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## Introduction

We appreciate the opportunity provided by this Consultation Paper to make comments on the nutrient composition proposals put forward. DGC is an associate member of the Infant Nutrition Council (INC) and has participated in the preparation of the INC submission to this consultation paper. This submission focuses on the issues of key importance and relevance to DGC.

Our comments focus on:

1. The opportunity this review 2.9.1 and associated schedules to make amendments to the Food Standards Code to better align with Codex in terms of general approaches as well as with respect to nutrient limits. Such Changes have the potential to reduce the time and resources required for compliance reviews and verifications by ANZ manufacturers, especially for manufacturers that produce infant formula products for export.
2. Aspects of proposed nutrient composition that are potentially problematic to DGC. In this context, we see this review as a timely opportunity to review nutrient requirements that are currently 'out of sync' with natural levels in formulas based on goat milk. Historically the composition of cows' milk and dairy ingredients sourced from cows' milk have been taken into consideration when setting nutrient limits. Goat milk based formulas are now an established segment of the international infant formula market and we recommend more consideration of goat milk as a base ingredient for infant formula.
3. Suggestions and recommendation to improve clarity and to eliminate or avoid unnecessary and unwarranted requirements.

*Please note that abbreviations used are as per CP2. Any abbreviations additional to those in CP2 are used in conjunction with full term when first used in this submission.*

## Comments on Approaches to Compositional Requirements

Please refer to table below for DGC recommendations to achieve improved alignment with Codex; enhanced consistency and/or clarity; and/or more efficient compliance checks.

**Table 1:** DGG comments on general approaches within the FSC

| | Current approach within the Food Standards Code | Recommended approach |
|---|---|---|
| **Upper levels for guidance** | Guidelines for infant formula products (S29-10). | To use the terminology used by Codex: Guidance Upper Limit (GUL) as is used within the consultation paper; and, to define the term Guidance Upper Level within the FSC so the rationale for these limits is clear and it is also clear that these are non-binding. |

| | | |
|---|---|---|
| **Nutrient limits on an energy basis** | Stated per 100kJ<br><br>Inconsistencies in conversions from per 100kcal to per 100kJ in the CX 72-1981 are replicated in the FSC and inconsistent numbers of significant figures also applied. This has resulted in inconsistencies between limits in the FSC and CX 72-1981 that were intended to be aligned causing manufacturers compliance issues. | Where limits are intended to align with those in CX-72-1981 apply the limits specified per 100kcal as the primary reference and calculate the per 100kJ limits using the conversion factor of 4.18 as specified in the FSC. This will eliminate the inconsistencies replicated from the Codex standard.<br><br>State all limits to 2 significant figures and use 3 significant figures where warranted. This yields greater alignment between limits specified per 100kcal and 100kJ.<br><br>List nutrient limits both per 100kcal and per 100kJ for infant formula products. This approach is used by Codex and by the EU. This would eliminate the need to undertake as many conversions as is currently the case. |
| **Permissions for voluntary nutrient additions** | Permitted to be used as a nutritive substance | Amend to listing these as Optional Ingredients as per Codex.<br><br>The use of the current approach has resulted in anomalies within the FSC, for example with Inulin-like fructans and Galacto-oligosaccharide (GOS) being deemed not to be permitted to be used as a nutritive substance yet 2′-O-fucosyllactose (2'F)L and lacto-N-neotetraose ( LNnt) are considered to be used as nutritive substances. Overall, we consider there is an unwarranted [redacted] ingredients within the FSC which results in extra complexity and work for product formulators and quality staff within industry and regulators alike. |
| **Unavailable carbohydrates Non-plant based oligosaccharides e.g. GOS, 2'FL and LNnt** | There is a distinction between Dietary Fibre and non-plant unavailable carbohydrates such as galacto-oligosaccharides, 2'FL and LNnt. Further, Dietary Fibre measured by the AOAC method (subject of A1178) recommended for addition to the FSC by FSANZ includes galacto-oligosaccharides. | Review the definition of Dietary Fibre within the FSC to more closely align with the Codex Dietary Fibre definition. Increased clarity on the status of different sources of unavailable carbohydrate is sought. It is recommended that more focus is placed on physiological benefits of use than natural (plant versus animal) sources of compounds that can also be produced synthetically or by microbial fermentation. |
| **Gluten in infant formula products** | Required to be not detected. This is effectively a moving goal post as analysis sensitivity improves. | Alignment with Codex which defines 'gluten free' foods as foods containing <20mg gluten/kg (CX 118-2015). |

