4 April 2022
196-22

Supporting document 2

Nutrient composition for infant formula products

Proposal P1028 – Infant Formula

Executive summary

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

Infant formula is 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). Other standards in the Code also contain provisions related to safety and food technology for infant formula, such as Standards 1.3.1 – Food Additives and 1.4.1 – Contaminants and Natural Toxicants.

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 its 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.

Throughout 2021, FSANZ released three consultation papers that discussed the regulatory options for Standard 2.9.1 and Schedule 29, to help inform the 1st Call for Submissions (CFS). Following the 2021 consultation, follow-on formula was reintroduced into the scope of the Proposal (see Section 1.2 of the CFS).

This Supporting Document (SD) is one of six developed to accompany the 1st CFS, and focuses on issues relating to the nutrient composition of infant formula products, including infant formula and follow-on formula. It is organised into three parts as follows:

- Part A: Infant formula
- Part B: Follow-on formula
- Part C: Infant formula products

Part A of this SD considers scientific assessments, stakeholder views and international regulations relating to infant formula. This section proposes a number of FSANZ's preferred regulatory approaches for the composition of macronutrients, micronutrients, optional substances, equivalents, conversion factors and ratios prescribed for infant formula. The majority of FSANZ's proposed regulatory decisions align with the *Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (Codex CXS 72-1981). Proposed composition requirements that do not align with Codex CXS 72-1981 are

where Standard 2.9.1 or Schedule 29 values were retained[1] or where the European regulation on compositional requirements for infant formula (EU 2016/127) was adopted[2] based on being the most appropriate level to ensure infant health and safety within Australia and New Zealand.

Part B of this SD considers scientific assessments, stakeholder views and international regulations, including recent progress on the Codex Proposed Draft Revised Standard for Follow-up Formula for Older Infants (6 -12 months) (Codex Draft Standard for FuFOI), relating to the revision of the Codex Standard for Follow up Formula (CXS 156-1987). The nutrient composition for the Codex Draft Standard for FuFOI is now held at Step 7, which indicates that it is at the final step prior to being submitted to the Codex Alimentarius Commission for adoption. FSANZ considered the nutrient composition for follow-on formula should only deviate from infant formula when there is substantiated science to support the differences in requirements between the age groups. This review does not consider the proposed Codex Draft Revised Standard for Follow-up Formula for Young Children (1 – 3 years) as within the Australian and Zealand (ANZ) market products formulated for young children aged above 12 months old are not considered infant formula products and are therefore outside the scope of the proposal.

FSANZ's preferred regulatory approaches for the composition of follow-on formula were to align with proposed composition for infant formula, except where the Codex Draft Standard for FuFOI level differed and was more appropriate within the ANZ context. The Codex Draft Standard for FuFOI maximum for calcium was adopted for follow-on formula due to the increased calcium requirements for infants aged 6 – 12 months. FSANZ proposed, in alignment with the Codex Draft Standard for FuFOI, that no minimum level was preferred for choline and myo-inositol.

Part C of this SD considers issues that relate to all infant formula products, which includes permitted forms, vitamin and mineral supplementation guidance, measuring scoop requirements and formula modifications such as low lactose/lactose free and partially hydrolysed proteins. FSANZ has adopted permitted forms present within CXS 72-1981 where appropriate, proposed to remove the guideline on advice regarding additional vitamin and mineral supplementation, proposed not to prescribe a standardised measuring scoop or ratio and has allowed partially hydrolysed proteins and low lactose/lactose free formulas within infant formula products.

FSANZ's proposed regulatory approaches are summarised below in Table 1. Proposed approaches are 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.

[1] Carbohydrate, Trans Fatty Acids, Arachidonic acid, Iron and the minimum for Linoleic acid and Taurine
[2] minimum level for Thiamin, Riboflavin and Vitamin K

Table 1 Proposed nutrient composition for infant and follow-on formula

Nutrient	Unit	Infant formula		Follow-on formula	
		Min	Max	Min	Max
Energy	kJ/L	2500	2950	2500	2950
Protein (cow)	g/100 kJ	0.43	0.7	0.43	0.7
Protein (soy)	g/100 kJ	0.54	0.7	0.54	0.7
Carbohydrates	g/100 kJ	NS	NS	NS	NS
Total fat	g/100 kJ	1.05	1.4	1.05	1.4
Linoleic acid (LA)	mg/100 kJ	90	330*	90	330*
α-Linolenic acid (ALA)	mg/100 kJ	12	NS	12	NS
Erucic Acid^	% total fatty acid	NS	1	NS	1
Docosahexaenoic acid (DHA)^	mg/100kJ	NS	7.2	NS	7.2
Arachidonic acid^	% total FA	NS	1	NS	1
Trans fatty acid^	% total FA	NS	4	NS	4
Phospholipids^	g/L	NS	2	NS	2
Vitamin A	µg RE/100 kJ	14	43	14	43
Vitamin B6	µg /100 kJ	8.5	45*	8.5	45*
Vitamin B12	µg /100 kJ	0.025	0.36*	0.025	0.36*
Niacin	µg /100 kJ	70	360*	70	360*
Riboflavin	µg /100 kJ	14.3	119*	14.3	119*
Vitamin C	mg/100 kJ	1.7	17*	1.7	17*
Vitamin D	µg /100 kJ	0.25	0.63	0.25	0.63
Vitamin E	mg α-TE/100 kJ	0.12	1.2*	0.12	1.2*
Vitamin K	µg /100 kJ	0.24	6.5*	0.24	6.5*
Phosphorus	mg/100 kJ	6	24*	6	24*
Calcium	mg/100 kJ	12	35*	12	43*
Magnesium	mg/100 kJ	1.2	3.6*	1.2	3.6*
Iron	mg/100 kJ	0.2	0.5	0.2	0.5
Folic acid	µg /100 kJ	2.5	12*	2.5	12*
Sodium	mg/100 kJ	5	14	5	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	0.25	24*	0.25	24*
Zinc	mg/100 kJ	0.12	0.36*	0.12	0.36*
Thiamin	µg /100 kJ	10	72*	10	72*
Biotin	µg /100 kJ	0.24	2.4*	0.24	2.4*
Copper	µg /100 kJ	8.5	29*	8.5	29*
Iodine	µg /100 kJ	2.5	14*	2.5	14*
Selenium	µg /100 kJ	0.48	2.2*	0.48	2.2*
Taurine^	mg/100 kJ	0.8	3	0.8	3
Lutein^	µg/100 kJ	1.5	5.0	1.5	5.0
Choline	mg/100 kJ	1.7	12*	NS	12*^
Myo-inositol	mg/100 kJ	1.0	9.5*	NS	9.5*^
L-Carnitine	mg/100 kJ	0.3	0.8	0.3^	NS^
Adenosine-5′-monophosphate^	mg / 100 kJ	NS	0.38	NS	0.38
Cytidine-5′-monophosphate^	mg / 100 kJ	NS	0.6	NS	0.6
Guanosine-5′-monophosphate^	mg / 100 kJ	NS	0.12	NS	0.12
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
Fluoride	µg /100 kJ	NS	24	NS	24
2′-O-fucosyllactose	mg / 100 kJ	NS	96[1]	NS	96[1]
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
Eicosapentaenoic acid	ratio	NS	≤ DHA	NS	≤ DHA

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

[1] A combination of 2′-O-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.

Retain restrictions on inulin-type fructans and galacto-oligosaccharides in Standard 2.9.1—7.

Table of contents

Abbreviations and glossary

Abbreviation or Term	Meaning
AA	Arachidonic acid C20:4, n-6
AI	Adequate intake—the average daily nutrient intake level based on observed or experimentally-determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate.
Amino acids	In this paper, refers to L-amino acids which are the only forms that are biologically active/available.
ANZ	Australia and New Zealand
ANZFA	Australia New Zealand Food Authority, the former name for FSANZ
α-TE	Alpha-tocopherol equivalent
Breast milk	A general term for human milk provided from a mother's breast (described as mature milk to distinguish it from colostrum).
CAC	Codex Alimentarius Commission
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CLA	Conjugated linoleic acid
Codex	Refers to Codex Alimentarius
Codex CXS 72-1981	Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants
Codex Draft Standard for FuFOI	Refers to the Proposed Draft Revised Standard for Follow-up Formula, Section A: Follow-up Formula for Older Infants (see 22REP/NFSDU Appendix III)
Complementary feeding	The gradual introduction of solid food and fluids along with the usual milk feed (breast milk or infant formula) to an infant's diet (Ministry of Health, 2008).
DFE	Dietary folate equivalents
DHA	Docosahexaenoic acid C22:6, n-3
DPA	Docosapentaenoic acid C22:5, n-3
EAR	Estimated average requirement
EC	European Commission
EC SCF	European Commission Scientific Committee on Food
EFSA	European Food Safety Authority
EPA	Eicosapentaenoic acid C20:5, n-3
ESPGHAN	European Society for Paediatric Gastroenterology, Hepatology and Nutrition
EU	European Union

EU 2016/127	European regulation on compositional requirements for infant formula
EWG	Electronic working group
FAO	Food and Agriculture Organization of the United Nations
Follow-on formula (FOF)	An infant formula product that is represented as either a breast milk substitute or replacement for infant formula and is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of six months, as defined in Standard 1.1.1 of the Code.
Follow-up formula (FUF)	Under CODEX STAN 156-1987, this is a food intended for use as a liquid part of the weaning diet for older infants (age 6-12 months) and for young children (age 12 -36 months).
FSMP	Food for Special Medical Purposes
GL	Guideline level
GMP	Good manufacturing practice
GUL	Guidance upper level
Infant	A person under the age of 12 months, as defined in Standard 2.9.1
Infant formula (IF)	An infant formula product represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months, as defined in Standard 1.1.1 of the Code
Infant formula product (IFP)	A product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants; as defined in Standard 1.1.1 of the Code
IOM	US Institute of Medicine
ISP	Isolated soy protein
JECFA	FAO/WHO Joint Expert Committee on Food Additives
JEMNU	Joint FAO/WHO Expert Meetings on Nutrition
LC-PUFA	Long chain polyunsaturated fatty acids
LSRO	Life Sciences Research Organization
MCT	Medium chain triglycerides
MoH	Ministry of Health (New Zealand)
NCF	Nitrogen conversion factor
NE	Niacin equivalents
NHMRC	National Health and Medical Research Council (Australia)
NRV	Nutrient reference value established by NHMRC & MoH (2006)
N.S.	Not stated
PDCAAS	Protein digestibility-corrected amino acid score

PL	Phospholipids
RE	Retinol equivalents
rNRV	Regulatory nutrient reference value
SAA	Sulphur Amino Acids (methionine and cysteine)
SD	Supporting document
Soy-based formula	An infant formula product in which soy protein isolate is the sole source of protein, as defined in Standard 2.9.1
Special Medical Purpose Products for infants (SMPPi)	Special Medical Purpose Product specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition for which standard infant formula or follow-on formula is not suitable; and is intended for use under medical supervision.
TFA	Trans fatty acids
The Code	Australia New Zealand Food Standards Code
UL	Upper Level of intake
US	United States of America
US FDA	US Food and Drug Administration
WHO	World Health Organization
WTO	World Trade Organization

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 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 remains safe, suitable and takes 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.

Following the 2021 Consultation Paper (FSANZ 2021 CP2) follow-on formula (FOF) was re-included into the scope of Proposal P1028. The scope of Proposal P1028 now includes all requirements for infant formula products in Standard 2.9.1.

As defined in section 2.9.1—3 follow-on formula means an infant formula product that:

(a) is represented as either a breast-milk substitute or replacement for infant formula; and

(b) is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.

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

1.1 The proposal to date

Reviewing an entire standard which regulates food for a very 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 five consultation papers[3] 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 Nutrition Assessment).
- 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).

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

- 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)
  - Consultation Paper 3 – Regulatory framework and definition (FSANZ 2021 CP3)

These five 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 particular consideration to the submissions received from FSANZ 2021 CP2. Other SDs accompanying this CFS give consideration to the matters raised in consultation papers 1 and 3.

1.2 2021 Stakeholder views

A total of 21 submissions were received in response to FSANZ 2021 CP2. As detailed in Table 1.2.1 below, 15 of the submissions were from industry and peak bodies, five from government bodies and one from a public health association.

Table 1.2.1 Number of submissions received in response to CP2 by stakeholder group

Industry and peak body
Australian Food and Grocery Council (AFGC)
Complementary Medicines Australia (CMA)
Dairy Australia
Dairy Companies Association of New Zealand (DCANZ)
Dairy Goat Co-operative New Zealand (DGC)
Danisco (a subsidiary of International Flavors and Fragrances Inc. (IFF))
Danone
Else Nutrition
European Vegetable Protein Association (EUVEPRO) & European Plant-based Foods Association (ENSA)
Fonterra
Global Organization for EPA and DHA Omega-3s (GOED)
Infant Nutrition Council Australia and New Zealand (INC)
Nestlé
New Zealand Food and Grocery Council (NZFGC)
UP International (Novalac)
TOTAL – 15
Government
Department of Health Tasmania
New South Wales Health and New South Wales Food Authority
New Zealand Food Safety (Ministry for Primary Industries)
Queensland Health
Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions
TOTAL – 5
Public Health
Dietitians Australia
TOTAL – 1

1.2.2 Issues not in scope

Submitters to FSANZ 2021 CP2 and other consultation papers proposed a number of changes that would have implications across the Code, or would create special prescription for infant formula products, and so inconsistency within the Code. Such inconsistency would

need strong justification. These issues, outlined in section 1.2 of the CFS, are out of scope for Proposal P1028 and will not be considered further.

