FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

26 April 2023
238-23

Supporting document 2

Nutrient composition for Infant Formula Products

Proposal P1028 – Infant Formula 2nd CFS

Executive summary

Food Standards Australia New Zealand (FSANZ) is reviewing regulatory requirements for infant formula products under Proposal P1028 – Infant formula.

Infant formula products are currently regulated under Standard 2.9.1 – Infant Formula Products and Schedule 29 – Special Purpose Foods in the Australia New Zealand Food Standards Code (the Code).

The protection of public health and safety is a primary objective for FSANZ. Infant formula products must be safe for formula-fed infants to consume, and the nutrient composition must support normal growth and development when infant formula is used as the sole or principal source of nutrition up to 12 months of age.

This Supporting Document (SD) is one of four developed to accompany the 2nd CFS and focuses on issues relating to the nutrient composition of infant formula products, including infant formula, follow-on formula and special medical purpose products for infants (SMPPi). It is organised into four parts as follows:

- Part A: General composition
- Part B: Infant formula
- Part C: Follow-on formula
- Part D: SMPPi

Each part of the SD considers the stakeholder comments from the 1st CFS, FSANZ response and further consideration where required. Part A, B and C of this SD address each regulatory requirement that relates to the composition of infant formula and follow-on formula including the nutrient ranges, sources, equivalents, permitted forms, conversion factors and ratios for macronutrients, micronutrients and nutritive substances. They also consider other general requirements such as units of measure, definition for Guidance Upper Levels (GUL), standardisation of the measuring scoop, vitamin and mineral supplementation and modified formulas.

FSANZ's current proposed regulatory approach for infant formula and follow-on formula nutrient composition is summarised below in Table 1 and incorporated into the following two

draft variations at Attachment A to the 2nd CFS:

- The draft variation amending Standard 2.9.1 (the primary draft variation)
- The draft variation amending Schedule 29 and other Standards and/or Schedules in the Code, as a consequence to the proposed amendments set out in the primary draft variation (the consequential draft variation).

The draft variations were made with consideration to the objectives of the Proposal, the requirements of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) and relevant risk management principles.

Table 1 – P1028 proposed infant formula and follow-on formula nutrient composition

Nutrient	Unit	Infant formula		Follow-on formula	
		Min	Max	Min	Max
Energy	kJ/L	2510	2930	2510	2930
Carbohydrates	g/100 kJ	NS	NS	NS	NS
Total fat	g/100 kJ	1.1	1.4	1.1	1.4
Linoleic acid (LA)	mg/100 kJ	90	335*	90	335*
α-Linolenic acid (ALA)	mg/100 kJ	12	NS	12	NS
Erucic Acid^	% total fatty acid	NS	1	NS	1
Docosahexaenoic acid (DHA)^	mg/100 kJ	NS	7*	NS	7*
Trans fatty acid^	% total fatty acid	NS	4	NS	4
Phospholipids^	mg/100 kJ	NS	72	NS	72
Protein (milk)	g/100 kJ	0.43	0.72	0.38	0.72
Protein (soy)	g/100 kJ	0.54	0.72	0.54	0.72
L-amino Acids					
Histidine	mg/100 kJ	10	NS	10	NS
Isoleucine	mg/100 kJ	22	NS	22	NS
Leucine	mg/100 kJ	40	NS	40	NS
Lysine	mg/100 kJ	27	NS	27	NS
Cysteine	mg/100 kJ	9	NS	9	NS
Methionine	mg/100 kJ	6	NS	6	NS
Phenylalanine	mg/100 kJ	19	NS	19	NS
Threonine	mg/100 kJ	18	NS	18	NS
Tryptophan	mg/100 kJ	8	NS	8	NS
Tyrosine	mg/100 kJ	18	NS	18	NS
Valine	mg/100 kJ	22	NS	22	NS
Vitamins					
Vitamin A	µg RE/100 kJ	14	43	14	43
Vitamin B_6	µg/100 kJ	8	42*	8	42*
Vitamin B_{12}	µg/100 kJ	0.02	0.36*	0.02	0.36*
Vitamin C	mg/100 kJ	1.7	17*	1.7	17*
Vitamin D	µg/100 kJ	0.24	0.63	0.24	0.63
Vitamin E	mg α-TE/100 kJ	0.14	1.2*	0.14	1.2*
Vitamin K	µg/100 kJ	0.24	6*	0.24	6*
Biotin	µg/100 kJ	0.24	2.4*	0.24	2.4*
Niacin	µg/100 kJ	70	359*	70	359*
Riboflavin	µg/100 kJ	14.3	120*	14.3	120*
Pantothenic acid	µg/100 kJ	96	478*	96	478*
Folic acid	µg/100 kJ	2.4	12*	2.4	12*
Thiamin	µg/100 kJ	10	72*	10	72*
Minerals					
Calcium	mg/100 kJ	12	35*	12	43*
Magnesium	mg/100 kJ	1.2	3.6*	1.2	3.6*
Iron	mg/100 kJ	0.14	0.48	0.24	0.48
Sodium	mg/100 kJ	4.8	14	4.8	14
Chloride	mg/100 kJ	12	38	12	38
Potassium	mg/100 kJ	14	43	14	43
Phosphorus	mg/100 kJ	6	24*	6	24*
Manganese	µg/100 kJ	0.24	24*	0.24	24*
Zinc	mg/100 kJ	0.12	0.36*	0.12	0.36*

Copper	µg/100 kJ	8	29*	8	29*
Iodine	µg/100 kJ	2.4	14*	2.4	14*
Selenium	µg/100 kJ	0.48	2.2*	0.48	2.2*
Nutritive substances					
Choline	mg/100 kJ	1.7	12*	NS	12*^
Myo-inositol	mg/100 kJ	1.0	10*	NS	10*^
L-Carnitine	mg/100 kJ	0.3	0.8*	0.3^	NS^
Fluoride	µg/100 kJ	NS	17	NS	17
2′-fucosyllactose^	mg/100 kJ	NS	961	NS	961
Taurine^	mg/100 kJ	NS	2.9	NS	2.9
Lutein^	µg/100 kJ	1.5	5.0	1.5	5.0
Lactoferrin ^	mg/100 kJ	-	40	-	40
Nucleotides					
Adenosine-5′-monophosphate^	mg/100 kJ	NS	0.36	NS	0.36
Cytidine-5′-monophosphate^	mg/100 kJ	NS	0.6	NS	0.6
Guanosine-5′-monophosphate^	mg/100 kJ	NS	0.40	NS	0.40
Inosine-5′-monophosphate^	mg/100 kJ	NS	0.24	NS	0.24
Uridine-5′-monophosphate^	mg/100 kJ	NS	0.42	NS	0.42
Total free nucleotide 5'-monophosphates^	mg/100 kJ	NS	3.8	NS	3.8
Ratios					
LA : ALA	ratio	5 : 1	15 : 1	5 : 1	15 : 1
Ca : P	ratio	1 : 1	2 : 1	1 : 1	2 : 1
Vitamin E : fatty acids	ratio	0.5mg : 1g	NS	0.5mg : 1g	NS
Arachidonic acid^	ratio	≥ DHA	NS	≥ DHA	NS
Eicosapentaenoic acid	ratio	NS	≤ DHA	NS	≤ DHA
Zn : Cu	ratio	Removed			
Sources					
Protein	Cow's milk protein, goat's milk protein, sheep milk protein, soy protein isolate and partially hydrolysed protein of one or more of these specified proteins				
Carbohydrate	Sucrose and/or fructose should not be added, unless needed as a carbohydrate source in infant formula or follow-on formula manufactured from protein hydrolysates, and provided the sum of these does not exceed 20% of available carbohydrates.				
Permitted forms and equivalents					
Vitamin A	***Retinol forms***: vitamin A (retinol), vitamin A acetate (retinyl acetate), vitamin A palmitate (retinyl palmitate), retinyl propionate ***Provitamin A forms***: beta-carotene				
Vitamin C	L-ascorbic acid, L-ascorbyl palmitate, calcium ascorbate, potassium ascorbate, sodium ascorbate				
Vitamin D	Vitamin D2, vitamin D3 and vitamin D (cholecalciferol-cholesterol)				
Thiamin	Thiamin hydrochloride, thiamin mononitrate				
Riboflavin	Riboflavin, riboflavin-5′-phosphate, sodium				
Niacin	Niacinamide (nicotinamide)				
Vitamin B_6	Pyridoxine hydrochloride, pyridoxine-5′-phosphate				
Folic acid	Naturally occurring folate will not be included in the permitted range for folic acid				
Pantothenic Acid	Calcium pantothenate, dexpanthenol, D-panthenol, calcium D-pantothenate, sodium D-pantothenate				
Vitamin B_{12}	Cyanocobalamin, hydroxocobalamin				
Biotin	d-biotin				
Vitamin E	dl-α-tocopherol, d-α-tocopherol concentrate, tocopherols concentrate mixed, d-α-tocopheryl acetate, dl-α-tocopheryl acetate, d-α-tocopheryl acid succinate, dl-α-tocopheryl succinate				
Vitamin K	Vitamin K1 as phylloquinone (phytonadione)				
Calcium	Calcium carbonate, calcium chloride, calcium citrate, calcium gluconate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium oxide, calcium phosphate, dibasic, calcium phosphate, monobasic, calcium phosphate, tribasic, calcium sulphate				
Chloride	Calcium chloride, magnesium chloride, potassium chloride, sodium chloride				
Copper	Copper gluconate, cupric sulphate, cupric citrate, cupric carbonate				
Iodine	Potassium iodate, potassium iodide, sodium iodide				
Iron	Ferric ammonium citrate, ferric pyrophosphate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferrous succinate, ferrous sulphate, ferric citrate, ferrous bisglycinate and ferrous sulphate				
Magnesium	Magnesium carbonate, magnesium chloride, magnesium gluconate, magnesium oxide, magnesium phosphate dibasic, magnesium phosphate tribasic, magnesium sulphate, magnesium hydroxide carbonate, magnesium hydroxide and magnesium salts of citric acid				

Manganese	Manganese chloride, manganese gluconate, manganese sulphate, manganese carbonate, manganese citrate
Phosphorus	Calcium glycerophosphate, calcium phosphate (dibasic), calcium phosphate (monobasic), calcium phosphate (tribasic), magnesium phosphate (dibasic), potassium phosphate (dibasic), potassium phosphate (monobasic), potassium phosphate (tribasic), sodium phosphate (dibasic), sodium phosphate (monobasic), sodium phosphate (tribasic).
Potassium	Potassium bicarbonate, potassium carbonate, potassium chloride, potassium citrate, potassium glycerophosphate, potassium gluconate, potassium hydroxide, potassium phosphate, dibasic, potassium phosphate, monobasic, potassium phosphate, tribasic, potassium L-lactate
Selenium	Seleno methionine, sodium selenate, sodium selenite
Sodium	Sodium bicarbonate, sodium carbonate, sodium chloride, sodium chloride iodised, sodium citrate, sodium gluconate, sodium hydroxide, sodium iodide, sodium lactate, sodium phosphate (dibasic), sodium phosphate (monobasic), sodium phosphate (tribasic), sodium sulphate, sodium tartrate
Zinc	Zinc acetate, zinc chloride, zinc gluconate, zinc oxide, zinc sulphate, zinc lactate and zinc citrate (zinc citrate dehydrate or zinc citrate trihydrate)
Choline	Choline chloride and choline bitartrate, choline, choline citrate and choline hydrogen tartrate
L-Carnitine	L-carnitine hydrochloride and L-carnitine tartrate
Units of expression	
Vitamin A	µg RE/100 kJ
Folic acid	µg/100 kJ
Vitamin E	α-TE/100 kJ
Niacin	µg/100 kJ
Linoleic acid (LA)	mg/100 kJ
α-Linolenic acid (ALA)	mg/100 kJ
Docosahexaenoic acid (DHA)^	mg/100 kJ
Conversion factors	
Nitrogen Conversion Factor (NFC)	Removed
Potential Renal Solute Level (PRSL)	Removed

NS = Not Specified * = GUL ^ = Voluntary Addition

[1] A combination of of 2′-fucosyllactose and lacto-N-neotetraose may reach a maximum of 96 mg/100 kJ, which contains not more than 24 mg of lacto-N-neotetraose.

Part D of this SD addresses stakeholder comments from *Supporting Document 4 – Special medical purpose products for infants* (FSANZ 2022b). Part D considers the overarching approach applied to SMPPi composition, composition for different medical conditions and pre-market assessment of SMPPi.

FSANZ's proposed regulatory approach for SMPPi nutrient composition is summarised below and incorporated into the primary draft variation at Attachment A to the 2nd CFS. The proposed primary and consequential draft variations were made with consideration to the objectives of the Proposal, the requirements of the FSANZ Act and relevant risk management principles.

The proposed variations :

- add a definition for *special medical purpose products for infants* to the Code
- amend Division 4 Infant formula products for special dietary use to reflect the following changes:
    - amend the title to special medical purpose products for infants;
    - revoke the following subsections: Products formulated for premature or low birthweight infants; Products for metabolic, immunological, renal, hepatic and malabsorptive conditions; and Products for specific dietary use based on a protein substitute; and
    - amend the composition subsection to require SMPPi contain the baseline composition of infant formula (see Table 1 for further details) except where deviation is required to address the product's medical purpose, or where it would otherwise prevent the sale of the product.

The proposed variations noted above will be accompanied by food additive permissions discussed in SD1, labelling changes discussed in SD3 and the restriction of sale discussed in section 2.3.6 of the 2nd CFS.

FSANZ also concluded that SMPPi will not require a standardised measuring scoop.

Table of contents

1 Introduction

Although breastfeeding is the recommended way to feed infants, a safe and nutritious substitute for breast milk is needed for infants who are not breastfed. Infant formula products are the only safe and suitable alternative to breast milk.

Infant formula products are primarily regulated within the Australia New Zealand Food Standards Code (the Code) through:

- Standard 2.9.1 – Infant formula products, and
- Schedule 29 – Special purpose foods.

While the standards in the Code that regulate infant formula products are mostly working well, Proposal P1028 aims to ensure these standards are appropriate, clear and functional now and into the future. The overarching goal of Proposal P1028 is to ensure that infant formula products remain safe and suitable and standards take account of current science, market developments and the international regulatory context. As part of its assessment of the Proposal, FSANZ is considering key stakeholder views, relevant Ministerial policy guidance and alignment with updated international regulations. Proposal P1028 was prepared under section 113(6) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) and is being assessed under the Major Procedure.

The protection of public health and safety is the primary objective for FSANZ. The nutrient composition of infant formula products is appropriately prescriptive to ensure that they provide sufficient energy and nutrients to promote normal growth and development of formula-fed infants, without posing a risk to infant health.

This document is divided into four parts - Part A: General nutrient composition; Part B: Infant formula; Part C: Follow-on formula; Part D: SMPPi - which consider each regulatory option and the associated stakeholder comments. Stakeholder comments can be found in each of the below tables, located in the body of the document:

General composition:

- Table 3 – General comments: summary of submitter comments and FSANZ response

Infant formula:

- Table 4 – Macronutrients: summary of submitter comments and FSANZ response
- Table 5 – Micronutrients: summary of submitter comments and FSANZ response
- Table 6 – Equivalents, conversion factors and units of expression: summary of submitter comments and FSANZ response
- Table 7 – Nutritive substances: summary of submitter comments and FSANZ response

Follow-on formula:

- Table 8 – Macronutrients: summary of submitter comments and FSANZ response
- Table 9 – Micronutrients: summary of submitter comments and FSANZ response
- Table 10 – Nutritive substances: summary of submitter comments and FSANZ response

SMPPi:

- Table 11 – SMPPi composition: summary of submitter comments and FSANZ response

Where further consideration or assessment of stakeholder comments is required, FSANZ response and further discussion has been moved below the table.

1.1 Assessment to date

Reviewing an entire standard which regulates food for a vulnerable population is complex. Therefore, ample opportunity for stakeholders to provide input into the process and for their

views to be considered is critical. To date, FSANZ has released six consultation papers[1] on this proposal:

- The 2016 Consultation paper focused on the regulation of infant formula. Infant Formula Products for Special Dietary Use (IFPSDU) and follow-on formula were excluded from scope (FSANZ 2016 CP).
    - The 2016 Nutrition Assessment supported FSANZ 2016 CP and informed the nutrition composition evaluation (FSANZ 2016 NA)
- The 2017 Consultation paper focused on IFPSDU. Many submissions to the 2016 paper requested IFPSDU be included in the Proposal's scope. This is because requirements for IFPSDU are founded on those for infant formula (FSANZ 2017 CP).
- The 2021 Consultation comprised of three main consultation papers which focused on matters regarding regulatory options for the 1st Call for Submission (CFS):
    - Consultation Paper 1 – Safety and Technology (FSANZ 2021 CP1)
    - Consultation Paper 2 – Nutrient Composition (FSANZ 2021 CP2)
        - Supporting Document 1 - Nutrition Assessment (FSANZ 2021 NA)
    - Consultation Paper 3 – Regulatory framework and definition (FSANZ 2021 CP3)
- The 1st Call for submissions (CFS) which was released alongside six supporting documents which outline FSANZ position of each regulatory aspect:
    - Supporting Document 1 – Safety and Food Technology (FSANZ 2022 SD1)
        - Attachment to SD1 – Microbiological safety of PIF
    - Supporting Document 2 – Nutrient composition (FSANZ 2022 SD2)
    - Supporting Document 3 – Labelling for provision of information (FSANZ 2022 SD3)
        - Attachment to SD3 – Consumer research on infant formula labelling
    - Supporting Document 4 – Special Medical Purpose Formula for infants (composition and labelling) (FSANZ 2022 SD4)
    - Supporting Document 5 – Costs and benefits (FSANZ 2022 SD5)
    - Supporting Document 6 – Assessment against the Ministerial Policy Guidelines (FSANZ 2022 SD6)

These papers and additional targeted consultation have enabled FSANZ to examine the available evidence, scope the regulatory issues and consider options to improve the current regulation.

This Supporting Document (SD) gives consideration to the submissions received from the 1st CFS.

The assessment of nutrient composition was guided by the approach set out in the FSANZ 2016 and 2021 NA's. The FSANZ 2016 NA followed an approach in which the Codex CXS 72-1981 provisions for each nutrient were assessed against a set of criteria.
These assessment criteria were (where applicable):

- origin of the current standards
- recommendations of key expert bodies
- comparison with human milk concentrations
- estimation of intakes and comparison with Australia and New Zealand (ANZ) Nutrient Reference Values (NRVs) for adequate and excess intakes
- physiological, biochemical or functional outcomes
- identification of new or emerging scientific evidence.

Compositional requirements for 33 constituents of infant formula—protein, carbohydrate, fat, vitamins (13), minerals and electrolytes (14), and nutritive substances (three)—as well as the energy content were reviewed.

[1] http://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

The FSANZ 2021 NA built on the FSANZ 2016 NA by addressing questions and concerns raised by submitters. For some nutrients further assessment was undertaken to consider whether aligning with the EU 2016/127 would pose a risk to infant health.
These assessment criteria were (where applicable):

- outline of the scientific basis of the current standards
- comparison with human milk concentrations, focusing on ANZ populations
- comparison with EFSA (2014a) recommendations and FSANZ (2016b) proposed levels
- estimation of intakes and comparison with ANZ NRVs for adequate and excess intakes (non-ANZ NRVs were used in circumstances when an ANZ value was not available)
- other relevant factors unique to the nutrient of interest such as the impact of manufacturing or other nutrients on the nutrient's bioavailability, history of apparent safe use, or the ANZ infant or maternal population
- when a potential risk was identified based on comparisons to human milk concentrations and NRVs, a review of scientific evidence which focused on primary research published after the FSANZ 2016 assessment and on ANZ populations
- if a potential risk was identified, a comparative assessment of the risk associated with the compositional requirements of the Code and Codex CXS 72-1981 was conducted.

1.2 Key Considerations

Key themes from the 1st CFS were captured in the Stakeholder Feedback Summary and published on the FSANZ webpage[2], alongside the stakeholder submissions.

To note, FSANZ was especially concerned with comments which stated that the FSANZ assessment was prioritising trade over public health when aligning with Codex Alimentarius. FSANZ has undertaken an independent, transparent and rigorous assessment process that considered the assessment criteria noted above, alongside updated research and evidence and stakeholder views. Further to this, the Codex Alimentarius standards, such as Codex CXS 72-1981, also undergo a rigorous assessment and are based on sound science provided by independent international risk assessment bodies or ad-hoc consultations organised by the Food and Agriculture Organization (FAO) and World Health Organization (WHO). The purpose of Codex Alimentarius is to develop and maintain international food standards that protect consumers' health and ensure fair practices in the food trade (FAO/WHO 2023). Codex Alimentarius standards are adopted globally by many national authorities and represent a larger portion of the regulatory landscape in comparison to one legislation, such as the EU or UK regulations. Where FSANZ has adopted Codex values there has been thorough assessment to ensure that the value is suitable in the ANZ population and that it does not pose a risk to the public health or safety of ANZ infants.

[2] https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

Part A General nutrient composition

2 Nutrient Composition with unanimous support

From the 1st CFS FSANZ received unanimous support on the nutrient composition permissions listed below and in Table 2. FSANZ notes the support for these permissions and concludes they will not be assessed further within the 2nd CFS. The below permissions are included within both the primary and consequential draft variation, expect where corrections have been made in line with International Standard Unit conversion factors and conventional rounding.

FSANZ received unanimous support for the following permissions:

- to manage protein quality through specifying minimum amino acid requirements, as noted in Table 2
- to not prescribe methods of analysis for dietary fibre
- to not define the fat source
- to retain voluntary permission for EPA and AA
- to list choline, L-carnitine and myo-inositol as mandatory substances in infant formula
- to remove the current guidance maximums for chromium and molybdenum in infant formula products.

Table 2 – Nutrient composition permissions that require no further consideration

Nutrient	Unit	Infant formula		Follow-on formula	
		Min	Max	Min	Max
Macronutrients					
Energy	kJ/L	2510	2930	2510	2930
Carbohydrates	g/100 kJ	NS	NS	NS	NS
Total fat	g/100 kJ	1.1	1.4	1.1	1.4
α-Linolenic acid (ALA)	mg/100 kJ	12	NS	12	NS
Erucic Acid^	% total fatty acid	NS	1	NS	1
Micronutrients					
Riboflavin	µg/100 kJ	14.3	120*	14.3	120*
Vitamin K	µg/100 kJ	0.24	6.0*	0.24	6.0*
Calcium	mg/100 kJ	12	35*	-	
Magnesium	mg/100 kJ	1.2	3.6*	1.2	3.6*
Sodium	mg/100 kJ	4.8	14	4.8	14
Chloride	mg/100 kJ	12	38	12	38
Potassium	mg/100 kJ	14	43	14	43
Pantothenic acid	µg/100 kJ	96	478*	96	478*
Manganese	µg/100 kJ	0.24	24*	0.24	24*
L-amino Acids					
Histidine	mg/100 kJ	10	NS	10	NS
Isoleucine	mg/100 kJ	22	NS	22	NS
Leucine	mg/100 kJ	40	NS	40	NS
Lysine	mg/100 kJ	27	NS	27	NS
Cysteine	mg/100 kJ	9	NS	9	NS
Methionine	mg/100 kJ	6	NS	6	NS
Phenylalanine	mg/100 kJ	19	NS	19	NS
Threonine	mg/100 kJ	18	NS	18	NS
Tryptophan	mg/100 kJ	8	NS	8	NS
Tyrosine	mg/100 kJ	18	NS	18	NS
Valine	mg/100 kJ	22	NS	22	NS
Nutritive substances					
2′-fucosyllactose	mg/100 kJ	NS	96[1]	NS	96[1]
Ratio					

LA : ALA	ratio	5 : 1	15 : 1	5 : 1	15 : 1
Ca : P	ratio	1 : 1	2 : 1	1 : 1	2 : 1
EPA	ratio	NS	≤ DHA	NS	≤ DHA
Permitted forms and equivalents					
Vitamin C	L-ascorbic acid, L-ascorbyl palmitate, calcium ascorbate, potassium ascorbate, sodium ascorbate				
Vitamin D	Vitamin D2, vitamin D3 and vitamin D (cholecalciferol-cholesterol)				
Thiamin	thiamin hydrochloride, thiamin mononitrate				
Riboflavin	Riboflavin, riboflavin-5′-phosphate, sodium				
Niacin	Niacinamide (nicotinamide)				
Vitamin B6	pyridoxine hydrochloride, pyridoxine-5′-phosphate				
Folic acid	Naturally occurring folate will not be included in the permitted range for folic acid				
Pantothenic Acid	Calcium pantothenate, dexpanthenol, -panthenol, calcium D-pantothenate, sodium D-pantothenate				
Vitamin B12	Cyanocobalamin, hydroxocobalamin				
Biotin	d-biotin				
Vitamin E	dl-α-tocopherol, d-α-tocopherol concentrate, tocopherols concentrate mixed, d-α-tocopheryl acetate, dl-α-tocopheryl acetate, d-α-tocopheryl acid succinate, dl-α-tocopheryl succinate				
Vitamin K	Vitamin K1 as phylloquinone (phytonadione)				
Calcium	calcium carbonate, calcium chloride, calcium citrate, calcium gluconate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium oxide, calcium phosphate, dibasic, calcium phosphate, monobasic, calcium phosphate, tribasic, calcium sulphate				
Chloride	calcium chloride, magnesium chloride, potassium chloride, sodium chloride				
Copper	Copper gluconate, cupric sulphate, cupric citrate, Cupric carbonate				
Iodine	potassium iodate, potassium iodide, sodium iodide				
Iron	Ferric ammonium citrate, ferric pyrophosphate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferrous succinate, ferrous sulphate, Ferric citrate, ferrous bisglycinate and ferrous sulphate				
Magnesium	Magnesium carbonate, magnesium gluconate, magnesium oxide, magnesium phosphate dibasic, magnesium phosphate tribasic, magnesium sulphate, Magnesium hydroxide carbonate, magnesium hydroxide and magnesium salts of citric acid				
Manganese	manganese chloride, manganese gluconate, manganese sulphate, manganese carbonate, manganese citrate				
Phosphorus	calcium glycerophosphate, calcium phosphate (dibasic), calcium phosphate (monobasic), calcium phosphate (tribasic), magnesium phosphate (dibasic), potassium phosphate (dibasic), potassium phosphate (monobasic), potassium phosphate (tribasic), sodium phosphate (dibasic), sodium phosphate (monobasic, sodium phosphate (tribasic).				
Potassium	Potassium bicarbonate, potassium carbonate, potassium chloride, potassium citrate, potassium glycerophosphate, potassium gluconate, potassium hydroxide, potassium phosphate, dibasic, potassium phosphate, monobasic, potassium phosphate, tribasic, Potassium L-lactate				
Selenium	seleno methionine, sodium selenite, sodium selenate				
Sodium	sodium bicarbonate, sodium carbonate, sodium chloride, sodium chloride iodised, sodium citrate, sodium gluconate, sodium hydroxide, sodium iodide, sodium lactate, sodium phosphate (dibasic), sodium phosphate (monobasic), sodium phosphate (tribasic), sodium sulphate, sodium tartrate				
Zinc	Zinc acetate, zinc chloride, zinc gluconate, zinc oxide, zinc sulphate, Zinc lactate and zinc citrate (zinc citrate dehydrate or zinc citrate trihydrate)				
Choline	Choline chloride and choline bitarate, Choline, choline citrate and choline hydrogen tartrate				
L-Carnitine	L-carnitine hydrochloride and L-carnitine tartrate				
Units of expression					
Vitamin A	µg RE/100 kJ				
Folic acid	µg / 100 kJ				
Vitamin E	α-TE / 100 kJ				
Niacin	µg / 100 kJ				
Linoleic acid (LA)	mg/100 kJ				
α-Linolenic acid (ALA)	mg/100 kJ				
Docosahexaenoic acid (DHA)^	mg/100 kJ				

NS = Not Specified * = GUL ~ = Levels may need to be determined by national authorities ^ = Voluntary Addition

[1] A combination of 2′-fucosyllactose and lacto-N-neotetraose may reach a maximum of 96 mg/100 kJ, which contains not more than 24 mg of lacto-N-neotetraose.