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## Comments on Proposed Nutrient Composition Parameters

DGC would firstly like to express its strong general support for the proposals put forward by FSANZ which will better align the nutrient composition for Infant Formula in the Food Standards Code to those in the Codex Infant Formula Standard (CX 72-1981). The increased harmonisation that will be achieved with international standards will greatly assist companies like DGC, which manufacture Infant Formula products for export. Key examples where there are currently significant discrepancies that are problematic are the requirements for amino acids and vitamin C.

There are some exceptions to this general support for alignment with the CX 72-1981, noting this Codex standard was last revised in 2007. These are as noted in the INC submission. DGC supports the modifications to the FSANZ proposals put forward in the INC submission. These are summarised in the INC Nutrient Comparison Table provided with their submission. For convenience, this summary table is also provided with our submission. We provide additional comments from DGC perspective on specific proposals below.

### Key issues

DGC wishes to highlight the following issues with regard to the proposed nutrient composition parameters and limits.

### Protein

### Calculation of protein content (NCF applied)

**DGC supports FSANZ's proposal to adopt 6.25 as the nitrogen conversion factor for all protein sources contingent on points below.**

Support for adoption of 6.25 as the nitrogen conversion factor for all protein sources is contingent on:

1. It is clear within the Food Standards Code that the minimum protein level specified is applicable for milk-based formulas (or more specifically for formulas based on cows' or goats' milk as per the revised compositional requirements for Codex Follow-up Formula for Older Infants).
2. A higher minimum protein requirement is set for soy-based formulas which takes into account the lower actual NCF for soy versus milk protein.
3. It being noted within the Food Standards Code that different minimum protein levels may need to be applied to protein sources other than milk or soy.

This approach is aligned with the approach taken within CX-72-1981 and by the EU. The Codex Follow-up Formula review working group is recommending the use of 6.25 NCF for the revised Codex compositional requirements for Follow-up Formula for Older Infants taking into account the findings and recommendations of JEMNU (JEMNU, 2019) report and the EU approach for infant formula products (EC 2016/127).

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## Proposal for prescribed permitted protein sources

**DGC does not support prescribed permitted protein sources for milk protein sources *but could support for non-mammalian milk protein and non-intact protein sources (other than hydrolysed milk proteins).***

. Key points:

- The underlying rationale for this proposal is to remove ambiguity about what protein sources require a pre-market assessment by FSANZ.
- DGC agrees that greater clarity is needed in the Food Standards Code about which protein sources for infant formula applications do require a premarket assessment by FSANZ.
- In addition, there needs to be clarity about the criteria that will be applied for assessment of new protein sources required to undergo such a pre-market assessment.
- DGC has reservations regarding positive lists because they tend to inhibit innovation and alignment with emerging nutritional science. However, in the absence of progress on P1024, DGC could support limited application of this approach for non-mammalian milk protein and non-intact protein sources (other than hydrolysed milk proteins). This would make it clear that protein sources in these categories require pre-market assessment by FSANZ.
- Taking this approach the prescribed permitted protein sources in these categories could be different for IFSPDU than for infant formula for healthy infants (for example amino acid based infant formulas).

Infant formula products fulfil a very important role. They are the only suitable alternative source of nourishment for infants with no, or inadequate, access to breastmilk to meet their nutritional needs through until they are old enough for complementary foods to be introduced. To exacerbate the situation young infants do not have fully developed immune and digestive systems so infants are a particularly vulnerable population group. It is critically important that the ingredients used, of which the protein source is key, are safe and suitable for use in infant formula products.

DGC's considers that all 'new' protein sources (not previously used for infant formula products) need to be carefully assessed prior to use in infant formula products but that such assessment should be graduated based on the potential risks posed. If a prescribed permitted protein source list approach is taken the bar for addition to such a list is set very high. We consider the risk for new milk sources, whether these are 'new' mammalian milk sources or 'new' mixes of mammalian milk proteins, is significantly lower than for non-milk protein sources.