1.2.3 EU alignment

The FSANZ 2021 CP2 received several submitter comments regarding alignment with EU 2016/127 as this was the most recent science-based assessment. EU 2016/127 is mostly based on the 2014 European Food Safety Authority (EFSA) recommendations (EFSA 2014). FSANZ assessed the science underpinning the EFSA 2014 recommendations within the FSANZ 2016 Nutrition Assessment and noted that the recommendations were generally not based on new science. EFSA also did not evaluate the maximums for micronutrients. The panel noted that:

> *'specifications for the currently permitted maximum amounts of micronutrients in formulae were mostly calculated as three to five times the minimum amounts established at the time and took into account the established history of apparent safe use and were not based on scientific evidence for adverse effects owing to the lack of such evidence for most nutrients.'*

FSANZ reiterates that the purpose of the proposal, in regard to harmonisation, is to align with international standards and not jurisdiction regulations. Where applicable, FSANZ 2021 CP2 considered EU 2016/127 and the EFSA findings to inform proposed options for amending Standard 2.9.1.

1.2.4 Follow-on formula

At the time of release of FSANZ 2021 CP2, follow-on formula was considered out of scope for Proposal P1028 (see Section 1.2 of the CFS). However following FSANZ 2021 CP2, FSANZ has introduced follow-on formula into the scope of the proposal. Submissions regarding follow-on formula in response to FSANZ 2021 CP2 have been addressed in Part B of this SD.

2. Part A: Infant Formula

2.1 Macronutrients

2.1.1 Stakeholder views

Table 2.1.1 Macronutrient issues raised by stakeholders

Issue & FSANZ 2021 CP2 proposed approach	Raised by	FSANZ response
Energy (2500 – 2950 kJ/L)	7 submissions (5 industry, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach as it aligns with Codex CXS 72-1981, no adverse health risks were identified and all submitters supported the proposed response. One submitter suggested that clarification is required in S29-2 to specify whether unavailable carbohydrates must be taken into account, or not, in the energy calculation. See discussion for further information.
Nitrogen Conversion Factor (NCF) (6.25)	14 submissions (11 industry, 3 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach as it aligns with the EU 2016/127 and Codex Draft Standard for FuFOI and is valid for whey and soy-based infant formula.
Protein range – cow's milk (0.43 – 0.7 g/100kJ)	9 submissions (7 industry, 2 government)	Most submitters agreed with the proposed approach to prescribe a permitted protein range of 0.43-0.7g/100 kJ. However all submitters did not support the range being applied only to cow's milk-based formulas. After assessment, FSANZ's preferred option is to retain that approach as it aligns with the EU 2016/127 minimum and Codex Draft Standard for FuFOI range and no evidence noting harm to infant health for this range.
Soy protein minimum (0.54g/100 kJ)	6 submissions (4 industry, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach as it aligns with the EU 2016/127 minimum and Codex Draft Standard for FuFOI.
Protein sources (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.)	15 submissions (11 industry, 1 public health, 3 government)	Views on the proposed approach were mixed. After assessment, FSANZ's preferred option is to retain the approach of CP2 as it aligns with the Ministerial Policy Guideline on the Regulation of Infant Formula Products (ANZ FRMC, 2011) and international regulations.
Protein quality (Maintain current requirements by mandating minimum amino	8 submissions (6 industry, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the

acid amounts)		reasons stated in FSANZ 2021 CP2.
Amino Acids (Align the minimum amounts of all amino acids with Codex CXS 72-1981)	6 submissions (4 industry, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach as it aligns with Codex CXS 72-1981.
Fat (1.05 – 1.4 g/100 kJ)	6 submissions (4 industry, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach as it aligns with Codex CXS 72-1981, EU 2016/127 and fat content levels found in human milk.
Linoleic Acid (LA) (90 – 330 (GUL) mg/100 kJ)	14 submissions (8 industry, 1 public health, 5 government)	Views on the proposed approach were mixed. See discussion below for further information. After assessment, FSANZ's preferred option is to retain the approach of CP2 as it addresses stability and palatability concerns while ensuring nutritional adequacy and safety within the ANZ infant population.
α-Linolenic Acid (ALA) (Minimum 12 mg/100kJ No Maximum)	3 submissions (1 industry, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach as it aligns with the EU 2017/17 minimum and Codex CXS 72-1981 range.
LA : ALA ratio (5:1–15:1)	4 submissions (3 industry, 1 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach as it aligns internationally.
Docosahexaenoic Acid (DHA) (7.2 (GUL) mg/100kJ)	11 submissions (8 industry, 1 public health, 2 government)	Most submitters did not agree with the proposed approach. See discussion below for further information. After assessment, FSANZ's preferred option is to retain the approach of CP2 as it alinsg with Codex CXS 72-1981 and the Codex Draft Standard for FuFOI.
Long Chain Polyunsaturated Fatty Acids (LC-PUFA), Eicosapentaenoic Acid (EPA), Arachidonic acid (AA) and their ratios (Approach unchanged from FSANZ 2016 CP)	1 submission (1 industry)	One industry submitter supported the proposed approach to retain current permissions for LC-PUFA, EPA, AA and their ratios. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2
LC-PUFA (specifically DHA) as voluntary ingredients (Retain voluntary permissions)	4 submissions (1 industry, 1 public health, 2 government)	Two government and one public health submitter did not support the proposed approach. An industry submitter supported the current voluntary permissions. After assessment, FSANZ's preferred option is to retain the CP2 approach as it aligns with Codex CXS 72-1981 and the Codex Draft Standard for FuFOI.

Fat Source (Retain current approach which restricts specific fats and no further definition of fat source.)	6 submissions (5 industry, 1 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain the current approach as it is similar to the approach taken in Codex CXS 72-1981. One government submitter outlined the Codex CXS 72-1981 exemption to prohibit commercially hydrogenated oils that may contain industrial TFA. See discussion below for further information.
Medium Chain Triglycerides (MCT) (Retain restriction within Std 2.9.5)	8 submissions (6 industry, 2 government)	Industry submitters did not agree with the proposed approach. Government submitters did agree. See discussion below for further information. After assessment, FSANZ's preferred option is to retain the current MCT restriction as the inclusion of MCT in infant formula does not provide any benefit to infant health, and that MCT are not normally present in significant amounts in breast milk.
Trans Fatty Acids (TFA) (Retain the current restriction for TFA at 4% of total fatty acids)	6 submissions (4 industry, 2 government)	There was mixed feedback on the proposed approach. See discussion below for further information. After assessment, FSANZ's preferred option is to retain the current restriction as aligning internationally would require a definition change within the Code, which is outside the scope of the proposal.
Phospholipids (PL) (Permit PL at 2 g/L (72 mg/100 kJ) and the maximum lecithin amount to 1 g/L)	9 submissions (7 industry, 2 government)	Industry submitters supported option 1 but with the limit being a GUL rather than a maximum. Government submitters agreed with the proposed approach for lecithin but sought further assessment for PL. After assessment, FSANZ's preferred option is to retain the approach of CP2 for the reasons stated below.
Myristic , Lauric and Erucic Acids (Approach unchanged from FSANZ 2016 CP)	5 submissions (3 industry, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Dietary Fibre (No change proposed)	8 submissions (6 industry, 2 government)	Submitters agreed with the proposed approach to not prescribe methods of analysis for dietary fibre. Many submitters commented on inconsistency in the definition of dietary fibre. Reviewing definitions is out of scope for P1028. Therefore, FSANZ will not consider this issue further and the preferred option is to progress with the CP2 approach.
Inulin-type fructans and galacto-oligosaccharides	8 submissions (6 industry, 2	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred

(Retain current permissions in Standard 2.9.1—7)	government)	option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Carbohydrate source (Adopt limits on sucrose and fructose that are aligned with Codex CXS 72-1981)	9 submissions (6 industry, 3 government)	Most submitters did not agree with the proposed approach. After assessment, FSANZ's preferred option is to retain the approach of CP2 for the reasons stated below.
Carbohydrate Range (Retain the current approach in Standard 2.9.1.which does not specify a permitted range for carbohydrate content.)	6 submissions (4 industry, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.

2.1.2 Discussion

Energy

FSANZ 2021 CP2 outlined the issue regarding energy factors used to calculate energy content of infant formula. One submitter suggested that clarification is required in S29-2 to specify whether unavailable carbohydrates must be taken into account, or not, in the energy calculation.

Paragraph 2.9.1—4(2)(a) states that energy must be calculated in accordance with section S29—2. Paragraph S29—2(1)(b) states that for paragraph 2.9.1—4(2)(a), the energy content of infant formula product must be calculated using the relevant energy factors set out in section S11—2. Subsection S11—2(2) Calculation of average energy content lists the energy factors for general components, including unavailable carbohydrate.

Therefore, this issue is addressed in the Code with no further clarification required.

Protein Range (Cow's Milk)

FSANZ 2021 CP2 proposed to prescribe a permitted protein range of 0.43 – 0.7 g/100 kJ for cow's milk-based infant formula. This is based on absence of evidence noting harm to infant health for this range, submitter comments to the FSANZ 2016 CP and consistency with EU 2016/127 regulations (minimum).

Nine submitters (seven industry and two government) commented on the proposed approach. Industry submitters agreed with the proposed approach while government submitters expressed concern that the upper level of the range is too high and proposed aligning with the EU 2016/127 maximum of 0.6g/100kJ. All submitters did not support the range being applied only to cow's milk-based formulas.

The EU 2016/127 maximum was considered in the FSANZ 2016 Nutrition Assessment and FSANZ 2021 CP2. The EU 2016/127 maximum is based on conclusions from EFSA that "there is no evidence of a physiological need for protein intakes at 3.0 g/100 kcal (equivalent to 0.7 g/100 kJ) in infancy" (EFSA 2014). The EFSA panel also acknowledged that "there is no scientific data available which allow the establishment precise cut-off values for the maximum protein content in infant formula."

Therefore, FSANZ's preferred option is to prescribe a permitted protein range of 0.43 – 0.7 g/100 kJ for cow's milk-based infant formula.

Protein Source

FSANZ 2021 CP2 proposed that 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 is based on the recent focus of new proteins being used in foods and the potential safety risks associated with their use in infant formulas if not approved through the pre-market assessment process.

Fifteen submitters (11 industry, one public health, and three government) commented on the proposed approach. Government and public health submitters support the proposed approach. However it was suggested that the wording be revised to that used in EU 2016/127 for better clarity. Most industry submitters did not support the proposed approach, citing the following reasons:

- not aligned with Codex CXS 72-1981
- there are infant formula products in the market using protein sources not included in the prescribed list e.g. sheep milk and rice
- inhibit innovation
- fat and carbohydrate sources are not limited so protein source should not be limited provided it is nutritionally adequate
- requirements for minimum amounts of amino acids ensures that the quality of the protein is suitable for infants.

FSANZ preferred approach to prescribe protein sources and allow pre-market assessment of sources outside those specified, is aligned with the Ministerial Policy Guideline on the Regulation of Infant Formula Products (ANZ FRMC, 2011) and international regulations. FSANZ is of the view that pre-market assessment of emerging plant based proteins allows innovation to occur while still protecting the health and safety of infants. As this is a specialised product used as sole source of nutrition within a vulnerable population, certainty is needed. Through pre-market assessment the protein source will need to demonstrate that it is safe, suitable, and provides benefit to normal growth and development, while also not interfering with absorption of other essential nutrients.

The proposed protein sources for infant formula include protein hydrolysates of one or more proteins normally used in infant formula. Protein hydrolysates in infant formula must only be *partially hydrolysed* with the purpose of meeting protein and amino acid requirements prescribed in the essential nutrient composition. A protein source that has been concentrated, refined or synthesised (e.g. hydrolysed) to a point of purification is considered a nutritive substance and will require pre-market approval (as per section 1.1.2 —12). Further to this, any enzyme used in the preparation of protein hydrolysates for infant formula needs to be approved within the Code.

Extensively hydrolysed proteins are only permitted in Special Medical Purpose Products for infants (SMPPi). SMPPi are highly specialised products, specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition for which standard infant formula or follow-on formula is not suitable. Further, extensively hydrolysed proteins require higher levels of differing food additives to support the feasibility and stability of the formula, which are not permitted in infant formula. The SMPPi category enables this increased flexibility to support the products special medical purpose. Further information on SMPPi can be found in section 2 and 3 of the CFS and SD4.

