

30 May 2016

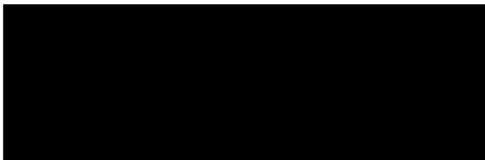
Food Standards Australia New Zealand  
PO Box 10559  
The Terrace  
Wellington 6143  
NEW ZEALAND

Email: [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au)

Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the ***Consultation Paper – Proposal P1028: Infant Formula***.

Yours sincerely



Katherine Rich  
**Chief Executive**



# ***Consultation Paper – Proposal P1028: Infant Formula***

**Submission by the New Zealand Food & Grocery  
Council**

**30 May 2016**

---

## NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council (“NZFGC”) welcomes the opportunity to comment on the.
2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over \$34 billion in the New Zealand domestic retail food, beverage and grocery products market, and over \$31 billion in export revenue from exports to 195 countries – some 72% of total merchandise exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 44% of total manufacturing income. Our members directly or indirectly employ more than 400,000 people – one in five of the workforce.

## OVERARCHING COMMENTS

3. NZFGC recognises that the Infant Nutrition Council Australia New Zealand (INC) draws on a wide range of manufacturing and ingredient supplier technical expertise specific to infant formula and for this reason, NZFGC generally supports the submission of the INC.
4. We therefore reflect in the following, the key points made by the INC in its submission.
5. We particularly support the position that breast feeding is best for infants and mothers and that only where the decision has been made not to breastfeed would infant formula be the best alternative.

## SPECIFIC COMMENTS

### ***Scope***

6. NZFGC recommends that the scope of Proposal P1028 is extended to cover infant formula products for special dietary use as Proposal P1028 will set the basis for composition of these products (outside of nutritional modifications relevant for the condition). There is no prospective Codex work in this area and it would be safe for Standard 2.9.1 to be updated to the greatest extent possible at this time.

### ***Composition***

7. NZFGC concurs with INC that harmonisation to the greatest extent possible with Codex and other relevant international standards is critical to ensuring the best science is applied to infant formula in New Zealand and Australia. The Codex work on infant formula reflects current views on nutritional requirements and safety provisions for infant formula. Alignment would also generally eliminate the prospect of trade barriers in the global infant formula market, especially if infant formula composition was able to be harmonised to Codex STAN 72-1981. It is for this latter reason that Codex is preferred over, for example, the EU regulations in all but a few cases even though the EU regulations have been recently updated. Countries generally defer to Codex rather than the EU when setting their national standards.
8. Concerning definitions, NZFGC considers the status quo should prevail until the follow-on formula requirements are reviewed.

### ***Protein***

9. NZFGC agrees with FSANZ that the protein minimum and maximum levels be maintained (subject to correct conversion to per 100 kJ). For the calculation of protein, NZFGC supports the conversion factor of 5.71 for soy protein sources but also supports further consideration of the conversion factors for milk protein sources noting that New Zealand

---

has generally supported 6.38 in Codex and IDF arenas. A solution may be to align with Codex and provide for all three factors: 5.71, 6.25 and 6.38.

10. NZFGC agrees with FSANZ on protein quality methodology but the DIAAS method should be considered as soon as more information is available. This may well occur before P1028 concludes and NZFGC would like to see this option remain on the table until the latest possible time prior to Final Assessment.
11. While NZFGC agrees with FSANZ on the minimums for many amino acids, we suggest alignment with Codex STAN 72-1981 minimums for tyrosine, phenylalanine, methionine, and cysteine. NZFGC notes that the quality of protein is important but compliance is not straightforward due to the natural variability in amino acid content of milk ingredients and minimising the quantity of excess, naturally occurring amino acids, whilst meeting the minimums.

### Fat

12. NZFGC supports retaining the minimum and lowering the maximum of fat content to align with Codex STAN 72-1981 as proposed by FSANZ. On essential fatty acid composition and units of expression, there are some areas that INC has identified where further work needs to be considered. While we suggest the primary unit of expression for essential fatty acids unit of expression should be aligned to other nutrients (mg/100kJ), we also recommend that provision be made for conversion to % total fatty acids provided along with assumptions used for calculation. The reason for this is because oil suppliers use this method more commonly.
13. We support medium chain tryglycerides (MCTs) being permitted, in line with the rationale for permitting MCTs as a processing aid for infant formula and for use in infant formula products for special dietary use where addition is scientifically substantiated and clinically evaluated for the condition. NZFGC does not support a lowering of the trans fatty acid content because of differences in definitions between the Food Standards Code and Codex.