DGC is in a unique position to comment on the proposal to prescribe protein sources. DGC commenced exporting goat milk based infant formula to two countries within the EU prior to EU

establishing prescribed permitted sources of protein for infant formula products in the mid 1990's. However, goat milk was not initially included in the prescribed protein list implemented by the EU. Consequently, if we wished to service EU markets, we had to navigate our way through the process to have goat milk protein added to this prescribed list. This proved to be very challenging as there was no clear roadmap at the outset. Work commenced on this endeavour in 1997 and continued for 16 years before this regulatory change was promulgated in 2013. During this period, DGC sponsored two clinical studies to assess the safety and suitability of goat milk as a protein source for infant formula products and made seven submissions to the European Food Safety Authority (EFSA) covering these trials and other research undertaken. In 2012 EFSA concluded goat milk protein was a safe and suitable protein source for infant formula products (EFSA, 2012) and the EU prescribed protein list was subsequently updated to include goat milk protein. Over the course of the16 years it took to achieve this regulatory change in the EU:

- Goat milk based infant formula usage increased in many markets, particularly in the Asia-Pacific region.
- The production of infant formulas with goat milk as the protein source in EU for export grew substantially as EU exporters did not need to meet the EU requirements for sale within the EU, but rather requirements that applied to export products that did not include prescribed protein sources.

Reflecting on this process, we conclude that the level of safety assessment required to achieve this regulatory outcome was disproportionate relative to the risk profile of goats' milk as an alternative protein source to cow's milk. Goats' milk is consumed as the primary mammalian milk source by a greater proportion of the human population across the globe than cows' milk including by young children. Safety is paramount but care needs to be taken to apply appropriate safeguards to avoid unwarranted costs to bring new product innovations to market. Criteria for assessments need to be clearly set out and need to be achievable in practice. Infant feeding clinical trials are very challenging to conduct. Further, ethically, there needs to be a very judicious approach to such trials given the level of intervention involved for infants and their caregivers.

In the absence of further progress on P1024 DGC suggests the following:

1. Adding text to Division 2 of Standard 2.9.1 which replicates the principles included in 3.1.1 of CX 72-1981:

   3.1.1 Infant formula is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be suitable for infant feeding. The nutritional safety and adequacy of infant formula shall be scientifically demonstrated to support growth and development of infants. All ingredients and food additives shall be gluten-free.

   Apart from the text on gluten, this text is not currently replicated within the Food Standards Code. This inclusion would strengthen the current provisions within the Food Standards Code regarding the ingredients used in infant formula manufacture including protein sources.

2. Consideration of implementing a prescribed permitted protein list for for non-mammalian milk protein and non-intact protein sources (excluding hydrolysed milk proteins) to ensure that all new protein sources in these categories must undergo a FSANZ pre-market assessment. If implemented there should be clear criteria set out for such assessments.

## Protein Quality

**DGC supports adoption of the protein quality criteria specified in Codex STAN 72-1981 1.1.3 a) Protein footnote 3).**

Codex STAN 72-1981 1.1.3 a) Protein footnote 3) reads as follows:

For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I); nevertheless for calculation purposes, the concentrations of tyrosine and phenylalanine may be added together. The concentrations of methionine and cysteine may be added together if the ratio is less than 2:1; in the case that the ratio is between 2:1 and 3:1 the suitability of the formula has to be demonstrated by clinical testing.

DGC notes that proposal by FSANZ to align the requirements in the Food Standards Code does not replicate this footnote in full. The underlined text is important and needs to be replicated to achieve full alignment with this Codex Standard.

## Fat

### DHA

DGC supports the proposal for voluntary permission for DHA to be retained in addition to the requirement for DHA ≥AA when DHA is added.

The DHA GUL proposed is not supported. It is recommended that the GUL be increased from 0.5 to 1.0% of TFA but expressed on an energy basis: 60mg/100kcal (14mg/100kJ). Alternatively, the GUL could be set to 50mg/100cal (12mg/100kJ) to align with the upper limit applied in EU.

The mean levels of DHA in breastmilk are reported to be 0.32% +/- 0.22% (SD) with a range of 0.06-1.4% (Brenna et al. 2007). Codex STAN 72-1981 sets a GUL of 0.5% of fatty acids but this does not reflect current recommendations. Koletzko et al. (2020) recommends that DHA preferably reaches 0.5% fatty acids, i.e. that DHA levels should be no less than this. We note that both the EU and China apply upper levels above the GUL proposed by FSANZ. DGC therefore supports increasing the GUL to align to 1% of fat maximum i.e. 60mg/100kcal (14mg/100kJ) or adopting 50mg/100kcal (12mg/100kJ) the upper limit that applies in the EU (EC 2016/127).