The ratio of total long chain omega 6 series fatty acids^ to total long chain omega 3 series fatty acids that is not less than 1.

3 General Composition

Table 3 – General comments: summary of submitter comments and FSANZ response

Issue	Comment	Submitter(s)	FSANZ Response
Necessity of follow-on formula	Follow-on formula is not a necessary product as the nutrient composition is almost identical to infant formula and infants who are not able to have breast milk should instead be fed infant formula from birth to 12 months of age. Additional nutrient requirements will be met through complimentary feeding. This raises concerns that consumers are currently being misled as to the necessity of follow-on formula and are unnecessarily switching from an infant formula product to follow-on formula.	NZMoH, VICDoH	FSANZ notes international regulations including Codex, the EU, UK, US, Turkey, China and South East Asia (SEA) include regulations and guidelines which prescribe separate composition for follow-on formula. To remove follow-on formula from the Code would be out of step internationally and inconsistent with the purpose of the Proposal to align with international regulations unless safety concerns have been identified.
Length of time an ingredient can remain as a voluntary addition	Consideration should be given to the duration of time an ingredient can maintain as a voluntary addition before it is reviewed for efficacy. Examples of such substances include DHA, ARA, EPA and lutein.	NSWFA	Following pre-market approval by FSANZ, FSANZ does not routinely reconsider voluntary ingredients after a certain length of time. This is not general practice and is not evident for permissions within the Code, apart from Application A1155 - 2'-FL and LNnT in infant formula and other products, for which the food ministers requested a five year review post approval. DHA, ARA, EPA and lutein have been present within infant formula regulation as voluntary permissions for over 20 years, with no concerns surrounding efficacy.
Independent expert group	FSANZ should consider establishing an independent expert group to provide additional expert advice and help to critically review the evidence.	WADoH	FSANZ acknowledges how an expert panel could improve regulatory clarity. However, the FSANZ Act does not allow the Code to establish such an independent expert panel as it does not come within the list of matters that can be included in a proposed draft variation as per section 16 of the FSANZ Act. This is a matter for the jurisdictions to consider.
Prioritisation of trade over public health	This submitter noted concern as they believe there has been little consideration for the optimal levels of nutrients for infants and instead FSANZ's priority has been to align with Codex levels, purely based on evidence of no harm to infants. This submitter believes this fundamentally prioritises trade over infant health.	VICDoH	FSANZ reiterates the conclusions of the FSANZ 2016 NA which assessed the nutrient levels present in Codex CXS 72-1981, within the context of the ANZ population. Levels assessed were found to be appropriate within the ANZ infant population and did not pose risk to infant health. FSANZ has considered multiple factors in proposing set ranges for nutrients within infant formula

Issue	Comment	Submitter(s)	FSANZ Response
			products, with the most important being the consideration of public health and safety.
Units of measure	Recommend that FSANZ align with the units stated per 100 kcal multiplied by 4.18 as the limits in Codex CXS 72-1981 were set on a kcal basis and the limits per 100 kJ listed within it were subsequently calculated from the kcal figures, in some cases incorrectly. This will result in better alignment of the revised Standard 2.9.1 with Codex CXS 72-1981. The Codex Draft Standard FuFOI has adopted this approach.	INC, AFCG, FCG, NES, NZFS	FSANZ has addressed the issue raised in section 3.1 below.
Units of measure	Present units in both kcal and kJ, as this is present in both Codex and the EU regulation.	INC, AFCG, FCG, NES	
Significant figures	Recommend that limits on nutrient composition are consistently stated to 2 significant figures (with exceptions like energy, where more significant figures are warranted, stated to 3 significant figures).	INC, AFCG, FCG, NES	
Guidance Upper Limits	Recommend that the term "GUL" is used and defined within the Code. Replacing the use of guideline maximum amounts to better align with Codex standards.	INC, AFCG, FCG, A2M, NZFGC	FSANZ has addressed the issue raised in the section 3.2 below.
Vitamin and Mineral Supplementation *FSANZ preferred option at the CFS was to:* • *Remove the voluntary guideline to provide advice regarding additional vitamin and mineral supplementation in S29—10(2) of the Code.*			
Yes, the preferred option is supported.	These submitters supported FSANZ preferred option to remove the voluntary guideline to provide advice regarding additional vitamin and mineral supplementation in S29—10(2) of the Code.	INC, FCG, NZFS, NZFGC, AFCG	While FSANZ appreciates the comments of DA, there is an absence of evidence to support this view within ANZ formula fed infants. FSANZ also notes that the advice regarding additional vitamin and mineral supplementation is a voluntary statement.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	This submitter did not support FSANZ's proposal to remove the guideline on advice regarding additional vitamin and mineral supplementation. This submitter believes tight regulation regarding additional supplementation should remain in place to ensure nutrient composition of infant formula matches breast milk, is within safe levels as without tight regulation this may lead to serious and potentially life-threatening safety and toxicity concerns.	DA	As no new evidence has been provided within the 1st CFS, FSANZ reiterates the discussion in the FSANZ 2022 SD2 and retains the position to remove the voluntary guidance to provide advice regarding additional vitamin and mineral supplementation.
Measuring scoop *FSANZ preferred option at the CFS was to:* • *Not standardise the scoop size or dilution ratio, and instead maintain existing requirement that a package of infant formula product in a powdered form must contain a scoop to enable the use of the infant formula product in accordance with the directions contained in the label on the package.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option.	INC, NZFS, DAN, AFCG, NZFGC, FCG,	FSANZ considered not standardising the scoop size or dilution ratio in section 4.3 of FSANZ 2022 SD2. Based on the variety of powder densities across products, standardisation was not appropriate or applicable. In regard to the comments of DA, FSANZ notes that manufacturers provide feeding guides that are based on the nutrient density of their product when reconstituted and also provide directions of use on product labels. Due to the differentiation between products, FSANZ does not deem it appropriate to prescribe consistent directions of use, feeding guides or instructions, as these should be applicable to the individual product.
No, the preferred option is not supported.	DA did not support FSANZ's preferred option and instead recommends standardised feeding guides, preparation instructions and diagrams, aligned with NHMRC Guidelines, be provided and be consistent across brands. VICDoH did not support FSANZ's preferred option and instead supports a standardised ratio of 1 scoop to 30 ml.	DA, VICDoH	

Issue	Comment	Submitter(s)	FSANZ Response
Modified Formulas			
No, the preferred option is not supported.	These submitters do not support FSANZ proposed framework that modified formula's for the dietary management of a particular disease or conditions should only be consumed under medical supervision and should be considered a SMPPi.	INC, FCG, DA, NAS, NZFGC, AFCG, DAN	Noted. FSANZ has addressed this issue within section 2 of the 2nd CFS. Additional stakeholder comments on this issue have been address in Table 2 to Appendix 1 of the 2nd CFS. FSANZ concludes that any infant formula product that is formulated for a specific disease, disorder or condition will be regulated as an SMPPi. Partially hydrolysed proteins and low lactose or lactose free will be regulated as infant formula or follow-on formula unless their formulation has been specifically developed for a specific disease, disorder or condition.

3.1 Units of measure

Four submitters (three industry, one government) recommended that FSANZ align with the calculation units stated as 100 kcal multiplied by 4.18 as the limits in Codex CXS 72-1981 were set on a kcal basis and the limits per 100 kJ listed within it were subsequently calculated from the kcal figures, in some cases incorrectly. The Codex Draft Standard FuFOI has adopted this approach and at CCNFSDU38 the Secretariat informed the Physical Working Group that once the corrections were finalised in the Codex Draft Standard FuFOI then consequential amendments would be made to the Codex CXS 72-1981.

The closer the Code's infant formula compositional requirements are able to align with international requirements, the fewer trade issues will arise. There are also no public health or safety issues associated with correcting the calculations for units of measure. This is specifically a technical calculation issue.

FSANZ acknowledges this error and will adopt/re-calculate the figures in alignment with the Codex Draft Standard FuFOI approach, which notes figures which will be amended in line with the International Standard Unit conversion factors and conventional rounding. From here on, figures will be reflective of the corrected calculation, unless referring to figures proposed at the 1st CFS.

Four (industry) submitters also recommended FSANZ present units in both kcal and kJ, as this is current practice in both Codex and the EU regulations. These submitters also recommend that limits on nutrient composition are consistently stated to 2 significant figures (with exceptions like energy, where more significant figures are warranted, stated to 3 significant figures).

Presenting units in both kcal and kJ is not current practice displayed in the Code. Including both units within Standard 2.9.1 and Schedule 29 through Proposal P1028, would result in inconsistencies within the Code. As kJ are used within the Australian and New Zealand market, FSANZ does not consider it necessary or appropriate to present values in both units.

Presenting units with two significant figures is not current practice displayed in the Code, or internationally within Codex CXS 72-1981 and EU 2016/127 regulations. While FSANZ acknowledges the technical difficulties surrounding formulation, including further significant figures does not align with the objectives of the Proposal. Therefore, as mentioned FSANZ will use conventional rounding to address significant figures.

3.2 Guidance Upper Levels

Five industry submitters recommended FSANZ replace the term "Guideline Maximum" used in Standard 2.1.9 and Schedule 29 with "Guidance Upper Levels" (GUL) as used in the Codex Standards. A submitter noted that auditors, verifiers and regulators regularly demonstrate they do not understand what a GUL is.

FSANZ has incorporated the term "GUL" in the 2021 Consultation paper 2 – Nutrient composition and the 2022 Supporting Document 2 – Nutrient Composition reports. Changing the term "Guideline Maximum" to GUL would create regulatory clarity and better alignment with Codex CXS 72-1981.

FSANZ 2021 CP2 explained guideline maximums as levels 'where the risk posed by the nutrient was "not of significance on the basis of current scientific knowledge" (ANZFA, 1999a). These are not binding and serve as guidance for industry in deriving formulations.

Codex currently provides the below note on GUL's:

> *"Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in infant formulas should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs."*

FSANZ is proposing the following note be included within both the primary and consequential draft variation at Attachment A to the 2nd CFS:

> *'Guidance Upper Levels are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and/or follow-on formula or due to technological reasons'.*

Part B Infant Formula

4 Macronutrients

Permissions for both infant formula and follow-on formula are discussed below, unless expressly mentioned in the follow-on formula section where a different nutrient range to infant formula is discussed.

Table 4 – Macronutrients: summary of submitter comments and FSANZ response

Issue	Comment	Submitter(s)	FSANZ Response
Carbohydrate source *FSANZ preferred option at the CFS was:* • *To prescribe carbohydrate source in alignment with Codex CXS 72-1981 and adopt limits on sucrose and fructose.*			
Yes, the preferred option is supported.	These submitters supported the preferred option. However, noted it was unclear how FSANZ proposes to refer to limits on sucrose and fructose as only the draft Codex Standard for FuFOI has limits specified. NZFS also supported consideration to specify when sucrose and fructose may be added to infant formula products, rather than an open statement.	INC, NZFGC, FCG, AFCG, NZFS, SO	FSANZ has addressed the issues raised in section 4.1 below. FSANZ's preferred option is to prohibit the addition of sucrose and/or fructose to infant and follow-on formula, unless needed as a carbohydrate source in infant formula or follow-on formula manufactured from protein hydrolysates and provided the sum of the added fructose and/or sucrose does not exceed 20% of available carbohydrates in the formula.
No, the preferred option is not supported.	These submitters did not support the preferred option, and instead support restricting glucose in addition to sucrose and fructose, in line with the EU 2016/17. NSWFA noted that Professor Woosung Sohn, Dental Public Health specialist, reported that although glucose is not as highly cariogenic as sucrose, a high content of, and prolonged exposure to glucose is still cariogenic.	NSWFA, VICDoH	

Issue	Comment	Submitter(s)	FSANZ Response
Unavailable carbohydrates *FSANZ preferred option at the CFS was:* • *The issue is addressed through the Code and no further clarification is required.*			
Request clarification	This submitter noted that the Code needs to be clarified as to whether unavailable carbohydrate must be taken into account in the calculation of energy.	NZFS	FSANZ has addressed the issue raised in section 4.2 below.
Nitrogen Conversion Factor (NCF) *FSANZ preferred option at the CFS was:* • *To adopt a single NCF of 6.25 for both diary and soy-based formula to align with Codex CXS 72-1981 and the draft Codex FUF Standard.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	INC, FCG, NZFS, AFCG, VICDoH, NZFGC,	While FSANZ appreciates the position of submitters who did not support the proposed option, no new evidence was provided for consideration at the 1st CFS. FSANZ reiterates the position of FSANZ 2021 CP2 and concludes the consequential draft variation retains a single NCF of 6.25 for both diary and soy-based formula to align with Codex CXS 72-1981, draft Codex FuFOI Standard and the EU 2016/127. The proposed consequential draft variation includes a note that explains the NCF and the calculation of protein content, however, is not identical to the text in Codex CXS 72-1981. FSANZ does not consider this additional text necessary from a legal standpoint.
No, the preferred option is not supported.	This submitter did not support FSANZ preferred option and instead prefer adopting all three nitrogen conversion factors (5.71 for soy, 6.25 for whey based, 6.38 for other).	A2M	
Recommend the footnote is updated.	Recommend the Infant Formula Products Standard footnote is updated to reflect the text outlined in full in the Codex IF Standard.	FCG	
Protein Range *FSANZ preferred option at the CFS was:* • *Prescribe a protein range of 0.43 – 0.72 g/100 kJ.* • *Prescribe a soy protein range of 0.54 – 0.72 g/100 kJ.*			

Issue	Comment	Submitter(s)	FSANZ Response
Yes, the preferred option is supported.	These submitters supported the preferred options and noted the recently revised Chinese regulation has a protein range of 0.43-0.72 g/100 kJ.	INC, AFCG, FCG, NZFS, NZFGC	FSANZ has previously responded to VICDoH request to adopt the EU 2016/17 protein maximum of 0.6 g/100 kJ in both the FSANZ 2022 SD2 (section 2.1.2) and FSANZ 2021 CP2 (Section 4.2). This decision was based on the conclusions of the FSANZ 2016 NA (Section 3.3) which noted that there is an absence of evidence demonstrating harm to infant health at the maximum level of 0.72g/100 kJ. This maximum level also has a long-standing history of use within the ANZ population as the level has been present within Standard 2.9.1 for over 20 years. Further to this, the maximum of 0.72g/100 kJ is aligned with Codex CXS 72-1981 and was recently re-established within the Codex Draft Standard for FuFOI. As no new evidence has been provided through the 1st CFS, FSANZ retains its position and concludes that the primary draft variation prescribes a protein range of 0.43 – 0.72 g/100 kJ for infant formula based on milk proteins and 0.54 – 0.72 g/100 kJ for infant formula based on soy proteins.
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred option to permit a maximum of 0.7 g/100 kJ and instead support 0.6 g/100 kJ in line with the EU. This is because there is no evidence of a physiological need for protein intakes at 0.7g/100 kJ.	VICDoH	
Amino Acids *FSANZ preferred option at the CFS was:* • *to align the minimum amounts of all amino acids with Codex CXS 72-1981.*			
Yes, the preferred option is supported.	These submitters supported the preferred option. Industry submitters also recommended that the addition of methionine and cysteine with a ratio greater than 2:1 be permitted if the suitability of the formula is demonstrated by clinical testing (as provided in both the Codex CXS 72-1981 and EU Regulation 2016/127).	INC, NZFGC, FCG, VICDoH, AFCG, SO	To align with Codex CXS 72-1981 and the EU 2016/127, the proposed consequential draft variation prescribes new minimum levels for methionine and cysteine of 6 mg/100 kJ and 9 mg/100 kJ, respectively. The proposed primary draft variation also requires infant formula to have a ratio of methionine to cysteine of no more than 3 to 1. This is further discussed in section 4.3 below.

Issue	Comment	Submitter(s)	FSANZ Response
Protein source *FSANZ preferred option at the CFS was:* • *protein sources in infant formula be specified to be cow's milk protein, goat's milk protein, protein hydrolysates of one or more proteins normally used in infant formula and soy protein isolate. This does not include extensively hydrolysed proteins or proteins hydrolysed for other nutritive purposes. Any protein sources outside of those specified would require pre-market assessment through FSANZ.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's approach to prescribe protein sources that have undergone pre-market assessment for use in infant formula products with the view that non-listed sources would require pre-market safety assessment before they could be included in the Code.	NSWFA, QLDH, VICDoH	FSANZ has addressed the issue raised in section 4.4 below.
Yes, the preferred option is supported.	This submitter supported FSANZ approach that protein fractions that are synthesised, extracted and/or concentrated above their background levels in existing ingredients in infant formula products are nutritive substances that require pre-market assessment. An example is lactoferrin, as detailed in the Approval Report for Application A1253.	NSWFA	
Yes, the preferred option is supported.	This submitter supported pre-market assessment for new sources of plant-based protein to ensure that issues related to protein digestibility and bioavailability of micronutrients is assessed, in addition to potential issues of allergenicity. Clarification on the requirements that would need to be fulfilled for a pre-market assessment for alternative sources of protein, as the assessment may differ to the pre-market assessment for an optional ingredient.	NZFS	

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	Submitters did not support FSANZ preferred option, and instead recommend protein source statement include wording similar to Codex “milk of cows or other animals or a mixture thereof...” to include mammalian milks such as buffalo, goat and specially sheep. Submitters also did not support FSANZ proposed approach to include a positive list of permitted protein sources and noted that sheep milk should be included within the protein source.	INC, NZFGC, FCG, SSM, BODCO, NZFGC, NZFS, AFGC, DAN	
No, the preferred option is not supported.	Submitters strongly opposed the exclusion of sheep milk proteins as a protein source in infant formula products.	INC, NZFGC, FCG, SSM, BODCO, PRO, NZFS, VICDoH, AFGC, MM, MMI, BRD, DAN	
No, the preferred option is not supported.	This submitter strongly opposed the specific list of permitted protein sources and plant based proteins, apart from soy, requiring pre-market assessment.	SO	
Request different wording.	This submitter suggested FSANZ reconsider the wording “normally used in formula” as it is ambiguous.	VICDoH	
Linoleic acid (LA) *FSANZ preferred option at the CFS was:* • *Prescribe a linoleic acid range of 90 – 335 mg/100 kJ.*			

Issue	Comment	Submitter(s)	FSANZ Response
Yes, the preferred option is supported.	These submitters supported the preferred option.	INC, NZFGC, FCG, NES, NZFS, AFCG, SO	While FSANZ appreciates the position of submitters who did not support the proposed option, no new evidence was provided for consideration at the 1st CFS. Alignment with the EU 2016/127 values for LA have been considered within the FSANZ 2021 CP2 and addressed again in the FSANZ 2022 SD2. FSANZ encourages submitters to refer to these discussions. As no new evidence has been provided, FSANZ retains its position and prescribes LA at a range of 90 – 335 (GUL) mg/100 kJ in infant formula products. This is based on the conclusions of the FSANZ 2016 and 2021 nutrition risk assessments, the stability and palatability associated with higher LA levels, history of safe use at current levels and no emerging safety or adequacy concerns for infants.
No, the preferred option is not supported.	These submitters did not support FSANZ preferred minimum for LA of 90 mg/100 kJ, and instead request the EU minimum of 120 mg/100 kJ is adopted, based on alignment with the EU, consistency with Specific Policy Principles (b to j) in the Policy Guideline on the Regulation of Infant Formula, FSANZ Act s18(1)(a) and s18(2)(a-d). Closer to levels noted in ANZ breast milk, and NHMRC NRVs.	DA, NSWFA, WADoH, VICDoH	
No, the preferred option is not supported.	These submitters did not support FSANZ's preferred maximum for LA of 330 mg/100 kJ as the maximum level is higher than the maximum found in breast milk and there is no apparent physiological or technical justification to set a higher upper level of 330 mg/100 kJ.	WADoH, VICDoH	
Docosahexaenoic acid (DHA) *FSANZ preferred option at the CFS was:* • *Retain the voluntary permission for DHA in infant formula products.* • *Replace the maximum for DHA with a GUL at 7 mg/100 kJ.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	INC, AFCG, NZFGC, FCG, NES	FSANZ has addressed the issue raised in section 4.5 below.
Partial support on the preferred option.	This submitter was still considering whether the addition of DHA should be mandatory or optional, however would not support an approach where DHA is not a permitted optional ingredient.	NZFS	

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred option to retain the voluntary permission for DHA.	VICDoH	
Request review of the evidence.	These submitters have requested a review of the evidence on DHA as an essential / partially essential nutrient, and whether it should be made mandatory.	WADoH, VICDoH	
Yes, the preferred option is supported.	These submitters supported replacing the maximum with a GUL. However, do not support the level of 7.2 mg/100 kJ and instead strongly recommend a GUL of 12 mg/100 kJ. This is based on the maximum level of DHA on the ANZ market currently exceeds the proposed maximum of 7.2 mg/100 kJ. These products would have to be withdrawn from the market.	INC, NZFG, FCG, AFCG, DAN	
Trans Fatty Acids *FSANZ preferred option at the CFS was:* • *Retain the current maximum limit of total trans fatty acids to be not more than 4% of the total fatty acids.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	INC, NZFGC, FCG, NES, NZFS, AFCG	FSANZ has provided a response to this issue in section 5.6.2 of FSANZ 2021 CP2 and section 2.1.2 of FSANZ 2022 SD2. As no new evidence has been provided through the 1st CFS, FSANZ retains its position that trans fatty acids must not exceed 4% of the total fatty acids.
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred option and instead supports a prohibition on commercially hydrogenated oils that may contain industrial TFA, in line with Codex. The submitter requests that FSANZ provide more information on the remaining percentage of naturally occurring dairy trans fats present in formula to determine whether a 4% of total fatty acids limit is required.	VICDoH	

Issue	Comment	Submitter(s)	FSANZ Response
Phospholipid maximum *FSANZ preferred option at the CFS was:* • *Set a phospholipid maximum of 2 g/L.*			
Yes, the preferred option is supported.	These submitters supported the preferred option, however, recommend that the limit be a GUL not a maximum, as a GUL is more appropriate to reflect the absence of adverse effects and low risk posed by phospholipid intake in infancy.	INC, NZFGC, FCG, AFCG	FSANZ has addressed the issue raised in section 4.6 below.
Yes, the preferred option is supported.	This submitter supported setting a maximum permitted amount of phospholipids at 2g/L, however, seek clarification for the units to be specified.	NZFS	
Yes, the preferred option is supported.	This submitter supported setting a GUL or maximum permitted amount of phospholipids at 2 g/L (72 mg/100 kJ)	NES	
No, the preferred option is not supported.	This submitter does not support FSANZ's preferred option to set a maximum of 2 g/L for phospholipids. In order to be consistent with the policy guidelines, FSANZ should provide further scientific assessment to justify adding phospholipids as a nutritive substance together with justification for the levels permitted (relative to the amounts found in breast milk).	VICDoH	
Lecithin *FSANZ preferred option at the CFS was:* • *Set a lecithin maximum of 1 g/L.*			
Yes, the preferred option is supported.	This submitter supports FSANZ's preferred option to limit lecithin as a food additive to 1 g/L.	VICDoH	FSANZ has addressed the issue raised in section 4.6 below.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	These submitters did not support FSANZ's preferred option to restrict lecithin as a food additive to 1 g/L and instead support retaining the original food additive permission for lecithin of 5000 mg/kg.	INC, FCG, NZFGC, AFCG, DAN	
MCT restriction *FSANZ preferred option at the CFS was to:* • *Retain the MCT restrictions prescribed in Standard 2.9.1, which include MCT's only being present in infant formula products if they are natural constituent of a milk-based ingredient of that formula or for a fat soluble vitamin that is specified in the table to section S29—9.*			
Yes, the preferred option is supported.	This submitter supported FSANZ preferred option to restrict MCT as these substances are intentionally added to pre-term formulas and should have permissions aligned with their functional purpose in these SMP formulas.	NSWFA	Special Medical Purpose Products for infants (SMPPi) are discussed in Part D of this SD and Appendix 1 Table 8 of the 2nd CFS. The composition prescribed for SMPPi allows flexibility to add substances where they are required for the products special medical purpose or would prevent the sale of the product. Based on this MCT will not be restricted from SMPPi where MCT addition is required for the products specific disease, disorder or condition.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	These submitters did not support FSANZ preferred option to restrict MCT as the restriction does not align with Codex or any other international jurisdiction. If the restriction is to be maintained, these submitters recommend changes to remove the existing ambiguity. The following wording is recommended: "*MCT oils means oils commercially manufactured via fractionation and /or esterification to yield a high proportion of medium chain saturated fatty acids (designated by 8.0 or 10.0).*" The Standard could then be amended to restrict the use of "MCT oils" as an ingredient other than for a fat-soluble vitamin as reflected in Standard 2.9.1(1)(a)(ii): "for a fat soluble vitamin that is specified in the table to section S29—9—a substance that was *used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the formula". These submitters do not agree that the definition for MCT is out of scope, as MCT is not used elsewhere in the Code.	INC, FCG, NZFGC, AFCG, DAN	While FSANZ appreciates the views of submitters who do not support the preferred option, no new evidence or new comments were provided for consideration at the 1st CFS. These comments have been previously addressed in the FSANZ 2021 CP2 and FSANZ 2022 SD2. The permission for MCTs in infant formula products was also assessed in the FSANZ 2016 NA. FSANZ proposes to retain the current MCT restriction on the basis that (1) these fats are not normally present in significant amounts in breast milk; (2) the long term effects of infants consuming a relatively high amount of saturated fats are unknown; and (3) the absence of convincing evidence that the inclusion of MCTs in infant formula has any benefit to infant health (ANZFA 1999; LSRO 1995). Substantial scientific evidence on the benefit and safety of MCT's in infant formula products would be required for FSANZ to remove the restriction on MCT's. As this evidence has not been provided, the restriction will continue to apply - infant formula products may only contain *MCT's if they are a natural constituent of a milk-based ingredient of that formula or for a fat-soluble vitamin that is specified in the table to section S29—9.*

4.1 Carbohydrate source

4.1.1 Background

Standard 2.9.1 does not currently prescribe carbohydrate source.