### Carbohydrates

14. In the absence of specific safety concerns or evidence of adverse effects in infants and the absence of market failure, no limits for carbohydrates should be specified. On definitions and calculations relevant to carbohydrate, NZFGC agrees with FSANZ that the provisions in the revised Code are appropriate for infant formula.

### Energy

15. NZFGC supports FSANZ's proposal to reduce the maximum energy amount to align with that in Codex STAN 72-1981.

### Vitamins, Minerals and Electrolytes

16. NZFGC strongly supports the continued use of non-binding GULs to serve as guidance for industry in designing formulations. GULs, therefore, should not be formally incorporated into Standard 2.9.1. Legally binding maximums should be used when there is evidence of the need for an upper level on safety grounds. NZFGC therefore supports FSANZ's proposal that some nutrients retain a GUL in Standard 2.9.1, and others be amended from a prescribed maximum to a GUL to align with Codex (as summarised in Table 7.2 of SD1).
17. NZFGC mostly agrees with FSANZ in relation to many of the vitamins and minerals reviewed. On folate, NZFGC notes that neither Codex nor the Food Standards Code (including Standard 2.9.1) use dietary folate equivalents (DFE) to express the folate

---

content of infant formula. NZFGC suggests alignment with Codex STAN 72-1981 to measure and express the content as folic acid.

18. NZFGC agrees with the proposal to exclude  $\beta$ -carotene from the total amount of vitamin A but assurance is needed that  $\beta$ -carotene can still be added into Infant formula. NZFGC agrees to an increased GUL for vitamin C and the proposed minimum for vitamin D. However, NZFGC recommends the vitamin D maximum is increased to align with the EU maximum. This is on the basis that otherwise there is currently only a narrow common range between Codex STAN 72-1981 and the EU regulation on vitamin D which is too tight to allow product formulation and manufacture in compliance with both sets of requirements.
19. NZFGC agrees with the current minimum and maximum for iron and supports the status quo for zinc. On selenium, NZFGC suggests retaining the current minimum but having a GUL for selenium. NZFGC suggests that neither a minimum nor maximum or GUL need be set for chromium and molybdenum.
20. In relation to permitted forms of vitamins, minerals and electrolytes NZFGC believes all the forms of nutrients permitted in Codex STAN 72-1981 should be permitted in Standard 2.9.1 for reasons of alignment, flexibility for manufacture and avoidance of trade barriers. NZFGC notes that for inclusion in Codex, these forms have been shown to be safe to use. A technological justification is not necessary as these are added for essential nutritional function.

#### Optional Substances

21. NZFGC supports FSANZ's preliminary view that choline should be listed as a mandatory substance in infant formula and agrees to the minimum proposed. However, NZFGC recommends the upper level **not** be a maximum but rather a GUL.
22. NZFGC supports FSANZ's view that L-carnitine should be mandatory and again supports the (increased) minimum. However, NZFGC has significant concerns from a manufacturing perspective with the proposed maximum, and suggests no maximum be set at this time. Legally binding maximums should be used only when there is evidence of the need for safety reasons and this is not the case for L-carnitine.
23. NZFGC supports the FSANZ preliminary view that inositol should be mandatory at the current minimum level and supports the current maximum being a GUL.
24. NZFGC supports retention of combined totals of nucleotides in principle but the level of that combined total needs to be determined. It is also important that the Food Standards Code is clear that this limit applies only when nucleotides are added.

#### ***Safety and Food Technology***

25. In general, NZFGC supports all the FSANZ proposals relating to directions to prepare bottles individually, directions for the storage of made up formula (although the statement that it is safe to store prepared formula for up to 24 hours in the refrigerator needs clarification that it is not prescribed and that there is flexibility for the time limit to be for up to 24 hours), directions on water used to reconstitute powdered infant formula, discarding leftover formula, directions for preparation and use, date marking of food, and storage instructions for opened infant formula.
26. NZFGC strongly opposes standardisation of measuring scoops for the reasons FSANZ has identified. The powder density of infant formula is affected by both the ingredients and the manufacturing process used and it is not possible for this to be standardised for all powdered infant formulas.

- 
27. NZFGC considers indicators on baby bottles to be out of scope of the Australia New Zealand Food Standards Code.
  28. NZFGC supports maintaining the current legibility requirements for infant formula in relation to other warning, advisory and other statements. NZFGC also supports the requirement that the infant formula label contain a statement of the specific source, or sources, of protein in the product.
  29. INC supports maintaining the mandatory statement about protein source and for it to be located immediately adjacent to the name of the infant formula (i.e. the prescribed name 'Infant Formula'). However, INC does not support prescribing where this should be located on the label.
  30. NZFGC supports the status quo in retaining all current warning and advisory statements but does not support additional warning statements in the absence of market failure or strong evidence that misuse is prevalent.
  31. NZFGC supports the status quo on the statement that infant formula may be used from birth and continuing the requirement for 'Infant Formula', as a prescribed name.