[redacted]

**Phospholipids**

DGC supports a GUL of 300mg/100kcal (72mg/100kJ) being applied in alignment with Codex STAN 72-1981.

**Lecithin**

DGC supports retaining the current provision in Schedule 15 for use of lecithin as a food additive emulsifier in Schedule 15.

We note that the maximum permitted level will effectively be reduced from the current 5g/L if an upper limit on phospholipid content is implemented as proposed. We could accept a maximum of 1g/L being applied for infant formula products as is applied by EU (EC 2016/127).

Lecithin is a food additive. We are surprised that it has been included within CP2 which deals with nutrient composition. We are not aware of any market failure relating to the current permissions regarding its use as a food additive that indicate a change to current permissions is warranted.

So saying, we acknowledge that there is an increasing international focus on minimising food additive use in infant formula products. In this context, compliance with a maximum usage rate of 1g/L has proven to be practically possible based on this provision having being in place in EU for many years. Similarly, based on our own understanding of its usage as a food additive in infant formula products a limit of 1g/L covers its typical range of use in these applications. The matrix of phospholipids within lecithin is significantly different to that found in human and other mammalian milks and has different metabolic impacts (Lecomte et al, 2016,Mathiaassen et al, 2015,Nejrup et al, 2017) suggesting safe guards to avoid excessive use may be prudent. We could therefore accept a maximum of 1g/L being applied but consider that any proposed change to the current limit should be supported by a FSANZ food additive assessment.

## Nucleotides

DGC requests the following amendment to 2.9.1-8:

Amend maximum stated of, “no more than 3.8 mg/100 kJ of nucleotide-5′-monophosphates,” to, “no more than 3.8mg/100kJ (16mg/100kcal) of free nucleotide-5'-monophosphates.

The limits that have been set for nucleotides were historically crafted to in response to nucleotide supplementation of cows’ milk based formulas. These have resulted in unintended consequences resulting in ambiguity regarding compliance, particularly for formulas using milk protein sources other than cows’ milk. This review provides an opportunity for amendments to overcome these issues. We background these issues and propose changes to the current provisions to resolve them.

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We have experienced problems with two aspects of the current provisions. The first being the maximum stated in 2.9.1-8 and the second being the maximum for guanosine-5'monophospate in S29.

Human and other mammalian milks contain free nucleotides with multiple levels of phosphorylation, free nucleosides, RNA and DNA. The concentrations of 'total potentially available nucleotides' are defined by some authors as the sum of free nucleosides, free nucleotides, nucleotide-containing adducts (such as NAD and uridine diphosphate (UDP) glucose) and nucleotide polymers have been reported to be around 10.5-11.0 mg/100kcal in milk from Asian, American and European mothers (EFSA, 2014). Consequently, there are differences in interpretation of what constitutes "total nucleotides."

In this context, it is interesting to note the following comment made by Schlimme et al, 2000, that the EU regulatory limits set take, "into account only those unmodified milk nucleotides that are released from mono-, oligo- and polymers during digestion and metabolism. It has not been considered that the whole TPAN content of human milk also includes the modified nucleot(s)ides that can be released in RNA breakdown reactions. The regulative potential of modified nucleosides seems to be prospective but is mainly unexplored."

The current maximum stated of, "no more than 3.8 mg/100 kJ of nucleotide-5′-monophosphates," in 2.9.1-8, goes some way to clarifying the nucleotide content to which it applies, but to avoid all ambiguity we ask that this amended to state, "no more than 3.8mg/100kJ (16mg/100kcal) of free nucleotide-5'-monophosphates. This change makes it clear that this maximum applies only to free nucelotdie-5'-monophosphates and that other sources of nucleotides and/or nucleosides present which can be reported on a 5'-monophosphate equivalent basis, are not to be included. This will facilitate compliance verification, for example to auditors and regulators in export markets. This is particularly important for goat milk based formulas as the natural levels of nucleotides are significantly higher in goats' milk than cows' milk (Prosser et al, 2008). To illustrate this point please refer to table 2. The total nucleotide monophosphates reported in this reference includes nucleosides converted to monophosphate equivalents in addition to free nucleotide monophosphates. Other variations of nucleotides included can be applied.