Further information on modified infant formula products can be found in section 4.4 below.

For the above reasons, FSANZ's preferred approach is that the 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 will need to undergo a premarket assessment through FSANZ.

LA

FSANZ 2021 CP2 proposed to retain the current minimum requirement (90 mg/100 kJ) for LA within Standard 2.9.1 and to align the maximum (GUL) with Codex CXS 72-1981 (330 mg/100 kJ).

Fourteen submitters (eight industry, one public health and five government) commented on the proposed approach. Most industry submitters agreed with the proposed approach to maintain the current minimum requirement for LA 90 mg/100 kJ as this allows for the lower end of the LA:ALA ratio of 5.1 to be achieved. Those submitters that did not support the proposed approach to maintain the current minimum requirement for LA 90 mg/100 kJ, preferred to align with EU 2016/127 and cited the Ministerial Policy Guideline on the Regulation of Infant Formula Products (ANZ FRMC, 2011) and breast milk minimums. One submitter commented on the maximum stating that there was no justification to align with the Codex CXS 72-1981 level of 330 mg/100 kJ as the highest levels found in breast milk are 300 mg/100 kJ.

These comments were raised in previous consultation and have been addressed in FSANZ 2021 CP2 Section 5.3, with no new information to add. Therefore, FSANZ's preferred approach is to retain the current minimum requirement (90 mg/100 kJ) for LA within Standard 2.9.1 and to align the maximum (GUL) with Codex CXS 72-1981 (330 mg/100 kJ).

DHA

FSANZ 2021 CP2 proposed to retain the DHA maximum within infant formula and change the units of expression from % total fatty acids to mg/100 kJ.

Eleven submitters (eight industry, one public health and two government) commented on the proposed approach. Most submitters supported the proposal for DHA to remain optional and in amounts not higher than AA when. However, the GUL of 0.5% of total fatty acids was not supported. It was suggested the GUL for DHA should be increased to 1.0%, noting that the mean levels of DHA in breast milk are reported to be 0.32% +/- 0.22% (SD) with a range of 0.06-1.4% and DHA preferably reaches 0.5% fatty acids, therefore 0.5% would be a target in accordance with this recommendation (Koletzko, 2020).

FSANZ 2016 Nutrition Assessment considered that the current maximum proportion of 1% total n-3 LC-PUFA in Standard 2.9.1 consists of DHA and smaller proportions of EPA and other n-3 LC-PUFA. From a review of specifications for DHA oil in the Code (Standard 1.3.4 – Identity and Purity), it is possible that present formulations of infant formula contain slightly more DHA than the Codex CXS 72-1981 GUL of 0.5% total fatty acids. However, FSANZ concluded that there was minor or no impact expected on current infant formula formulations if the maximum for all n-3 LC-PUFAs in the Code were replaced by a GUL for DHA (and other relevant ratios).

Based on alignment with Codex CXS 72-1981 and the Codex Draft Standard for FuFOI, FSANZ's preferred option is to retain the DHA GUL within infant formula and change the units of expression from % total fatty acids to mg/100 kJ, in section 29—8. A DHA GUL of 0.5% total fatty acids, as prescribed in Standard 2.9.1, converted using maximum fat content (1.5 g/100 kJ) is equivalent to 7.2 mg/100 kJ of DHA.

LC-PUFA (specifically DHA) as voluntary ingredients

FSANZ 2021 CP2 proposed retaining the voluntary permission for DHA. Four submitters (one industry, one public health and two government) commented on this approach. Industry supported the retention of DHA and other LC-PUFA's as a voluntary ingredient, however other submitters did not support the proposed approach and noted that addition of voluntary ingredients, such as LC-PUFA's, are used to market products as 'premium' and these ingredients should be assessed for a substantiated beneficial effect and if no effect is found the permission to add voluntarily should be removed.

FSANZ reiterates the findings of FSANZ 2016 Nutrition Assessment which state the mandatory inclusion of a minimum amount of DHA was based on mixed and inconclusive studies on infant development. Further to this, the assessment concluded that a mandatory minimum for DHA was not supported by the evidence and that it is appropriate to control DHA when present with a guidance limit. This approach is reiterated by the Codex Draft Standard for FuFOI. The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) has agreed that the addition of DHA to follow-up formula for older infants remain optional as there remains a lack of rigorous studies or scientific consensus as to the need to mandate its addition. Moreover, the CCNFSDU noted that the optional addition of DHA to follow-on formula should align with that specified in the Infant Formula Standard (Codex CXS 72-1981) and also concluded that the addition of ARA and EPA remain as optional.

In regard to submitter concerns, FSANZ acknowledges that some products are marketed as 'premium' within product ranges. However, within the 2021 label survey a correlation between labelling as 'premium' and the product price was not evident. Product differentiation is common practice within the food industry and is also beneficial to international exports.

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 rationale and aligning with the conclusions of FSANZ 2016 CP and FSANZ 2021 CP2, Codex CXS 72-1981 and the Codex Draft Standard for FuFOI, FSANZ proposes to retain the current voluntary addition of DHA and other LC-PUFA's.

Fat Source

FSANZ 2021 CP2 proposed retaining the current prescription on fat sources. Standard 2.9.1 does not specify or prohibit any particular sources of fat. Instead, specific requirements which restrict fat composition are listed in section 2.9.1—11 and section S29—8. Submitters to FSANZ 2021 CP2 were all supportive of this approach and therefore FSANZ will progress with the CP2 approach.

One government submitter outlined the Codex CXS 72-1981 prohibition on commercially hydrogenated oils that may contain industrial TFA. This issue was addressed in section 5.6.2 of FSANZ 2021 CP2, which concluded that aligning with Codex CXS 72-1981 for TFA would require a change in the definition of TFA in the Code. FSANZ considers this to be out of scope for the proposal. The proposed option is to retain the current restriction for TFA at 4% of total fatty acids. FSANZ considers this an appropriate requirement as TFA are naturally occurring as endogenous components of milk fat and allowing total TFA content at a maximum of 4% of total fatty acids still provides adequate restrictions on the amount of TFA,

including those that are commercially hydrogenated.

Medium Chain Triglycerides

FSANZ 2021 CP2 proposed to retain the current restrictions on MCT.

Eight submitters (six industry and two government) commented on the proposed approach. Government submitters supported the proposed approach. Industry submitters did not support the proposed approach citing a lack of safety concerns and misalignment internationally. Of those that did not support, most requested that the definition be clarified to include 'oil' e.g. "medium chain triglyceride oil means oil containing triacyglycerols that contain predominantly the saturated fatty acids designated by 8:0 and 10:0."

Safety concerns and international alignment were addressed in FSANZ 2021 CP2. Changes to definitions are out of scope for P1028. Therefore, FSANZ proposes to retain the current restrictions on MCTs.

Trans Fatty Acids

FSANZ 2021 CP2 proposed to retain the current restriction for TFA at 4% of total fatty acids.

Six submitters (four industry and two government) commented on the proposed approach. Industry submitters supported the proposed approach however some requested that FSANZ review the definition of trans fatty acids in the Code to align more closely with the Codex CXS 72-1981 definition. This is addressed above and FSANZ proposes to retain the current restriction for TFA at 4% of total fatty acids.

Phospholipids

FSANZ 2021 CP2 proposed to set the maximum permitted amount of phospholipids (PL) at at 2 g/L (72 mg/100 kJ) and the maximum lecithin amount to 1 g/L (option 3). Nine submitters (seven industry and two government) commented on the proposed approach. Industry submitters supported a limit being set on phospholipids only (option 1) but the limit being a GUL rather than a maximum. Industry submitters also commented on lecithin not being included in FSANZ 2021 CP1 given it is a food additive. This is out of scope for Proposal P1028. Government submitters supported setting a limit of 1 g/L for lecithin but sought further assessment to determine scientific rationale for phospholipids addition as a nutritive substance and for the amounts permitted. The issues raised by submitters were raised in the FSANZ 2016 CP and addressed in the FSANZ 2021 CP2 Section 5.6.3.

FSANZ proposes to set the maximum permitted amount of phospholipids (PL) at at 2 g/L (72 mg/100 kJ) and the maximum lecithin amount to 1 g/L (option 3).

Carbohydrate Source

FSANZ 2021 CP2 proposed to adopt limits on sucrose and fructose that are aligned with Codex CXS 72-1981. Nine submitters (six industry and three government) commented on the proposed approach. Most submitters did not agree. Of those that opposed, most industry submitters preferred option 1 (no restrictions on carbohydrate source) and most government submitters preferred option 3 (adopt guidelines from EU 2016/127). Industry submitters cited no current safety failure, no barrier to trade and opposition to a positive list of permitted carbohydrates. Government submitters cited glucose should also be limited.

FSANZ proposes to adopt limits on sucrose and fructose that are aligned with Codex CXS 72-1981. This option is supported by safety concerns cited in previous consultations,

FSANZ's safety assessment conducted in 2002 and by international requirements that come into place in 2020 that are in line with Codex CXS 72-1981.

2.1.3 Preferred composition

Table 2.1.3 Preferred macronutrient composition for infant formula

Nutrient	Unit	Change Proposed	Proposed Approach		Standard 2.9.1 (Schedule 29)		Codex CXS 72-1981		EU 2016/127	
		(Y/N)	Min	Max	Min	Max	Min	Max	Min	Max
Energy	kJ/L	Yes	2500	2950	2500	3150	2500	2950	2500	2930
Protein (cow)	g/100 kJ	Yes	0.43	0.7	0.45	0.7	0.45	0.7	0.43	0.6
Protein (soy)	g/100 kJ	Yes	0.54	0.7	NS	NS	0.5	0.7	0.54	0.67
Total fat	g/100 kJ	Yes	1.05	1.4	1.05	1.5	1.05	1.4	1.1	1.4
LA	mg/100 kJ	Yes	90	330*	90	371	70	330*	120	300
ALA	mg/100 kJ	Yes	12	NS	11	57	12	NS	12	24
DHA	mg/100kJ	Yes	NS	7.2	NS	NS	NS	0.5^	4.8	12
PL	g/L	Yes	NS	2	NS	NS	NS	2	NS	2
TFA	% total FA	No	NS	4	NS	4	NS	3	NS	3
Myristic & Lauric acid	% total FA	No	NS	NS	NS	NS	NS	20	NS	NS
Erucic Acid	% total FA	No	NS	1	NS	1	NS	1	NS	0.4
AA	% total FA	No	NS	1	NS	1	≥ DHA	NS	NS	1
Carbohydrate	g/100 kJ	No	NS	NS	NS	NS	2.2	3.3	2.2	3.3

* = GUL ^ = % total fatty acids

Retain restrictions on inulin-type fructans and galacto-oligosaccharides in Standard 2.9.1—7.

Additional proposed macronutrient requirements such as sources, factors and quality are noted within sections 2.1.1 and 2.1.2 above.

2.2 Micronutrients

2.2.1 Stakeholder views

Table 2.2.1 Micronutrient issues raised by stakeholders

Issue & FSANZ 2021 CP2 proposed approach	Raised by	FSANZ response
Vitamin A (14 - 43 µg RE/100 kJ)	5 submissions (2 industry, 3 government)	Industry submitters agreed with the proposed approach. Government submitters did not agree with the proposed maximum. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Vitamin D (0.25 – 0.63 µg /100 kJ)	3 submissions (2 industry, 1 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Vitamin E (0.12 - 1.2* mg α-TE /100 kJ)	5 submissions (3 industry, 2 government)	While the proposed range was acceptable to submitters, most preferred to align with the EU's slightly higher minimum. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.

