future proof and as result consideration of liquid, ready-to-use formula may be required. This has been noted for both copper and vitamin C. Lowering the minimum for copper may pose infants that consume ready-to-use IF at higher risk of not meeting their copper requirements.

7.3.6 Vitamin C (maximum)

Ready-to-use IF require a higher vitamin C maximum due to greater losses in liquid products but potentially placing infants using powered IF vitamin C intake well above the NHMRC AI for infants. In the Codex standards it states for vitamin C that *'GUL has been set to account for possible high losses over shelf-life in liquid formulas; for powdered products lower upper limits should be aimed for'.* Consideration of such a statement may be appropriate if the higher vitamin C maximum is chosen.

PHS supports the EU maximum of 7.2mg/100kJ as this is more in line with levels in breastmilk and would still meet the NHMRC AI for infants.

7.3.8 Iodine

PHS supports FSANZ proposed approach to align the minimum iodine with the EU (3.6 ug/100kJ). PHS notes that the study used by FSANZ to assess iodine sufficiency was based off South Australian women. South Australia is known to be iodine replete with the eastern seaboard states at greatest risk of iodine deficiency. The Australian Health Survey: Biomedical Results for Nutrients 2011-12 indicates that South Australia's median urinary iodine concentration is higher than the Australian average and is the fourth highest jurisdiction. As a result, South Australia may not be an adequate measure of iodine status of the ANZ population. The AHS Biomedical Survey also found that mandatory fortification may not be enough to meet the additional iodine requirements of pregnant women. It is therefore prudent to increase the minimum iodine levels in infant formula.

7.3.9 Zinc and Zn:Cu ratio

PHS does not support FSANZ proposed approach to align with Codex STAN 1972-81. PHS supports the EU 2016/127 regulations which set a minimum and maximum for both cows milk or goats milk and soy protein isolates.

Whilst the literature suggests that it is technologically possible to remove phytic acid from soy based formula, a level of 1-2% can impair absorption of minerals. The study by Vandenplas et al. (2014) noted that soy based infant formula did not result in any negative impact on growth however, the same study did note that '*modern soy infant formula contain higher micronutrients (Ca, Zn, Fe etc) when compared with cow's milk protein'*.

Stating this clearly in the Standards that higher levels are necessary for soy based formula due to reduced bioavailability provides clarity for Industry and reduces the risk of reaching the UL for infants on cow's milk based formula.

Adopting the EU standards should not impede trade and is unlikely to impact Industry as FSANZ 2021 survey found that products on the ANZ market fit within this range for zinc.

7.3.10 Iron

PHS does not support FSANZ proposed approach to retain the current minimum and maximum in Standard 2.9.1 without further analysis of the literature.

Whilst PHS acknowledges that iron deficiency can have a serious impact on health and later development of infants and children too much iron has also been found to have an impact. ESFA (2014) states that '*Studies suggest that the absorption of iron cannot be down-regulated before the age of 9 months with a risk of overload in those infants with sufficient iron stores but high iron intakes'*.

A number of studies assessing the long term developmental outcomes in children and adolescents who received high iron (0.4mg/100kJ) and low iron (0.08mg/100kJ) infant formula at 6 months found poorer cognitive outcomes with the high iron infant formula both at 10

years of age and 16 years of age (Lozoff et al., 2012; Gahagan et al., 2019). Note the high iron infant formula is lower that the maximum in Standard 2.9.1.

A more recent study has looked at iron status of infants less than 6 months. They concluded that reducing infant formula from 8mg/L to 2mg/L (0.3mg/100kJ to 0.07mg/100kJ) marginally reduced iron stores but did not increase the risk of iron deficiency at 4 or 6 months. Bjormsjo et al. (2021) supported the conclusion that 2mg/L (0.07mg/100kJ) is an adequate and safe level of iron fortification in a well nourished population with low risk of iron deficiency and that the results in iron status are more similar to breastfed infants.

Whilst PHS has not done a through literature review of iron levels in infant formula these studies do suggest that further consideration is required to determine the minimum and maximum levels in infant formula.

7.4 Other ratios, equivalents, and nutrient interactions

7.4.1 Phosphorous and the calcium: phosphorus (Ca: P) ratio

PHS supports FSANZ proposed approach to adjust Standard 2.9.1 to align with Codex minimum Ca: P ratio of 1:1.

Whilst PHS acknowledges the minimum and maximum for phosphorous and calcium are generally aligned with Standard 2.9.1, Codex STAN 72-1981 and EU2016/127 the EU have modified the phosphorus to take into consideration reduced bioavailability.

PHS supports separate standards for soy based infant formula to accommodate the reduced bioavailability of nutrients and to reduce the need for higher maximums in cows and goats milk based formulas.

7.5 Permitted forms of micronutrients

B-carotene

PHS does not support retaining B-carotene as discussed in section 7.2.1.

Vitamin D_2

PHS does not support the proposed approach by FSANZ to retain two permitted forms of vitamin D without further assessment of the bioavailability of Vitamin D_2. Currently Codex only permits D_3 based on the uncertainty of the bioavailability of vitamin D_2 in infants. PHS does notes that Codex Draft Standard for FUF is likely to include both however PHS would like to see the evidence for this change in the First Call for submissions.

8 Other Optional substances

PHS understands that optional ingredients have been permitted in the Code to enable Industry to innovate and improve infant formula to improve the health outcomes of infants fed formula.

However, Standard 2.9.1 currently has no mechanism to enable these substances to be either:

1) added to all infant formula once there is evidence that the ingredient has a substantiated beneficial role in the normal growth and development of infants, OR
2) there is not enough evidence that they have a substantiated role in normal growth and development and therefore their permission should be revoked.