We understand that the current maximum applies to natural plus added nucleotide-5'-monophosphates and support its retention provided the additional clarity provided by insertion of 'free' as requested and shown above is implemented.

[redacted]

**Table 2: Composition of the non-protein nitrogen fraction of whole milk powders or infant and follow-on formulae made from goat or cow milk.**

| | Goat | | | Cow | | |
|---|---|---|---|---|---|---|
| | Whole milk powder | Infant formula | Follow-on formula | Whole milk powder | Infant formula | Follow-on formula |
| Total nucleotide monophosphates[a] | 10.1 | 4.0 | 5.7 | ND | ND | ND |
| Polyamines | 0.06 | 0.016 | 0.037 | 0.041 | 0.012 | 0.016 |
| Free amino acids | 21.3 | 9.7 | 12.4 | 5.9 | 9.2 | 9.9 |
| Urea | 28 | 11 | 14 | 22 | 7 | 14 |
| Creatinine | 1.4 | 1.0 | 1.0 | 1.8 | 1.0 | 1.0 |
| Carnitine | 2.1 | 1.6 | 1.6 | 2.1 | 1.7[b] | 1.8[b] |
| Sialic acid | 10.5 | 4.8 | 5.0 | 19.9 | 6.8 | 11.1 |

The concentrations of individual components were determined in reconstituted powders and their nitrogen content calculated. All concentrations are in mg/100 ml reconstituted powder or formulae. ND, not determined. [a]The nucleosides were converted to monophosphate equivalents and summed with the nucleotide monophosphates to obtain total nucleotide monophosphate levels. [b]Contains added carnitine.

*Source: Prosser et al, 2008.*

**Guanosine 5'-monophosphate nucleotide**

DGC requests that the maximum for Guanosine 5'-monophosphate in S29 is increased to 1.7mg/100kcal (0.40mg/100kJ) to accommodate the natural levels in goat milk based formulas.

Other alternative approaches that could be considered:

1. an editorial note within the Foods Standards Code which states that the maximums specified for specific nucleotide 5'mono-phosphates only apply when that specific nucleotide 5'mono-phosphate is added (or only apply to amounts that may be added).
2. Amending upper limits specified for specific 5'monophosphate nucleotides from maximums to GULs.

The level of guanosine 5'-monophosphate in goat milk based infant formulas exceeds the current maximum set for this nucleotide of 0.12mg/100kJ.

**Table 3: Nucleotide, polyamine and sialic acid concentrations in whole goat milk (WGM), and young child formula (HMF) and infant formula (LMF) based on goat milk**

| Component | WGM | HMF | LMF |
|---|---|---|---|
| Nucleotides (mg 100 $mL^{-1}$) | | | |
| AMP | 0.81 ± 0.20 *(19)* | 0.36 ± 0.03 *(12)* | 0.31 ± 0.08 *(17)* |
| CMP | 0.89 ± 0.07 *(21)* | 0.71 ± 0.05 *(24)* | 0.37 ± 0.05 *(21)* |
| IMP | <LOD | <LOD | <LOD |
| GMP | 1.92 ± 0.13 *(46)* | 1.19 ± 0.07 *(40)* | 0.85 ± 0.09 *(47)* |
| UMP | 0.58 ± 0.07 *(14)* | 0.72 ± 0.05 *(24)* | 0.28 ± 0.05 *(15)* |
| Total | 4.22 ± 0.34 | 2.99 ± 0.13 | 1.82 ± 0.13 |

*Source: Tolenaars et al, 2021.*

Assuming that infant formula has an energy content of 65kcal/100ml (270kJ/100ml) the mean level of GMP is 0.31mg/100kJ with levels as high as 0.4mg/100kJ possible.

It is our interpretation that the maximums applied for individual 5'-monophosphate nucleotides are intended to constrain nucleotide supplementation of formulas, not the nucleotide levels intrinsically present. There is ambiguity on this point and the current maximum has proved problematic for compliance verification.