Vitamin K (0.24 – 6.5* µg /100 kJ)	4 submissions (2 industry, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Thiamin (10 - 72* µg /100 kJ)	5 submissions (3 industry, 2 government)	While submitters supported retaining the current minimum of 10 ug/100 kJ, some would prefer this aligned with the EU 2016/127 value of 9.6 ug/100 kJ. Most submitters supported increasing the current maximum (GUL). However one government submitter did not support this approach. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Riboflavin (14.3 - 95.6* µg /100 kJ)	5 submissions (3 industry, 2 government)	Government submitters agreed with the proposed approach to align with the EU 2016/127 permitted range. Industry submitters did not agree with the proposed approach. After assessment, FSANZ's preferred option is to retain the CP2 approach for the minimum and adopt the Codex CXS 72-1981 GUL of 119 µg/100 kJ for the reasons stated below.
Niacin (70 - 360* µg /100 kJ)	3 submissions (2 industry, 1 government)	Industry submitters agreed with the proposed approach. The government submitter supported aligning with EU 2016/127 range rather than Codex CXS 72-1981. This issue was considered in FSANZ 2021 CP2 and is addressed again in Section 2.2.2 of this document. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Vitamin B6 (8.5 - 45* µg /100 kJ)	4 submissions (2 industry, 2 government)	Industry submitters agreed with the proposed approach to align with the Codex CXS 72-1981 permitted range. Government submitters supported aligning with EU 2016/127 minimum and reconsidering the maximum to more closely align with breast milk. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Vitamin B12 (0.025 - 0.36 µg /100 kJ)	3 submissions (2 industry, 1 government)	Industry submitters agreed with the proposed approach to align with the Codex CXS 72-1981 permitted range. The government submitter supported aligning with EU 2016/127 ranges. This issue was considered in FSANZ 2021 CP2 and is addressed again in Section 2.2.2 of this document. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated

		in FSANZ 2021 CP2.
Pantothenic acid (96 - 478 µg /100 kJ)	4 submissions (3 industry, 1 government)	Industry submitters agreed with the proposed approach to align with the Codex CXS 72-1981 permitted range. The government submitter supported aligning with EU 2016/127 ranges. This issue was considered in FSANZ 2021 CP2 and is addressed again in Section 2.2.2 of this document. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Folic acid (2.5 - 12* µg /100 kJ)	5 submissions (3 industry, 2 government)	Industry submitters agreed with the proposed approach to align with the Codex CXS 72-1981 permitted range. The government submitter supported aligning with EU 2016/127 ranges. This issue was considered in FSANZ 2021 CP2 and is addressed again in Section 2.2.2 of this document. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Vitamin C (1.7 - 17* mg/100 kJ)	4 submissions (2 industry, 2 government)	Industry submitters agreed with the proposed approach. Government submitters did not support the proposed approach. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Biotin (0.24 - 2.4* µg /100 kJ)	4 submissions (2 industry, 2 government)	Industry and one government submitter agreed with the proposed approach. One government submitter agreed with the proposed approach for the minimum but supports aligning the maximum with the EU 2016/127 (1.8 ug/100 kJ). After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Iron (0.2 - 0.5 mg/100 kJ)	7 submissions (5 industry, 2 government)	Industry submitters agreed with the proposed approach for the maximum range but did not support the proposed minimum, instead supporting the Codex CXS 72-1981 minimum level of 0.1 mg/100 kJ. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Calcium (12 - 35* mg/100 kJ)	3 submissions (2 industry, 1 government)	Industry submitters agreed with the proposed approach to align with the Codex CXS 72-1981 permitted range. The government submitter supported aligning with EU 2016/127 ranges. This issue was considered in FSANZ 2021

		CP2 and is addressed again in Section 2.2.2 of this document. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Phosphorus (6 - 24* mg/100 kJ)	2 submissions (2 industry)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Magnesium (1.2 - 3.6 mg/100 kJ)	3 submissions (2 industry, 1 government)	Industry submitters agreed with the proposed approach to align with the Codex CXS 72-1981 permitted range. The government submitter supported aligning with EU 2016/127 ranges. This issue was considered in FSANZ 2021 CP2 and is addressed again in Section 2.2.2 of this document. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Sodium (5 - 14 mg/100 kJ)	3 submissions (2 industry, 1 government)	Industry submitters agreed with the proposed approach to align with the Codex CXS 72-1981 permitted range. The government submitter supported aligning with the EU 2016/127 ranges. This issue was considered in FSANZ 2021 CP2 and is addressed again in Section 2.2.2 of this document. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Chloride (12 - 38 mg/100 kJ)	3 submissions (2 industry, 1 government)	Industry submitters agreed with the proposed approach to align with the Codex CXS 72-1981 permitted range. The government submitter supported aligning with the EU 2016/127 ranges. This issue was considered in FSANZ 2021 CP2 and is addressed again in Section 2.2.2 of this document. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Potassium (14 - 43 mg/100 kJ)	3 submissions (2 industry, 1 government)	Industry submitters agreed with the proposed approach to align with the Codex CXS 72-1981 permitted range. The government submitter supported aligning with the EU 2016/127 ranges. This issue was considered in FSANZ 2021 CP2 and is addressed again in Section 2.2.2 of this document. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.

Manganese (0.25 - 24* µg /100 kJ)	3 submissions (2 industry, 1 government)	Industry submitters agreed with the proposed approach to align with the Codex CXS 72-1981 permitted range. The government submitter supported aligning with the EU 2016/127 ranges. This issue was considered in FSANZ 2021 CP2 and is addressed again in Section 2.2.2 of this document. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Iodine (3.6 - 10 µg /100 kJ)	10 submissions (7 industry, 3 government)	Industry submitters do not agree with the proposed approach, instead supporting alignment with the Codex CXS 72-1981 range. Government submitters support the proposed approach to align with the EU 2016/127 minimum but one does not support the proposed maximum. After assessment, FSANZ's preferred option is to adopt the Codex CXS 72-1981 range of 2.5 – 14 µg/100 kJ for the reasons stated below.
Selenium (0.48 - 2.0 µg /100 kJ)	8 submissions (7 industry, 1 government)	All submitters agreed with the proposed approach to increase the minimum to 0.48 µg/100 kJ. The government submitter supported the proposed approach for the maximum. Industry submitters did not support the proposed approach for the maximum, instead supporting alignment with the Codex CXS 72-1981 GUL and not setting a maximum. After assessment, FSANZ's preferred option is to retain the selenium minimum proposed in CP2 and adopt the Codex CXS 72-1981 GUL of 2.2 µg/100 kJ, for the reasons stated below.
Copper (8.5 - 29* µg /100 kJ)	4 submissions (2 industry, 2 government)	Industry submitters agreed with the proposed approach to align with the Codex CXS 72-1981 permitted range. Government submitters did not agree with the proposed approach. See discussion below for further information. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Zinc (0.12 - 0.36* mg/100 kJ)	5 submissions (2 industry, 3 government)	Industry submitters agreed with the proposed approach to align with the Codex CXS 72-1981 permitted range. Government submitters did not agree with the proposed approach. This issue was considered in FSANZ 2021 CP2 and is addressed again in Section 2.2.2 of this document. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.

2.2.2 Discussion

Vitamin A

FSANZ 2021 CP2 proposed retaining the current permitted range for vitamin A as it aligned with Codex CXS 72-1981 and breast milk concentrations. In addition to international alignment, this was also based on the absence of data indicating that the current maximum of 43 µg/100 kJ is associated with adverse health effects in infants, the uncertainty around the basis for EU 2016/127, and the objective of this proposal to align with Codex CXS 72-1981 where possible.

Five submitters (two industry, three government) commented on the proposed option. Two submitters supported the proposed approach. Three submitters did not support the proposed maximum based on the Codex CXS 72-1981 maximum equating to infant intakes that would exceed upper levels and the lower EU 2016/127 maximum (27.2 µg/100 kJ) resulting in a slight exceedance of the UL for infants aged 6-12 months, but within the range considered to pose low risk to infant health.

FSANZ 2016 Nutrition Assessment determined that the existing maximum could lead to exceedance of the National Health and Medical Research Council (NHMRC) UL for vitamin A (600 µg/100 kJ) for infants 0-12 months but this exceedance was unlikely to occur continuously over the period of formula feeding. There was no additional evidence that the current maximum amount was associated with adverse health effects.

Based on no new evidence being present and alignment with Codex CXS 72-1981, Codex Draft Standard for FuFOI and breast milk concentrations, FSANZ's preferred option is to retain the current permitted range for vitamin A.

Vitamin E

FSANZ 2021 CP2 proposed adopting the Codex STAN 72-1981 vitamin E minimum and GUL (0.12 – 1.2 mg α-TE/100 kJ).

Five submitters (three industry and two government) commented on the proposed option, preferring to instead align with the EU 2016/127 slightly higher minimum (0.14 mg/100 kJ) on the basis that it is derived from more recent evidence. However, Codex has more recently proposed the same vitamin E minimum and GUL as Codex STAN 72-1981 for the Codex Draft Standard for FuFOI.

Based on alignment with Codex CXS 72-1981 and the Codex Draft Standard for FuFOI, FSANZ's preferred option is to adopt the range of 0.12 – 1.2 mg α-TE/100 kJ.

Thiamin

FSANZ 2021 CP2 proposed retaining the current Standard 2.9.1 minimum of 10 µg/100 kJ. FSANZ also proposed revising the GUL to 72 µg/100 kJ to align with Codex CXS 72-1981. All submitters supported retaining the current minimum however, some would prefer it was aligned with the slightly lower EU 2016/127 value of 9.6 µg/100 kJ. FSANZ 2021 CP2 notes that the current minimum (which is similar to EU 2016/127) is more consistent with breast milk concentration. No trade implications would result as products formulated at the lower minimum will still meet Codex CXS 72-1981.

While most submitters supported revising the current maximum (GUL) to 72 µg/100 kJ to align with Codex CXS 72-1981, this was not supported by one government submitter that noted that the proposed maximum was six times higher than the levels found in breast milk

and considered that no rationale was provided for the change. The maximum was considered in the FSANZ 2016 Nutrition Assessment 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. Therefore the FSANZ 2016 Nutrition Assessment concluded that aligning the maximum with Codex CXS 72-1981 is unlikely to pose a risk to infant health.

Based on the above information FSANZ's preferred option is to retain the current Standard 2.9.1 minimum of 10 µg/100 kJ and revise the GUL to 72 µg/100 kJ.

Riboflavin

FSANZ 2021 CP2 proposed revising the permitted range for riboflavin to align with the EU 2016/127 range of 14.3 to 95.6 µg/100 kJ.

Five submitters (three industry, two government) commented on the proposed option. Government submitters supported the proposed option. Industry submitters did not support the proposed option, instead preferring to align with the current Standard 2.9.1 minimum of 14 µg/100 kJ and the Codex CXS 72-1981 maximum of 119 µg/100 kJ as the FSANZ 2016 Nutrition Assessment concluded that the permitted range under Codex CXS 72-1981 would provide a low risk to infant health.

Additional assessment in 2021 re-examined FSANZ's preliminary view on the permitted range for riboflavin and considered whether the range set under EU 2016/127 poses a low risk to infant health. FSANZ concluded that the permitted range under both Codex CXS 72-1981 and EU 2016/127 would pose a low risk to infant health.

Regarding the minimum, the EU 2016/127 minimum is unlikely to impact trade since products formulated at the lower minimum would still meet Codex CXS 72-1981. The riboflavin content in infant formula currently sold in Australia and New Zealand is consistent with EU 2016/127.

Regarding the maximum, the Codex CXS 72-1981 GUL also aligns with the Codex Draft Standard for FuFOI and allows for formula that may need to comply to both Codex CXS 72-1981 and the EU 2016/127 to do so. As there are no nutritional adequacy or safety risks associated with adopting the Codex CXS 72-1981GUL, as concluded by the FSANZ 2016 and 2021 Nutrition Assessments, and this value better aligns with the Codex Draft Standard for FuFOI, FSANZ has proposed to adopt a GUL of 119 µg/100 kJ for infant formula.

Based on the above information FSANZ's preferred option is to revise the permitted range for riboflavin to align with the EU 2016/127 minimum of 14.3 µg/100 kJ and the Codex CXS 72-1981 GUL of 119 µg/100 kJ.

Vitamin B6

FSANZ 2021 CP2 proposed to revise the permitted range for vitamin B6 by adopting the Codex CXS 72-1981 range of 8.5 - 45 µg/100 kJ.

Four submitters (two industry, two government) commented on the proposed approach. Industry submitters supported the proposed approach to align with Codex CXS 72-1981. Government submitters did not support the proposed approach indicating that the Codex CXS 72-1981 range is not based on the minimum and maximum levels in breast milk.

The FSANZ 2021 Nutrition Assessment estimated vitamin B6 intake using the EU 2016/127 minimum amount against the AI. This showed that infants aged 0 - 6 months met the AI,

however was substantially lower than half the AI value for infants aged 6 - 12 months. Therefore, the assessment concluded that use of the EU 2016/127 minimum amount of 4.8 µg/100 kJ may pose a risk to infant health. The minimum amount of 9 µg/100 kJ in Schedule 29 or 8.5 µg/100 kJ in Codex CXS 72-1981 would mitigate this risk.

The FSANZ 2016 Nutrition Assessment determined that intakes based on the Codex CXS 72-1981 permitted range are unlikely to pose a risk to infant health. There was also no evidence indicating excessive vitamin B6 intakes in formula-fed infants.

The minimum proposed in FSANZ 2021 CP2 also closely aligns with the minimum prescribe in both follow-on formula regulations (Codex Draft Standard for FuFOI and the EU 2016/127 ANNEX II). The basis for the proposed vitamin B6 maximum was alignment with international standards, no ANZ UL for vitamin B6 for infants aged 0 – 12 months and of vitamin B6 toxicity in ANZ formula fed infants.

Based on the above, FSANZ's preferred option is to align with the Codex CXS 72-1981 permitted range for vitamin B6 of 8.5 - 45 µg/100 kJ.

Vitamin C

FSANZ 2021 CP2 proposed to retain the current minimum in Standard 2.9.1 for vitamin C of 1.7 mg/100 kJ and align the maximum with the Codex CXS 72-1981 maximum of 17 mg/100 kJ.