Codex CXS 72-1981 permits the addition of glucose as a source of carbohydrate and notes that *"lactose and glucose polymers should be the preferred source of carbohydrate in formula based on cow's milk protein and hydrolysed protein"* with a total carbohydrate limit of 3.3 g/100 kJ. Codex Draft Standard for FuFOI prescribes limits on sucrose and fructose and notes these sources should not be added, unless needed as a carbohydrate source, and must not exceed 20% of available carbohydrates.

The EU 2016/17 prescribes a positive list of permitted carbohydrate sources which includes lactose, maltose, sucrose, glucose, glucose syrup or dried glucose syrup, malto-dextrins, pre-cooked starch and gelatinised starch.

Table 4.1.1 - Current regulations for carbohydrate sources

Carbohydrate source	Units	Standard 2.9.1		Codex CXS 72-1981		Codex Draft Standard for FuFOI		EU 2016/17	
		Min	Max	Min	Max	Min	Max	Min	Max
Carbohydrate	g/100 kJ	NS	NS	2.2	3.3	2.2	3.3	2.2	3.3
Lactose	g/100 kJ	NS	NS	NS	NS	NS	NS	1.1	NS
Sucrose	% CHO[1]	NS	NS	NS^	NS^	NS	20*	NS	20
Glucose	% CHO[1]	NS	NS	NS^	NS^	NS	20*	NS	0.5 g/100 kJ
Glucose syrup or dried glucose syrup	g/100 kJ	NS	NS	NS	NS	NS	NS	NS	0.2
Pre-cooked starch and/or gelatinised starch	% CHO[1]	NS	NS	NS	NS	NS	30	NS	30

^should be avoided *sucrose and fructose combined [1] total carbohydrate

In 2021 and 2022 FSANZ's preferred option for carbohydrate source was to adopt limits on sucrose and fructose that are aligned with Codex CXS 72-1981.This preference was based on safety concerns cited by government submitters, the outcome of FSANZ's safety assessment conducted in 2002 (ANZFA 2002), and by international requirements that come into place in 2020 including EU 2016/127 and Codex CXS 72-1981.

4.1.2 Stakeholder comments

Seven submitters (four industry, three government) commented on FSANZ preferred option in the 1st CFS for carbohydrate source. The views of submitters were mixed. Submitters that supported the preferred option noted it was unclear how FSANZ was proposing to impose limits on sucrose and fructose as only the draft Codex Standard for FuFOI has limits specified. Submitters that did not support the preferred option recommended a restriction on glucose in addition to sucrose and fructose, in line with the EU 2016/17. One submitter noted FSANZ's preferred option appeared to be predominately influenced on the desire to align with Codex.

One submitter provided advice from a Dental Public Health specialist who supports limits on both sucrose and fructose, reporting that although glucose is not as highly cariogenic as sucrose, a high content of, and prolonged exposure to, glucose is still cariogenic.

4.1.3 Discussion

EFSA has recommended that glucose should not be added to infant formula due to the increased osmolarity of the formula, not because of a public health or safety risk. The cariogenic properties of glucose were not reported as health consequences associated with the composition of infant and follow-on formula by EFSA (EFSA, 2014). In some cases, increased osmolarity may lead to an increased incidence of diarrhoea. Glucose is still permitted for addition to infant formula products containing protein hydrolysates in order to mask the bitter taste of these formulas.

The amount of carbohydrate within infant formula products, regulated by Standard 2.9.1, is self-limiting and dependant on the energy, protein and fat content of the product. Considering this, infant formula would not have a “high content” of glucose. There are also directions for use on the label and infant feeding guidelines to mitigate the risk of cariogenic health consequences. The water supply in most metropolitan and many regional areas in ANZ are fluoridated and it is assumed that this water will be used in preparing most infant formula products. Fluoride has a maximum limit of 17 µg /100 kJ within infant formula products on the ANZ market. The Australian Drinking Water Guidelines and New Zealand Drinking Water Standards help to improve the cariogenic and oral health of infants and the structure of bones and teeth (NHMRC and MoH 2006). For infants and older infants who are living in areas where the household water supply is not fluoridated, further advice should be sought from a health professional. Further information on fluoride in infant formula products can be found at section 7.2.

Breast milk contains glycaemic carbohydrates of which lactose, a disaccharide of glucose and galactose, is the primary sugar. Breast milk does not contain sucrose or fructose, which is why some regulations have restrictions on these sugars. As glucose is a naturally occurring constituent of breast milk and there is an absence of evidenced to suggest that formulas containing glucose may increase risk to public health or safety, FSANZ will not exclude glucose as a carbohydrate source. This approach aligns with the Codex Draft Standard for FuFOI, which is based on the most recent evidence.

A submitter to the 1st CFS supported further consideration of when sucrose and fructose may be added to infant formula products, instead of stating “unless needed” in alignment with Codex CXS 72-1981 and the draft Codex Standard for FuFOI. The EU 2016/127 only allows the addition of sucrose and glucose to infant formula manufactured from protein hydrolysates in order to mask the bitter taste of these formulae (EFSA, 2014). FSANZ understands that providing further clarification may provide regulatory clarity to both manufactures and enforcement agencies.

4.1.4 Conclusion

It is not deemed necessary for public health and safety to establish a list of permitted carbohydrates. FSANZ’s preferred option is to restrict the addition of sucrose and fructose, unless needed as a carbohydrate source, and the sum of the added fructose and/or sucrose does not exceed 20% of available carbohydrates. FSANZ does not propose to prescribe a positive list of carbohydrate sources and does not propose to restrict the addition of glucose.

This amendment is noted in the proposed primary draft variation at subsection 2.9.1—5(2) and 2.9.1—5(3) of Attachment A to the 2nd CFS.

4.2 Unavailable carbohydrate

Clarity surrounding unavailable carbohydrate and whether it must be taken into account for

the calculation of energy for infant formula products was requested by one submitter (government) during the 1st CFS. FSANZ acknowledges that this is a long standing issue, and clarity has been requested through the 2016, 2021 and 2022 consultations.

Standard 1.1.2 – Definitions of the Food Standards Code defines carbohydrate as: carbohydrate, other than in the definition of beer (section 1.1.2—3), means *available carbohydrate or *available carbohydrate by difference. Unavailable carbohydrate is therefore not captured by this definition. This definition applies to Standard 1.2.8 – Nutrition Information Requirements. The formats for the NIP in Schedule 12 – Nutrition Information Panel do not list unavailable carbohydrate as a sub-group nutrient underneath 'carbohydrate'. However, the format in Schedule 12 does allow the inclusion of 'any other nutrient or biologically active substance to be declared'. Unavailable carbohydrate can therefore be included as a line in the NIP and contribute to the total energy of the product at the food manufacturers discretion.

As discussed in FSANZ 2016 NA and 2021 CP2, FSANZ maintained that classification of carbohydrates as available or unavailable is a decision for manufacturers. FSANZ has also previously noted that definitions and the method of calculation relevant to carbohydrate identity in the Code are fit for purpose for general foods and infant formula products. Further discussion on the definitions and application of available carbohydrate, available carbohydrate by difference and unavailable carbohydrate can be found in section 5 of 2016 Supporting Document 1 – Definitions & nutrient composition, section 6 of 2021 Consultation paper 2 – Nutrient composition and section 2.1.2 of 2022 Supporting Document 2 – Nutrient Composition.

Based on the above discussion and FSANZ previous assessments, FSANZ maintains that the decision of whether to include unavailable carbohydrate in the calculation of energy for infant formula products should be at the discretion of the food manufacturer.

4.3 Methionine to cysteine ratio

Breast milk is cysteine-rich and methionine-poor, however infant formula products are commonly based on cow, goat and sheep milk proteins that are poor in cysteine but rich in methionine. To ensure that some cysteine is present in infant formula, the Code currently prescribes an absolute minimum cysteine content of 6 mg/100 kJ (see section S29—6).

Submitters to the 1st CFS recommended inclusion of the option for clinical evaluation of the suitability for formula with methionine to cysteine ratios greater than 2 as is included in both the Codex CXS 72-1981 and EU 2016/127.

Codex CXS 72-1981 requires *'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'.*

EU 2016/127 requires *'for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine: cysteine ratio is not greater than 2… the ratio of methionine: cysteine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3)'.*

The Codex CXS 72-1981 minimums for sulphur-containing amino acids (SAA) such as methionine and cysteine are not expressed as a summed amount because they were derived using a more accurate analytical methodology that quantified individual SAA. FSANZ has adopted the Codex CXS 72-1981 minimums for indispensable amino acids in infant formula products, which closely align to those prescribed by the EU 2016/127. In alignment with Codex CXS 72-1981 and the EU 2016/127, the proposed consequential draft variation introduces minimum levels for methionine and cysteine of 6 mg/100 kJ and 9 mg/100 kJ, respectively. The adoption of these minimums allows the removal of summed requirements

in Schedule 29 for the cysteine, cystine and methionine total and the cysteine and cysteine total. FSANZ notes that for calculation purposes, cysteine and methionine can be added together, however the minimum requirement for each amino acid will be prescribed separately in Schedule 29.

The methionine to cysteine ratios prescribed in Codex CXS 72-1981 are based on the ratio in breast milk (1:1), the ratio in cow and goat milk (~3:1), the potential imbalance which can affect methionine conversion to cysteine and nitrogen utilisation from non-essential amino acids (Garlick 2006).

To ensure adequate levels of cysteine are present within infant formula, Standard 2.9.1 will require infant formula to have a ratio of methionine to cysteine of no more than 3 to 1. This ratio will regulate methionine and cysteine levels in conjunction with their prescribed minimums in Schedule 29. This ratio will only apply to infant formula and will not extend to follow-on formula. This is on the basis that younger infants may not have fully active cystathionase, which is the liver enzyme that converts methionine to cysteine. Because of this cysteine is only considered conditionally essential for younger infants, however, is not considered essential for infants over 6 months of age. This is consistent with Codex Draft Standard for FuFOI and EU 2016/127 ANNEX II.

4.3.1 Conclusion

In alignment with Codex CXS 72-1981 and the EU 2016/127, FSANZ has included minimum levels for methionine and cysteine as 6 mg/100 kJ and 9 mg/100 kJ, respectively. The proposed primary draft variation also requires infant formula to have a ratio of methionine to cysteine of no more than 3:1. These requirements have been introduced to ensure consistency with current international requirements that have a long standing history of use and scientific literature (EFSA 2014).

4.4 Protein source

4.4.1 Current regulations

The definition of infant formula products under Standard 2.9.1 requires that the product must be based on “milk or other edible food constituents of animal or plant origin”. Similarly, Codex CXS 72-1981 defines infant formula as a product based on “milk of cows or other animals or mixture thereof and other ingredients proven to be suitable for infant feeding”. The EU 2016/127 specifies that infant formula must be manufactured from cow milk or goat milk proteins, soya protein isolates, alone or in a mixture with cow milk or goat milk proteins.

Standard 2.9.1 does not currently have a prescribed protein source statement.

4.4.2 Previous considerations

FSANZ has consulted on the protein source for infant formula products within the 2016, 2021 and 2022 consultations. Throughout the consultations mixed stakeholder views were raised regarding the need for a prescriptive protein source list, the protein sources which should be permitted and the requirements for pre-market assessment.

Within the 2021 CP2 FSANZ considered the safety concerns associated with new proteins potentially being used in infant formula products and proposed the protein source be specified to be cow milk protein, goat milk protein, protein hydrolysates of one or more proteins normally used in infant formula, and soy protein isolate. FSANZ retained this position within the 1st CFS.

4.4.3 Stakeholder comments

Fifteen submitters (eleven industry, four government) responded to the proposed approach in the 1st CFS. The views of submitters were mixed; however some clear trends were established. Submitters that supported the preferred option noted that an explicit list of protein sources would increase regulatory clarity and encourage manufacturers to seek pre-market assessment for new protein sources. Other submitters also agreed that protein fractions that are synthesised, extracted and/or concentrated require pre-market assessment. Another submitter supported FSANZ position that new sources of plant-based protein require pre-market assessment to ensure that issues related to protein digestibility and bioavailability of micronutrients are assessed, in addition to potential issues of allergenicity.

Submitters that did not support FSANZ's preferred option recommending that the protein source statement reflect wording similar to Codex CXS 72-1981 "milk of cows or other animals or a mixture thereof..." to allow the inclusion of mammalian milks such as buffalo, goat and sheep. These submitters also opposed the approach of an explicit list of permitted protein sources, arguing it would inhibit future innovation.

Thirteen submitters strongly opposed the exclusion of sheep milk protein from infant formula products.

One submitter also suggested FSANZ reconsider the wording of "normally used in formula" as it is thought to be ambiguous in a regulatory setting.

4.4.4 Discussion

Prescribed protein sources

FSANZ 2021 CP2 proposed that the Code specify which protein sources are permitted in infant formula in order to mitigate potential safety risks associated with new proteins being used in infant formula products that have not been approved through the pre-market assessment process. Prescribing permitted protein sources increases regulatory clarity and also aligns with international regulation, such as the EU 2016/127. As infant formula products are formulated for a particularly vulnerable population and are the most prescriptive food within the Code, it is warranted to prescribe permitted protein sources.

Submitters that did not support a prescribed list of protein sources noted this approach did not align with Codex CXS 72-1981 and would inhibit future innovation. While this approach varies from Codex CXS 72-1981, the way Codex and the Code define infant formula, follow-on formula and infant formula products are different and subject to varying nuances associated with the differences between Codex as a guidance document and the Code as a legislative instrument. FSANZ considers that prescribing protein sources ensures that the protein used in infant formula products is nutritionally adequate as well as being safe for vulnerable consumers. This approach does not limit innovation or diversity of protein sources. Manufacturers may apply for permission to add other mammalian or plant-based protein sources to infant formula products through the pre-market assessment process.

Pre-market assessment

It is FSANZ's continued view that protein sources not included in the prescribed list, as well as any protein fractions that have been synthesised, extracted and/or concentrated above their background levels in existing ingredients in infant formula products, would be required to undergo pre-market assessment before being permitted in infant formula products. Pre-market assessment ensures that issues related to protein digestibility and bioavailability of micronutrients is assessed, in addition to potential issues of allergenicity.

One submitter requested clarification on the requirements that would need to be fulfilled for a pre-market assessment for alternative sources of protein, as the assessment may differ to the pre-market assessment for an optional ingredient. FSANZ acknowledges that there may be differences in assessment between optional ingredients, such a novel foods and nutritive substances, and new protein sources. The FSANZ Application Handbook sets out the requirements of pre-market assessment. These requirements are out of scope of the Proposal. Clarification surrounding the requirements of pre-market assessment can also be discussed within the confidential pre-market assessment process that FSANZ offers.

Sheep milk protein

Following the 1st CFS and stakeholder workshops conducted with industry, jurisdictions and public health professionals, FSANZ recognised the importance of including sheep milk protein as a permitted protein source in infant formula products. In particular, FSANZ recognises:

- Sheep milk's comparable protein and amino acid profile to cow and goat milk
- The history of use of sheep milk has within the New Zealand and international market
- The acceptance and inclusion of sheep milk within New Zealand government authority publications, policy and infant feeding guidance (NZMoH 2021, NZMPI 2014)
- The significant investment by the New Zealand Government into the emerging sheep dairy industry, such as the Primary Growth Partnership: Sheep – Horizon Three
- The Ministerial Policy Guideline specific policy principle (B) which states 'the regulation of infant formula products should not be inconsistent with the national nutrition policies and guidelines of Australia and New Zealand that are relevant to infant feeding'

From a nutrient composition perspective, sheep milk is considerably similar to cow and goat milk, as it contains similar protein content and high amino acid sequence identities (evidenced in Table 4.4.4.1 below), macronutrients and other constituents (evidenced in Table 4.4.4.2) and micronutrients (evidenced in Table 4.4.4.3 below). The fatty acid profile of sheep milk is quite similar to that of goat milk. The FAO have also published a comparison of the nutrient composition in sheep milk compared to breast milk, which evidenced their similarities in composition, especially protein and amino acid sequence (FAO, 2103). Based on the comparable nutrition composition and food matrix, FSANZ considers sheep milk as a protein source for use in infant formula products to be safe and suitable.

Table 4.4.4.1 Protein and Amino Acid content of milk from different mammalian species (Claeys, 2014)

Nutrient	Unit	Sheep	Goat	Cow
Protein	mg/100 g	4.5 - 7.0	3.0 - 5.2	3.0 - 3.9
Histidine	mg/100 g	167	98	100
Isoleucine	mg/100 g	338	207	140
Leucine	mg/100 g	587	314	290
Lysine	mg/100 g	513	290	270
Threonine	mg/100 g	268	240	150
Tryptophan	mg/100 g	84	44	50
Valine	mg/100 g	448	240	160
Methionine	mg/100 g	155	80	60
Cysteine	mg/100 g	35	46	20
Phenylalanine	mg/100 g	284	155	160

Tyrosine	mg/100 g	281	179	150

Table 4.4.4.2 Macronutrient and other constituents of milk from different mammalian species (Park, 2006 & 2007)

Nutrient	Sheep	Goat	Cow
Fat (%)	7.9	3.8	3.6
Solids-not-fat (%)	12	8.9	9
Lactose (%)	4.9	4.1	4.7
Protein (%)	6.2	3.4	3.2
Casein (%)	4.2	2.4	2.6
Albumin, globulin (%)	1	0.6	0.6
Non-protein N (%)	0.8	0.4	0.2
Ash (%)	0.9	0.8	0.7
kJ/100 mL	439	293	289

Table 4.4.4.3 Micronutrient content of milk from different mammalian species (Park, 2006 & 2007)

Constituents	Unit	Sheep	Goat	Cow
Calcium	mg/100 g	193	134	122
Phosphorus	mg/100 g	158	121	119
Magnesium	mg/100 g	18	16	12
Potassium	mg/100 g	136	181	152
Sodium	mg/100 g	44	41	58
Chlorine	mg/100 g	160	150	100
Iron	mg/100 g	0.08	0.07	0.08
Copper	mg/100 g	0.04	0.05	0.06
Manganese	mg/100 g	0.007	0.32	0.02
Zinc	mg/100 g	0.57	0.56	0.53
Iodine	mg/100 g	0.02	0.022	0.021
Selenium	µg/100 g	1	1.33	0.96
Vitamin A	IU/100 g	146	185	126
Vitamin D	IU/100 g	7.2	2.3	2
Thiamin	mg/100 g	0.08	0.068	0.045
Riboflavin	mg/100 g	0.376	0.21	0.16
Niacin	mg/100 g	0.416	0.27	0.08
Pantothenic acid	mg/100 g	0.408	0.31	0.32
Vitamin B6	mg/100 g	0.08	0.046	0.042
Folic acid	µg/100 g	5	1	5
Biotin	µg/100 g	0.93	1.5	2
Vitamin B12	µg/100 g	0.712	0.065	0.357
Vitamin C	mg/100 g	4.16	1.29	0.94

Further to this, Commercial Confidential Information CCI submissions from the 1st CFS provided evidence which demonstrates a history of use within the New Zealand market and infant population.

In New Zealand, sheep milk is recommended by the Ministry of Health (NZMoH) as one of the three standard dairy-based protein sources suitable for infants. This is evident within the *Healthy Eating Guidelines for New Zealand Babies and Toddlers (0-2 years old)* which states "when breast milk is not available, a dairy-based infant formula (made from cow, goat or sheep milk) is the next best choice for most babies. Research suggests that no particular infant formula offers benefits over any other". Its use is also noted by the New Zealand Ministry of Primary Industries (NZMPI) within the Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children which states "dairy-based means the formula contains, as its predominant protein constituent, protein derived or processed from milk extracted from a milking animal such as a

cow, goat or sheep". FSANZ does not wish to create inconsistencies between the Code and the recommendations of NZMoH and NZMPI, nor does it wish to undermine or discredit these rigorous and considered pieces of work. FSANZ also understands that creating regulation that is inconsistent with national nutrition policies and guidelines would not meet policy principle (B) of the Ministerial Policy Guideline which states "the regulation of infant formula products should not be inconsistent with the national nutrition policies and guidelines of Australia and New Zealand that are relevant to infant feeding".

NZMPI have also initiated the Primary Growth Partnership (PGP) which is a joint venture between government and industry that invests in long-term innovation programmes to increase the market success of the primary industries. Sheep – Horizon Three is a current PGP program which aims to build a high value and sustainable New Zealand sheep dairy industry by building a fit-for-purpose New Zealand sheep milk farming system. The initiatives within this program include developing and selling sheep milk infant formula products, which are reported to have the potential to grow sales and expand the export market (Sapere Research Group, 2020).

FSANZ proposes to add sheep milk protein as a permitted protein source in infant formula products. This decision is based on the equivalent composition of sheep, cow and goat milks; sheep milk's highly comparable composition with breast milk; the inclusion of sheep milk within NZ infant feeding guidance; and its history of use within the NZ population.

Other mammalian milk

FSANZ acknowledges the request of industry submitters to refer to mammalian milks in alignment with Codex CXS 72-1981 and appreciates the increasing contributions of buffalo, sheep and camel milk in the recent years. However, FSANZ concludes that this wording is not appropriate within the Australian context due to its ambiguity and the potential to capture breast milk as a protein source, which is not the purpose of Standard 2.9.1 or Proposal P1028. Breast milk is an incredibly complex area of regulation and policy which intersects human tissue and food due to its varying use and properties (Commonwealth of Australia, 2014). Breast milk does not currently have any specific Australian regulatory requirements and its regulation as a human tissue or food is at the discretion of jurisdictions. Because of this, using the term mammalian milks could create inconsistencies between policy advice and regulation and does not alleviate the concerns surrounding regulatory clarity of protein sources in infant formula products. Through the 1st CFS FSANZ did not receive scientific evidence or evidence demonstrating an established history of use in infant formula products for mammalian milks other than sheep milk. FSANZ is also not aware of any other mammalian milk sources outside of cow, goat and sheep currently on the ANZ market. Based on the lack of evidence provided to support this request, the risk of inconsistencies between policy advice and regulation and the ambiguous nature of the wording, FSANZ will not be prescribing 'mammalian milks' as protein sources within infant formula products.

Rice protein

A submitter to the 1st CFS requested that rice protein be permitted as a protein source in infant formula products, as rice protein formulas have been available globally for over two decades. FSANZ notes that rice protein formulas are recommended for infants with cow milk protein allergy. While FSANZ appreciates that rice-based infant formulas are available globally, FSANZ has not been supplied with evidence that demonstrates that these formulas are categorised outside of specialised medical formulas. FSANZ also notes that rice protein is not included within the protein sources prescribed in the EU 2016-127. Rice protein is an incomplete protein source for human infants, with limiting amino acids lysine and threonine. While fortification of rice protein with these two limiting amino acids can improve its protein quality there is limited evidence that suggests rice protein provides an adequate alternative to standard milk or soy-based formula (Koo, 2007). Rice protein can be used as a protein

source within SMPPi, however based on the limited evidence provided to FSANZ at the 1st CFS and the limited evidence available publicly, FSANZ will not be including rice protein as a protein source in infant formula products.

Wording of the statement

FSANZ acknowledges that the wording 'normally used in infant formula' is ambiguous and could be interpreted in different ways, therefore creating issues surrounding enforceability. As a key focus of Proposal P1028 is to increase the regulatory clarity of Standard 2.9.1 FSANZ acknowledges the importance of amending this.