Due to the current Standard not having a mechanism to achieve this there are optional ingredients that have been 'optional' for over 20 years without a review of the evidence. This is not in line with protecting infant health and safety as there may be infants on formula that are missing out on key nutrients. Alternatively, there may be consumers purchasing infant formula (often at a premium price) because it contains an optional ingredient that may not have a substantiated beneficial role in growth and development.

PHS requests that FSANZ review all optional ingredients as part of this review, including lutein, taurine and nucleotides, of which all of these have been added to infant formula for greater than 10 years without a review.

PHS also requests that FSANZ consider a mechanism to review the evidence after a specific timeframe (e.g. 5 years after gazettal) to ensure any future optional ingredients are either added to all infant formula or revoked.

8.1 Choline

PHS supports FSANZ proposed approach to mandate choline in infant formula, however PHS would like FSANZ to undertake additional work to determine the minimum level.

Currently the EU recommend 6mg/100kJ compared with Codex and the Code of 1.7mg/100kJ. This difference appears to be based on whether the total choline is calculated in breast milk or only a fraction of the choline is calculated.

The EU recommendation is based on ESFA advice to meet the nutrient requirements of all infants and is based on the total choline concentration in breast milk (160mg/L or approx. 6mg/100kJ). This same value was used in the development of the NHMRC choline AI for infants aged 0-6 months. This level would allow infants on infant formula to obtain adequate choline which is essential to support rapid growth rate and optimal development.

The lower level proposed by FSANZ is insufficient to meet the choline requirements for infants. This is based on a breast milk concentration of 20mg/L which does not include all available sources of choline. Whilst PHS acknowledges that none of the additional sources of choline found in breast milk are permitted forms in infant formula this should not preclude infant formula from meeting the nutritional needs of these infants.

PHS is also interested to know how much naturally occurring choline is in cows milk based infant formula as milk is a good source of total choline. This needs to be considered when deciding on the minimum and maximum levels in infant formula.

As stated in the *Ministerial Policy Guideline on Infant Formula Products* the composition of breast milk should be used as the primary reference for determining the composition of infant formula. PHS would like to understand why FSANZ have recommended only a fraction of the choline be considered and not the total choline concentration in breast milk.

As choline is now considered an essential nutrient it should be present in infant formula at a level that meets the needs of all infants.

8.2 L-carnitine

PHS supports FSANZ proposed approach to mandate L-carnitine at the levels 0.3mg/100kJ – 0.8mg/100kJ) This minimum aligns with both Codex-STAN 72-1981 and the EU 2016/127.

8.3 Inositol

PHS supports FSANZ proposed approach to mandate Inositol

Reference

Björmsjö, M.; Hernell, O.; Lönnerdal, B.; Berglund, S.K. Reducing Iron Content in Infant Formula from 8 to 2 mg/L Does Not Increase the Risk of Iron Deficiency at 4 or 6 Months of Age: A Randomized Controlled Trial. Nutrients 2021, 13, 3.

Campos-Giménez E, Bénet S, Oguey Y, Martin F, Redeuil K (2018) The contribution of minor folates to the total vitamin B9 content of Infant formula and clinical nutrition products. Food Chem. 249: 91- 97

EFSA (2014b) Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies (NDA) on the essential composition of infant and follow-on formula. The EFSA Journal 12(7):3760. http://www.efsa.europa.eu/en/efsajournal/pub/3760

Gahagan S, Delker E, Blanco E, Burrows R, Lozoff B. Randomized Controlled Trial of Iron-Fortified versus Low-Iron Infant Formula: Developmental Outcomes at 16 Years. J Pediatr. 2019 Sep;212:124-130.e1. doi: 10.1016/j.jpeds.2019.05.030. Epub 2019 Jun 26. PMID: 31253407; PMCID: PMC715250

Koletzko B, Bergmann K, Brenna JT, Calder PC, Campoy C, Clandinin MT, Colombo J, Daly M, Decsi T, Demmelmair H (2020) Should formula for infants provide arachidonic acid along with DHA? A position paper of the European Academy of Paediatrics and the Child Health Foundation. Am. J Clin. Nutr. 2020, 111, 10–16.

Lozoff B, Castillo M, Clark KM, Smith JB. Iron-fortified vs low-iron infant formula: developmental outcome at 10 years. Arch Pediatr Adolesc Med. 2012 Mar;166(3):208-15. doi: 10.1001/archpediatrics.2011.197.

O'Sullivan T, Wilson C, Hafekost K, Mitrou F, Lawrence D (2014) Narrative Review: The Relationship between dietary trans-fatty acids and adverse health outcomes.

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.

Stokes A, Campbell K, Yu H, Szymlek-Gay E, Abbott G, He Q, Zheng M (2021) Protein Intake from Birth to 2 Years and Obesity Outcomes in Later Childhood and Adolescence: A Systematic Review of Prospective Cohort Studies. Adv. Nutr. 2021 nmab034

Vandenplas, Y., Castrellon, P., Rivas, R., Gutiérrez, C., Garcia, L., Jimenez, J., . . . Alarcon, P. (2014). Safety of soya-based infant formulas in children. *British Journal of Nutrition, 111*(8), 1340-1360.

Weber M, Grote V, Closa-Monasterolo R, Escribano J, Langhendries JP, Dain E, Giovannini M, Verduci E, Gruszfeld D, Socha P, Koletzko B; European Childhood Obesity Trial Study Group. Lower protein content in infant formula reduces BMI and obesity risk at school age: follow-up of a randomized trial. Am J Clin Nutr. 2014 May;99(5):1041-51.