Four submitters (two industry, two government) commented on this approach. Most submitters supported the proposed approach. One government submitter supported aligning the minimum to the Codex CXS 72-1981 minimum of 2.5 mg/100 kJ and aligning the maximum to the EU 2016/127 maximum of 7.2 mg/100 kJ.

FSANZ's 2013-14 label survey (Appendix 1 – Labelled composition available on the ANZ market) indicated that the lowest labelled vitamin C content in the sample was 1.8 mg/100 kJ. If the Codex CXS 72-1981 of 2.5 mg/100 kJ was adopted, some manufacturers may need to adjust formulations to comply. The highest reported content was 6.8 mg/100 kJ. The survey mainly consisted of powdered products.

FSANZ needs to consider all forms of infant formula. The FSANZ 2016 Nutrition Assessment concluded that the increased maximum is unlikely to pose a risk to infant health. The higher Codex CXS 72-1981 GUL takes into account possible higher losses of vitamin C. The Codex Electronic Working Group review of the Codex Draft Standard for FOI noted that during normal storage conditions significant losses in vitamin C can occur during the shelf life of products, ranging from 20 to 50% in powdered products and up to 75% in liquid products. Allowing for potential breakdown losses of 75%, 72 mg/100 kJ could be reduced over the shelf life of a liquid infant formula to 1.8 mg/100 kJ. Based on median energy intake and assuming consumption of 0.8 L/day, this amount translates to an intake of 39 mg/day. The NHMRC AI for vitamin C is 25 mg/day for infants. Given that heat is also known to affect stability of vitamin C, it is possible that the level in infant formula could be further reduced during preparation.

Based on the above, FSANZ's preferred option is to retain the current minimum in Standard 2.9.1 for vitamin C of 1.7 mg/100 kJ and align the maximum with the Codex CXS 72-1981 maximum of 17 mg/100 kJ.

Biotin

FSANZ 2021 CP2 proposed to adopt the EU 2016/127 minimum (0.24 µg /100 kJ) and the

Codex CXS 72-1981 GUL (2.4 µg /100 kJ). This range was proposed as it aligns closely with breast milk biotin concentrations and was unlikely to impact trade since products formulated for either EU 2021/127 or Codex CXS 72-1981 were accounted for within the range.

Four submitters (two industry and two government) commented on the proposed approach. Submitters supported adopting the EU 2016/127 minimum, noting one government submitter raised concerns regarding if the minimum needs of older infants would be met by the proposed range (addressed in SD4). Most submitters supported the proposed GUL, however one government submitter preferred adopting the EU 2016/127 maximum.

FSANZ's preferred option is to retain the proposed option from FSANZ 2021 CP2 of 0.24 - 2.4 (GUL) µg /100 kJ. The proposed range does not pose nutritional adequacy or safety risks to ANZ infants and the maximum more closely aligns with breast milk concentrations and the GUL proposed in Codex Draft Standard for FuFOI.

Iron

FSANZ 2021 CP2 proposed to retain the current S29—9 range for iron of 0.2 – 0.5 mg/100 kJ.

Seven submitters (five industry, two government) commented on the proposed approach. Industry submitters considered that the minimum level of iron 0.20 mg/100 kJ does not allow European formulated products complying to the Codex CXS 72-1981 minimum of 0.11 mg/100 kJ to be imported directly into ANZ without prior reformulation. One government submitter suggested that further consideration is required to determine the minimum and maximum levels. One government submitter supported a range of 0.14 – 0.31 mg/100 kJ in cow's milk-based formula.

The FSANZ 2016 Nutrition Assessment concluded that lowering the minimum to the Codex CXS 72-1981 minimum could pose a risk to infant health as the Codex CXS 72-1981 minimum is substantially lower than Standard 2.9.1. The 2021 Nutrition Assessment compared the minimum in Standard 2.9.1 to the levels in breast milk. The minimum amount (0.2 mg/100 kJ) would equate to an estimated absorbed iron of 0.02 mg/100 kJ from cow's milk-based formula and 0.014 mg/100 kJ from soy-based formula. The estimated iron absorbed from infant formula when using the minimum level in Standard 2.9.1 would be almost double that from breast milk (0.012 – 0.013 mg/100 kJ).

The minimum amounts in EU 2016/127 are lower than the average amount in breast milk when accommodating for difference in absorption.

Based on the above rationale and close alignment with the proposed Codex Draft Standard for FuFOI, FSANZ's preferred option is to retain the range of 0.2 – 0.5 mg/100 kJ.

FSANZ also considered submitter comments regarding setting a separate iron range for soy based formulas. The majority of submitters agreed with FSANZ proposed approach and noted that the range proposed by FSANZ accounts for older infants and soy-based formulas, and therefore it is unnecessary to set different iron levels for soy based formulas.

Iodine

FSANZ 2021 CP2 proposed to align the minimum amount with EU 2016/127 (3.6 µg/100 kJ) and retain the S29—9 maximum (10 µg/100 kJ).

Ten submitters (seven industry, three government) commented on the proposed approach. Industry submitters did not agree with the proposed approach, instead supporting alignment

with the Codex CXS 72-1981 range (2.5 – 14 µg/100 kJ). One government submitter supported alignment with the EU 2016/127 maximum (6.9).

In light of submitter comments and the re-inclusion of follow-on formula into proposal P1028 FSANZ considers it appropriate to reassess the proposed approach with further consideration given to the Codex Draft Standard for FuFOI. The FSANZ 2016 Nutrition Assessment concluded that the Codex CXS 72-1981 prescribed range would be unlikely to pose risk to infant health, for both 0-6 and 6-12 months and was appropriate for ANZ infants. More recently the proposed draft Codex Standard for FuFOI includes the same range.

Based on the above discussions, FSANZ's preferred option is to align with the Codex CXS 72-1981 and Codex Draft Standard for FuFOI proposed range of 2.5 – 14 µg/100 kJ. This range also closely aligns with the EU's follow-on formula range for iodine of 2.5 – 12 µg/100 kJ.

Selenium

FSANZ 2021 CP2 proposed to increase the selenium minimum to 0.48 µg /100 kJ. This level is consistent with recent international regulations, would meet the ANZ AI and is slightly higher than breast milk concentrations of ANZ mothers, a population that may not be selenium sufficient. FSANZ also proposed to increase the maximum level for selenium to 2.0 µg /100 kJ to align with EU 2016/127.

Eight submitters (seven industry and one government) commented on selenium. Industry submitters did not support the proposed approach for the maximum, instead supporting alignment with the Codex CXS 72-1981 and Codex Draft Standard for FuFOI GUL of 2.2 µg /100 kJ.

In light of inclusion of follow-on formula into the proposal, FSANZ's preferred option is to now align, where possible, with the proposed Codex Draft Standard for FuFOI. The FSANZ 2016 Nutrition Assessment concluded that the Codex GUL was unlikely to pose a risk to infant health and the 2021 Nutrition Assessment noted that for breast milk concentrations equivalent to 2.2 µg/100 kJ were not associated with adverse effects.

Based on the above discussion, FSANZ's preferred option is to retain the proposed minimum of 0.48 µg /100 kJ and align with the proposed Codex Draft Standard for FuFOI GUL of 2.2 µg /100 kJ.

Copper

FSANZ 2021 CP2 proposed to align the permitted range for copper with Codex CXS 72-1981 at 8.5 – 29 (GUL) µg /100 kJ.

Four submitters (two industry and two government) commented on the proposed approach. Industry submitters agreed with the proposed approach however government submitters did not, instead suggesting that the minimum should be at least 9.2 µg/100 kJ and the maximum should be 24 µg/100 kJ, in line with EU 2016/127. Government submitters commented that the Codex CXS 72-1981 minimum factors in additional copper from added water and that ready-to-feed formulas may not meet the daily requirement. They also commented that the EU 2016/127 maximum best reflects breast milk.

The FSANZ 2016 Nutrition Assessment noted that the Codex CXS 72-1981 minimum is within the reported range for breast milk from studies conducted in Japan and the United States (Casey 1995, Yamawaki 2005, Lonnerdal 2008). Based on European studies, EFSA 2014 reported a higher range of copper in breast milk which is the basis for the EU 2016/127

minimum. FSANZ notes that copper deficiency is rare in humans except pre-term infants. In addition, the Codex CXS 72-1981 levels have been proposed for inclusion in the Codex Draft Standard for FuFOI.

Based on the above discussion, FSANZ's preferred option is to align the permitted range for copper to with Codex CXS 72-1981at 8.5 – 29 (GUL) µg /100 kJ.

2.2.3 Preferred composition

Table 2.2.3 Preferred micronutrient composition for infant formula

Nutrient	Unit	Change Proposed	Proposed Approach		Standard 2.9.1 (Schedule 29)		Codex CXS 72-1981		EU 2016/127	
		(Y/N)	Min	Max	Min	Max	Min	Max	Min	Max
Vitamin A	µg RE/100 kJ	No	14	43	14	43	14	43	16.7	27.2
Vitamin D	µg /100 kJ	No	0.25	0.63	0.25	0.63	0.25	0.6	0.48	0.6
Vitamin E	mgα-TE/100kJ	Yes	0.12	1.2*	0.11	1.1	0.12	1.2*	0.14	1.2
Vitamin K	µg /100 kJ	Yes	0.24	6.5*	1	5.0*	1	6.5*	0.24	6
Thiamin	µg /100 kJ	Yes	10	72*	10	48*	14	72*	9.6	72
Riboflavin	µg /100 kJ	Yes	14.3	119*	14	86*	19	119*	14.3	95.6
Niacin	µg /100 kJ	Yes	70	360*	130	480*	70	360*	100	360
Vitamin B6	µg /100 kJ	Yes	8.5	45*	9	36	8.5	45*	4.8	41.8
Vitamin B12	µg /100 kJ	Yes	0.025	0.36*	0.025	0.17*	0.025	0.36*	0.02	0.12
Pantothenic acid	µg /100 kJ	Yes	96	478*	70	360*	96	478*	100	480
Folic acid	µg /100 kJ	Yes	2.5	12*	2	8	2.5	12*	3.6	11.4
Vitamin C	mg/100 kJ	Yes	1.7	17*	1.7	5.4*	2.5	17*	0.96	7.2
Biotin	µg /100 kJ	Yes	0.24	2.4*	0.36	2.7	0.4	2.4*	0.24	1.8
Iron	mg/100 kJ	No	0.2	0.5	0.2	0.5	0.1	NS	0.07	0.31
Calcium	mg/100 kJ	Yes	12	35*	12	33*	12	35*	12	33.5
Phosphorus	mg/100 kJ	Yes	6	24*	6	25	6	24*	6	21.5
Magnesium	mg/100 kJ	Yes	1.2	3.6*	1.2	4.0	1.2	3.6*	1.2	3.6
Sodium	mg/100 kJ	Yes	5	14	5	15	5	14	6	14.3
Chloride	mg/100 kJ	Yes	12	38	12	35	12	38	14.3	38.2
Potassium	mg/100 kJ	Yes	14	43	20	50	14	43	19.1	38.2
Manganese	µg /100 kJ	Yes	0.25	24*	0.24	24	0.25	24*	0.24	24
Iodine	µg /100 kJ	Yes	2.5	14*	1.2	10	2.5	14*	3.6	6.9
Selenium	µg /100 kJ	Yes	0.48	2.2*	0.25	1.19	0.24	2.2*	0.72	2
Copper	µg /100 kJ	Yes	8.5	29*	14	43	8.5	29*	14.3	24
Zinc	mg/100 kJ	Yes	0.12	0.36*	0.12	0.43	0.12	0.36*	0.12	0.24

* = GUL NS = not specified

2.3 Equivalents, conversion factors and units of expression

2.3.1 Stakeholder views

Table 2.3.1 Equivalents, conversion factors and units of expression issues raised by stakeholders

Issue & FSANZ 2021 CP2 proposed approach	Raised by	FSANZ response
Vitamin A (Express vitamin A as µg RE/100 kJ, and exclude β-carotene from the vitamin A	6 submissions (3 industry, 3 government)	Submitters agreed with the proposed approach to express vitamin A requirements as µg RE/100 kJ and exclude β-carotene from the vitamin A calculation. However, government

calculation)		submitters did not agree with retaining B-carotene as a permitted form of vitamin A in section 29–7. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Folic acid (Express folic acid/folate as µg folic acid/100 kJ. Naturally occurring folate will not be included in the permitted range.)	8 submissions (5 industry, 3 government)	Most industry submitters agreed with the proposed approach. Government submitters did not support the proposed approach. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Vitamin E (Adopt α-TE)	5 submissions (3 industry, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Niacin equivalents (Restricted to Niacinamide)	4 submissions (3 industry, 1 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Fatty Acids (LA, ALA, DHA) (mg/100 kJ)	9 submissions (5 industry, 4 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.

2.3.2 Discussion

Vitamin A

FSANZ 2021 CP2 proposed to express vitamin A requirements as µg RE/100 kJ, and exclude β-carotene from the vitamin A calculation, while retaining the permission for β-carotene as a permitted form of vitamin A in section S29–7.