The intent of this statement 'normally used in infant formula' was to capture protein sources used in infant formula which create a product that is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant. This intent was to be inferred by the definition of infant formula products.

FSANZ considers wording 'of one or more of these specified proteins' better infers the intent of the regulatory decision.

4.4.5 Conclusion

Based on the above discussions FSANZ is proposing:

- to prescribe the protein sources that are permitted for infant formula products, specified to be 'cow milk protein, goat milk protein, sheep milk protein, soy protein isolate and partially hydrolysed protein of one or more of these specified proteins', and
- any protein sources outside of those specified above will be required to undergo a pre-market assessment through FSANZ.

This proposal is reflected in the proposed primary draft variation at subsection 2.9.1—6(1).

4.5 Docosahexaenoic acid (DHA)

4.5.1 Background

Standard 2.9.1 permits the optional presence of DHA and Codex CXS 72-1981 permits addition of DHA to infant formula products as an optional ingredient. The EU 2016/127 requires the mandatory addition of DHA to infant formula products.

The FSANZ 2016 NA concluded that mandatory inclusion of a minimum amount of DHA was based on mixed and inconclusive studies on infant development and there is no evidence that voluntary DHA addition, as currently prescribed in both Standard 2.9.1 and Codex CXS 72-1981, poses a risk to infant health.

Based on alignment with Codex CXS 72-1981 and the Codex Draft Standard for FuFOI, FSANZ's preferred option at the 1st CFS was to adopt a GUL for DHA within infant formula products of 7 mg/100 kJ. FSANZ also proposed to retain the voluntary permission for DHA.

4.5.2 Stakeholder comments

Eight submitters (five industry, three government) responded to the proposed approach in the 1st CFS. The views of submitters were mixed with no consensus on voluntary addition of DHA to infant formula products.

Industry submitters also requested the proposed GUL be increased to 12 mg/100 kJ, on the

basis that the maximum level of DHA on the ANZ market currently exceeds the proposed maximum of 7 mg/100 kJ.

4.5.3 Discussion

Voluntary permissions

DHA is a non-essential fatty acid as it is synthesised from the essential fatty acid ALA. The FSANZ 2016 NA concluded that mandatory addition of DHA was based on mixed and inconclusive studies on infant development.

FSANZ also reiterated in the FSANZ 2021 CP2 and FSANZ 2022 SD2 that FSANZ will not undertake further assessment on the optional addition of LC-PUFA's as there is (1) a long standing permission and no sound evidence of safety concerns; (2) consistency with international regulations (including recent discussions on the revision of the proposed Codex Draft Standard for FuFOI); (3) no lack of regulatory certainty; and (4) assessment against the Ministerial Policy Guideline on the Regulation of Infant Formula (ANZ FRMC, 2011) only applies to new ingredients or substances.

Based on the above, FSANZ continues to conclude that DHA should retain its voluntary permission in infant formula products.

DHA : AA ratio

The maximum level for DHA has a direct effect on the requirements for Arachidonic acid (AA) and further flow on effects to Vitamin E and other LC-PUFA permissions in infant formula products. Therefore, the DHA maximum cannot be considered in isolation.

The FSANZ 2016 NA noted concerns pertaining to safety if DHA was added without providing adequate amounts of AA. Within the 1st CFS FSANZ proposed to retain the AA limit at no more than 1% total fatty acids. As FSANZ has changed the DHA permission from % total fatty acids to mg/100 kJ, for consistency purposes FSANZ has decided to change the AA amount to be controlled by a ratio with DHA; Where AA is ≥ DHA.

Expressing this permission as a ratio instead of % total fatty acids is consistent with Codex CXS 72-1981 and the Codex Draft Standard for FuFOI. It also ensures the ratio between DHA and AA is maintained, no matter the composition of total fatty acids and level of DHA.

DHA GUL

While FSANZ appreciates the position of submitters to the 1st CFS, FSANZ does not agree that a higher GUL for DHA is appropriate. FSANZ notes that the EU 2016/127 maximum DHA amount of 12 mg/100 kJ has very different regulatory parameters to those FSANZ is proposing. The EU 2016/127 maximum DHA is a mandatory addition to infant formula, it is a maximum not a GUL and AA content is controlled by % of total fat content. FSANZ considers that the regulatory intent of a GUL provides manufactures with enough flexibility surrounding the DHA maximum to account for considerations of manufacturing and analytical tolerances.

4.5.4 Conclusion

Based on the conclusions of the FSANZ 2016 NA, alignment with Codex CXS 72-1981 and the Codex Draft Standard for FuFOI, regulatory consistency and the lack of sound evidence of safety concerns, the proposed consequential draft variation will permit DHA as an optional ingredient with a GUL of 7 mg/100 kJ in infant formula products. DHA will also be regulated through a ratio with AA, where AA must be ≥ DHA.

4.6 Phospholipids

FSANZ 1st CFS received six submissions (four industry, two government) which presented mixed feedback on the preferred option. Industry submitters requested the limit be presented as a GUL instead of a maximum. A government submitter did not support FSANZ's preferred option to set a maximum and instead requested FSANZ provide further scientific assessment to justify adding phospholipids as a nutritive substance. Another government submitter supported FSANZ preferred option and requested the units of expression be clarified as almost all specifications are currently per 100 kJ for infant formula products (with the exception of energy and some fatty acids).

FSANZ clarifies that the phospholipid maximum is a restriction and should not be confused as a permission for addition of a nutritive substance. Therefore, adapting the phospholipid maximum to a GUL is not appropriate. The EU 2016/17 and Codex CXS 72-1981 do not express the phospholipid maximum as a GUL either.

Phospholipids are naturally occurring constituents of milk and the intent of the restriction is to ensure phospholipids are not added to infant formula products at levels above those naturally occurring in milk. There is no permission in Standard 2.9.1 or Schedule 29 for phospholipid use as a nutritive substance, it is strictly a restriction in fatty acid composition. Further to this, phospholipids are not permitted to be labelled in NIS. This restriction has been present within Standard 2.9.1 since its establishment, which was prior to the development of the Ministerial Policy Guideline. Based on the above rationale, FSANZ will not be applying the Ministerial Policy Guideline retrospectively to a nutrient restriction.

FSANZ acknowledges that for consistency and clarity phospholipids should be expressed as mg/100 kJ. Therefore, FSANZ will limit the phospholipid maximum at 72 mg/100 kJ.

4.7 Lecithin

FSANZ acknowledges that submissions to the FSANZ 2021 CP2 regarding phospholipid and lecithin were not addressed within the 1st CFS. While FSANZ considered submissions on phospholipids, they were not considered and assessed in conjunction with lecithin as a food additive.

Within the 2021 CP2, FSANZ proposed three options for the phospholipid and lecithin permissions within infant formula products:
(1) Restrict the phospholipid content to 2 g/L, or
(2) Restrict the lecithin content to 1 g/L, or
(3) Both (1) and (2).

FSANZ also requested information (including quantitative evidence) about the approaches, particularly from manufacturers that may be disproportionately impacted by these restrictions. The FSANZ 2021 CP2 received six submissions (four industry, two government), of which one submitter did not provide a favoured option, three submitters supported option 1 and two submitters supported option 3. These submissions can be found on the FSANZ website.

Since the 2021 CP2, follow-on formula has been re-introduced into Proposal P1028. Within FSANZ 2022 SD2, FSANZ proposed a maximum permitted level for phospholipids of 2 g/L for both infant formula and follow-on formula.

FSANZ 1st CFS received four submissions (four industry, one government). Industry submitters did not support a maximum permitted level of 1 g/L for lecithin and instead supported retaining the current maximum permitted level of 5000 mg/kg. Whereas the

government submitter supported the 1 g/L.

Following consideration of submissions to the 1st CFS, FSANZ has considered the impact of lowering the maximum permitted level for lecithin to 1 g/L, in line with the EU 2016/17. As the lecithin maximum (5 g/L) is currently aligned across infant formula and follow-on formula within the Code and Codex, the approach to lower the maximum would require reformulation of products currently complying with both regulations. FSANZ has given further consideration to the issue and is proposing the following:

- phospholipid maximum of 72 mg/100 kJ
- drafted alongside wording similar to Codex CXS 72-1981 ('the **total** content of phospholipids should not exceed 2.1 g/L')
- retention of the food additive maximum permitted level for lecithin of 5 g/L

In conjunction with the above points, readers should see note 3 to subsection 1.1.1—10(6) of the Code which clarifies that *In some cases, a provision refers to the total amount of a substance added to a food. In these cases, the total amount applies irrespective of whether the substance was used as a food additive, used as a processing aid or used as a nutritive substance"*.

The above approach mitigates concerns related to phospholipids from lecithin as these levels will be directly addressed by a restriction to the phospholipid content. The limit for phospholipids applies to the total phospholipid content, which is inclusive of phospholipids from lecithin as well as other sources (e.g. LC-PUFA, vegetable oils, milk fat). This approach aligns with Codex CXS 72-1981, does not pose risk to infant health and will require substantially less reformulation for products on the ANZ market.

5 Micronutrients

Table 5 – Micronutrients: summary of submitter comments and FSANZ response

Issue	Comment	Submitter(s)	FSANZ Response
Vitamin A *FSANZ preferred option at the CFS was:* • *Vitamin A range of 14 - 43 µg RE/100 kJ.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option.	NZFS, INC, FCG, NZFGC, AFCG	FSANZ has addressed the issue raised in section 5.1 below.
No, the preferred option is not supported.	These submitters did not support FSANZ's preferred maximum and instead recommended the EU 2016/127 maximum of 27.2 µg RE/100 kJ. These submitters also queried whether there may be potential to exceed the ANZ UL.	WADoH, VICDoH	
Vitamin B6 *FSANZ preferred option at the CFS was:* • *Vitamin B6 range of 8 - 42 (GUL) µg/100 kJ.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option.	NZFS, INC, FCG, NZFGC, AFCG	While FSANZ appreciates the position of submitters who did not support the preferred option, no new evidence was provided for consideration at the 1st CFS.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred option and instead recommends aligning with the EU 2016/127 minimum of 4.8 µg/100 kJ and retaining the current maximum 36 µg/100 kJ. This is based on EFSA most recent review of vitamin B6 levels. This submitter requested that FSANZ determines a GUL that better reflects the upper levels in breast milk or consider retaining the current maximum of 36 µg/100 kJ, with scientific justification for the level.	VICDoH	The position of the submitter has been considered within the FSANZ 2021 CP2 and is addressed again in the FSANZ 2022 SD2. FSANZ encourages the submitter to refer to these discussions. As no new evidence has been provided, FSANZ retains its position and prescribes vitamin B6 at a range of 8 – 42 (GUL) µg/100 kJ in infant formula products. This is based on the conclusions of the FSANZ 2021 NA which concluded that use of the EU 2016/127 minimum amount of 4.8 µg/100 kJ may pose a risk to infant health. Whereas the FSANZ 2016 NA determined that intakes based on the Codex CXS 72-1981 permitted range are unlikely to pose a risk to infant health.
Vitamin B12 *FSANZ preferred option at the CFS was:* • *Vitamin B12 range of 0.02 – 0.36 (GUL) µg/100 kJ.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option (0.02 – 0.36 (GUL) µg/100 kJ).	NZFS, INC, FCG, NZFGC, AFCG	FSANZ has addressed the issue raised in section 5.2 below.
No, the preferred option is not supported.	These submitters did not support FSANZ's preferred maximum and instead support retaining the current maximum of 0.17 (GUL) µg/100 kJ as this better reflects levels found in breast milk. WADoH requested a review of the evidence on levels of B12 to confirm the evidence for infant health including from the perspective of breast milk levels of B12; and the principle of avoiding unnecessary excesses of substances in infant formula (maximum level).	VICDoH, WADoH	

Issue	Comment	Submitter(s)	FSANZ Response
Riboflavin maximum *FSANZ preferred option at the CFS was:* • *Riboflavin range of 14.3 – 120 (GUL) µg/100 kJ.*			
No, the preferred option is not supported.	This submitter noted that no nutrition or health-based rationale has been provided for why the level should be raised to being more than eight times the minimum, noting breast milk ranges from 9.8 –22 µg/100 kJ.	VICDoH	FSANZ has addressed the issue raised in section 5.3 below.
Niacin *FSANZ preferred option at the CFS was:* • *Niacin range of 70 – 359 (GUL) µg/100 kJ.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred minimum 70 µg/100 kJ.	INC, FCG, NZFGC, AFCG	FSANZ notes that there was unanimous support for the proposed niacin GUL of 359 µg/100 kJ. FSANZ has addressed the niacin minimum in section 5.4 below.
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred GUL of 359 µg/100 kJ.	INC, FCG, NZFS, AFCG, NZFGC,	
Partially supported the preferred option.	This submitter was still considering the proposed minimum as intakes based on 70µg /100 kJ would fall below the NHMRC Adequate Intake (AI).	NZFS	
No, the preferred option is not supported.	These submitters did not support FSANZ preferred option, and instead request FSANZ consider a review of the evidence to further support the reduction of the minimum from 130 µg/100 kJ to 70 µg/100 kJ.	WADoH, VICDoH	

Issue	Comment	Submitter(s)	FSANZ Response
Vitamin C *FSANZ preferred option at the CFS was:* • *Vitamin C range of 1.7 – 17 mg/100 kJ.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred range (1.7 – 17 mg/100 kJ).	INC, FCG, NZFS, AFCG, NZFGC,	While FSANZ appreciates the position of submitters who did not support the proposed option, no new evidence was provided for consideration at the 1st CFS. Vitamin C has been assessed within both FSANZ 2016 NA and FSANZ 2021 NA and further consideration has been given to the position in FSANZ 2021 CP2 and FSANZ 2022 SD2. FSANZ encourages submitters to refer to these discussions and assessments. Further to FSANZ's own independent assessment, the maximum (17 mg/100 kJ) was reiterated within the Codex Draft Standard for FuFOI, on the basis of scientific evidence and the recommendations of the electronic Working Group (eWG). A maximum of 17 mg/100 kJ does not pose risk to infant health and there is no evidence that formula-fed infants consume unsafe amounts of vitamin C. The Codex CXS 72-1981 vitamin C maximum is higher than the EU 2016/127 as it accounts for vitamin C degradation and liquid infant formula products (CCNFSDU 2006). FSANZ considers the higher maximum crucial to ensure adequacy is achieved and to counter degradation that occurs during shelf life, heating and storage conditions. Based on FSANZ 2016 NA, the vitamin C minimum in Schedule 29 is a midpoint between Codex CXS 72-1981 and the EU 2016/127 minimum, is comparable to levels in breast milk and meets the ANZ AI. As no new evidence has been provided, FSANZ retains its position and prescribes vitamin C at a range of 1.7 – 17 (GUL) mg/100 kJ in infant formula products.
No, the preferred option is not supported.	These submitters did not support FSANZ's preferred range. They request a review of the evidence on the minimum and maximum levels as they relate to infant needs and for consistency in approach regarding the impact of shelf life losses, scurvy risk safety factor, and the Codex minimum of 2.5 mg/100 kJ. They note the high maximum of 17 mg/100 kJ in comparison to maximum level set by EU of 7.2 mg/100 kJ, the principle of avoiding unnecessary excesses of substances in infant formula and the need to take into account any risk of nutrient interactions.	WADoH, VICDoH	

Issue	Comment	Submitter(s)	FSANZ Response
Vitamin D *FSANZ preferred option at the CFS was:* • *Vitamin D range of 0.24 – 0.63 µg/100 kJ.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred range.	NZFS, INC, AFCG, VICDoH, NZFGC,	FSANZ has addressed the issue raised in section 5.5 below.
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred range and instead request the maximum to be increased to 0.72 µg/100 kJ in line with the revised Codex Follow-up formula standard and EU.	FCG	
Vitamin E *FSANZ preferred option at the CFS was:* • *Vitamin E range of 0.12 – 1.2 mg/100 kJ.*			
Yes, the preferred option is supported.	This submitter supported FSANZ's preferred minimum of 0.12 mg/100 kJ.	VICDoH	FSANZ notes there was unanimous support for the vitamin E maximum of 1.2 mg/100 kJ. FSANZ's retains this position, which is present in the table to S29—5 and S29—6 of the proposed consequential draft variation. FSANZ has addressed the vitamin E minimum in section 5.6 below.
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred GUL of 1.2 mg/100 kJ.	INC, FCG, NZFS, AFCG, VICDoH, NZFGC,	
No, the preferred option is not supported.	These submitters did not support proposed minimum and instead recommend alignment to the EU and setting a slightly higher minimum of 0.14 mg/100 kJ (0.60 mg/100 kcal) with no additional vitamin E PUFA requirement, provided that SMPPi are able to be aligned to Codex.	INC, FCG, NZFS, NZFGC, AFCG, DAN, SO	

Issue	Comment	Submitter(s)	FSANZ Response
Phosphorus *FSANZ preferred option at the CFS was:* • *Vitamin E range of 6 – 24 (GUL) mg/100 kJ.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred range of (6 – 24 (GUL) mg/100 kJ)	INC, FCG, NZFS, AFCG, NZFGC,	While FSANZ appreciates the position of submitters who did not support the proposed option, no new evidence was provided for consideration at the 1st CFS. The position of VICDoH to set ranges that aligned with the EU and prescribed separate ranges for soy and milk-based formula has been comprehensively considered within the FSANZ 2021 CP2. FSANZ encourages submitters to refer to these discussions. As no new evidence has been provided, FSANZ retains its position and prescribes phosphorus at a range of 6 – 24 (GUL) mg/100 kJ in infant formula products. The GUL prescribed accommodates for the higher concentration of phosphorus in soy-based formula.
No, the preferred option is not supported.	This submitter does not support FSANZ's preferred range of (6 – 24 (GUL) mg/100 kJ) and instead requests the range aligns with the EU in separating out regulatory requirements to: • 6 – 21.5 mg/100 kJ for cow or goat based formulas and • 7.2 – 24 mg/100 kJ for formula containing soy	VICDoH	
Iron *FSANZ preferred option at the CFS was:* • *Iron range of 0.2 – 0.5 mg/100 kJ.*			
Yes, the preferred option is supported.	This submitter supported FSANZ's preferred maximum 0.5 mg/100 kJ, after correction of conversion factor to 0.48 mg/100 kJ.	NZFS	FSANZ has addressed the issue raised in section 5.7 below.
No, the preferred option is not supported.	These submitters did not support the proposed range as it is not aligned internationally.	INC, FCG, VICDoH, NZFGC, AFCG, DAN	

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	This submitter did not support FSANZ preferred minimum (0.2 mg/100 kJ) as it does not align with Codex CXS72-1981 or EU 2016/127. A lower minimum requirement is suitable for infants in the first year of life.	NZFS	
No, the preferred option is not supported.	This submitter did not support FSANZ preferred maximum (0.5 mg/100 kJ) as this does not align with Codex CXS72-1981 or EU 2016/127. Instead support EU level of 0.31 mg/100 kJ.	VICDoH	
Request review of the evidence.	These submitters requested a review of the evidence on the minimum and maximum levels of iron given there may be potential for some infants to reach excess iron intakes, noting that the EFSA recommends lower minimum of 0.14 mg/100 kJ and a maximum of 0.31 mg/100 kJ.	WADoH, VICDoH	
Iron (soy) *FSANZ preferred option at the CFS was:* • *Iron range of 0.2 – 0.5 mg/100 kJ.*			
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred option to not specify a separate range for soy products and instead supports a range of 0.2 - 0.5 mg/100 kJ for soy-based formula to allow for reduced absorption from phytic acid content.	VICDoH	FSANZ has addressed the issue raised in section 5.7 below.
Folic acid *FSANZ preferred option at the CFS was:* • *Folic acid range of 2.4 – 12 (GUL) µg/100 kJ.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred range.	NZFS, INC, FCG, NZFGC, AFCG	While FSANZ appreciates the position of submitters who did not support the proposed option, no new evidence was provided for consideration at the 1st CFS.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred range of (2.4 – 12 (GUL) µg/100 kJ) and instead supports use of Dietary Folate Equivalents, including all sources of folate and a permitted range of 3.6 – 11.4 µg/100 kJ, in line with the EU.	VICDoH	The position of the submitter to align with the EU and use Dietary Folate Equivalents as the unit of expression has been comprehensively considered within the FSANZ 2021 CP2. FSANZ encourages the submitter to refer to these discussions. As no new evidence has been provided, FSANZ retains its position and prescribes folic acid at a range of 2.4 – 12 (GUL) µg/100 kJ in infant formula products and naturally occurring folate will not be included in the permitted range.
Zinc *FSANZ preferred option at the CFS was:* • *Zinc range of 0.12 – 0.36 (GUL) mg/100 kJ.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred range of 0.12 – 0.36 (GUL) mg/100 kJ.	NZFS, INC, FCG, NZFGC, AFCG	While FSANZ appreciates the position of submitters who did not support the proposed option, no new evidence was provided for consideration at the 1st CFS. The position of VICDoH and NSWFA has been considered within the FSANZ 2021 CP2 and is addressed again in the FSANZ 2022 SD2. FSANZ encourages submitters to refer to these discussions. As no new evidence has been provided, FSANZ retains its position and prescribes zinc at a range of 0.12 – 0.36 (GUL) mg/100 kJ in infant formula products. This higher maximum accommodates the higher concentration of zinc in soy-based formula.
No, the preferred option is not supported.	These submitters did not support FSANZ's preferred GUL of 0.36 mg/100 kJ, instead support aligning with the EU maximum of 0.24 mg/100 kJ and request further information on why it is desired to adopt the Codex range for Zinc. VICDoH also supports setting different levels for cow's milk and soy formula (0.18 - 0.3 mg/100 kJ for soy), consistent with the approach for other nutrients where lower bioavailability in soy products exists.	VICDoH, NSWFA	
Thiamin *FSANZ preferred option at the CFS was:* • *Thiamin range of 10 – 72 (GUL) µg/100 kJ.*			

Issue	Comment	Submitter(s)	FSANZ Response
Yes, the preferred option is supported.	This submitter supported FSANZ's preferred range.	NZFS	While FSANZ appreciates the position of submitters who did not support the proposed option, no new evidence was provided for consideration at the 1st CFS. The position of VICDoH has been considered within the FSANZ 2021 CP2 and is addressed again in the FSANZ 2022 SD2. The GUL of 72 µg/100 kJ was considered in the FSANZ 2016 NA which identified that the range set in Codex CXS 72-1981 met all of the nutrition assessment criteria. No new evidence emerged to indicate that the Codex CXS 72-1981 and Standard 2.9.1 maximums should not align. The level proposed is also supported by the EC SCF (2003), ESPGHAN (2005), the CCNFSDU eWG and was re-established in the Draft Codex Standard for FuFOI. As no new evidence has been provided, FSANZ retains its position and prescribes thiamin at a range of 10 – 72 (GUL) µg/100 kJ in infant formula products.
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred range, however, would also support the EU 2016/127 minimum of 9.6 µg/100 kJ.	INC, FCG, NZFGC, AFCG	
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred GUL of 72 µg/100 kJ, and instead supports retaining the current range of 10 - 48 µg/100 kJ for thiamin on the basis that this best supports infant requirements and limits the provision of unnecessary amounts of thiamine to less than five times the minimum. If FSANZ intends to proceed with a level of 72 µg/100 kJ, clear evidence to justify this level needs to be provided.	VICDoH	
Biotin *FSANZ preferred option at the CFS was:* • *Biotin range of 0.24 – 2.4 (GUL) µg/100 kJ.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred range.	INC, FCG, NZFS, AFCG, NZFGC,	While FSANZ appreciates the position of submitters who did not support the proposed option, no new evidence was provided for consideration at the 1st CFS. The position of VICDoH has been considered within the FSANZ 2021 CP2 and is addressed again in the FSANZ 2022 SD2. FSANZ encourages submitters to refer to these discussions. As no new evidence has been provided, FSANZ retains its position, and the proposed consequential draft variation prescribes biotin at a range of 0.24 – 2.4 (GUL) µg/100 kJ in infant formula products.
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred maximum 2.4 (GUL) µg/100 kJ) and instead supports aligning the maximum with the EU Level of 1.8 µg/100 kJ.	VICDoH	

Issue	Comment	Submitter(s)	FSANZ Response
Copper *FSANZ preferred option at the CFS was:* • *Copper range of 8.5 – 29 (GUL) µg/100 kJ).*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred range of (8.5 – 29 (GUL) µg/100 kJ).	INC, FCG, NZFS, AFCG, NZFGC,	While FSANZ appreciates the position of submitters who did not support the proposed option, no new evidence was provided for consideration at the 1st CFS. The position of VICDoH has been considered within the FSANZ 2021 CP2 and is addressed again in the FSANZ 2022 SD2. FSANZ encourages submitters to refer to these discussions. Excluding the amount of copper contributed by potable water, the estimated intake of copper for infants 0-6 months consuming formula prepared from powder is 186 µg/day, which is within 10% of the ANZ AI (200 µg/day). It is assumed that this estimated intake would not be consistent across the whole feeding period. FSANZ also notes that copper deficiency is rare in humans except in pre-term infants. Pre-term products are highly specialised, generally available through neo-natal paediatrics and supplied where medically necessary. As no new evidence has been provided, FSANZ retains its position, and the proposed consequential draft variation prescribes copper at a range of 8 – 29 (GUL) µg/100 kJ in infant formula products.
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred range of (8.5 – 29 (GUL) µg/100 kJ), and instead supported a range of 9.2 - 24 µg/100 kJ. The minimum is based on the minimum required to meet the NHMRC AI and the maximum aligns with EU 2016/127 regulation.	VICDoH	
Iodine *FSANZ preferred option at the CFS was:* • *Iodine range of 2.4 – 14 µg/100 kJ.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred range.	INC, FCG, NZFS, AFCG, NZFGC, SO	FSANZ has addressed the issue raised in section 5.8 below.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred range and instead supports a range of 3.6 – 6.9 µg/100 kJ.	VICDoH	
Selenium *FSANZ preferred option at the CFS was:* • *Selenium range of 0.48 – 2.2 (GUL) µg/100 kJ.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred range of (0.48 – 2.2 (GUL) µg/100 kJ).	INC, FCG, NZFS, AFCG, NZFGC,	The position of VICDoH has been considered within the FSANZ 2021 CP2 and is addressed again in the FSANZ 2022 SD2. The ANZ UL for young infants was based on studies showing that a human milk concentration of 60 µg/L (equivalent to 2.2 µg/100 kJ, i.e. the amount prescribed in Codex CXS 72-1981) was not associated with adverse effects. The FSANZ 2021 NA noted that breast milk concentrations equivalent to 2.2 µg/100 kJ were not associated with adverse effects. As no new evidence has been provided, FSANZ retains its position, and the proposed consequential draft variation prescribes selenium at a range of 0.48 – 2.2 (GUL) µg/100 kJ in infant formula products.
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred maximum of 2.2 (GUL) µg/100 kJ, and instead supports a maximum of 2 µg/100 kJ, in line with the EU as this level resulted in intakes that fell just below the ANZ UL of 45 µg/day, whereas the Codex level results in infant intakes above the UL (48 µg/day).	VICDoH	

5.1 Vitamin A

FSANZ has considered submissions that did not support the proposed option. However, no new evidence was provided for consideration at the 1st CFS. Alignment with the EU 2016/127 maximum value for vitamin A was considered in FSANZ 2021 CP2, FSANZ 2021 NA and addressed again in the FSANZ 2022 SD2. FSANZ encourages submitters to refer to these discussions.

