New Zealand Food Safety
Haumaru Kai Aotearoa

Project Officer Proposal P1028
Food Standards Australia New Zealand
PO Box 10559
The Terrace
Wellington 6036

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Tēnā koe,

Proposal P1028 – Consultation paper 2 – Nutrient Composition

Thank you for the opportunity to comment on this proposal.

New Zealand Food Safety (NZFS) acknowledges that breastfeeding is the recommended way to feed infants. For infants who are not breastfed, a safe and nutritious substitute for breast milk is needed. Infant formula products are the only safe and suitable alternative to breast milk.

NZFS appreciates the work FSANZ has undertaken with this proposal, and looks forward to the opportunity to comment further, in due course. At this point in time NZFS has chosen to provide comments mainly on aspects where specific questions are being posed to submitters and where those relate to the expertise of NZFS. We will provide more detailed comments at a later stage of the process on other aspects covered in this consultation paper.

General comments

NZFS is in general support of the approach taken by FSANZ which is informed by the Ministerial Policy Guidelines on the Regulation of Infant Formula Products. We support an approach whereby consistency is sought with Codex and other international standards to enable harmonisation of trade; but where differences do occur with international standards that these are based on risk-analysis using best available scientific evidence to meet the nutritional requirements of infants in Australia and New Zealand.

As this is such a large piece of work it would be useful if FSANZ could provide a summary table of the proposed nutrient composition for infant formula products. If possible, this could be extended to a comparison table to the current requirements and the Codex Infant Formula Standard.

Implications of changes in compositional requirements for Follow-on Formula
NZFS supports the recent update by FSANZ to expand the scope of this work to include follow-on formula.

Compositional requirements for infant formula and follow-on formula are very similar as they are formulated to meet the nutritional needs of infants of overlapping age ranges (infant formula 0-12 months, follow-on formula 6-12 months); and both products are covered in the same standard.

[redacted]

FSANZ has considered the work of the Codex Committee of Nutrition and for Special Dietary Use (CCNFSDU) which was co-chaired by New Zealand to review the essential composition of follow-up formula. NZFS supports FSANZ to continue to consider the Codex review when broadening the scope of this work to both infant and follow-on formula products. One of the guiding principles for establishing compositional requirements for follow-up formula for infants aged 6-12 months in the review was to align where possible with the Codex Infant Formula Standard unless differences were scientifically justified.

It is important the regulatory requirements for the two products are reviewed simultaneously. This ensures products for infants can keep pace with the latest scientific evidence and international standards. Furthermore, it will minimise disruption to industry by maintaining harmonisation across product categories.

Protein source
FSANZ proposes to limit the types of protein sources that are permitted for infant formula products to: cow's milk protein, goat's milk protein, protein hydrolysates of one or more proteins normally used in infant formula, and soy protein isolate.

NZFS does not support this limited approach as it does not align with the Codex Infant Formula Standard, or draft Codex Standard for Follow-up Formula. The Codex Standards state:

> 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.
>
> 3.1.1 Follow-up formula for older infants 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 safe and suitable for the feeding of older infants. The nutritional safety and adequacy of follow-up formula for older infants shall be scientifically demonstrated to support growth and development of older infants.

There does not appear to be any scientific justification to exclude protein from other animal milks in the standard and this approach would impact on products that are currently on the market (e.g. sheep milk formula products). In the equivalent Codex standards, it is noted that for formula based on non-cows' or non-goats' milk protein other minimum values may need to be applied and this allows for other protein sources to be used in the future.

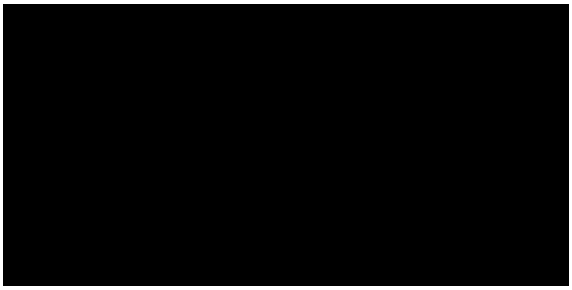
Variation of levels of nutrients inherent in ingredients
NZFS would like to acknowledge that there are some nutrients that are known to have variability in the milk ingredients which may need to be further considered by FSANZ to ensure that this can be adequately accommodated in the establishment of maximum levels and guiding upper levels(GULs).

Guiding upper levels
NZFS supports the continuation of the use of GULs for micronutrient composition but notes that the Food Standards Code currently lacks a definition. It would be useful to include a definition.

Technical calculation errors from kcal to kJ

NZFS notes that some inconsistencies in the conversion of kcal to kJ remain and suggest that these should be rectified as they can cause issues in exporting products. In the draft Codex Standard for Follow-up Formula the technical calculation errors have been addressed.