Six submitters (three industry and three government) commented on the proposed approach. Industry submitters supported the proposed approach. Government submitters supported expressing vitamin A requirements as µg RE/100 kJ and excluding β-carotene from the vitamin A calculation but did not support retaining the permission for β-carotene as a permitted form of vitamin A in section S29–7. Government submitters noted there was no justification for its addition to infant formula and it could be misleading to permit it as a form of vitamin A but not calculate it.

Due to a lack of safety concern, FSANZ is reluctant to remove the existing permission. For this reason, and based on alignment with Codex CXS 72-1981, the Codex Draft Standard for FuFOI, EU 2016/127 and other international regulations, FSANZ's preferred option is to express vitamin A requirements as µg RE/100 kJ, and exclude β-carotene from the vitamin A calculation, while retaining the permission for β-carotene as a permitted form of vitamin A in section S29–7.

Folic acid

FSANZ 2021 CP2 proposed to express folic acid/folate as µg folic acid/100 kJ, with naturally occurring folate excluded from the permitted range. This proposal aligns with Codex CXS 72-1981 and with the Codex Draft Standard for FuFOI. One government submitter did not support this approach and instead supported the use of dietary folate equivalents (DFE) as it is consistent with the ANZ NRV's and the EU 2016/127. However, as addressed in FSANZ 2021 CP2, naturally occurring folate present in ingredients in infant formula, such as cow's and soy milk, is low or below the level of detection (Campos-Gimenez, 2018). The major component found in infant formulas is folic acid, which is added to meet the requirements for this vitamin. Because of this, use of DFE or applying extra analysis to measure the contribution of folate from ingredients is unjustified.

Another submitter requested that 'folate' be replaced with 'folic acid' in Schedule S29. FSANZ notes that this will be considered at the point when and if drafting of Code amendments occurs.

2.3.3 Preferred composition

Table 2.4.3 Preferred equivalents, conversion factors and units of expression for infant formula

Nutrient	Change Proposed	Proposed Approach	Standard 2.9.1 (Schedule 29)
	(Yes/No)	Equivalents	Equivalents
		Conversion Factors	Conversion Factors
		Units of Expression	Units of Expression
Vitamin A	No	Retinol, retinyl acetate, retinyl palmitate, retinyl propionate, β-carotene	Retinol, retinyl acetate, retinyl palmitate, retinyl propionate, β-carotene
	Yes	exclude β-carotene from the vitamin A calculation	NS
	No	µg RE/100 kJ	µg RE/100 kJ
Folic Acid	No	Folic acid	Folic acid
	Yes	Naturally occurring folate will not be included in the permitted range	NS
	No	µg / 100 kJ	µg / 100 kJ
Vitamin E	No	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	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
	No	NS	NS
	Yes	α-TE / 100 kJ	mg/100 kJ
Niacin	No	Niacinamide	Niacinamide
	No	Add niacin and any niacin provided from the conversion of the amino acid tryptophan, using the conversion factor 1:60.	Add niacin and any niacin provided from the conversion of the amino acid tryptophan, using the conversion factor 1:60.
	No	µg / 100 kJ	µg / 100 kJ
Fatty Acids (LA, ALA, DHA)	No	NA	NA
	No	NA	NA
	Yes	mg/100 kJ	% total fatty acids

NA = Not Applicable

2.4 Ratios

2.4.1 Stakeholder views

Table 2.4.1 Ratio issues raised by stakeholders

Issue & FSANZ 2021 CP2 proposed approach	Raised by	FSANZ response
Zn : Cu (remove)	4 submissions (3 industry, 1 government)	Industry submitters agreed with the proposed approach. One government submitter did not support the proposed approach. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
LA : ALA (5:1 – 15:1)	6 submissions (4 industry, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Ca : P (1 : 1)	5 submissions (4 industry, 1 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Vitamin E : fatty acids (0.5 mg vitamin E per gram of any PUFA)	6 submissions (5 industry, 1 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.

2.4.2 Discussion

Zn : Cu

FSANZ 2021 CP2 proposed that the prescribed Zn:Cu ratio be removed. This was based on the FSANZ 2016 Nutrition Assessment noting limited evidence to support the need for a Zn:Cu ratio in infant formula and concluded that removing the Zn:Cu ratio from Standard 2.9.1 would have minimal impact on micronutrient status of healthy term infants. Four submitters (three industry and one government) commented on this proposed option. The three industry submitters supported the proposed option. The government submitter supported a ratio as close to 10:1 as possible but suggested that if the ratio is removed, that guidance be included in Standard 2.9.1 for industry to provide zinc and copper in a ratio as close to 10:1 as possible. This was considered in response to submissions received to the FSANZ 2016 CP where the majority of submitters also supported removing the ratio. Based on the FSANZ 2016 Nutrition Assessment and FSANZ 2021 CP2, FSANZ's preferred option is to remove the Zn:Cu ratio from Standard 2.9.1.

2.4.3 Preferred composition

Table Preferred ratios for infant formula

Nutrient	Change Proposed (Y/N)	Proposed Approach		Standard 2.9.1 (Schedule 29)		Codex CXS 72-1981		EU 2016/127	
		Min	Max	Min	Max	Min	Max	Min	Max
Zn : Cu	Yes	NS	NS	NS	15 : 1	NS	NS	NS	NS
LA : ALA	No	5 : 1	15 : 1	5 : 1	15 : 1	5 : 1	15 : 1	NS	NS
Ca: P	Yes	1 : 1	2 : 1	1.2 : 1	2 : 1	1: 1	2 : 1	1: 1	2 : 1
Vitamin E : fatty acids	No	0.5mg : 1g	NS	0.5mg : 1g	NS	0.5mg : 1g	NS	NS	NS
EPA	No	NS	≤ DHA	NS	≤ DHA	NS	≤ DHA	NS	≤ DHA

NS = not specified

Ratio of total long chain omega 6 series fatty acids (C> = 20) to total long chain omega 3 series fatty acids (C> = 20) that is not less than 1.

2.5 Other nutritive substances

2.5.1 Stakeholder views

Table 2.5.1 Other nutritive substances issues raised by stakeholders

Issue & FSANZ 2021 CP2 proposed approach	Raised by	FSANZ response
Fluoride (Compositional limit of 24 µg/100 kJ)	8 submissions (7 industry, 1 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Choline (Listed as a mandatory substance)	9 submissions (6 industry, 1 public health, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Choline (Minimum: 1.7 mg/100 kJ)	8 submissions (5 industry, 1 public health, 2 government)	Most submitters agreed with the proposed approach. The government and public health submitters supported alignment with the EU 2016/127 minimum of 6 mg/100 kJ. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Choline (GUL: 12.0 mg/100 kJ)	7 submissions (5 industry, 1 public health, 1 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Choline (Permitted forms: choline chloride, choline bitartrate, choline, choline citrate and choline hydrogen tartrate)	4 submissions (4 industry)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
L-carnitine (Listed as a mandatory substance)	12 submissions (10 industry, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.

L-carnitine (Minimum: 0.3 g/100 kJ)	9 submissions (7 industry, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
L-carnitine (GUL: 0.8 mg/100 kJ)	11 submissions (9 industry, 2 government)	Only government submitters agreed with the proposed approach. Industry submitters did not agree with the proposed approach and did not support a GUL at all. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
L-carnitine (Permitted forms: L-carnitine hydrochloride and L-carnitine tartrate)	5 submissions (5 industry)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Inositol (Listed as a mandatory substance)	10 submissions (8 industry, 2 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Inositol (Minimum: 1.0 mg/100 kJ)	6 submissions (5 industry, 1 government)	Most submitters agreed with the proposed approach. One government submitter did not agree with the proposed approach. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Inositol (GUL: 9.5 mg/100 kJ)	6 submissions (5 industry, 1 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Inositol (Listing the permitted form of inositol as myo-inositol)	3 submissions (3 industry)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Nucleotides (Retain both the current permission in Schedule 29 and the maximum total limit of nucleotides prescribed in Standard 2.9.1.)	9 submissions (6 industry, 3 government)	There was mixed support for the proposed approach. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Chromium and molybdenum (Remove current GULs for general infant formula. Limits for chromium and molybdenum are only to apply to SMPPi, see SD4)	3 submissions (2 industry, 1 government)	Submitters agreed with the approach proposed in CP2. After assessment, FSANZ's preferred option is to retain that approach for the reasons stated in FSANZ 2021 CP2.
Taurine (Not addressed in FSANZ 2021 CP2)	4 submissions (1 industry, 3 government)	Submitters noted that taurine was not covered within FSANZ 2021 CP2. After assessment, FSANZ's preferred option is

		to retain the current permission for the reasons stated below.
Lutein (Not addressed in FSANZ 2021 CP2)	4 submissions (1 industry, 3 government)	Submitters noted that lutein was not covered within FSANZ 2021 CP2. After assessment, FSANZ's preferred option is to retain the current permission for the reasons stated below.

2.5.2 Discussion

Choline (Minimum: 1.7 mg/100 kJ)

FSANZ 2021 CP2 proposed that choline be listed with a minimum of 1.7 mg/100 kJ, to align with Codex CXS 72-1981.

Eight submitters (five industry, one public health and two government) commented on the proposed option. Most submitters agreed with the proposed approach. The government and public health submitters did not agree, instead supporting alignment with the EU 2016/127 minimum of 6 mg/100 kJ.

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 proposes that using the range of 1.7–12.0 mg/100 kJ for this nutrient is appropriate. This approach is supported by the FSANZ 2016 Nutrition Assessment which noted that mandatory inclusion of choline in the range in Codex CXS 72-1981 is unlikely to pose a risk to infant health. Therefore, FSANZ's preferred option is to retain the current minimum for choline of 1.7 mg/100 kJ.

L-carnitine (GUL: 0.8 mg/100 kJ)

FSANZ 2021 CP2 proposed that the current maximum level within Schedule 29 (0.8 mg/100 kJ) should be retained, however presented as a GUL to account for the natural variability of L-carnitine content in differing milks, to provide flexibility for manufacturers and to avoid trade barriers.

Eleven submitters (nine industry and two government) commented on the proposed approach. Government submitters agreed with the proposed approach. Industry submitters did not agree with the proposed approach to include a GUL for L-carnitine due to the absence of a UL and misalignment with Codex CXS 72-1981 and EU 2016/127. Submitters also noted the absence of indications of any untoward effects of higher L-carnitine intakes in infants and noted that not all manufacturer's currently label the L-carnitine content on products and that the New Zealand *Food for Export - Exemptions from Domestic Compositional Requirements No. 10 2021* lists a number of exemptions for L-carnitine for dairy-based infant formula.

FSANZ's current maximum in Schedule 29 (0.8 mg/100 kJ) reflects the upper levels present in breast milk and aligns with the Life Sciences Research Organization suggestion that a

maximum level based on the upper end of the usual range found in breast milk is also appropriate. There is insufficient evidence to support removal of a maximum or GUL, therefore FSANZ's preferred option is to retain the current maximum level within Schedule 29 (0.8 mg/100 kJ) but presented as a GUL.

Inositol (Minimum: 1.0 mg/100 kJ)

FSANZ 2021 CP2 proposed that the current minimum level within Schedule 29 (1.0 mg/100 kJ) for inositol should be retained. This aligns with Codex CXS 72-1981.

Six submitters (five industry and one government) commented on the proposed approach. Industry submitters supported the proposed approach. The government submitter did not support the proposed approach, noting that the minimum is five times lower than breast milk.

FSANZ notes this comment. Inositol has been found to reach a relatively stable concentration of around 130–325 mg/L (20–50 mg/100 kcal) in mature breast milk (EFSA 2014). The GUL proposed by FSANZ fits within this this range. The proposed range for inositol is 4–40 mg/100 kcal which is equivalent to 1–10 mg/100 kJ. This value is reflective of the rounded proposed range of 1–9.5 mg/100 kJ. It is also important to note that endogenous *de novo* synthesis of inositol appears to be efficient in newborn infants (EFSA 2014).

Therefore FSANZ's preferred option is to retain the current minimum level within Schedule 29 for inositol (1.0 mg/100 kJ).

Nucleotides

FSANZ 2021 CP2 proposed to retain both the current permission for nucleotides in Schedule 29 and the maximum total limit of nucleotides prescribed in Standard 2.9.1.

Nine submitters (six industry and three government) commented on the proposed approach. Industry submitters supported the continued inclusion of nucleotide-5′-monophosphates as optional ingredients. However, for clarity, industry submitters requested that the maximum stated of no more than 3.8 mg/100 kJ of nucleotide-5′-monophosphates in 2.9.1—8 is stated as no more than 3.8 mg/100 kJ (16 mg/100 kcal) of *free* nucleotide-5'-monophosphates. Industry submitters did not support the retention of minimums for nucleotides believing this to be out of alignment globally, noting that no minimums are set by the US, Canada or the EU. Some industry submitters also requested that the maximum applied to Guanosine-5′-monophosphate (GMP) be reconsidered from 0.12 to 0.40 mg/100 kJ in recognition of the levels of this free mono-phosphate nucleotide found naturally in goat milk-based formulas and in alignment with the upper end of average levels found in breast milk.