In regard to submitter comments querying the potential to exceed the UL set by the NHMRC for infants in the age range of 6 to 12 months, FSANZ would like to refer submitters to discussions in section 3.6 of the FSANZ 2016 NA. This assessment concluded that while there is potential to exceed the UL, the UL established by the NHMRC can be considered conservative. Moreover, the assessment noted that the estimate is based on the maximum amount and represents an amount that is unlikely to occur continuously over the period of formula feeding. Aside from the potential exceedance of the UL, there is no additional evidence that supports lowering the maximum from the current Standard 2.9.1 and Codex CXS 72-1981 amount. This level also more closely reflects the upper levels in breast milk of 3 – 38.3 µg RE/100 kJ (EFSA 2014).

FSANZ also notes that vitamin A content in infant formula products is subject to losses during storage, transport and shelf life (Cha´vez-Servı´n, 2007), which further justifies the need for the higher maximum level.

As no new evidence has been provided, FSANZ retains its position and the proposed consequential draft variation prescribes vitamin A at a range of 14 – 43 µg RE/100 kJ in infant formula products. This is based on the conclusions of the FSANZ 2016 NA and FSANZ 2021 NA, it reflects the level in breast milk, has a history of safe use at current levels and is aligned with Codex CXS 72-1981 and the Codex Draft Standard for FuFOI.

5.2 Vitamin B12

FSANZ has considered the submissions which did not support the preferred option. However, no new evidence was provided for consideration at the 1st CFS. In the 2016 NA, FSANZ concluded that alignment with Codex CXS 72-1981 was unlikely to pose a risk to infant health as it met the assessment criteria (noted above in Section 1.1). The range aligned with Standard 2.9.1, was comparable to breast milk and enabled nutrient requirements to be met.

The preferred option (Codex CXS 72-1981 GUL) was also re-established within the Draft Codex Standard for FuFOI on the basis of the safe history of use within the Codex CXS 72-1981 standard and the recommendations of the International Expert Group (Koletzko, 2013). The re-establishment of this GUL within the Draft Codex Standard for FuFOI resulted from a thorough review of the evidence, which considered levels of vitamin B12 in breast milk and the potential for unnecessary excesses associated with the maximum level.

As previously stated, FSANZ considers the nutrient composition for follow-on formula should only deviate from infant formula when there is substantiated science to support the differences in needs between the age groups. There is international consistency across regulations that infant formula and follow-on formula have the same range for vitamin B12.

Based on the above discussion, FSANZ retains its position to prescribe vitamin B12 at a range of 0.02 – 0.36 (GUL) µg/10 kJ in infant formula and follow-on formula.

5.3 Riboflavin

FSANZ notes that the previous position of a government submitter supported a maximum that was four times higher than the referenced maximum amount in breast milk and the current guideline maximum within Schedule 29 is also four times this amount. While FSANZ acknowledges that the preferred maximum is higher than that of the EU 2016/127 and the Code, it is important to acknowledge and contextualise that maximum riboflavin amounts in infant formula products are typically higher than those in breast milk as they are based off the AI. The Codex CXS 72-1981 riboflavin values were modelled on an AI of 300 - 400 µg/day for infants, whereas EFSA recommendations are based on a slightly lower estimated AI of 300 µg/day.

Excess riboflavin consumption has not been associated with adverse effects in humans and there is no UL established by the SCF or by the NHMRC and NZ MOH (EFSA 2014, NHMRC and NZ MOH 2006).

It is also important to note that the preferred maximum aligns with the Codex Draft Standard for FuFOI and allows formula to comply with both Codex and the EU regulation.

As no new evidence was submitted during the 1st CFS, FSANZ retains its position to require riboflavin at a level between 14.3 – 120 (GUL) µg/100 kJ in infant formula products.

5.4 Niacin

Three submitters did not support the proposed minimum because intakes based on 70µg /100 kJ would fall below the NHMRC AI, and the minimum is considerably lower than the minimum level currently prescribed in Schedule 29 (130 µg/100 kJ).

As noted in the FSANZ 2016 NA and the CX/NFSDU15/37/5 there are slight differences in the assumptions made in the derivation of the two values based on the niacin content of human milk. The amount listed in Standard 2.9.1 originates from the LSRO recommendation which was based on niacin intakes in breastfed infants and includes the tryptophan contribution (LSRO, 1998). Whereas the basis for the Codex CXS 72-1981 minimum is breast milk concentrations of niacin which exclude the tryptophan contribution.

Further to this, in the EFSA opinion, the upper end of the range of niacin in human milk was used to establish adequate intake levels and consequently the EU 2016/127 minimum requirement of 100 µg/100 kJ, whereas a mid-point of the range was used to establish the minimum of the Codex Standard for Infant Formula. Once the contribution of tryptophan from formula are taken into account the adequate intake for niacin equivalents is met (Codex Alimentarius, 2015).

There is also no evidence that infants consuming formula based on the Codex CXS 72-1981 minimum amount do not meet their niacin requirement. Therefore, FSANZ concludes that the proposed consequential draft variation should prescribe a minimum niacin content of 70 µg/100 kJ.

5.5 Vitamin D

5.5.1 Background

The permitted range for vitamin D in Schedule 29 (0.25 – 0.63 µg/100 kJ) is comparable to that in Codex CXS 72-1981 (0.25 – 0.6 µg/100 kJ). The permitted range for vitamin D under EU 2016/127 was recently revised to 0.48 – 0.6 µg/100 kJ (European Commission 2019).

For follow-on formula the Codex Draft Standard FuFOI and EU 2016/127 (Annex II) are both

aligned with a maximum of 0.72 µg/100 kJ, however, have different minimums of 0.24 µg/100 kJ and 0.48 µg/100 kJ, respectively.

Table 5.5.1 - Permitted range for vitamin D

Nutrient	Unit	The Code Schedule 29–9		Codex CXS 72-1981		Codex Draft Standard for FuFOI		EU 2016/127 ANNEX I		EU 2016/127 ANNEX II	
		Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Vitamin D	µg/100 kJ	0.25	0.63	0.25	0.6	0.24	0.72	0.48	0.6	0.48	0.72

In 2016 FSANZ considered it appropriate to retain the vitamin D range of 0.25 – 0.63 µg/100 kJ on the basis that no safety concerns had been identified with using the range, it aligns closely with international regulations and is wide enough to be achievable for product formulation and manufacturing. FSANZ retained this view within the FSANZ 2021 CP2 and FSANZ 2022 SD2. At the 1st CFS FSANZ proposed to retain the same range for follow-on formula.

5.5.2 Stakeholder comments

Six submitters (four industry, two government) responded to the proposed vitamin D range for infant formula in the 1st CFS. Five submitters supported the proposed range for infant formula, while one submitter did not support the range and instead requested the maximum be 0.72 µg/100 kJ.

An additional six submitters responded to the proposed vitamin D range for follow-on formula, with none of the submitters supporting the proposed maximum. These submitters recommended adopting a maximum of 0.72 µg/100 kJ in line with Codex Draft Standard FuFOI and EU 2016/127 (Annex II). These submitters noted that maintaining the current maximum would not allow for recipe harmonisation with international jurisdictions, particularly the EU. A product formulated under the EU and Food Standards Code requirements would require a vitamin D range of 0.48–0.63mg/100 kJ. This range is too narrow and would not allow for raw material, analytical and processing variability.

5.5.3 Discussion

FSANZ's preferred option from the 1st CFS for infant formula was considered the most appropriate range for the ANZ population and is aligned with the maximum value in Codex CXS 72-1981 and EU 2016/127. FSANZ notes that the higher maximum level established in the EU 2016/127 (Annex II) is based on their difference in vitamin D requirements for this age group, a consequence of limited exposure to sunlight. The draft Codex Standard for FuFOI has a higher vitamin D maximum to accommodate the variation in regional exposure to sunlight and consequential differences in requirements. FSANZ does not consider either of these rationales applicable to the ANZ population or infant formula. There is not substantial evidence to suggest that the vitamin D maximum needs to be increased for infant formula. FSANZ therefore does not propose to raise the maximum level for infant formula in the Code to the level permitted in the draft Codex Standard for FuFOI and EU 2016/127 (Annex II).

In regard to the maximum permitted level for follow-on formula, submitters asserted that the ANZ NRV's are based on outdated studies, and that the contribution of vitamin D from complimentary foods would be very limited due to the fact that FSANZ does not permit fortification of infant foods. Submitters also pointed out that the EU does allow fortification of infants foods, has a higher maximum of 0.72 µg/100 kJ and further argued there were no associated safety concerns with this higher maximum permitted level.

While FSANZ appreciates the position and comments of submitters, the submissions

received did not outline any key differences between the vitamin D requirements for infants aged 0 – 6 months and infants aged 6 – 12 months. FSANZ reiterates that the ANZ AI for 0 – 6 and 7 – 12 months is the same at 5.0 µg/day. The EFSA vitamin D DRV's for infants aged 7-11 months has been set at 10 µg/day, which is double the ANZ AI. The EFSA DRV for vitamin D is the basis for the higher maximum level in the EU 2016/127 (Annex II) follow-on formula legislation.

Further to this, reported vitamin D deficiency resulting in rickets in infants is rare in ANZ (NHMRC, 2013), vitamin D can be synthesised endogenously, and low vitamin D intakes do not necessarily lead to inadequate vitamin D status as it is more readily associated with behavioural traits such as exposure to sunlight (EFSA, 2014). The vitamin D content of breast milk (<1 µg/L) is highly variable and generally lower than levels present within formula (Munns, 2006). It is generally recognised that exclusively breastfed infants with minimal exposure to sunlight do not obtain adequate vitamin D (NHMRC and MoH 2006). Breastfed older infants largely rely on complimentary foods and exposure to sunlight to reach adequate vitamin D levels.

FSANZ's retains the position that the composition between infant formula and follow-on formula should only vary where there is substantiated scientific evidence that demonstrates a different nutrient requirement between the age ranges. FSANZ considers this information is not established for the ANZ population and therefore does not propose to change the maximum permitted level.

5.5.4 Conclusion

Because there are no safety or adequacy concerns identified with the current permitted range of 0.24 – 0.63 µg/100 kJ, the range aligns most closely with international regulations, the range is wide enough to be achievable for product formulation and manufacturing and meets the vitamin D requirements based on the ANZ AI, the proposed consequential draft variation prescribes a vitamin D range of 0.24 – 0.63 µg/100 kJ for both infant formula and follow-on formula.

5.6 Vitamin E

Table 5.6 - Permitted range for vitamin E

Nutrient	Unit	Human milk concertration[1]		The Code Schedule 29–9		Codex CXS 72-1981		Codex Draft Standard for FuFOI		EU 2016/127 ANNEX I		EU 2016/127 ANNEX II	
		Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Vitamin E	mg/100 kJ	2	5	0.11	1.1	0.12	1.2*	0.12	1.2*	0.14	1.2	0.14	1.2

[1] *mg/L (EC SCF 2003)* * = GUL

Seven submitters (five industry, two government) responded to the proposed vitamin E minimum (0.12 mg/100 kJ) for infant formula products in the 1st CFS. One submitter supported the proposed minimum, while six submitters did not and instead recommended aligning with the slightly higher EU 2016/127 minimum (0.14 mg/100 kJ). Some submitters also requested no additional vitamin E PUFA requirements. Submitters noted this would result in the removal of the existing conditions around vitamin E PUFA which would be easier to set and check from a compliance perspective.

Currently the minimum required level in the Code and Codex CXS 72-1981 does not meet the ANZ AI. FSANZ considers the EU 2016/127 vitamin E minimum to better meet the ANZ AI. This assessment can be found in the FSANZ 2016 NA. FSANZ therefore proposes to prescribe a vitamin E minimum required level of 0.14 mg/100 kJ.

The FSANZ 2016 NA includes a comprehensive assessment of the vitamin E to PUFA ratio which evidences the importance of the ratio in infant formula products. Based on the conclusions of the FSANZ 2016 NA, the proposed primary draft variation also retains the requirement that infant formula and follow-on formula must contain no less than 0.5 mg of vitamin E/g of polyunsaturated fatty acids.

5.7 Iron

5.7.1 Background

The permitted range for iron varies across different standards and regulations (Table 5.7.1). Different ranges are set depending on the infant age group and whether the formula is milk or soy-based. In more recently reviewed standards (EU 2016/127 and the Codex Draft Standard FuFOI), the required minimum and maximum amount of iron are higher for formula for older infants (6-12 months) and formula based on soy protein. Currently Schedule 29 prescribes one range for iron that applies to both milk and soy-based infant formula and follow-on formula.

Table 5.7.1 - Permitted range for iron

Nutrient	Unit	Human milk concertration[1]		The Code Schedule 29–9		Codex CXS 72-1981		Codex Draft Standard for FuFOI		EU 2016/127 ANNEX I		EU 2016/127 ANNEX II	
		Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Iron (milk)	mg/100 kJ	0.007	0.014	0.2	0.5	0.1	~	0.24	0.48	0.07	0.31	0.14	0.48
Iron (soy)	mg/100 kJ			0.2	0.5	0.1	NS	0.36	0.6	0.11	0.48	0.22	0.60

[1] Sources: EFSA (2014a), the IOM (2001), and Concha et al. (2013). The bioavailability of iron from human milk, cow's milk-based infant formula, and soy-based infant formula differs. Therefore, a direct comparison between regulatory requirements and levels in human milk is inappropriate.

The FSANZ 2016 NA concluded that lowering the iron minimum to the Codex CXS 72-1981 minimum had potential to pose a risk to infant health as the lower amount could increase the incidence of iron deficiency or iron deficiency anaemia. The assessment also concluded the current maximum specified by Schedule 29 was unlikely to pose a risk to infant health since estimated intakes were below the NHMRC UL for iron.

FSANZ's 2013–14 and 2021 label survey of infant formula found the iron content of all formula fell within the minimum and maximum levels required in both the Codex CXS 72-1981 and Schedule 29 provisions.

As discussed in the FSANZ 2021 CP2, stakeholders supported FSANZ's 2016 view to retain the range currently specified in Schedule 29 and also supported adopting the Codex CXS 72-1981 and/or EU 2016/127 ranges.

Following FSANZ 2021, CP2 stakeholders asserted that the minimum required level of iron (0.20 mg/100 kJ) would not allow European formulated products which complied to the Codex CXS 72-1981 minimum of 0.11 mg/100 kJ to be imported directly into ANZ without prior reformulation.

FSANZ preferred option at the 1st CFS was to retain the range of 0.2 – 0.5 mg/100 kJ.

5.7.2 Stakeholder comments

Eight submitters (five industry, three government) responded to the proposed approach in

the 1st CFS. The views of submitters were mixed with no consensus on both the proposed maximum and minimum, however no stakeholders supported the proposed minimum. One government submitter supported the proposed maximum, while another government submitter did not. Six submitters did not support the proposed range as it is not aligned internationally. Another government submitter did not support the proposed minimum and requested a lower minimum aligned with Codex CXS 72-1981 or EU 2016/127 be considered.

5.7.3 Discussion

Based on extensive submitter feedback FSANZ is reconsidering the ranges prescribed for iron in infant formula and follow-on formula. FSANZ's initial assessments and considerations took place prior to the re-introduction of follow-on formula into the scope of the Proposal. FSANZ is taking the opportunity at the 2nd CFS to re-assess if separate ranges specific to infants aged 0 – 6 months and 6 – 12 months are more appropriate. FSANZ had noted in previous assessments (FSANZ 2016, FSANZ 2021b) that infant formula should meet the requirements of infants aged 0 – 12 months, however based on the differing requirements for infants within this age group, the introduction of complimentary foods at around 6 months of age and the definitions for infant formula and follow-on formula within the Code, FSANZ considers it appropriate to establish nutrient composition for each product specific to the nutrient requirements of the age group.

FSANZ also notes that the infant formula standard is legislation that is to be followed by manufacturers and does not extend to health advice and/or guidance. Concerns relating to older infants not meeting their iron requirements can be mitigated through the caregivers selecting follow-on formula that has a higher minimum iron level, introduction of solid foods and referring to infant feeding guidance (NHMRC and NZ MOH 2006).

While iron requirements in infancy continue to be of some concern since iron deficiency is the most common micronutrient deficiency worldwide (Domellof, 2014), full-term infants have iron stores sufficient to cover their needs for a couple of months and, when exclusively breastfed, most healthy term infants need no extra iron up to six months of age (EFSA, 2014). Breast milk iron concentrations typically range from 0.007 – 0.014 mg/100 kJ (EFSA 2014, IOM 2001, Concha 2013).

For infants 0 – <6 months, to receive the same amount of absorbed iron as breastfed infants and meet the ANZ AI (0.2 mg/day), cow's milk-based formula-fed infants aged 0 – <6 months should have an iron intake of 1 – 2 mg/day. The estimated iron intakes using the EU 2016/127 minimum amounts for cow's milk-based infant formula (1.53 mg/day) is above the target intake of 1–2 mg/day for infants aged 0 – <6 months. Therefore, the risk of harm to younger infants' health due to an inadequate iron intake would be low if FSANZ adopted the EU 2016/127 minimum amounts for milk-based infant formula. The EC SCF (2003) recommended the minimum iron amount be increased from 0.07 mg/100 kJ to 0.1 mg/100 kJ in Codex CXS 72-1981 to allow for the lower bioavailability of iron in soy-based formula (EC SCF, 2003).

Based on the above conclusions, FSANZ considers a minimum of 0.14 mg/100 kJ to be appropriate for ANZ infants. FSANZ also notes, in line with the EC SCF recommendations, that a minimum of 0.14 mg/100 kJ is appropriate for both milk and soy-based infant formula. The 0.14 mg/100 kJ value aligns with the EU 2016/127 and Codex CXS 72-1981 when corrected in accordance with the International Standard Unit conversion factors and conventional rounding.

For infants 6 – <12 months, the estimated iron intakes using the EU 2016/127 minimum amounts for cow's milk-based infant formula and follow-on formula (1.14 mg/day and 2.29

mg/day, respectively) is substantially lower than half the EAR value for infants aged 6–<12 months (3.5 mg/day). Estimated iron intakes using the EU 2016/127 minimum amounts for soy-based formula, is also substantially lower than half the EAR value for this age group when considering the lower iron absorption efficiency.

Therefore, for infants aged 6 – <12 months, FSANZ considers that the range prescribed within Schedule 29 of 0.2 – 0.5 mg/100 kJ (corrected to 0.24 – 0.48 mg/100 kJ) to be safe and suitable. This is supported by FSANZ 2016 NA and FSANZ 2021 NA and is aligned with the recently reviewed Codex Draft Standard FuFOI. FSANZ considers this range to be appropriate especially within the ANZ population where it has been recently reported that 90% of older infants had inadequate iron intakes (Netting, 2022).

FSANZ also considers the retention of the iron maximum for both infant formula and follow-on formula to be suitable and safe across younger and older infants. FSANZ has considered the risks associated with infants in the ANZ population consuming formulas with an iron maximum of 0.48 mg/100 kJ and concludes it is unlikely to pose a risk to infant health (FSANZ, 2016). FSANZ also notes that this maximum has been present within the ANZ market for over 20 years and has seen no evidence to suggest that the level is at risk of causing harm to infants. Estimated intakes based on this amount would also not exceed the UL. The Schedule 29 maximum of 0.5 mg/100 kJ is corrected to 0.48 mg/100 kJ in accordance with the International Standard Unit conversion factors and conventional rounding.

5.7.4 Conclusion

FSANZ reiterates that iron is a difficult nutrient to assign nutrient composition ranges due to differences in absorption between formula and breast milk (FSANZ 2016). This is evidenced in the varying ranges in international regulations and the differences in absorption between formula and breast milk (FSANZ 2016). However, based on a desire to meet the ANZ NRV's, a consideration of infant iron absorption from formula, the desire to improve alignment with international regulations and the recommendations of EFSA and the EC SCF, FSANZ will amend Schedule 29 to require between 0.14 – 0.48 mg/100 kJ of iron to be added to infant formula and between 0.24 – 0.48 mg/100 kJ of iron to be added to follow-on formula. This amendment can be seen in the tables to S29—5 and S29—6 within the proposed consequential draft variation.

5.8 Iodine

5.8.1 Background

Schedule 29 prescribes an iodine minimum of 1.2 µg/100 kJ in line with levels found in breast milk. This level is considerably lower than the Codex CXS 72-1981, Codex Draft Standard for FuFOI and EU 2016/127 minimums. The iodine maximum also varies across the different regulations.

Table 5.8.1 - Permitted range for iodine

Nutrient	Unit	Human milk concertration[1]		The Code Schedule 29–9		Codex CXS 72-1981		Codex Draft Standard for FuFOI		EU 2016/127 ANNEX I		EU 2016/127 ANNEX II	
		Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Iodine	µg/100 kJ	1.9	3.8	1.2	10	2.5	14*	2.4	14*	3.6	6.9	3.6	6.9

[1] *EFSA (2014a)* * = GUL

In the 2021 CP2 FSANZ proposed to adopt the EU 2016/127 minimum (3.6 µg/100 kJ) and retain the existing Schedule 29 maximum (10 µg/100 kJ). The 2021 label survey reported the

range of iodine in infant formula products to be 2.19 – 8.42 µg/100 kJ.

Following the re-inclusion of follow-on formula into the Proposal, FSANZ changed its position after consideration of the best range to include across both formulas. With the recent review of the Codex Draft Standard for FuFOI, FSANZ used the evidence and discussions that underpinned the CCNFSDU's decisions to help inform Proposal P1028. FSANZ also considers that the composition between infant formula and follow-on formula should only vary where there is substantiated scientific evidence that demonstrates a different nutrient requirement between the age groups. Both the EU 2016/127 and Codex prescribe the same iodine range for infant formula and follow-on formula. Following consideration of the Codex Draft Standard for FuFOI and the FSANZ 2016 NA conclusions, FSANZ considered it appropriate to adopt the range recently reinstated by Codex Alimentarius within the Codex Draft Standard for FuFOI of 2.4 – 14 (GUL) µg/100 kJ.

5.8.2 Stakeholder comments

Six submitters (four industry, two government) responded to the proposed iodine range for infant formula in the 1st CFS. Five submitters supported the proposed range for infant formula, while one submitter did not support the range and instead requested the EU 2016/127 range be adopted as it better meets the ANZ NRVS (AI and UL). This submitter also noted the Huynh study based on South Australia iodine intakes, cited in previous assessments, cannot be extrapolated to the rest of the Australian population given South Australia was in the minority for being iodine replete (likely due to higher soil and water levels).

5.8.3 Discussion

FSANZ notes the comments from submitters who did not support the proposed option at the 1st CFS and acknowledges that the Huynh study should not be extrapolated to the rest of the Australian population.

Minimum

While the EU 2016/127 minimum (3.6 µg/100 kJ) better meets the ANZ 0 – 6 months AI of 90 µg/day, it is important to note that the NHMRC AI was calculated by multiplying the average intake of breast milk (0.78 L/day) by the average concentration of iodine in breast milk (115 µg/L). The 0 – 6 months AI was further used to model the AI for infants aged 7 – 12 months (NHMRC and NZ MOH 2006). Based on its establishment FSANZ does not consider the ANZ AI to be the most appropriate health-based guidance value to use in setting the iodine range for infant formula products. This is because the iodine content of breast milk varies substantially according to maternal intakes and expert organisations such as WHO, UNICEF and ICCIDD do not recommend basing dietary requirements for iodine on breast milk concentrations (WHO, 2007). This approach was also used during the derivation of European dietary intake reference values for iodine and by the CCNFSDU eWG.

The iodine minimum of 1.9 µg/100 kJ prescribed in Schedule 29 has been present within the ANZ market for over 20 years. Since the establishment of this level in infant formula products, ANZ implemented mandatory iodine fortification. The iodine content of potable water varies across ANZ from about 10–50 µg/L (FSANZ 2008) and potentially contributes to iodine intakes in formula-fed infants. For infants 0 – <6 months, this would lead to an additional 8 – 40 µg/day iodine intake, depending on where the infant lives. Further to this, FSANZ also notes that lower iodine status in breastfed infants compared with formula fed infants has been reported internationally (Jin 2021, Andersson 2010, Skeaff 2005, Næss 2022).