#### ***Nutritive Substances and Novel Foods***

32. Proposal P1024 excluded all Part 2.9 standards from its scope, including Standard 2.9.1. NZFGC strongly supports all Part 2.9 standards, including Standard 2.9.1, being included within the scope of Proposal P1024 and the framework proposed in the Proposal going forward. This will ensure consistency and clarity for all standards particularly those that use make reference to nutritive substances.
33. NZFGC believes that Standard 2.9.1 can be included and still be in line with the Policy Guideline on Infant Formula Products. Just as FSANZ drew on a wide range of expertise within FSANZ for the purposes of preparing this Consultation for the Review of Infant Formula, we believe a similar broad input needs to be applied to a broader approach for Proposal P1024.

#### ***Contaminants***

34. NZFGC supports FSANZ's views in relation to acrylonitrile, tin, vinyl chloride, arsenic and lead but considers that further consideration is needed in relation to aluminium.
35. NZFGC agrees with FSANZ on melamine, not to introduce a regulatory requirement for this adulterant.
36. NZFGC strongly supports collocation of all MLs for contaminants in a single Standard to enhance transparency and usability. NZFGC believes that the appropriate units for MLs relating to contaminants for infant formula should be based on mg/kg as sold. NZFGC considers that a definition of contaminant is not necessary in the Code.

#### ***Food Additives and Processing Aids***

37. Where a food additive is performing a technological function in the final product, NZFGC considers that, in principle, it is preferable to be aligned with Codex to facilitate innovation and harmonisation of trade where safety and technological justification have already been established. NZFGC supports retaining the status quo for processing aids for infant formula.

---

### ***Carry-over Principle for Food Additives***

38. NZFGC strongly supports continuation of the carry-over principle for food additives in infant formula. As well, NZFGC supports alignment with Codex in relation to permitted carry-over additives. We would point out that Codex **does** permit additives that may be present in any food as a result of carry-over from a raw material or an ingredient. These are technologically necessary for the quality of the ingredient in the product.

### ***Labelling***

39. Concerning provision of information, NZFGC maintains that the declaration of macronutrient sub-groups in a nutrition information statement is permitted and should be retained.

40. To support informed choice, NZFGC supports the INC view that nutrient content and general level health claims on nutrients (other than essential nutrients) should be conditionally permitted to allow for brand differentiation and informed choice for the caregiver. NZFGC has analysed the Policy Guideline on Infant Formula Products and the WHO Code and its local adaptation (INC New Zealand Code of Practice) and considers all can be satisfied with such a permission.

### ***Ingredients Lists and Nutrition Information Statements***

41. NZFGC considers that ingredients lists and nutrition information statements are fundamentally different and that they have different functions for the product. NZFGC does not support additional prescription on how nutrients are labelled. NZFGC strongly opposes a prescribed format of nutrition statement across product labels. This would present significant issues for consumer understanding of this information and potential trade barriers. A mandated format creates a real barrier to trade both for exports and imports.

### ***Other issues***

#### ***Conversion factors***

42. NZFGC notes that technical corrections are intended to be made to primary limits on nutrient composition specified in Codex STAN 72-1981 on the basis that a number of the per 100 kcal limits have not been correctly converted to a per 100kJ basis in this Codex standard. INC has identified that these errors have led to some values being applied in Standard 2.9.1 that are intended to be aligned with Codex being incorrectly stated. INC has provided a comprehensive list of these errors and NZFGC supports their correction as soon as possible, potentially through a technical amendment in advance of the conclusion of P1028 in several years' time. It is important that technical errors are corrected at the earliest possible time following identification to preserve the integrity of both the Food Standards Code and FSANZ.

#### ***Transitional Timings and other Infant Formula Products***

43. NZFGC notes that transition has not yet been canvassed and requests that any transitional period be of reasonable length to allow adequate time to implement changes, particularly for imported infant formula that is not manufactured in Australia and New Zealand. The practicality and feasibility of a staged transition might also be considered if necessary. As noted above, NZFGC advocates for the scope of Proposal P1028 to be extended to cover infant formula products for special dietary use, but different transitional arrangements may be appropriate for these products if this scope change is implemented.

44. Lastly, while the scope of Proposal P1028 relates to infant formulas only, NZFGC recognises that it will, in future proposals, underpin the review of the remaining infant formula products. NZFGC requests that transitional arrangements are considered in the context of the products in Standard 2.9.1 that are not currently within scope of Proposal P1028.