Government submitters did not support the proposed approach to maintain a voluntary permission for nucleotides, suggesting further research is required to determine the need and if there is a need, they should be mandated. FSANZ considers it is not reasonable to remove the voluntary addition of nucleotides to infant formula as this would be inconsistent with EU 2016/127 and Codex CXS 72-1981. As EU 2016/127, Codex CXS 72-1981 and Standard 2.9.1 are all currently consistent and there is no known safety concern associated with the consumption of nucleotides FSANZ's preferred option is to retain the current voluntary permission within the Standard 2.9.1.

FSANZ acknowledges that minimums are out of step globally. Therefore, FSANZ's proposes to remove the current minimums for nucleotides.

FSANZ will not be increasing the maximum for GMP, as the current maximum aligns with the EU 2016/127 maximum.

FSANZ also notes that section 2.9.1—8(b) will be amended to state that infant formula must not contain 'more than 3.8 mg/100 kJ of *free* nucleotide-5′-monophosphates', as this is consistent with other international standards.

In conclusion, it is FSANZ's preferred option is to:

- retain the current voluntary permission for nucleotides in Schedule 29
- remove the minimum levels for nucleotides prescribed in Standard 2.9.1
- amend the wording in 2.9.1—8(b) to state '*free* nucleotide-5′-monophosphates'.

Taurine

Four submitters (one industry, three government) commented that taurine was not covered in FSANZ 2021 CP2. One industry submitter supported no changes to the current voluntary permission. Whereas, three government submitters considered that the optional ingredient needed to be reviewed within the proposal and FSANZ should commit to reviewing the ingredient at regular periods, such as every five years.

The taurine maximum within Standard 2.9.1 is aligned with Codex and the EU regulation, for both infant formula and follow-on formula, at 3 mg/100 kJ. Standard 2.9.1 also prescribes a minimum amount of 0.8 mg/100 kJ for taurine, whereas Codex and the EU regulation do not.

FSANZ's preferred option is to retain the current permission for taurine, however FSANZ is seeking further information from submitters on this issue to inform future considerations.

Lutein

Four submitters (one industry, three government) commented that lutein was not covered in FSANZ 2021 CP2. One industry submitter supported no changes to the current voluntary addition permissions. Whereas, three government submitters considered that the optional ingredient needed to be reviewed within the proposal and FSANZ should commit to reviewing the ingredient at regular periods, such as every five years.

FSANZ notes both Codex and the EU regulation do not have specific permissions for lutein in infant formula or follow-on formula. However Codex STAN 72-1981 does include permissions for optional ingredients that can be added in order to provide substances ordinarily found in breast milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant or to provide other benefits that are similar to outcomes of populations of breastfed babies.

FSANZ's preferred option is to retain the current permission for lutein, however FSANZ is seeking further information from submitters on this issue to inform future considerations.

2'-O-fucosyllactose (2'-FL) alone or in combination with Lacto-N-neotetraose (LNnT)

As 2'-FL alone or in combination with LNnT was only recently permitted in section S29– 5 in 2019, FSANZ considers it appropriate to retain the permission. For further details please see Application A1155 – 2'-FL and LNnT in infant formula and other products and Application A1190 – 2'-FL in infant formula and other products (FSANZ 2019, FSANZ 2021e).

2.5.3 Preferred composition

Table 2.5.3 Other nutritive substances for infant formula

Nutrient	Change Proposed (Y/N)	Units	Proposed Approach			Standard 2.9.1 (Schedule 29)		
			Vol/Man	Min	Max	Vol/Man	Min	Max
Choline	Yes	mg / 100 kJ	Man	1.7	12	Vol	1.7	7.1
L-Carnitine	Yes	mg / 100 kJ	Man	0.3	0.8*	Vol	0.21	0.8
Inositol	Yes	mg / 100 kJ	Man	1.0	9.5*	Vol	1.0	9.5
Chromium	Yes	µg /100 kJ	NS	NS	NS	Vol	NS	2.0*
Molybdenum	Yes	µg /100 kJ	NS	NS	NS	Vol	NS	3.0*
Taurine	No	mg/100 kJ	Vol	0.8	3	Vol	0.8	3.0
Lutein	No	µg/100 kJ	Vol	1.5	5.0	Vol	1.5	5.0
2′-O-fucosyllactose ^	No	mg/100 kJ	Vol	NS	96	Vol	NS	96
Nucleotides								
Adenosine-5′-monophosphate	Yes	mg / 100 kJ	Vol	NS	0.38	Vol	0.14	0.38
Cytidine-5′-monophosphate	Yes	mg / 100 kJ	Vol	NS	0.6	Vol	0.22	0.6
Guanosine-5′-monophosphate	Yes	mg / 100 kJ	Vol	NS	0.12	Vol	0.04	0.12
Inosine-5′-monophosphate	Yes	mg / 100 kJ	Vol	NS	0.24	Vol	0.08	0.24
Uridine-5′-monophosphate	Yes	mg / 100 kJ	Vol	NS	0.42	Vol	0.13	0.42
Total free nucleotide 5'-monophosphates	Yes	mg / 100 kJ	Vol	NS	3.8	Vol	≤ 3.8	NS

NS = not specified * = GUL Vol = Voluntary addition, Man = Mandatory Addition

^A combination of 2′-O-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

2.5.3.1 Proposed composition once reconstituted

Fluoride

After assessment, FSANZ's preferred option is to set a compositional limit for fluoride of 24 µg/100 kJ when prepared ready for consumption and to remove the labelling statements relating to dental fluorosis in paragraph 2.9.1—23(1)(b). This limit is not set out in the above composition table as it will be addressed within paragraph 2.9.1—23(2)(a). This is based on the conclusions of FSANZ 2021 CP2.

3. Part B: Follow-on Formula

The proposed nutrient composition for follow-on formula is informed by past FSANZ assessments (FSANZ 2016, FSANZ 2021) which assessed ANZ infants aged 0 – 6 months and 6 – 12 months. It was also considered alongside recent progress on the proposed Codex Draft Standard for FuFOI (6 -12 months), relating to the revision of the Codex Standard for Follow up Formula (CXS 156-1987). The nutrient composition for the Codex Draft Standard for FuFOI is now held at Step 7, which indicates that it is at the final step prior to being submitted to the Codex Alimentarius Commission for adoption.

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. This review does not consider the proposed Codex Draft Revised Standard for Follow-up Formula for Young Children (1 – 3 years) as within the ANZ market products formulated for young children aged above 12 months are not considered infant formula products and are therefore outside the scope of the proposal.

3.1 General stakeholder views

FSANZ 2021 CP2 received submissions regarding follow-on formula. These submissions and FSANZ's proposed response are captured blow.

Table 3.1 Stakeholder views and FSANZ proposed response regarding follow-on formula

Issue	Raised by	FSANZ proposed response
Consideration of alignment between infant formula and follow-on formula requirements	11 submissions (7 industry, 3 government, 1 public health)	FSANZ considers that there should be alignment between infant formula and follow-on formula unless there is substantiated science to support the differences in needs between the age groups.
Follow-on formula remaining in Standard 2.9.1	1 submission (1 public health)	FSANZ confirms that follow-on formula will continue to be regulated within Standard 2.9.1.
Five year transitional period, with additional stock in trade provisions for the implemented changes of P1028	3 submissions (3 industry)	Transitional periods can be considered at the point when drafting is prepared. Any drafting must be the subject of further public consultation.
Any novel proteins must conduct a comprehensive pre-market assessment before being permitted in infant and follow-on formula, including impact on bioavailability of nutrients	1 submissions (1 public health)	Addressed above in section 2.1.2.
Regard to the Ministerial Policy Guideline on the Regulation of Infant Formula	1 submissions (1 government)	Addressed within SD 6 to this CFS.

3.2 Macronutrients

3.2.1 Stakeholder views

Table 3.2.1 Macronutrient issues raised by stakeholders

Issue	Raised by	FSANZ proposed response
Remove Potential Renal Solute Load (PRSL) from Standard 2.9.1	1 submissions (1 industry)	After assessment, FSANZ's preferred option is to remove PRSL from Standard 2.9.1 for the reasons stated below.
Protein minimum 0.38 g/100 kJ	3 submissions (3 industry)	FSANZ's preferred option is to adopt a protein minimum of 0.43 g/100 kJ in follow-on formula, in line with the proposed composition for infant formula and the Codex Draft Standard for FuFOI.
Protein maximum (varying options)	4 submissions (4 industry)	FSANZ's preferred option to retain the protein maximum of 0.7 mg/100 kJ in follow-on formula for the reasons stated in section 2.2.2 and below.
FSANZ to review the use of voluntary ingredients, including DHA and other LC-PUFA, in infant and follow-on formula products	1 submissions (1 public health)	FSANZ's preferred option is to retain the voluntary addition of DHA and other LC-PUFA in follow-on formula for the reasons stated in section 2.2.2 and below.
Requirement for DHA to be no less than AA	4 submissions (4 industry)	FSANZ's preferred option is that the same requirement for infant formula be applied to follow-on formula. Therefore, a GUL will be applied to DHA and the prescription for AA will be required at no more than 1% of the total fatty acids.
Phospholipid upper limit Remove maximum or align with the Codex Draft Standard for FuFOI limit.	4 submissions (4 industry)	FSANZ's preferred option is to adopt a GUL for phospholipid of 2 g/L in follow-on formula for the reasons stated below.

3.2.2 Discussion

FSANZ proposes that for total fat and α-Linolenic acid it is appropriate for follow-on formula to align with the nutrient composition ranges proposed in the FSANZ 2021 CP2. The proposed composition also aligns with the Codex Draft Standard for FuFOI. Submitters to the FSANZ 2021 CP2 supported the composition proposed by FSANZ and noted no other issues. Further discussions on these nutrients can be found within section 2.1 above.

FSANZ has also proposed to retain the current Standard 2.9.1—7 restrictions for inulin-type fructans and galacto-oligosaccharides in infant formula, noted in section 2.1.1 above. This approach is also FSANZ's preferred option for follow-on formula.

Energy

There is a slight difference in energy ranges between Codex CXS 72-1981 (2500 – 2950 kJ/L) and the Codex Draft Standard for FuFOI (2510- 2930 kJ/L) due to differing energy conversion factors. Submitters supported the proposed approach to align with Codex STAN

72-1981 proposed in FSANZ 2021 CP2. Based on conclusions of FSANZ 2021 CP2, submitter support and alignment with Codex CXS 72-1981, FSANZ's preferred option is to adopt any energy range of 2500 – 2950kJ/L for follow-on formula.

Protein

FSANZ's preferred option is to adopt the proposed option, for both cows and goats milk and soy protein isolate, noted within FSANZ 2021 CP2. The Codex Draft Standard for FuFOI also proposes a minimum protein level between 0.38 and 0.43 g/100 kJ for follow-on formula based on non-hydrolysed milk protein and states that hydrolysed protein should be evaluated for safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence. Non-hydrolysed and hydrolysed milk proteins are discussed in further detail within SD4.

Potential renal solute load

Standard 2.9.1 prescribes a maximum PRSL for follow-on formula of no more than 8 mOsm/100 kJ. Five industry submitters recommended removing the PRSL from follow-on formula as 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/100kJ) 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).

Based on the above rationale and international alignment, FSANZ's preferred option is to remove the maximum PRSL from Standard 2.9.1.

Carbohydrates

Standard 2.9.1 does not directly specify a minimum or maximum level of carbohydrate for follow-on formula as it is indirectly controlled by the regulations on protein, fat and energy content. FSANZ 2016 CP reported calculated carbohydrate amounts based on Standard 2.9.1 provisions demonstrated that Standard 2.9.1 and Codex CXS 72-1981 were effectively aligned for minimum and maximum carbohydrate amounts. This conclusion is also applicable to follow-on formula due to the proposed composition aligning with infant formula and proposals for energy, protein and fat content in the Codex Draft Standard for FuFOI.

Based on international alignment and support to the FSANZ 2016 CP and FSANZ 2021 CP2 consultation papers to retain the current approach within Standard 2.9.1, FSANZ proposes to not specify a permitted range for carbohydrate content within follow-on formula.

Linoleic acid

FSANZ received opposing comments on the minimum prescription for linoleic acid to FSANZ 2021 CP2, these are discussed within section 2.1.2 above. Based on the rationale provided, the conclusion of the FSANZ 2021 Nutrition Assessment and suitability within the ANZ population, it is FSANZ's preferred option to adopt a linoleic acid range of 90 – 330 mg/100 kJ for follow-on formula.