Maximum

A submitter to the 1st CFS commented that the proposed Codex CXS 72-1981 GUL of 14 µg/100 kJ would potentially exceed the UL for one to three year olds. As noted by the submitter there is a lack of evidence that supports the rationale that formula products with a GUL of 14 µg/100 kJ are at risk of causing harm to infants. This GUL has a history of use internationally since its establishment in Codex CXS 72-1981. The maximum iodine amount is difficult to set due to the large variability in the iodine content of cow's milk which depends on season, and hygienic and agricultural techniques (EC SCF 2003). The FSANZ 2016 NA also concluded that adoption of the Codex CXS 72-1981 maximum was unlikely to pose a risk to infant health.

5.8.4 Conclusion

Based on the above discussion, FSANZ concludes that the proposed consequential draft variation prescribes an iodine range of 2.4 – 14 (GUL) µg/100 kJ in infant formula products.

6 Equivalents, units of expression and ratios

Table 6 – Equivalents, conversion factors and units of expression: summary of submitter comments and FSANZ response

Issue	Comment	Submitter(s)	FSANZ Response
Vitamin A: equivalents and units of expression *FSANZ preferred option at the CFS was:* • *Express vitamin A requirements as µg RE/100 kJ.* • *Exclude β-carotene from the vitamin A calculation.* • *Permit β-carotene as a form of vitamin A.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option.	NZFS, INC, FCG, NZFGC, AFCG	Section S29-7 permits β-carotene as a provitamin A form within infant formula products and food for special medical purposes (FSMP). FSMP requirements do not exclude β-carotene from the vitamin A calculation, however, these foods can vary from the prescribed composition were needed to address a special medical purpose. FSANZ considers that compositional parameters set for infant formula products should vary were needed to address adequacy and safety concerns because these products are used as sole source of nutrition for a vulnerable population. FSANZ considers the exclusion of β-carotene from the vitamin A calculation an
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred option to permit β-carotene as a form of vitamin A and exclude it from the vitamin A calculations.	VICDoH	
Yes, the preferred option is supported.	These submitters supported FSANZ preferred option to retain the permission for β-carotene as a permitted form of vitamin A.	INC, FCG, NZFGC, AFCG	

Issue	Comment	Submitter(s)	FSANZ Response
Request further information.	These submitters sought clarification on the need to retain permission for β-carotene when it is excluded from the vitamin A calculation. NSWFA requested further information from FSANZ on whether beta-carotene is used in the calculation of Vitamin A values in other foods. The decision to exclude beta-carotene from Vitamin A calculations for infant formula products could lead to discrepancies in the application of the Code to foods.	NZFS, WADoH, VICDoH, NSWFA	important amendment in the Code to ensure infants are receiving adequate amounts of vitamin A that are bioavailable. FSANZ has retained β-carotene as a permitted form of provitamin A in infant formula, despite being excluded from vitamin A calculations because: • it is a natural component of milk, • it has a long standing history of use, and • there is an absence of associated safety concerns. The permission also aligns with Codex CXS 72-1981, the Codex Draft Standard for FuFOI, EU 2016/127 and other international regulations. Therefore, the proposed primary and consequential draft amendments would require vitamin A to be expressed as µg RE/100 kJ; and remove β-carotene from the vitamin A calculations and declaration.
Niacin: equivalents *FSANZ preferred option at the CFS was:* • *No proposed changes to the equivalents, conversion factors or units of expression for niacin.*			
Yes, the preferred option is supported.	Submitters supported FSANZ's preferred option presented in Table 2.4.3 of SD2. However, note the conversion factor listed in Table 2.4.3 may have been erroneously copied from Note 2 for S29—21 *Amounts of nutrients for food for special medical purposes represented as a sole source of nutrition*.	NZFS, INC, FCG, NZFGC, AFCG	FSANZ notes this was an oversight and there will be no conversion factor for tryptophan to niacin for infant formula products.
Zn : Cu ratio *FSANZ preferred option at the CFS was:* • *Remove the Zn : Cu ratio of 15 : 1 (maximum) for infant formula.* • *Remove the Zn : Cu ratio of 20 : 1 (maximum) for follow-on formula.*			

Issue	Comment	Submitter(s)	FSANZ Response
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to remove the Zn:Cu ratio.	NZFS, INC, FCG, NZFGC, AFCG	FSANZ notes there is limited evidence to support the need for a Zn:Cu ratio in formula and the FSANZ 2016 NA concluded that removing the Zn:Cu ratio from Standard 2.9.1 would have minimal impact on the micronutrient status of healthy term infants. The proposed range for zinc in infant formula and follow-on formula is 0.12 – 0.36 (GUL) mg/100 kJ, which is consistent with Codex CXS 72-1981 and the Codex Draft Standard for FuFOI. The range currently prescribed in section S29—9 is 0.12 – 0.43 mg/100 kJ. Given the new proposed maximum is a GUL, the range for zinc has remained similar. The proposed range for copper in infant formula and follow-on formula is 8 – 29 (GUL) µg /100 kJ, which is aligned with Codex CXS 72-1981 and the Codex Draft Standard for FuFOI. The range currently prescribed in section S29—9 is 14 – 43 µg /100 kJ. Because high zinc intakes can impact on copper bioavailability, Standard 2.9.1 specifies that the zinc to copper (Zn:Cu) ratio must not exceed 15:1 for infant formula, and 20:1 for follow-on formula. Codex CXS 72-1981 does not specify a Zn:Cu ratio. Furthermore, the EC SCF (2003), ESPGHAN (Koletzko et al. 2005), and EFSA (2014) do not make any recommendations for a Zn:Cu ratio. The Zn:Cu ratio in human milk is about 10:1 (Lonnerdal 1989). Using the midpoint of the Codex CXS 72-1981 minimum and maximum amounts for zinc and copper, the Zn:Cu ratio would be about 12:1. This ratio is closer to that found in breast milk and therefore, it is concluded that adopting the Codex CXS 72-1981 ranges for copper and zinc and removing the Zinc to Coper ratio from Standard 2.9.1 is unlikely to pose a risk to infant health. FSANZ concludes that the Zinc to Coper ratio will be removed from Standard 2.9.1.
Request further information.	This submitter requested further information on how the proposed changes for zinc and copper levels impacted on the ratio of Zn:Cu to help determine whether a set ratio was required. This submitter requested FSANZ explain how the zinc to copper ratio will be maintained to reflect levels in breast milk and how copper levels in formula (particularly ready to feed, which is currently used in hospital settings) will be sufficient.	VICDoH	

Issue	Comment	Submitter(s)	FSANZ Response
Vitamin E : PUFA ratio *FSANZ preferred option at the CFS was to:* • *Retain the Vitamin E : fatty acid ratio of 0.5mg : 1g (minimum) - NS (maximum.)*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option.	NZFS, VICDoH	FSANZ has addressed the issue raised in section 5.6 above.
No, the preferred option is not supported.	These submitters did not support FSANZ's preferred and instead recommend removal.	INC, FCG, NZFGC, AFCG	
AA : DHA ratio *FSANZ preferred option at the CFS was to:* • *Require AA at no more than 1% of total fatty acids.*			
No, the preferred option is not supported.	These submitters noted there is an error in the footnotes in the 1st CFS. They support a ratio where AA ≥ DHA and recommend aligning with Codex CXS 72-1981, which does not include an AA maximum but instead includes a ratio with DHA, rather than retaining the current limit of 1% fatty acids.	INC, FCG, NZFGC, AFCG	FSANZ has addressed the issues raised in section 4.5 above. FSANZ concludes that expressing this permission as a ratio instead of % total fatty acids is consistent with Codex CXS 72-1981 and the Codex Draft Standard for FuFOI. It also further ensures the ratio between DHA and AA is kept no matter the composition of total fatty acids and varying levels of DHA. The proposed primary draft variation regulates DHA through a ratio with AA, where AA is ≥ DHA.
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred option and instead recommends the GUL should be 0.5% total fatty acids rather than in alignment with EU 2016/127.	VICDoH	

7 Nutritive substances

Table 7 – Nutritive substances: summary of submitter comments and FSANZ response

Issue	Comment	Submitter(s)	FSANZ Response
Choline *FSANZ preferred option at the CFS was to:* • *Permit choline as a mandatory substance in infant formula.* • *Prescribe a choline range of 1.7 - 12 (GUL) mg/100 kJ.* • *Permit the following forms of choline: choline, choline citrate, choline hydrogen tartrate, choline chloride and choline bitarate.*			
Yes, the preferred option is supported.	These submitters supported all of FSANZ's preferred options.	INC, FCG, NZFS, AFCG, NZFGC,	As discussed in the FSANZ 2022 CP2, the EU 2016/127 minimum is based on the recommendation of EFSA 2014 which was based on the choline concentration in breast milk of 160 mg/L. This concentration includes all sources of choline. The lower Codex CXS 72-1981 and Schedule 29 amount is based on milk concentration of 20 mg/L which does not include all available sources of choline. None of the additional choline sources found in breast milk are permitted forms for choline under either standard. Since the current minimum is a better reflection of breast milk concentration of choline itself, and not additional potentially bioactive forms, FSANZ concludes that the proposed consequential draft variation prescribes choline as a mandatory substance in infant formula with a range of 1.7 – 12 (GUL) mg/100 kJ.
No, the preferred option is not supported.	These submitters did not support FSANZ preferred option to permit choline at 1.7 - 12 (GUL) mg/100 kJ and instead support a higher range that aligns with the EU 2016/127 range of 6 - 12 mg/100 kJ, given that EU 2016-127 levels are more aligned with breast milk choline values.	DA, NSWFA, VICDoH	

Issue	Comment	Submitter(s)	FSANZ Response
L-carnitine *FSANZ preferred option at the CFS was to:* • *Permit L-carnitine as a mandatory substance in infant formula.* • *Prescribe a L-carnitine range of 0.3 – 0.8 (GUL) mg/100 kJ.* • *Permit the following forms of L-carnitine: L-carnitine hydrochloride and L-carnitine tartrate as new forms in addition to existing permission.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to revise the minimum to 0.3 mg/100 kJ, corrected to 0.29 mg/100 kJ.	INC, FCG, LON, NZFS, VICDoH, NZFGC, AFCG	Mean levels of total carnitine are reported to be 0.2 – 0.4 mg/100 kJ in human milk, 0.8–1.6 mg/100 kJ in cow's milk and 0.8–1.1 mg/100 kJ in goat's milk (EFSA 2014; Olagaray et al. 2018). The proposed GUL of 0.8 mg/100 kJ aligns with levels present in breast milk and the change from maximum to GUL accommodates the naturally occurring levels in cow's and goat's milk. Both the FSANZ 2016 NA and FSANZ 2021 NA concluded that on the basis of a lack of suitable information to assess the safety of high L-carnitine concentrations, it cannot be ruled out that the lack of a specification for a maximum amount of L-carnitine in infant formula, as is the case for Codex CXS 72-1981 and EU 2016/127, may pose a risk to infant health. Based on the above, FSANZ concludes that the proposed consequential draft variation prescribes L-carnitine as a mandatory substance in infant formula with a range of 0.3 – 0.8 (GUL) mg/100 kJ.
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to specify a GUL of 0.8 mg/100 kJ.	LON, NZFS, VICDoH	
No, the preferred option is not supported.	These submitters recommended there is no maximum as FSANZ's approach is not aligned with international regulations (EU, CODEX, GB) or expert scientific opinions (SCF 2003, EFSA 2014, Koletzko 2005), which do not recommend any maximum or GUL. Dairy-based infant formula products typically contain higher levels of L-Carnitine than the GUL currently proposed, due to the natural and variable content of L-Carnitine in dairy ingredients.	INC, FCG, NES, NZFGC, AFCG	

Issue	Comment	Submitter(s)	FSANZ Response
Myo-inositol *FSANZ preferred option at the CFS was to:* • *Permit myo-inositol as a mandatory substance in infant formula.* • *Prescribe a myo-inositol range of 1 – 9.5 (GUL) mg/100 kJ.*			
Yes, the preferred option is supported.	These submitters supported prescribing myo-inositol as a mandatory substance in infant formula with a range of 1 - 9.5 (GUL) mg/100 kJ.	INC, FCG, NZFS, AFCG VICDoH, NZFGC,	FSANZ notes that the myo-inositol concentration measured in mature breast milk (> 4 weeks post-partum) was reported by EFSA to be 130–325 mg/L (EFSA 2014). However, breast milk myo-inositol concentrations have been noted to be highly variable and to decline with time of lactation (Pereira et al. 1990). The minimum in Standard 2.9.1 of 1.0 mg/100 kJ is based on the recommendations from the LSRO (1998), aligns with Codex CXS 72-1981 and closely aligns with the EU 2016 127. This minimum accounts for the variance in breast milk concentrations and myo-inositol that is synthesised endogenously. The maximum amount aligns with the upper level found in breast milk. FSANZ queries what NSWFA are referring to when stating "changes made by the EU to increase minimum inositol levels to be more comparable with breast milk" as the EU 2016/127 prescribes a minimum of 0.96 mg/100 kJ. FSANZ concludes that the proposed consequential draft variation prescribes myo-inositol as a mandatory substance in infant formula with a range of 1 – 9.5 (GUL) mg/100 kJ.
No, the preferred option is not supported.	These submitters noted the minimum levels of inositol in infant formula products are cited as being below those in breast milk (pg 37 of SD2) and requested further information to explain why minimum levels of inositol, lower than breast milk, are supported given changes made by the EU to increase minimum inositol levels to be more comparable with breast milk.	NSWFA, VICDoH	
Nucleotides *FSANZ preferred option at the CFS was to:* • *Retain nucleotides as an optional substance in infant formula.* • *Amend Schedule 29 to not specify the minimum amount for nucleotides.* • *Amend the maximum for nucleotide-5'-monophosphates in Standard 2.9.1 to account for total free nucleotide-5'-monophosphates.*			

Issue	Comment	Submitter(s)	FSANZ Response
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to retain the current permissions for nucleotides as optional substances.	INC, FCG, NZFS, NZFGC, AFCG	FSANZ notes that nucleotides have held a voluntary permission in Schedule 29 for the past 20 years. FSANZ does not consider it appropriate to remove permissions unless there is substantiated evidence to support the removal. This is not the case for nucleotides, as there is an absence of evidence to suggest the voluntary permission in infant formula is burdening infant systems. FSANZ also notes that as nucleotides are present in breast milk they are not considered unnecessary ingredients within infant formula. As no new evidence was submitted to the 1st CFS, FSANZ retains its position and concludes that nucleotides will be optional substances within infant formula, based on alignment with EU 2016/127 and Codex CXS 72-1981 and no known safety concern associated with infant consumption of nucleotides.
No, the preferred option is not supported.	These submitters did not support FSANZ's preferred option to maintain optional status for nucleotides. They argue that FSANZ should determine whether nucleotides are an important component in a breast milk substitute for optimal growth and development; and make them available in all infant formula products, or remove the permission to avoid burdening infant systems with unnecessary ingredients.	VICDoH, WADoH	
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to remove the current minimums for all nucleotides and amend the maximum for total limit of nucleotides in Standards 2.9.1 to limit for total **free** nucleotides.	INC, FCG, NZFS, AFCG, NZFGC	FSANZ notes this comment from submitters and has incorporated the term "free" nucleotides into the proposed consequential draft variation. The proposed consequential draft variation is also reflective of the removal of minimum amounts for nucleotides.
Request further information.	This submitter requested further information on minimum levels of nucleotides in infant formula products required to achieve the desired functional purpose. It was suggested that this information is necessary as page 12 of SD3 of the 1st CFS, provides evidence that caregivers use the Nutrition Information Statement (NIS) to make product comparisons.	NSWFA	FSANZ notes that the removal of the minimum requirements for nucleotides is aligned with the EU 2016/127, USA and Canadian regulations and the recommendations of the LSRO (1998), EC SCF (2003) and ESPGHAN (2005). As nucleotides can be produced via de novo synthesis in infants and have wide variance in ranges, the evidence shows it is difficult to conclude a minimum level for their functional purpose in infant formula products. The LSRO (1998), EC SCF (2003) and ESPGHAN (2005) do not recommended setting a minimum because of this. The amount of nucleotides within infant formula products will still be captured on the NIS, despite the proposed consequential draft variation not prescribing minimum levels. This alleviates concerns regarding caregivers making product comparisons.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	This submitter requested the maximum for adenosine-5′-monophosphate (AMP) be lowered to 0.36 mg/100 kJ in line with the EU 2016/127 regulation.	NZFS	Based on the conclusions of EFSA (2014) and alignment with the EU 2016/127, FSANZ will lower the maximum for adenosine-5′-monophosphate (AMP) from 0.38 mg/100 kJ to 0.36 mg/100 kJ.
No, the preferred option is not supported.	These submitters did not support FSANZ preferred option for the Guanosine-5′-monophosphate (GMP) maximum and recommend that the upper limit specified for GMP is amended from a maximum to a GUL or to a higher maximum (0.40 mg/100 kJ) which accommodates the natural levels in goat milk based infant formula.	INC, FCG, NZFS, DGC, NZFGC, AFCG	FSANZ acknowledges this request from submitters and considers that the composition of infant formula products should reflect the inherent levels of base ingredients. As goats' milk is commonly used in infant formula products in the ANZ market and has naturally higher levels of GMP, FSANZ considers it appropriate to increase the GMP maximum from 0.12 to 0.40 mg/100 kJ to account for this.
Taurine *FSANZ preferred option at the CFS was to:* • *Retain the current permissions for taurine, however sought views from stakeholders.*			
No, the preferred option is not supported.	These submitters did not support a taurine minimum as this would be more consistent with international recommendations.	INC, FCG, NZFGC, AFCG	FSANZ has addressed the issue raised in section 7.1 below.
Request further evidence.	These submitters suggested FSANZ consider a review of evidence on taurine as an essential / partially essential nutrient, and as such, whether these ingredients should be mandatory.	WADoH, VICDoH	
No, the preferred option is not supported.	This submitter does not support retaining taurine as an optional ingredient.	VICDoH	

Issue	Comment	Submitter(s)	FSANZ Response
Lutein *FSANZ preferred option at the CFS was to:* • *Retain the current permissions for lutein, however sought views from stakeholders.*			
No, the preferred option is not supported.	These submitters recommend no minimum for lutein, as this would be more consistent with international recommendations.	INC, FCG, NZFGC, AFCG	The lutein levels prescribed in Schedule 29 were assessed through Application A594 - Lutein as a nutritive substance in infant formula. As these requirements have already been assessed and consulted through a statutory process, FSANZ will be retaining the minimum and maximum currently prescribed in Schedule 29 for lutein of 1.5 – 5 µg/100 kJ. FSANZ encourages submitters to review this application for further information.
Request further information.	This submitter suggests FSANZ consider a review of evidence on lutein as an essential/partially essential nutrient, and as such, whether these ingredients should be mandatory.	WADoH	
Fluoride *FSANZ preferred option at the CFS was to:* • *Prescribe a compositional limit for fluoride of 24 µg/100 kJ when prepared ready for consumption.* • *Remove the labelling statements relating to dental fluorosis in paragraph 2.9.1—23(1)(b).*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to increase to 24 µg/100 kJ of fluoride in alignment with Codex.	VICDoH, INC, FCG, NZFGC, AFCG	FSANZ notes the support for a fluoride maximum of 24 µg/100 kJ in alignment with Codex and removal of the labelling statements on dental fluorosis. FSANZ also notes the enforceability issues surrounding prescribing a maximum for fluoride content when prepared ready for consumption. FSANZ has re-assessed fluoride levels based on
Yes, the preferred option is supported.	These submitters supported the removal of the labelling statements on dental fluorosis.	INC, FCG, NZFGC, AFCG, NZFS, DAN	

Issue	Comment	Submitter(s)	FSANZ Response
Request the addition is specified on a product “as sold” basis.	These submitters recommended the permission relate to the fluoride content of the product on an “as sold” basis, as water is the main contributor to the fluoride content of infant formula as consumed. NZFS recommended the compositional limit relate to the fluoride content of the product prior to reconstitution for powdered and concentrated infant formula products, and per 100 mL as sold for ready-to-drink formula. This approach is enforceable and is currently used to activate the existing labelling statements for dental fluorosis.	INC, FCG, NZFGC, AFCG, NZFS, DAN	infant formula products “as sold” to avoid compliance and enforcement issues. See section 7.2 below for further details.

7.1 Taurine

7.1.1 Background

Taurine has held a permission within Schedule 29 as an optional ingredient in infant formula products for the past 20 years, which demonstrates its history of use. The maximum amount prescribed in Schedule 29 aligns with Codex CXS 72-1981 and the EU 2016/127. Taurine is present in breast milk and there is data that suggests its inclusion in infant formula is of nutritional benefit to infants (FSANZ 2002). There is also an absence of data that suggests there are any toxicity issues or adverse reactions related to the addition of taurine in infant formula products (EFSA 2016).

Across Codex CXS 72-1981 and the EU 2016/127 taurine can be voluntarily added to infant formula products at a maximum level of 3 mg/100 kJ.

Table 7.1.1 Permitted range for taurine

Nutrient	Unit	The Code Schedule 29–9		Codex CXS 72-1981		Codex Draft Standard for FuFOI		EU 2016/127 ANNEX I		EU 2016/127 ANNEX II	
		Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Taurine	mg/100 kJ	0.8	3	NS	3	NS	2.9	NS	2.9	NS	2.9

7.1.2 Stakeholder comments

During the 1st CFS FSANZ sought views from stakeholders on the permission for taurine, as it had not previously been consulted on during P1028. The response from stakeholders on the optional permission was mixed. Six submitters (four industry, two government) responded to the proposed taurine permission for infant formula products with four submitters not supporting the taurine minimum on the basis that it was not aligned with international recommendations. Two submitters requested FSANZ review the evidence on taurine as an essential nutrient and its voluntary permission.

7.1.3 Discussion

FSANZ considers it appropriate to retain the optional addition of taurine to infant formula. This is consistent with Codex CXS 72-1981 and the EU 2016/127. FSANZ also considers that as taurine is an amino acid found in breast milk; it is absent in cow's milk; and infants have little ability to synthesise their own taurine stores (Tochitani, 2022); the removal of taurine's optional permission could pose risk to infant health. Taurine has been shown to hold importance in the diet of pre-term and term infants, as well as low birth weight infants (Chesney, 1998). FSANZ considers the permission for taurine to be safe and suitable for the intended benefit which has been evaluated and established, as demonstrated by its history of use. This rationale and decision was also evident in the Codex Draft Standard for FuFOI, where the eWG supported retention of taurine as an optional substance in follow-up formula, in alignment with the Codex CX 72-1981.

Regarding the taurine range, FSANZ acknowledges the position of submitters which note the current minimum isn't aligned internationally. As an optional ingredient to infant formula products, FSANZ does not consider removing the minimum level will pose risk to infant health.

7.1.4 Conclusion

Based on alignment with Codex CXS 72-1981, Codex Draft Standard for FuFOI and the EU

2016/127, no evidence of adverse effects, and a history of safe use, FSANZ concludes that the proposed consequential draft variation prescribes taurine as an optional ingredient in infant formula and follow-on formula with no minimum and a corrected maximum of 2.9 mg/100 kJ.

7.2 Fluoride

7.2.1 Background

In the FSANZ 2021 CP2, infant fluoride exposures were estimated based on the fluoride content for several brands of infant formula powder and water fluoride concentrations of 0, 0.5, 1.0 and 1.5 mg F/L. The exposures were compared with the updated NHMRC UL for 0-6 months of 1.2 mg/day and 7-12 months of 1.8 mg/day (NHMRC and NZ MOH 2017). The assessment concluded that at the optimal level of water fluoridation (1.0 mg/L) and current levels of fluoride concentration in infant formula powders (milk and soy-based), it was unlikely that infants consuming infant formula as recommended would consume even half the UL recommendations for fluoride daily. Based on the assessment, FSANZ proposed to set a compositional limit for fluoride of 24 µg/100 kJ (when reconstituted) which aligned with Codex CXS 72-1981 and EU 2016/127.

The current standard also includes labelling statements relating to dental fluorosis. FSANZ proposed to remove this requirement.

7.2.2 Stakeholder comments

Seven submitters (five industry, two government) responded to the proposed fluoride limit for infant formula products in the 1st CFS. Five submitters supported increasing the limit to 24 µg/100 kJ in line with Codex CXS 72-1981. However, submitters also recommended that the compositional limit related to the fluoride content of the product prior to reconstitution. Prescribing the limit as “when prepared ready for consumption” or as “reconstituted” takes into account the fluoride content of water which is outside the control of manufacturers and creates issues surrounding enforcement and compliance.

Six submitters commented on the labelling requirements for dental fluorosis and supported the proposal to remove this requirement.

See Table 7 for further details.

7.2.3 Discussion

FSANZ considers removal of the labelling statements on dental fluorosis to be appropriate and setting a compositional limit for fluoride at a level that minimises the risk of dental fluorosis provides a mechanism to protect infant health and safety and will align with international regulations.

Based on feedback from the 1st CFS, FSANZ has re-considered the fluoride limit for infant formula products on an ‘as sold basis’.

Firstly, we note that Codex CXS 72-1981 states ‘*fluoride should not be added to infant formula. In any case its level should not exceed 100 µg /100 kcal (24 µg/100 kJ) in infant formula prepared ready for consumption as recommended by the manufacturer’*. We also note that EU 2016/127 also takes the same approach in not permitting addition of fluoride and sets a compositional maximum of 24 µg/100 kJ for infant formula and follow-on formula ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

As water in ANZ is fluoridated, the fluoride requirement is not easily aligned with international regulations. The higher limit cannot be applied within the ANZ context unless the permission in the Code is based on the product 'as reconstituted'. Therefore, the Codex CXS 72-1981 and EU 2016-127 "prepared ready for consumption" levels cannot be used in a comparative assessment when determining fluoride limits for infant formula products 'as sold'.