Goat milk infant formula manufactured by DGC has been clinically evaluated and assessed by EFSA to be a safe and suitable sole source of nutrition for infants (EFSA, 2012). Based on the clinical trials sponsored, and other research undertaken by DGC, goats' milk protein is now one of the prescribed permitted protein sources for infant formula in the EU (EC 2016/127). Goats' milk has also been recognized by Codex as a protein source for infant formula products during the revision of the Codex Follow-up Formula Standard. There are no safety concerns relating to the intrinsic composition of goat milk based formulas including the nucleotide content.

DGC therefore requests that FSANZ reconsider the maximum applied to GMP. Increasing this maximum from 0.12 to 0.40mg/100kJ (1.7mg/100kcal) is suggested. This accommodates the levels of this free mono-phosphate nucleotide found naturally in goat milk-based formulas and is in alignment with the upper end of average levels found in human milk (EFSA, 2014).

We would very much appreciate if the ambiguity caused by the current maximum being addressed. If there is no appetite to amend the maximum as suggested other possible alternatives that would help to overcome the difficulties could be considered, such as:

1. an editorial note within the Foods Standards Code which states that the maximums specified for specific nucleotide 5'mono-phosphates only apply when that specific nucleotide 5'mono-phosphate is added (or only apply to amounts that may be added). OR
2. Amending upper limits specified for specific 5'monophosphate nucleotides from maximums to GULs.

Regarding this second option, in our view there is no reason that the upper limits specified for the 5'monophosphates in S-29 need to be specified as maximums rather than GULs. The maximum for total free 5'phosphate nucleotides safeguards against excessive nucleotide supplementation.

## Follow-on Formula

Standard 2.9.1 covers Follow-on Formula for infants from 6-12 months as well as Infant Formula and IFSPDU. INC advocated that Follow-on formula be included in the scope of P1028 in its response to P1028 CP1 2021. Since the release of CP2 2021 FSANZ has advised INC that the scope of P1028 will be expanded to include Follow-on Formula. DGC fully supports this extension and offers the following comments and recommendations regarding Follow-on formulas.

## Potential renal solute load

DGC strongly recommends that the limit for potential renal solute load be removed from Standard 2.9.1. There is no limit placed on potential renal solute load in CX 72-1981, the compositional limits set for Follow-up Formula for Older Infants in the draft revision of the Codex FUF Standard in progress (CCNFSDU, 2020) or in the EU regulations covering Infant and Follow-on Formulas (EC 2106/127). The potential renal solute load requirement is not warranted from a risk management perspective and should be removed to eliminate unwarranted and unnecessary requirements.

## Different Nutrient Limits Recommended for Follow-on Formula

Currently most nutrient limits for infant formula in the Food Standards Code also apply to follow-on formula. The following table lists nutrient limits for Follow-on Formula, which DGC recommends, differ from those proposed by INC for infant formula

**Table 4: DGC comments and recommendations for Follow-on Formula**

| Nutrient | INC proposed limits for Infant Formula | Different limits proposed for Follow-on Formula |
|---|---|---|
| **Protein limits (for formulas based on intact milk protein)** | Min: 1.8g/100kcal (0.43g/100kJ)<br><br>Max: 3.0g/100kcal (0.72g/100kJ) | Retain existing min for Follow-on Formula: Min: 1.6g/100kcal (0.38g/100kJ)<br><br>Set max as for Infant Formula: 3.0g/100kcal (0.72g/100kJ) or at 3.5g/100kcal (0.84g/100kJ) as initially proposed by New Zealand to CCNFSDU for Follow-up Formula for Older Infants. |
| **Vitamin D maximum** | Max: 2.6ug/100kcal (0.63ug/100kJ) | Max: 3.0ug/100kcal (0.72ug/100kJ) to align with maximum specified by Codex for Follow-up Formula for Older Infants in the Codex Follow-up Formula standard currently under revision. |
| **Calcium GUL** | GUL:140mg/100kcal (33mg/100kJ) | GUL:180mg/100kcal (43mg/100kJ) to align with maximum specified by Codex for Follow-up Formula for Older Infants in the Codex Follow-up Formula standard currently under revision. |
| **Iron minimum** | Min: 0.45mg/100kcal (0.11mg/100kJ) | Retain existing min: Min: 0.20 mg/100kJ (0.84mg/100kcal) or amend to 1.0mg/100kcal (0.24mg/100kJ) to align with maximum specified by Codex for Follow-up Formula for Older Infants in the Codex Follow-up Formula standard currently under revision. |
| **Choline, Inositol and L-carnitine** | Mandatory | Permitted for voluntary addition as is currently the case |

| | | |
|---|---|---|
| **DHA** | Requirement for AA≥DHA where DHA is added | No requirement for AA≥DHA where DHA is added |
| **Phospholipid GUL** | GUL: 300mg/100kcal (72mg/100kJ) | No upper limit as currently applies or we could consider alignment with limit set by Codex for Follow-up Formula for Older Infants in the revision of the Codex Follow-up Formula standard. This applies the same limit as CX 72-1981. |