Nāku noa, nā



Questions for submitters
General question related to the Consultation paper
1. In addition to your submission 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. In New Zealand, infant formula that is manufactured for export-only must still comply with the compositional requirements set in the Food Standards Code. The Ministry for Primary Industries can issue an exemption from the compositional requirements of the Food Standards Code under Food Act 2014. These exemptions are nutrient and country specific. Many of the markets that New Zealand infant formula manufacturers export to have adopted the Codex Infant Formula Standard (CXS 72-1981) into their regulations. Closer alignment of the Food Standards Code infant formula compositional requirements with those of the Codex infant formula standard would result in fewer exemptions needed and facilitate trade. 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. N/A
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. Support the current minimum converted to mg/100 kJ. 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? N/A 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. NZFS has no data on LA levels in commercially available infant formula internationally but notes the recently updated China GB standard range for LA is 0.07g/100kJ to 0.33g/100kJ for infant formula and follow-on formula.
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. ***Minimum iron requirements for cows' milk-based formula***

Questions for submitters

FSANZ has proposed a minimum composition of 0.2 mg/100 kJ for iron in cows' milk-based formula – this is far higher than that of Codex and the EU. The rationale provided is that infant formula products must be suitable for both infants aged 0-6 and 6-12 months. As iron requirements are higher at 6 months of age this approach to setting compositional requirements for older infants would lead to a divergence of approaches between FSANZ and other regulations globally which prioritise the requirements of younger infants in establishing compositional requirements for infant formula.

The preferred minimum of 0.2 mg/100 kJ is also higher than the minimum of 0.14 mg/100 kJ specified in the EU for formula that is intended to be used from the first months of infancy and the whole first year of life. The EFSA assessment assumed that 75% of iron requirements should be met by complementary foods whereas FSANZ have assumed that 50% of iron requirements should be met by complementary foods. The nutrition risk assessment then draws a conclusion that this poses a risk to infant health.

The Ministerial Policy Guidelines under Specific Policy Principles – Composition state that:

> d) The composition of infant formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole source of nutrition up to six months of age.

NZFS considers that the risk assessment that FSANZ has conducted may be more relevant to product targeted to older infants, such as follow-up formula, and may not be broadly applicable to those products that are targeted specifically to the 0-6 month age range. We note that the Ministerial Guidelines focus the composition for infants up to six months of age and would request FSANZ to reconsider the minimum requirements based on the differences with international standards and the amount of iron that should be provided by complementary foods in this age group.

	Proposed approach	Codex infant formula	Codex draft follow-on formula	EU infant formula	EU follow-on formula
Minimum	0.2 mg/100 kJ	0.1 mg/100 kJ	0.24 mg/100 kJ	0.07 mg/100 kJ	0.14 mg/100 kJ
Maximum	0.5 mg/100 kJ	N.S.	0.48 mg/100 kJ	0.3 mg/100 kJ	0.48 mg/100 kJ
Soy-based formula					
Minimum			0.36 mg/100 kJ	0.11 mg/100 kJ	0.48 mg/100 kJ
Maximum			0.6 mg/100 kJ	0.22 mg/100 kJ	0.6 mg/100 kJ

Iron requirements for soy-based formula

NZFS supports the decision to establish separate requirements for soy-based products, particularly if the minimum iron content of infant formula is reconsidered. We note that the retaining the current minimum and maximum levels would not enable manufacturers to produce soy-based products to be in line with international requirements unless the maximum was increased to 0.6 mg/100 kJ. We note

Questions for submitters
that the minimum level would also need to be considered to take into account for the potential differences in bioavailability of iron in these products.
Questions about setting a separate phosphorus range for soy-based infant formula. (Section 7.4.1)
7. Do you support setting a separate phosphorous range for soy-based infant formula? Please provide your rationale and evidence to support your answer. NZFS supports the proposed approach to adjust the current phosphorus maximum to a GUL of 24 mg/100 kJ to align with the draft Codex Standard for Follow-Up Formula and the Codex Infant Formula Standard. This GUL should accommodate the higher phosphorus levels in formula products based on soy protein isolate.

Additional comments on specific compositional requirements
Nitrogen conversion factors
NZFS support FSANZ's proposed option, Option 1, to adopt a nitrogen conversion factor (NCF) of 6.25 for all protein sources. This approach will align with the Codex Infant Formula standard, draft Codex standard for Follow-up Formula and EU regulation which utilise a consistent nitrogen conversion factor (6.25) and prescribe different minimum protein requirements to accommodate the differences the protein composition of soy-based formulas. It is a pragmatic approach given the limitations identified in the Consultation Paper. The footnote in the draft Codex Standard for Follow-up Formula is as follows: For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products. The minimum value applies to cows' and goats' milk protein. For follow-up formula for older infants based on non-cows' or non-goats' milk protein other minimum values may need to be applied. For follow-up formula based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.54 g/100 kJ) applies. It is important to note that the Codex Infant Formula Standard also states the protein levels are based on NCF 6.25 but that 5.71 is generally used for other soy products. In November CCNFSDU will be considering the report from the Joint FAO/WHO Expert Meeting on Nutrition (JEMNU) on the issue of NCFs for infant formula products. The report of the electronic working group is now available here. The recommendation in the working group report is to agree that the NCF of 6.25 is retained in the standard. This is on the basis that the JEMNU report noted that the Expert Panel was *'unclear whether the recommended ranges of protein provided in the relevant Codex standards are to ensure adequate delivery of amino acids or of total protein'* and that a review of the NCF for infant formula was also necessary.