FSANZ 2016 NA evaluated fluoride levels which incorporated the potential addition of fluoride levels from water at the levels between 0.7–1.0 mg/L, as recommended by the Australian Drinking Water Guidelines and New Zealand Drinking Water Standards. While these guidelines specify 1.5 mg F/L as the maximum, it is extremely unlikely that water with a fluoride concentration of 1.5 mg/L would be used to reconstitute infant formula powder. As the median fluoride level found in milk based infant formula in Australia was less than 2.5 µg/100 kJ it would require concentrations of fluoride six times higher than normal to reach the UL for infants.

7.2.4 Conclusion

Based on the calculations provided at Appendix 3 (and within the FSANZ 2021 CP2), FSANZ is proposing to retain the Standard 2.9.1 fluoride limit of 17 µg/100 kJ, as it is the most appropriate value within the ANZ context and accounts for the fluoride content in ANZ water supplies. This level did not reach the UL for the different scenarios outlined in Appendix 1. FSANZ will prescribe a fluoride limit of 17 µg/100 kJ for all infant formula product, including powdered, concentrated and ready-to-drink products. The fluoride maximum can be seen within the proposed primary draft variation at subsection 2.9.1—5(4). This drafting is similar to that of the EU 2016/127. As mentioned above, this limit varies from the limits prescribed in Codex CXS 72-1981 and the EU 2016/127 due to the requirements applying to the product as sold, not as reconstituted. While the levels differ, products formulated for both markets can comply with all three regulations.

Part C Follow-on formula

8 Macronutrients

Table 8 – Macronutrients: summary of submitter comments and FSANZ response

Issue	Comment	Submitter(s)	FSANZ Response
Protein range *FSANZ preferred option at the CFS was to:* • *Prescribe a protein range of 0.43 – 0.72 g/100 kJ.* • *Prescribe a soy protein range of 0.54 – 0.72 g/100 kJ.*			
No, the preferred option is not supported.	These submitters did not support FSANZ's preferred option of a protein minimum 0.43 g/100 kJ, and instead recommended a minimum of 0.38 g/100 kJ for follow-on formula as assessed in FSANZ Application *A1173 – Minimum protein in follow-on formula.*	INC, FCG, NZFS, AFCG, NZFGC,	FSANZ acknowledges the oversight in the 1st CFS which did not incorporate Application *A1173 – Minimum protein in follow-on formula.* FSANZ will adopt a protein minimum of 0.38 g/100 kJ for follow-on formula in line with the conclusions of the application. FSANZ also acknowledges the corrected figure for the protein maximum of 0.72 g/100 kJ and has included this within the proposed primary draft variation. The maximum of 0.72 g/100 kJ holds a long standing history of use within the ANZ population as the level has been present within Standard 2.9.1 for over 20 years. Across Standard 2.9.1, Codex Alimentarius and the EU regulation, protein maximums do not deviate between infant formula and follow-on formula. Unless there is substantiated science which evidences a need for a higher protein level in follow-on formula, FSANZ does not consider it appropriate to have different levels across the products. The maximum of 0.72 g/100 kJ is aligned with Codex CXS 72-1981 and was recently re-established within the Codex Draft Standard for FuFOI. The maximum of 0.72 g/100 kJ is also more closely aligned to the EU 2016/17 regulation. Based on the above points FSANZ will not be adopting the maximum from the Chinese FuF Standard.
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to prescribe a maximum of 0.7g/100 kJ, *corrected to 0.72 g/100 kJ.	NZFS	
No, the preferred option is not supported.	These submitters did not support FSANZ's preferred option for a protein maximum of 0.7 g/100 kJ and instead recommends 0.8 g/100 kJ in alignment with China's FuF standard.	INC, FCG, NES, NZFGC, AFCG	
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to prescribe a range of 0.54 – 0.7 g/100 kJ for soy protein.	NZFS, INC, FCG, NZFGC, AFCG	

Issue	Comment	Submitter(s)	FSANZ Response
			FSANZ will also retain the range for soy protein of 0.54 – 0.7 g/100 kJ in follow-on formula.
Potential Renal Solute Level (PRSL) *FSANZ preferred option at the CFS was to:* • *Remove the PRSL from Standard 2.9.1 and Schedule 29.*			
Yes, the preferred option is supported.	These submitters supported FSANZ preferred option to remove the maximum PRSL from Standard 2.9.1	INC, FCG, NZFGC, AFCG	While FSANZ appreciates the comments of submitters who do not support the proposed option, FSANZ clarifies that the PRSL in Standard 2.9.1 is a prescribed calculation used to measure the renal solute load in infant formula products. This subsection does not prescribe any labelling requirements and is not associated with provision of information. FSANZ is also not considering making the PRSL a mandatory declaration. Health professionals can request this information directly from formula manufacturers. As discussed in the 2022 SD2, the Codex Draft Standard for FuFOI, Codex CXS 72-1981 and EU 2016/127 do not prescribe a maximum PRSL. These international regulations do not prescribe a maximum PRSL as maximum protein amounts, which contribute to PRSL, are already prescribed through the maximum level of the range. FSANZ considers there is minimal risk associated with removal of the maximum PRSL. This is evidenced from a recent study that concluded healthy infants consuming a predominantly liquid diet have sufficient renal concentrating ability to maintain water balance even if the diet would provide a PRSL comparable to cow's milk (46 mOsm/100 kcal or 11 mOsm/100 kJ) and WHO state that from the age of 4 months infants have a matured renal function and metabolic interconversion system which can manage a higher dietary protein content (Fomon 2020, Michaelsen 2000).
No, the preferred option is not supported.	These submitters did not support the removal of PRSL from Standard 2.9.1 and argued it should be retained on the label because paediatric dietitians use this information (which is difficult and time consuming to find) for specific medical conditions. While acknowledging that a mandatory requirement for this information may create a trade barrier, the submitters argued that the PRSL should be included on labels where possible.	NSWFA, VICDoH	

Issue	Comment	Submitter(s)	FSANZ Response
			As no new evidence has been provided, FSANZ retains its position and will remove the maximum PRSL from Standard 2.9.1.
Carbohydrate source *FSANZ preferred option at the CFS was to:* • *Prescribe carbohydrate source in alignment with Codex CXS 72-1981 and adopt limits on sucrose and fructose.*			
Recommend further consideration of wording.	These submitters recommended consideration is given to including the rationale for guidance to avoid the use of sucrose and fructose from the draft Codex Standard FuF for Older Infants.	INC, FCG, NZFGC, AFCG	FSANZ has addressed this issue in section 4.1 above. The same permission for carbohydrate source will be applied to all infant formula products.

9 Micronutrients

Table 9 – Micronutrients: summary of submitter comments and FSANZ response

Issue	Comment	Submitter(s)	FSANZ Response
Vitamin D *FSANZ preferred option at the CFS was to:* • *Prescribe a Vitamin D range of 0.25 – 0.63 µg/100 kJ in follow-on formula.*			
No, the preferred option is not supported.	These submitters do not support the preferred Vitamin D maximum level for follow-on formula, and instead recommended a maximum of 0.72 µg/100 kJ in line with Codex and EU.	DAN, FCG, NES, AFCG NZFGC, INC	FSANZ has addressed this issue in section 5.5 above.

Issue	Comment	Submitter(s)	FSANZ Response
Calcium *FSANZ preferred option at the CFS was to:* • *Prescribe a calcium range of 12 – 43 (GUL) mg/100 kJ in follow-on formula.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to prescribe a calcium range of 12 – 43 (GUL) mg/100 kJ.	NZFS, INC, FCG, NES, NZFGC, AFCG	The GUL proposed at the 1st CFS is appropriate to meet the needs of infants aged 6 – 12 months. The increased GUL is based on recognition that older infants have achieved a greater degree of renal maturation at this age, that the ANZ AI is higher for this age group, reduced intakes of follow-up formula at this age, and that calcium intakes are often limited in the diets of this age group. FSANZ considers increasing the calcium maximum in line with the above factors to be of benefit to the health of older infants. As there is an absence of evidence to indicate that this maximum would cause harm to the health of older infants, FSANZ retains its position and prescribes a calcium GUL of 43 mg/100 kJ within the proposed consequential draft variation.
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred option to increase the calcium maximum for follow-on formula to 43 (GUL) mg/100 kJ on the basis that follow-on formula is a breast milk substitute, not a treatment modality, and should use breast milk from healthy mothers and breastfed infants as the primary reference.	VICDoH	

10 Nutritive substances

Table 10 – Nutritive substances: summary of submitter comments and FSANZ response

Issue	Comment	Submitter(s)	FSANZ Response
Choline *FSANZ preferred option at the CFS was to:* • *Prescribe a choline range of NS – 12 (GUL) mg/100 kJ in follow-on formula.* • *Retain the voluntary permission for choline in follow-on formula.*			

Issue	Comment	Submitter(s)	FSANZ Response
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to retain the voluntary permission for choline in follow-on formula	INC, FCG, NES, DA, NZFS, AFCG, NZFGC,	FSANZ notes that choline has held a voluntary permission in Schedule 29 for the past 20 years and this permission is consistent with the recently re-established Codex Draft Standard for FuFOI. Requiring the mandatory addition of choline in follow-on formula would be inconsistent with international regulations such as Codex and the EU. While FSANZ acknowledges that choline is recognised as an essential nutrient, it can be synthesised endogenously and provided by other foods in the complementary diet of older infants. Therefore, FSANZ retains its position and prescribes choline as a voluntary ingredient in follow-on formula. This permission is reflective of choline and its functional role as a nutrient. FSANZ notes the submitter comments and retains the position to remove the choline minimum and prescribe a GUL of 12 mg/100 kJ in the proposed consequential draft variation.
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred option to retain the voluntary permission for choline in follow-on formula as it is considered an essential nutrient for infants throughout infancy (and beyond) and is present in breast milk throughout the first 12 months.	VICDoH	
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to remove the minimum for choline and state as not specified.	NZFS, INC, FCG, AFCG, NZFGC	
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to increase the maximum to 12 mg/100 kJ and express as a GUL	INC, FCG, NZFS, AFCG, NZFGC,	
Requests further explanation.	This submitter requested information from FSANZ on the functional purpose of Choline in follow-on-formula (pg. 51of SD2). It is unclear why Choline is being added, is it serving a technological or nutritional purpose?	NSWFA	

Myo-inositol

FSANZ preferred option at the CFS was to:

- *Prescribe a myo-inositol range of NS – 10 (GUL) mg/100 kJ in follow-on formula.*
- *Retain the voluntary permission for myo-inositol in follow-on formula.*

Issue	Comment	Submitter(s)	FSANZ Response
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to retain the voluntary permission for myo-inositol in follow-on formula	NZFS, INC, FCG, NES, NZFGC, AFCG	FSANZ notes that myo-inositol has held a voluntary permission in Schedule 29 for the past 20 years and this permission is consistent with the recently re-established Codex Draft Standard for FuFOI. In line with other optional ingredients in follow-on formula FSANZ will be retaining the voluntary permission, prescribing a GUL and removing the minimum level. As myo-inositol can be synthesised endogenously and is provided by other foods in the complementary diet of older infants, a minimum value and mandatory permission is not required. Voluntary addition of myo-inositol is reflective of the Codex Draft Standard for FuFOI, its presence in breast milk and its longstanding permission in Schedule 29.
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred option to retain the voluntary permission for myo-inositol and did not support not setting a minimum level in follow-on formula.	VICDoH	
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to remove the minimum for myo-inositol and state as "not specified".	NZFS, INC, FCG, AFCG, NZFGC,	
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to retain a maximum of 9.5 mg/100 kJ but express as a GUL.	NZFS, INC, FCG, AFCG, NZFGC,	
Requests further explanation.	This submitter requested information from FSANZ on the justification for addition of myo-inositol to follow-on-formula (6-12 months of age) (pg. 51 of SD2) as EFSA has suggested it can be synthesised endogenously and provided by other foods in the complementary diet from around 6 months of age.	NSWFA	
L-carnitine *FSANZ preferred option at the CFS was to:* • *Prescribe a L-carnitine range of 0.3 – NS mg/100 kJ in follow-on formula.* • *Retain the voluntary permission for L-carnitine in follow-on formula.*			
Yes, the preferred option is supported.	These submitters supported FSANZ preferred option to retain the voluntary permission for L-carnitine in follow-on formula.	INC, FCG, NES, NZFS, LON, AFCG, NZFGC,	FSANZ notes that L-carnitine has held a voluntary permission in Schedule 29 for the past 20 years and this permission is consistent with the recently re-established Codex Draft Standard for FuFOI. While the Codex Draft Standard for FuFOI does not

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	This submitter did not support FSANZ's preferred option to retain the voluntary permission for L-carnitine in follow-on formula.	VICDoH	prescribe a set range for L-carnitine, and instead notes 'levels may need to be determined by national authorities', the standard still prescribes L-carnitine as an optional ingredient in follow-on formula. FSANZ does not consider it appropriate to remove permissions unless there is substantiated evidence to support the removal. This is not the case for L-carnitine, as there is a lack of evidence to suggest the voluntary permission in follow-on formula is not of benefit to infants. As no new evidence has been provided since the 1st CFS, FSANZ will retain its position and prescribe L-carnitine as a voluntary ingredient in follow-on formula with a minimum of 0.3 mg/100 kJ and no specified maximum. L-carnitine tartrate will also be noted as a permitted form of L-carnitine in Schedule 29.
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to increase the minimum to 0.3 mg/100 kJ	LON, NZFS	
No, the preferred option is not supported.	These submitters did not support FSANZ's preferred option to increase the minimum to 0.3 mg/100 kJ. Recommend no minimum for L-carnitine be defined which would be more consistent with international regulations.	INC, FCG, NZFGC, AFCG	
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to remove the maximum for L-carnitine and state as not specified in follow-on formula.	LON, FCG, INC, NZFGC	
Requests further explanation.	This submitter requests information from FSANZ on the purpose of L-carnitine in follow-on-formula (pg. 51 of SD2) as it is not specified in Codex and the EU. EFSA has further noted that it should not be mandatory in follow-on-formulas due to the addition of other complementary foods from around 6 months of age and endogenous synthesis.	NSWFA	
Yes, the preferred option is supported.	This submitter supported FSANZ's preferred option to permit L-carnitine tartrate as a permitted form of L-carnitine in S29.	LON	

Nucleotides

FSANZ preferred option at the CFS was to:

- *Retain the voluntary permission for all nucleotides in follow-on formula.*
- *Amend the maximum for total limit of nucleotides in Standard 2.9.1 to account for total free nucleotides.*

Issue	Comment	Submitter(s)	FSANZ Response
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to retain the current permissions for nucleotides as optional substances	INC, FCG, NZFS, NES, NZFGC, AFCG	FSANZ notes that nucleotides have held a voluntary permission in Schedule 29 for the past 20 years. FSANZ does not consider it appropriate to remove permissions unless there is substantiated evidence to support the removal. Given the lack of evidence to suggest the voluntary permission in infant formula is burdening infant systems, and that nucleotides are present in breast milk, they are not considered unnecessary ingredients within infant formula. As no new evidence was submitted to the 1st CFS, FSANZ retains its position and concludes that nucleotides will be optional substances within follow-on formula, based on alignment with EU 2016/127 and the Draft Codex Standard FuFOI and no known safety concern associated with the consumption of nucleotides. FSANZ will also remove the current minimums for all nucleotides, in alignment with the regulatory decisions made for infant formula.
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to remove the current minimums for all nucleotides	INC, FCG, NZFS, NZFGC, AFCG	
No, the preferred option is not supported.	These submitters did not support FSANZ's preferred option to maintain optional status for nucleotides.	VICDoH	
Taurine *FSANZ preferred option at the CFS was to:* • *Retain the voluntary permission for taurine in follow-on formula.* • *Prescribe a L-carnitine range of 0.8 – 3 mg/100 kJ in follow-on formula.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to retain the current permissions for taurine as optional substances.	INC, FCG, NES, AFCG, NZFGC,	FSANZ has addressed the issue raised in the taurine discussion above.
No, the preferred option is not supported.	These submitters did not support FSANZ's preferred option to retain Taurine as an optional ingredient	VICDoH	

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	These submitters did not support preferred minimum and instead recommend no minimum for taurine be defined which would be more consistent with international regulations.	INC, FCG, NZFGC, AFCG	
Yes, the preferred option is supported	These submitters supported FSANZ preferred maximum of 3 mg/100 kJ.	INC, FCG, NZFGC, AFCG	
Lutein *FSANZ preferred option at the CFS was to:* • *Retain the voluntary permission for lutein in follow-on formula.* • *Retain a lutein range of 1.5 – 5 mg/100 kJ in follow-on formula.*			
Yes, the preferred option is supported	These submitters support FSANZ's preferred option to retain the current permissions for lutein as optional substances.	INC, FCG, NES, NZFGC, AFCG	The lutein levels prescribed in Schedule 29 were assessed through *Application A594 – Lutein as a nutritive substance in infant formula*. As these requirements have already been assessed and consulted through a statutory process, FSANZ will be retaining the minimum and maximum currently prescribed in Schedule 29 for Lutein of 1.5 – 5 µg/100 kJ.
Yes, the preferred option is supported	These submitters supported FSANZ preferred minimum and maximum which has previously been assessed by FSANZ as part of Application A594 – Lutein as a nutritive substance in infant formula.	INC, FCG, NZFGC, AFCG	

Part D Special Medical Purpose Products for infants

Table 11 – SMPPi composition: summary of submitter comments and FSANZ response

Issue	Comment	Submitter(s)	FSANZ Response
Overarching approach for SMPPi composition			
Yes, the preferred option is supported.	Submitters supported FSANZ's proposed approaches for the regulation of SMPPi where there are set principles and requirements, to ensure that they are safe, beneficial and effective for the infants for whom they are intended, based on generally accepted scientific data.	DA, INC	Submitters agreed with the approach proposed in SD4 of the 1st CFS. After assessment, FSANZ's preferred option is to retain the proposed approach and principles.
No, the preferred option is not supported.	This submitter noted that there are insufficient regulatory controls being proposed in relation to composition and pre-market assessment requirements, requirements to be evidence based, prohibited representations and a prescribed name.	VICDoH	FSANZ does not consider the regulatory controls proposed within SD4 of the 1st CFS to be insufficient. FSANZ has considered the diversity of SMPPi, the rapidly evolving scientific evidence which they are based on, and the need for adequate flexibility to allow access to these products. Because of these factors it is not appropriate to set detailed compositional rules for such products. The pre-market assessment prohibited representations and prescribed name are discussed SD3 in further detail.
Inclusion of text from the EU 2016/128	This submitter supported the inclusion of a statement, similar to that in EU Directive (EU) 2016/128, that requires the composition of a SMPPi product (including any modifications to meet the medical purpose) to be *demonstrated by generally accepted scientific data as: safe, beneficial and effective in meeting the specific nutritional requirements of the intended infant subpopulation. It is important that the manufacturer and/or supplier of the product holds the data that supports the product's composition.*	NZFS	FSANZ will not include the suggested statement in the proposed primary draft variation. As "specially formulated to be safe, beneficial and effective" is vague and open terminology which does not support enforcement and compliance. Australian and New Zealand food laws already expressly require that all food sold - including infant formula - must be safe and must be suitable. The added benefit of restating in the Code an existing requirement imposed by those Acts (i.e., through mandating that the food also 'be proven to be safe') appears unclear, noting the requirement imposed on FSANZ by paragraph 59(b) of the FSANZ Act.

Issue	Comment	Submitter(s)	FSANZ Response
Approach for the base composition of SMPPi products *FSANZ preferred option at the CFS was for SMPPi composition to allow:* • *Deviation from baseline composition, prescribed in Standard 2.9.1, to address the special medical purpose.* • *Alignment with international standards and regulations (i.e. Codex, EU, and USA).* • *Pose no unintentional restrictions for import and supply from international manufacturers.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred approach that base composition of SMPPi should meet the specific compositional requirements for infant formula products, unless there is a sound medical and scientifically supported reason to deviate to address the medical purpose of the product.	NZFS, VICDoH	Submitters agreed with the approach proposed in SD4 of the 1st CFS. After assessment, FSANZ's preferred option is to retain the proposed approach and allow the nutrient composition of SMPPi products to deviate from the specific compositional requirements for infant formula products where required to address the product's special medical purpose.
Yes, the preferred option is supported.	These submitters supported FSANZ preferred approach that the compositional requirements for SMPPi are flexible enough to ensure undisrupted access to SMPPi products, as the wellbeing and sustenance of infants rely on their availability. These submitters also noted that deviations from baseline compositional requirements should alternatively be able to meet the mandatory compositional requirements set out in international regulations, with the inclusion of permitted forms and additives.	NES, INC	FSANZ acknowledges the need to allow SMPPi products to not only deviate from the specific compositional requirements of infant formula products, but also to meet other international regulations such as Codex CXS 72-1981 and EU 2016/128. As SMPPi products are predominantly manufactured and produced internationally it is essential to minimise trade barriers and allow sick infant access to the nutrition they require. Subsection 2.9.1—32(2) of the proposed primary draft variation notes that a compositional requirement is not required if it would prevent the sale of SMPPi that has been specifically formulated for a specific disease, disorder or medical condition. The regulatory intent of this subsection is to allow continued sale of SMPPi by providing flexibility on compositional parameters that align with other international regulations.

Issue	Comment	Submitter(s)	FSANZ Response
Composition for premature or low birthweight infant formulas *FSANZ preferred option at the CFS was:* • *Products formulated for premature or low birthweight infants will be regulated as SMPPi and can deviate from the infant formula baseline composition where needed for the products special medical purpose.* • *FSANZ will not propose any specific nutrient composition requirements for the condition and will allow manufacturers to deviate the formula where required to address the product's special medical purpose.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	NES, INC, DAN	Submitters agreed with the approach proposed in SD4 of the 1st CFS. FSANZ's preferred option is to retain the proposed approach. The proposed primary draft variation is reflective of this, and specific nutrient composition requirements for premature or low birthweight infant formulas (originally prescribed at subsection 2.9.1—13) will be removed from Standard 2.9.1.
Composition for metabolic, immunological, renal, hepatic and malabsorptive conditions *FSANZ preferred option at the CFS was:* • *To remove the guideline maximum for manganese (7.2 µg) from S29—10, which is specific for infant formula products specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.* • *Products formulated for satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions will be regulated as SMPPi and can deviate from the infant formula baseline composition where needed for the products special medical purpose.* • *FSANZ will not propose any specific nutrient composition requirements for the condition and will allow manufacturers to deviate the formula where required to address the product's special medical purpose.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	NES, INC, DAN	Submitters agreed with the approach proposed in SD4 of the 1st CFS. FSANZ's preferred option is to retain the proposed approach. The proposed primary draft variation reflects this, and the manganese guideline maximum for infant formula products specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions (originally prescribed at subsection 29—10) will be removed from Schedule 29.

Issue	Comment	Submitter(s)	FSANZ Response
Require further justification for the removal of the manganese guideline maximum.	This submitter noted that products for metabolic, immunological, renal, hepatic and malabsorptive conditions have a significantly lower guideline maximum amount for manganese than for standard infant formula (7.2 µg/100 kJ compared to 24 µg/100 kJ). FSANZ proposes to increase the maximum level to align with standard formula. FSANZ has not indicated why a lower level was originally set. Justification for why a lower limit was originally set and the risk of increasing the level is requested, as well as further risk assessment to determine a guideline maximum amount for both standard and SMPPi that is not associated with increased risk of neurotoxicity.	VICDoH	The manganese guideline maximum for metabolic, immunological, renal, hepatic and malabsorptive conditions was established due to concerns that some infants with liver disease may not be able to excrete usual levels of manganese. The guideline maximum was established to guide manufacturers to prepare formula for such infants with a much lower manganese content (FSANZ, 1999). As this guideline maximum was used as guidance to manufacturers and was not legally binding, FSANZ considers its regulatory intent to be the same as the new proposed Division for SMPPi. Products for metabolic, immunological, renal, hepatic and malabsorptive conditions are still expected to be specially formulated for the products special medical purpose and have composition that reflects this. Due to the medical nature of these products FSANZ does not consider removing this guideline maximum to be associated with increased risk of neurotoxicity.
Composition for products for specific dietary use based on a protein substitute *FSANZ preferred option at the CFS was:* • *The compositional requirements noted in section 2.9.1—15 are no longer required.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	NES, INC, DAN	Submitters agreed with the approach proposed in SD4 of the 1st CFS. FSANZ's preferred option is to retain the proposed approach.

Issue	Comment	Submitter(s)	FSANZ Response
Medium Chain Triglycerides composition in SMPPi products *FSANZ preferred option at the CFS was:* • *To include a permission for the addition of MCT to SMPPi to address the product's medical purpose. However, specific compositional limits will not be set and are to be determined based on the products special medical purpose, supported by generally accepted scientific data.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	NES, INC, NZFS, DAN, VICDoH	Submitters agreed with the approach proposed in SD4 of the 1st CFS. After assessment, FSANZ's preferred option is to retain the proposed approach.
Molybdenum and chromium composition in SMPPi products *FSANZ preferred option at the CFS was:* • *To allow the voluntary addition of molybdenum and chromium in SMPPi where required to address the specific disease, disorder or medical condition.* • *FSANZ will include a permission for the addition of molybdenum and chromium to SMPPi to address the product's medical purpose. However, specific compositional limits will not be set and are to be determined based on the products special medical purpose, supported by generally accepted scientific data.* • *FSANZ will not permit other forms of molybdenum and chromium in the Code. If these forms are required for the medical purpose of the product they will be allowed to be used under the SMPPi requirements.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	NES, INC, NZFS, DAN, VICDoH,	Submitters agreed with the approach proposed in SD4 of the 1st CFS. After assessment, FSANZ's preferred option is to retain the proposed approach.
No, the preferred option is not supported.	This submitter opposes FSANZ's proposal to not permit other forms of molybdenum and chromium, as both chromium chloride and ammonium molybdenum are permitted for FSMP in Section S29—20 of the Code; Codex for Formula for Special Medical Purpose Intended for Infants; and the EU for Infant Food for Special Medical Purposes.	INC	FSANZ acknowledges the issue raised by submitters and clarifies that while permitted forms (of any substance) will not be prescribed within the proposed primary or consequential draft variation, this does not mean they are prohibited for SMPPi. The amendments to the proposed primary draft variation do not prescribe a permitted form requirement for substances used as a nutritive substance in SMPPi.