## Transition arrangements

DGC fully supports INC's request for a five-year transition period, with additional stock in trade provisions, for the implementation of changes from P1028. This period is appropriate given the significand number, scope and complexity of changes proposed. It 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).

Further, it is strongly recommended that the current standard and any revised Standard should run in parallel over the transition period.

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# Responses to Questions for Submitters included in the consultation paper

| **Questions for submitters** |
|---|
| *General question related to the Consultation paper* |
| 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.<br><br>Proposed compositional limits that could affect market opportunities for infant formula products have been covered above. In particular, changes are recommended to the proposed GUL for DHA and the proposed maximum for guanosine 5'-monophosphate in this regard. The proposals put forward by FSANZ for amino acid requirements and vitamin C are welcomed as the lack of harmonisation of the current requirements for these nutrients with CX 72-1981 are problematic.<br><br>It is also pertinent here to comment on transition arrangements. It is very important that these arrangements allow for orderly transition, which includes minimisation of product and/or packaging write-offs, and do not create barriers to maintaining product availability. Given the significant number, scope and complexity of changes proposed we recommend a five-year transition period with additional stock-in-trade provisions and with current and revised regulations operating in parallel during the course of the transition period.<br><br>2. With the proposed approaches for Standard 2.9.1 or Schedule 29 in this Consultation paper, will small or large businesses be disproportionately impacted if a new permission or restriction does not align with international regulations or standards? ? If so can you specify how by providing quantitative evidence where possible?<br><br>No. In our view, all infant formula businesses will be significantly impacted and the degree of impact will not proportionate to business size. The impact for each business depend on the number of their product formulations impacted by the proposed changes and the cost of steps needed in order to comply with amended requirements. |
| *Questions about the minimum LA requirement. (Section 5.3)* |
| 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.<br><br>DGC supports retaining the current LA minimum but for this to be stated on an energy basis as 375mg/100kcal (90mg/100kJ).<br><br>The existing permitted range of LA levels provides sufficient flexibility to achieve appropriate balance between LA, ALA and LCPUFA's with or without DHA addition.<br><br>4. Are there any technical issues related to increasing the LA minimum in Standard 2.9.1 to align with the higher EU 2016/127 level of 120 mg/100 kJ? |

| Questions for submitters |
|---|
| It is technically feasible to comply with the minimum LA applied by the EU of 120mg/100kJ.<br><br>However, we support retaining the existing LA minimum in the Food Standards Code to allow greater flexibility to achieve appropriate balance between LA, ALA and LCPUFAs with or without DHA addition (noting that DHA addition is mandatory in the EU).<br><br>5. Can you provide data on the LA levels in commercially available infant formula internationally? This information can be provided as 'Commercial in confidence' if required.<br><br>The levels of LA in infant formula products manufactured by DGC vary between formulations but are typically within the range 100 – 250mg/100kJ. [redacted] |
| *Questions about setting separate maximum iron levels for soy-based infant formula. (Section 7.3.3.5)* |
| 6. Do you support setting a separate iron maximum for soy-based infant formula? Please provide your rationale and evidence to support your answer.<br><br>No comment as outside of DGC's scope of expertise. |
| *Questions about setting a separate phosphorus range for soy-based infant formula. (Section 7.4.1 )* |
| 7. Do you support setting a separate phosphorus range for soy-based infant formula? Please provide your rationale and evidence to support your answer.<br><br>No comment as outside of DGC's scope of expertise. |

## References

Brenna et al, 2007.Docosahexaenoic and arachidonic acid concentrations in human breastmilk worldwide. American Journal of Clinical Nutrition, 85, 1457-1464.

CCNFSDU, 2020. REP20/NFSDU Report of the 41st session of the Codex Committee on Nutrition and Foods for Special Dietary Uses held 24-29th November 2019.

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