Issue	Comment	Submitter(s)	FSANZ Response
Permitted forms in SMPPi *FSANZ preferred option at the CFS was:* • *FSANZ did not state a preferred option for permitted forms in SMPPi.*			
Suggest forms from other internaional regulations are permitted for SMPPi.	Submitters suggested the drafting reference permitted forms are allowed from the following international regulations: • CAC/GL 10-1979 • EU609/2013 p. 35–56. Must also include vitamins and trace minerals where requirements of CAC/GL 10/1979 or EU Regulations may not align precisely with those set out in the Food Standards Code.	NES, INC	FSANZ acknowledges the request, however referencing to other international guidelines is not common practice within the Code and requires continued maintenance. As noted above, the amendments to the proposed primary draft variation do not prescribe permitted from requirements for substances used in SMPPi. This allows flexibility surrounding permitted forms.
Request further information.	These submitters recommended there be regulatory clarity on the permitted forms allowed for SMPPi (L-methyl folate) and FSANZ should consider this further.	INC, FCG, NZFGC, AFCG, DAN	
Pre-market assessment requirements for SMPPi products *FSANZ preferred option at the CFS was:* • *SMPPi regulations should be flexible enough to accommodate new ingredients or future innovation for the specific disease, disorder or medical condition for which the food has been formulated.* • *The addition of optional/new substances to SMPPi will require pre-market approval, unless the addition is made for the products special medical purpose.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	NZFS, NES, INC	Substances within SMPPi that are added for the product's special medical purpose do not require pre-market assessment.

Issue	Comment	Submitter(s)	FSANZ Response
Request the proposed flexibility extended further than the products special medical purpose.	Submitters noted that the proposed flexibility does not go far enough as there are other optional substances not for the product's special medical purpose that should also not require pre-market assessment as they are clearly permitted internationally, having undergone required scrutiny and assessment.	NZFS, INC, NES	FSANZ agrees, and clarifies that substances permitted internationally that have previously undergone rigorous assessment will also not require pre-market assessment from FSANZ. As noted above, deviation from the baseline composition of infant formula is allowed where it would prevent the sale of the SMPPI. If a substance was present in an SMPPi due to permissions internationally the proposed draft variation would permit its inclusion to allow continued access to these specialised products.
No, the preferred option is not supported.	Submitters noted that self-substantiation is not appropriate for infant formula products. Pre-market safety assessment should be required for all additional and/or new substances added to infant formula products consistent with existing provisions in the Code. Without pre-market assessment there may be regulatory uncertainty and inconsistency. NSWFA recommended the addition of a positive list of Infant Formula Product for Special Medical Purpose, overseen by an independent expert panel that provides a flexible, yet independent means to ensure the desired protection for high-risk, low volume products manufactured internationally.	VICDoH, NSWFA	FSANZ has considered the wide diversity of SMPPi, the rapidly evolving scientific evidence which they are based on and the need to allow adequate flexibility to support the development and importation of these products. As such FSANZ does not consider it appropriate to subject SMPPi products to the time intensive and complicated process of pre-market assessment, especially as these substances are added for the products special medical purpose or have already undergone rigorous assessment internationally. FSANZ acknowledges how an expert panel could improve regulatory clarity. However, the FSANZ Act does not allow the Code to establish an independent expert panel as it does not come within the list of matters that can be included in a proposed draft variation as per section 16 of the FSANZ Act. This is a matter for the jurisdictions to consider.
Measuring scoop for SMPPi *FSANZ preferred option at the CFS was:* • *To exempt SMPPi from a standardised measuring scoop.*			
Yes, the preferred option is supported.	• These submitters supported the preferred option.	NES, INC, NZFS, DAN, VICDoH	Submitters agreed with the approach proposed in SD4 of the 1st CFS. FSANZ's preferred option is to retain the proposed approach and exempt SMPPi from a standardised measuring scoop.

Appendix 1 - Fluoride and infant formula calculation

The recently revised AU and NZ NRVs for fluoride have:

- Reaffirmed the AI for children aged 7 months to 8 years to be 0.05 mg/kg bw/day
- Withdrawn the AI for infants aged 0 - 6 months
- Revised the UL for fluoride for infants and children up to 8 years from 0.10 to 0.20 mg/kg bw/day. Updated bodyweight information was used to present the UL as 1.2 mg/day for infants aged 0 – 6 months and 1.8 mg/day for infants aged 7 – 12 months

NHMRC Nutrient Reference Values (2017)

Age	Upper level of intake
0 – 6 months	1.2 mg/day
7 - 12 months	1.8 mg/day

Under Australian and New Zealand Drinking water guidelines *(NHMRC 2011, MoH 2018)*

- Maximum permitted fluoride concentration in drinking water = 1.5 mg/L
- Minimum level for a protective effect against dental caries is about 0.5 mg/L
- The critical figure is 1.0 mg/L as this is the point at which maximal protection against dental caries is reached with minimum risk of dental fluorosis.

Under Standard 2.9.1 Infant formula, fluorosis statement if:

- Fluoride level in IF powder > 17µg/100 kJ

Under Codex CXS 72- 1981 when prepared 'as recommended':

- Maximum fluoride should not exceed 24 µg/100 kJ

Question 1: Does powdered infant formula prepared with tap water contain levels of fluoride that may pose a risk to health and safety if consumed?

Several calculations were performed using a popular brands of infant formula powder and water fluoride contents of 0, 0.5, 1.0 and 1.5 mg F/L. It is important to note that the critical level for water fluoridation is 1.0 mg/L and the maximal level of 1.5 mg/L is not considered generally relevant to Australian conditions.

Example brand 1 formula powder for one-month-old male infant (4.4 kg):

1. Formula energy content = 280 kJ/100 mL as prepared
2. Recommended energy intake (EER) = 2000 kJ/day
3. Prepared with 12.5 g powder + 90mL water (to provide 280 kJ)
4. Estimated formula volume = 715 mL Estimated water volume = 626 mL water (and 87 g infant formula powder) per 2000 kJ

Table A1: Male infant one-month-old using brand 1 formula powder

(1)	(2)	(3)	(4)	(3) + (4)
F level in water mg/L[3]	**F level in IF powder µg/100 kJ[4] (µg/2000 kJ or µg/day[5])**	**F intake water mg/day (per 626 mL)**	**F intake IF powder mg/day**	**Total est. F intake mg/day**
Median level found in Au IF powder	0 (0)	0	0.00	0.00
	2 (40)	0	0.04	0.04
	4 (80)	0	0.08	0.08
0	8 (160)	0	0.16	0.16
2.9.1 Fluorosis statement required >17 µg/100 kJ	16 (320)	0	0.32	0.32
	20 (400)	0	0.40	0.40
STAN 72-1981 max	24 (480)	0	0.48	0.48
	25 (500)	0	0.50	0.50
Median level found in Au IF powder	0 (0)	0.31	0.00	0.31
	2 (40)	0.31	0.04	0.35
	4 (80)	0.31	0.08	0.39
0.5	8 (160)	0.31	0.16	0.47
2.9.1 Fluorosis statement required >17 µg/100 kJ	16 (320)	0.31	0.32	0.63
	20 (400)	0.31	0.40	0.71
	25 (500)	0.31	0.50	0.81
Median level found in Au IF powder	0 (0)	0.63	0.00	0.63
	2 (40)	0.63	0.04	0.67
	4 (80)	0.63	0.08	0.71
1.0[6]	8 (160)	0.63	0.16	0.79
2.9.1 Fluorosis statement required >17 µg/100 kJ	16 (320)	0.63	0.32	0.95
	20 (400)	0.63	0.40	1.03
	25 (500)	0.63	0.50	1.13
Median level found in Au IF powder	0 (0)	0.94	0.00	0.94
	2 (40)	0.94	0.04	0.98
	4 (80)	0.94	0.08	1.02
1.5[7]	8 (160)	0.94	0.16	1.10
2.9.1 Fluorosis statement required >17 µg/100 kJ	16 (320)	0.94	0.32	1.26
	20 (400)	0.94	0.40	1.34
	25 (500)	0.94	0.50	1.44

F = Fluoride IF = Infant Formula

[3] Water fluoridation levels from 0 to 1.5 mg/L were used in these calculations to account for water fluoride concentration variation. While 1.5 is the maximum allowed fluoride content in Australian tap water, in practice 1.0 mg/L is recognised as the optimum level for both reduction of dental caries and minimisation of risk of severe dental fluorosis.

[4] A wide range of fluoride content of milk-based infant formula powder was used (0 – 25 µg/100 kJ) in these calculations in order to encompass the CXS 72- 1981 maximum allowed and the Standard 2.9.1 labelling statements at 17 µg/100 kJ). The Codex standard is marked with a green background in the table and the Standard 2.9.1 trigger for labelling in gold. The median concentration of fluoride was 2.37 µg/100 kJ in milk-based formula powder (Clifford et al. [2009]) and this is indicated with the blue shading. It is important to note that the CXS 72- 1981 refers to formula reconstituted as recommended, and Standard 2.9.1 refers to infant formula powder prior to reconstitution so the only CXS 72-1981 figure to consider for each Table is that which uses water with zero fluoride content.

[5] To convert µg F/100KJ to µg F/day (2000 kJ) multiply by 20

[6] Optimally fluoridated water (1.0 mg/L) results in a daily fluoride intake from reconstituted milk-based formula of approximately half the UL.

[7] It is extremely unlikely that water with a fluoride concentration of 1.5 mg/L would be used to reconstitute infant formula powder. As the median fluoride level found in milk-based infant formula in Australia was less than 2.5 µg/100 kJ it would require concentrations of fluoride six times higher than normal to reach a level that would (a) trigger labelling statements and (b) reach the UL for infants.

Example brand 2 formula powder for three-month-old male infant (6 kg):

1. Formula energy content = 280 kJ/100 mL as prepared
2. Recommended energy intake (EER) = 2400 kJ/day
3. Prepared with 12.5 g powder + 90mL water provides 280 kJ
4. Estimated formula volume = 857 mL
5. Estimated water volume = 749 mL water (and 104 g infant formula powder) per 2400 kJ

Table A2: Male infant three-month-old using brand 2 formula powder

(1)	(2)	(3)	(4)	(3) + (4)
F level in water mg/L	**F level in IF powder µg/100 kJ (µg/2400 kJ or µg/day)**	**F intake water mg/day (per 749 mL)**	**F intake IF powder mg/day (per 104 g)**	**Total est. F intake mg/day**
Median level found in Au IF powder **0** 2.9.1 Fluorosis statement required >17 µg/100 kJ	0 (0)	0	0.00	0.00
	2 (48)	0	0.05	0.05
	4 (96)	0	0.10	0.10
	8 (192)	0	0.19	0.19
	16 (384)	0	0.38	0.38
	20 (480)	0	0.48	0.48
STAN 72-1981 max	24 (576)	0	0.58	0.58
	25 (600)	0	0.60	0.60
Median level found in Au IF powder **0.5** 2.9.1 Fluorosis statement required >17 µg/100 kJ	0 (0)	0	0	0.00
	2 (48)	0.37	0.05	0.47
	4 (96)	0.37	0.10	0.47
	8 (192)	0.37	0.19	0.56
	16 (384)	0.37	0.38	0.75
	20 (480)	0.37	0.48	0.85
	25 (600)	0.37	0.60	0.97
Median level found in Au IF powder **1.0**[8] 2.9.1 Fluorosis statement required >17 µg/100 kJ	0 (0)	0.75	0	0.75
	2 (48)	0.75	0.05	0.80
	4 (96)	0.75	0.10	0.85
	8 (192)	0.75	0.19	0.94
	16 (384)	0.75	0.38	1.13
	20 (480)	0.75	0.48	1.23
	25 (600)	0.75	0.60	1.35
Median level found in Au IF powder **1.5** 2.9.1 Fluorosis statement required >17 µg/100 kJ	0 (0)	1.12	0	1.12
	2 (48)	1.12	0.05	1.17
	4 (96)	1.12	0.10	1.22
	8 (192)	1.12	0.19	1.31
	16 (384)	1.12	0.38	1.50
	20 (480)	1.12	0.48	1.60
	25 (600)	1.12	0.60	1.72

F = Fluoride IF = Infant Formula

[8] A 3-month-old male infant consuming reconstituted milk-based infant formula at recommended levels would reach the UL when optimally fluoridated water was used only if the milk powder contained levels of fluoride seven times that currently found (Clifford et al. 2009).

Example brand 3 formula powder form male seven-month-old infant (8.4 kg):

1. Formula energy content = 275 kJ/100 mL as prepared
2. Recommended energy intake (EER) = 2800 kJ/day
3. Prepared with 13 g powder + 90 mL water provides 275 kJ
4. Estimated formula volume = 1018 mL
5. Estimated water volume = 920 mL water (and 133 g infant formula powder) per 2800 kJ

Table A3: Male infant seven-month-old (8.4 kg) consuming 2800 kJ/day of brand 3 formula powder

(1)	(2)	(3)	(4)	(3) + (4)
F level in water mg/L	**F level in IF powder µg/100 kJ (µg/2800 kJ or day[9])**	**F intake water mg/day (at 920 mL)**	**F intake IF powder mg/day**	**Total est. F intake mg/day**
Median level found in Au IF powder	0 (0)	0	0.00	0.00
	2 (56)	0	0.06	0.06
	4 (112)	0	0.11	0.11
0	8 (224)	0	0.22	0.22
2.9.1 Fluorosis statement required >17 µg/100 kJ	16 (448)	0	0.45	0.45
	20 (560)	0	0.56	0.56
STAN 72-1981 max	24 (672)	0	0.62	0.62
	25 (700)	0	0.70	0.70
	0 (0)	0.46	0.00	0.00
Median level found in Au IF powder	2 (56)	0.46	0.06	0.52
	4 (112)	0.46	0.11	0.57
	8 (224)	0.46	0.22	0.68
0.5	16 (448)	0.46	0.45	0.91
2.9.1 Fluorosis statement required >17 µg/100 kJ	20 (560)	0.46	0.56	1.02
	25 (700)	0.46	0.70	1.16
	0 (0)	0.92	0.00	0.92
Median level found in Au IF powder	2 (56)	0.92	0.06	0.98
	4 (112)	0.92	0.11	1.03
	8 (224)	0.92	0.22	1.14
1.0	16 (448)	0.92	0.45	1.37
2.9.1 Fluorosis statement required >17 µg/100 kJ	20 (560)	0.92	0.56	1.48
	25 (700)	0.92	0.70	1.62
	0 (0)	1.38	0.00	1.38
Median level found in Au IF powder	2 (56)	1.38	0.06	1.44
	4 (112)	1.38	0.11	1.49
	8 (224)	1.38	0.22	1.60
1.5[10]	16 (448)	1.38	0.45	1.83
2.9.1 Fluorosis statement required >17 µg/100 kJ	20 (560)	1.38	0.56	1.94
	25 (700)	1.38	0.70	2.08

F = Fluoride IF = Infant Formula

[9] To convert F level in infant formula powder from µg/100 kJ to µg/day (2400 kJ) multiply by 24

[10] Fluoride levels in reconstituted infant formula would not reach the UL unless water fluoridated at the maximum allowable level was used, and infant formula powder contained approximately 8 times the amount of fluoride currently seen.

Example brand 4 formula powder for 3-month-old male infant (6 kg):

1. Formula energy content = 281 kJ/100 mL as prepared
2. Recommended energy intake (EER) = 2400 kJ/day
3. Prepared with 13 g powder + 90mL water provides 281 kJ
4. Estimated formula volume = 854 mL
5. Estimated water volume = 752 mL water (and 109 g infant formula powder) per 2400 kJ

Table A4: Male infant 3-month-old (6kg) consuming brand 4 formula powder

(1)	(2)	(3)	(4)	(3) + (4)
F level in water mg/L	**F level in IF powder µg/100 kJ[11] (µg/2400 kJ or day)**	**F intake water mg/day (at 752 mL)**	**F intake IF powder mg/day**	**Total est. F intake mg/day**
	0 (0)	0	0.00	0.00
Median level found in Au IF powder	4 (96)	0	0.10	0.10
	5 (120)	0	0.12	0.12
	8 (192)	0	0.19	0.19
0	16 (384)	0	0.38	0.38
2.9.1 Fluorosis statement required >17 µg/100 kJ	20 (480)	0	0.48	0.48
STAN 72-1981 max	24 (576)	0	0.58	0.58
	25 (600)	0	0.60	0.60
	0 (0)	0.38	0.00	0.00
Median level found in Au IF powder	4 (96)	0.38	0.10	0.48
	5 (120)	0.38	0.12	0.50
	8 (192)	0.38	0.19	0.57
0.5	16 (384)	0.38	0.38	0.76
2.9.1 Fluorosis statement required >17 µg/100 kJ	20 (480)	0.38	0.48	0.86
	25 (600)	0.38	0.60	0.98100kJ
	0 (0)	0.75	0	0.75
Median level found in Au IF powder	4 (96)	0.75	0.10	0.85
	5 (120)	0.75	0.12	0.87
	8 (192)	0.75	0.19	0.94
1.0[12]	16 (384)	0.75	0.38	1.13
2.9.1 Fluorosis statement required >17 µg/100 kJ	20 (480)	0.75	0.48	1.23
	25 (600)	0.75	0.60	1.35
	0 (0)	1.13	0.00	1.13
Median level found in Au IF powder	4 (96)	1.13	0.10	1.23
	5 (120)	1.13	0.12	1.25
	8 (192)	1.13	0.19	1.32
1.5	16 (384)	1.13	0.38	1.51
2.9.1 Fluorosis statement required >17 µg/100 kJ	20 (480)	1.13	0.48	1.61
	25 (600)	1.13	0.60	1.73

F = Fluoride IF = Infant Formula

[11] A wide range of fluoride concentrations in soy-based infant formula was used in these calculations to include the Standard 2.9.1 label trigger of 17 µg F/100 kJ formula powder and the CXS 72-1981 maximum level of 24 µg F/ 100 kJ when made as recommended. The median concentration of fluoride in soy-based formula powder was 5.15 µg/100 kJ (Clifford et al [2006]).

[12] A male 3-month-old infant would only have a fluoride intake over the UL if powder were reconstituted at the optimal level with powder containing approximately four times the levels currently found (Clifford et al. 2009) or water at the maximum fluoride level allowed was to be used for reconstitution.

References

Andersson M, Aeberli I and Wüst N (2010). The Swiss iodized salt program provides adequate iodine for school children and pregnant women, but weaning infants not receiving iodine-containing complementary foods as well as their mothers are iodine deficient. Accessed January 2023.

ANZFA (2002) Supplementary Final Assessment (Inquiry – S.24) Report. Proposal P93 – Review of Infant Formula. Australia New Zealand Food Authority, Canberra. http://www.foodstandards.gov.au/code/proposals/pages/proposalp93reviewofinfantformula/p93finalassessreport1397.aspx

CCNFSDU (2006) Report of the 27th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses. Codex Ailimentarius Commission, Rome. Accessed January 2023.

CCNFSDU (2007): Report of the 28th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses. Codex Ailimentarius Commission, Rome. Accessed January 2023.

Codex (2023). Report of the 23rd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses: 23REP/NFSDU Appendix III Section A: Follow-up Formula for Older Infants. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-43%252FFinal%2BReport%252FREP23_NFSDUe.pdf

Cha´vez-Servı´n J,Castellote A, Rivero M, Lo´pez-Sabater C (2008) Analysis of vitamins A, E and C, iron and selenium contents in infant milk-based powdered formula during full shelf-life. Accessed November 2022.

Chesney R, Helms R, Christensen M, Budreau A, Han X and Sturman J (1998) The role of taurine in infant nutrition. Adv Exp Med Biol. 1998;442:463-76. doi: 10.1007/978-1-4899-0117-0_56. PMID: 9635063.

Claeys W, Cardoen S, De Block J, Huyghebaert A, Raes K, Dewettinck K and Herman L (2014) Consumption of raw or heated milk from different species: An evaluation of the nutritional and potential health benefits Food Control, 42, 188-201.

Commonwealth of Australia (2014) - Donor human milk banking in Australia – issues and background paper | Australian Government Department of Health. Accessed January 2023.

EC SCF (2003) Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae. European Commission Health and Consumer Protection Directorate- General, Brussels.

EFSA (2014) Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 12 (7): 3760. DOI: 10.2903/j.efsa.2014.3760.

FAO (2013) Milk and dairy products in human nutrition (fao.org). Food and Agriculture Organization of the United Nations. Rome.

FAO/WHO (2023) Codex Alimentarius International Food Standards. Accessed January 2023.

Fomon S (2000) Potential Renal Solute Load: Considerations Relating to Complementary Feedings of Breastfed Infants. *Pediatrics*.; 106 (Supplement_4): 1284. 10.1542/peds.106.S4.1284.

FSANZ (1999) Preliminary Inquiry Report – Proposal P93: Review of Infant Formula. FSANZ, Canberra.

FSANZ (2002) Supplementary Final Assessment – Proposal P93: Review of Infant Formula. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/pages/proposalp93reviewofinfantformula/p93infantf

ormulasor.aspx

FSANZ (2016) Consultation paper – Proposal P1028. Supporting Document 1, Attachment A1.1 - Nutrition Assessment. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Documents/P1028-Consult-SD1-Attach-A1.pdf.

FSANZ (2017): Consultation Paper – Proposal P1028. Regulation of Infant formula – Infant formula products for special dietary use. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx.

FSANZ (2019) Approval Report – A1155 – 2'-FL and LNnT in infant formula and other products. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/applications/Pages/A1155.aspx.

FSANZ (2021) Consultation Paper 2 – Nutrient Composition. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx.

FSANZ (2021b) Consultation Paper 2 – Nutrient Composition. Supporting Document 1 – Nutrition Assessment. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx.

FSANZ (2022) Supporting Document 2 – Nutrient Composition. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx.

FSANZ (2022b) Supporting Document 4 – Special medical purpose products for infants. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx.

Garlick PJ (2006) Toxicity of methionine in humans. J Nutr 136(6 Suppl):1722S–1725S

Jin Y, Coad J, Skeaff S, and Zhou S (2021) Iodine status of postpartum women and their infants aged 3, 6 and 12 months – Mother and Infant Nutrition Investigation (MINI). Br J Nutr 127, 570–579.

Koletzko B, Baker S, Cleghorn G, Neto UF, Gopalan S, Hernell O, Hock QS, Jirapinyo P, Lonnerdal B, Pencharz P, Pzyrembel H, Ramirez-Mayans J, Shamir R, Turck D, Yamashiro Y, Zong-Yi D (2005) Global standard for the composition of infant formula: recommendations of an ESPGHAN coordinated international expert group. J Pediatr Gastroenterol Nutr 41(5):584–599

Koletzko B, Bhutta Z, Cai W (2013). Compositional requirements of follow-up formula for use in infancy: Recommendations of an international expert group coordinated by the early nutrition academy. *Ann Nutr Metab*. 2013;62:44-54.

Koo (2007) Rice protein-based infant formula: current status and future development - PubMed (nih.gov)

MacIntyre p, Murphy S, Stelwagen K and Moore D (2020) Progress Review of Sheep – Horizon Three Programme. Sapere Research Group.

Michaelsen KF, Weaver L, Branca F, Robertson A. (2000) Feeding and Nutrition of Infants and Young Children: Guidelines for the WHO European Region, with Emphasis on the Former Soviet Countries.

Ministry of Health (2018) Drinking-water Standards for New Zealand 2005 (revised 2018). Wellington: Ministry of Health.

Ministry of Health (2021) Healthy Eating Guidelines for New Zealand Babies and Toddlers (0–2 years old). Wellington: Ministry of Health.

NHMRC and NZ MOH (2006) Nutrient Reference Values for Australia and New Zealand.

Commonwealth of Australia, Canberra. http://www.nrv.gov.au/.

National Health and Medical Research Council (2011) Australian Drinking Water Guidelines, Paper 6 National Water Quality Management Strategy. National Resource Management Ministerial Council, Commonwealth of Australia, Canberra.

Næss S, Aakre I, Strand A, Dahl L, Kjellevold M, Stokland A, Nedrebø B, and Markhus M (2022). Infant iodine status and associations with maternal iodine nutrition, breast-feeding status and thyroid function. British Journal of Nutrition, pp.1–10.

NZMPI (2014) Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children. Wellington: Ministry for Primary Industries.

Olagaray K, Shaffer J, Armendariz C, Ballamine A, Jacobs S, Titgemeyer E & Bradford B (2018). Relative bioavailability of carnitine delivered by ruminal or abomasal infusion or by encapsulation in dairy cattle. J Dairy Sci. 101(3): 2060-71. DOI: 10.3168/jds.2017-13656

Park Y and Haenlein G (2006). Handbook of Milk of Non-Bovine Mammals|| Goat Milk-Chemistry and Nutrition. , 10.1002/9780470999738(), 34–58. doi:10.1002/9780470999738.ch3.

Park Y, Juárez M, Ramos M andHaenlein G (2007). Physico-chemical characteristics of goat and sheep milk. Small ruminant research, 68(1), 88-113.

Skeaff S, Ferguson E, McKenzie J (2005) Are breast-fed infants and toddlers in New Zealand at risk of iodine deficiency? Nutrition 21, 325–331.

Tochitani S (2022) Taurine: A Maternally Derived Nutrient Linking Mother and Offspring. *Metabolites* 12, no. 3: 228. https://doi.org/10.3390/metabo12030228

WHO, Unicef, International Council for the Control of Iodine Deficiency Disorders (2007) Assessment of iodine deficiency disorders and monitoring their elimination: A guide for programme managers.