DHA

Standard 2.9.1 does not include a prescription for DHA for follow-on formula, however the Codex Draft Standard for FuFOI proposes a maximum of 7.2 mg/100 kJ and the EU 2016/127 regulation for follow-on formula prescribes a range of 4.8 – 12 mg/100 kJ. FSANZ 2021 CP2 proposed to retain the DHA GUL within infant formula and change the units of expression from % total fatty acids to mg/100 kJ. A DHA GUL of 0.5% total fatty acids, as prescribed in Standard 2.9.1, converted using maximum fat content (1.5 g/100 kJ) is equivalent to 7.2 mg/100 kJ of DHA. Further discussions on the DHA maximum can be found in section 2.2.2 above. Based on alignment with Codex CXS 72-1981 and the Codex Draft Standard for FuFOI, FSANZ's preferred option is to extend the 7.2 (GUL) mg/100 kJ DHA voluntary addition in Standard 2.9.1 for infant formula to follow-on formula.

Arachidonic acid

Standard 2.9.1 currently prescribes AA content as no more than 1% of total fatty acids. Whereas, the Codex Draft Standard for FuFOI, proposes AA should reach at least the same concertation as DHA. The presentation between each statement differs. However, as noted above DHA is being prescribed as 0.5% of total fatty acids (7.2 (GUL) mg/100 kJ), which evidences a similar relationship between the fatty acids is present with AA required at higher levels. It is FSANZ's preferred option that the AA requirements within Standard 2.9.1 be retained for follow-on formula, which is consistent with the EU 2016/127.

Trans Fatty Acid

FSANZ 2021 CP2 proposed retaining the current prescription for TFA, as discussed above in section 2.1.2. It is FSANZ's preferred option to align with the FSANZ 2021 CP2 proposed approach and retain the current restriction for trans fatty acids at 4% of TFA in follow-on formula.

Lauric and Myristic acid

Myristic and lauric acid do not have permissions in Standard 2.9.1 or EU 2016/127. However, Codex CXS 72-1981 and the Codex Draft Standard FuFOI permit both fatty acids at a maximum of 20% of total FA content combined. FSANZ 2021 CP2 proposed to retain the current approach for these fatty acids. Stakeholder views received through previous consultations have supported this approach. Based on the conclusions of FSANZ 2021 CP2, FSANZ proposes to retain the current approach of not prescribing a range for myristic and lauric acids for follow-on formula.

Erucic Acid

The maximum level of erucic acid is consistent across Standard 2.9.1 and Codex for both infant formula and follow-on formula. Based on international harmonisation, FSANZ sees it appropriate to retain the current maximum level for eurcic acid of 1% of total fatty acids in follow-on formula.

Phospholipids

Standard 2.9.1 does not set a maximum amount for PL in infant formula or follow-on formula products, whereas Codex and the EU regulation do. Within FSANZ 2021 CP2, FSANZ proposed to align within international regulations and set a maximum of 2 g/L for PL in infant formula. Based on the rationale provided within FSANZ 2021 CP2 and aligning with international regulations, FSANZ proposes to apply a maximum of 2 g/L of PL for follow-on formula.

3.2.3 Preferred composition

Table 3.2.3 Preferred macronutrient composition for follow-on formula

Nutrient	Unit	P1028 follow-on formula	P1028 infant formula	Standard 2.9.1 (follow-on formula)	Codex CXS 72-1981	Codex Draft Standard for FuFOI	EU 2016/127 ANNEX I	EU 2016/127 ANNEX II
Energy	kJ/L	2500 - 2950	2500 - 2950	2500 - 3550	2500 - 2950	2510 - 2930	2500 – 2930	2500 - 2930
Protein (cow)	g/100 kJ	0.43 – 0.7	0.43 – 0.7	0.38 – 1.3	0.45 – 0.7	0.43 – 0.72	0.43 – 0.6	0.38 – 0.6
Protein (soy)	g/100 kJ	0.54 – 0.7	0.54 – 0.7	0.45 – 1.3	0.5 – 0.7	0.54 – 0.72	0.54 – 0.67	0.54 – 0.67
Carbohydrates	g/100 kJ	NS	NS	NS	2.2 – 3.3	2.2 – 3.3	2.2 – 3.3	2.2 – 3.3
Total fat	g/100 kJ	1.05 – 1.4	1.05 – 1.4	1.05 – 1.5	1.05 – 1.4	1.1 – 1.4	1.1 – 1.4	1.1 – 1.4
ALA	mg/100 kJ	12 – NS	12 – NS	1.1 – 4%^	12 – NS	12 – NS	12 – 24	12 – 24
LA	mg/100 kJ	90 – 330*	90 – 330*	9 – 26%^	70 – 330*	72 – 335*	120 – 300	120 - 300
DHA	mg/100kJ	NS - 7.2	NS - 7.2	NS	NS - 0.5%^	NS – 7*	4.8 – 12	4.8 – 12
AA	% total FA	NS – 1	NS – 1	NS – 1	≥ DHA	≥ DHA	NS – 1	NS – 1
TFA	% total FA	NS - 4	NS - 4	NS - 4	NS – 3	NS - 3	NS – 3	NS – 3
Lauric & Myristic acid	% total FA	NS	NS	NS	NS - 20	NS - 20	NS	NS
Erucic Acid	% total FA	NS - 1	NS – 1	NS – 1	NS – 1	NS – 1	NS – 0.4	NS – 0.4
PL	g/L	NS – 2	NS – 2	NS	NS – 2	NS – 2	NS – 2	NS – 2

* = GUL NS = not specified ^ = % total fatty acids

Retain restrictions on inulin-type fructans and galacto-oligosaccharides in Standard 2.9.1—7.

3.3 Micronutrients

3.3.1 Stakeholder views

Table 3.3.1 Micronutrient issues raised by stakeholders

Issue	Raised by	FSANZ proposed response
Vitamin D Maximum 0.72 ug/100 kJ	4 submissions (4 industry)	After assessment, FSANZ's preferred option is to adopt a vitamin D maximum of 0.63 ug/100 kJ for the reasons stated below.
Calcium GUL 43mg / 100kJ	4 submissions (4 industry)	After assessment, FSANZ's preferred option is to adopt a GUL of 43 mg/100 kJ for the reasons stated below.
Iron minimum Retain 0.20 mg/100 kJ or Adopt 0.24 mg/100 kJ	4 submissions (4 industry)	After assessment, FSANZ's preferred option is to retain an iron minimum of 0.20 mg/100 kJ for the reasons stated below.
Phospholipid upper limit Remove maximum or align with Codex FuFOI limit	4 submissions (4 industry)	After assessment, FSANZ's preferred option is to adopt a GUL for phospholipid of 2 g/L for the reasons stated below.

3.3.2 Discussion

FSANZ considers that for phosphorus and magnesium it is appropriate for follow-on formula to align with the nutrient composition ranges proposed in the FSANZ 2021 CP2. The

proposed composition also aligns with the Codex Draft Standard for FuFOI. Submitters to the FSANZ 2021 CP2 supported the composition proposed by FSANZ and noted no other issues. Further discussions on these nutrients can be found within section 2.2.

Niacin, vitamin B12, folic acid, sodium, chloride, potassium, pantothenic acid and manganese received mixed responses during FSANZ 2021 CP2. Government submitters addressed their preference for alignment with EU 2016/127 over the Codex CXS 72-1981 due to EFSA conducting its review more recently. These views have been addressed previously in FSANZ 2021 CP2 and FSANZ would like to reiterate the discussions noted within the consultation paper and the purpose of the proposal is to align with Codex CXS 72-1981 where possible. FSANZ would also like to note in most cases the Codex Draft Standard for FuFOI closely aligns to the proposed approach. Further rationale surrounding this decision can be found in section 2.2.2 above and FSANZ 2021 CP2. Despite not receiving unanimous support it is FSANZ's preferred option to adopt the FSANZ 2021 CP2 nutrient composition for follow-on formula for niacin, vitamin B12, folic acid, sodium, chloride, potassium, pantothenic acid and manganese.

Vitamin A

The prescribed range for vitamin A is consistent across Standard 2.9.1 and Codex CXS 72-1981. As noted in the 2016 Nutrition Assessment the AI for infants aged 6–<12 months (430 µg/day) was calculated from vitamin A intake from breast milk plus vitamin A from complementary foods (i.e. as retinol equivalents) which includes some carotenes. The assessment concluded that the estimated minimum intake compared to the AI value that was reported to be from breast milk intake alone (186 µg/day) (NHMRC and MoH 2006) met the Codex CXS 72-1981 vitamin A minimum and is unlikely to pose a risk to health of older infants.

The Codex Draft Standard for FuFOI applies a higher minimum of 18 µg RE/100 kJ, which is based on the updated WHO/FAO and EFSA vitamin A requirements of 400 µg RE/day (WHO/FAO, 2004). However, this is not reflective of the ANZ population and also does not account for the additional intake of vitamin A from complementary foods noted within the ANZ AI.

Based on the suitability for the ANZ population, alignment with the basis of the ANZ AI, harmonisation with the proposed nutrient composition for infant formula and Codex CXS 72-1981, FSANZ's preferred option is to retain the current vitamin A range within Standard 2.9.1 of 14 – 43 µg RE/100 kJ for follow-on formula.

Vitamin B6

FSANZ 2021 CP2 proposed to adopt the Codex CXS 72-1981 range for vitamin B6 of 8.5 – 45 (GUL) µg /100 kJ for infant formula. This range closely aligns with the Codex Draft Standard for FuFOI and the EU 2016/127 ANNEX II maximum. Opposing views were raised in response to the proposed approach noted within FSANZ 2021 CP2. Industry submitters supported the proposed approach and government submitters supported adoption of the EU 2016/127 minimum and a maximum level based on alignment with maximum levels in breast milk. The 2021 Nutrition Assessment concluded that the EU 2016/127 Vitamin B6 minimum may pose risk to older infants' health as it did not ensure the AI was met. The minimum proposed in FSANZ 2021 CP2 also closely aligns with the minimum prescribed in EU follow-on formula regulations (EU 2016/127 ANNEX II) and as proposed for the Codex Draft Standard for FuFOI. The basis for the proposed vitamin B6 maximum was alignment with international standards, no ANZ UL for infants aged 0 – 12 months and no known evidence of vitamin B6 toxicity in ANZ formula fed infants. Based on the conclusions of FSANZ 2021 CP2, FSANZ 2021 Nutrition Assessment and close alignment with international

regulations, FSANZ's preferred option is to adopt the range proposed for infant formula of 8.5 – 45 (GUL) µg /100 kJ for follow-on formula.

Riboflavin

FSANZ 2021 CP2 proposed adoption of the EU 2016/127 range for riboflavin of 14.3 – 95.6 µg /100 kJ for infant formula. Three (industry) submitters did not support adopting the EU 2016/127 maximum level as the 2016 Nutrition Assessment concluded that the permitted Codex CXS 72-1981 range would provide a low risk to infant health. These industry submitters all supported use of the Codex CXS 72-1981 GUL instead. This GUL also aligns with the Codex Draft Standard for FuFOI and allows formula that may need to comply to both Codex and the EU regulation, to do so. As there are no nutritional adequacy or safety risks associated with adopting the Codex CXS 72-1981 GUL, concluded by FSANZ 2016 CP and FSANZ 2021 CP2, and this value better aligns with that proposed for the Codex Draft Standard for FuFOI, FSANZ is proposing to adopt a range of 14.3 - 119 (GUL) µg /100 kJ for both infant formula and follow-on formula.

Vitamin C

FSANZ 2021 CP2 proposed to retain the Standard 2.9.1 vitamin C minimum (1.7 mg/100 kJ) and adopt the Codex CXS 72-1981 GUL (17 mg/100 kJ). This was based on ensuring infants meet the minimum vitamin C requirements. The Codex CXS 72-1981 GUL also accounts for possible high losses of vitamin C during shelf life and high temperatures. This range has also been proposed for the Draft Standard for FuFOI. Support was received on the vitamin C minimum, however the vitamin C maximum received mixed views between industry and government submitters. Further discussions of issues raised during FSANZ 2021 CP2 can be found in section 2.2.2 above. Based on the conclusions of the 2021 CP2 and Nutrition Assessment, FSANZ's preferred option is to adopt the range proposed within the FSANZ 2021 CP2 of 1.7 – 17 (GUL) mg/100 kJ for follow-on formula.

Vitamin D

FSANZ 2021 CP2 proposed retaining the current prescription for vitamin D of 0.25 – 0.63 µg/100 kJ for infant formula. This closely aligns with Codex CXS 72-1981, is the most appropriate range for the ANZ population and was supported by all submissions to FSANZ 2021 CP2. Submitters to FSANZ 2021 CP2 recommend that FSANZ consider adopting a higher vitamin D maximum in line with the Codex Draft Standard for FuFOI and EU 2016/127 ANNEX II for follow-on formula. However, this higher level reflects evidence from EFSA about elevated vitamin D requirements for infants where exposure to sunlight is limited. FSANZ notes this is not specific to the ANZ population and notes AI's much higher than that specified in the ANZ NRVs (NHMRC, 2016). Concerns were also raised with the maximum level (0.72 µg /100 kJ) as it was believed to be excessive and did not take into consideration the contribution of vitamin D from foods, or the adverse effects of exceeding the UL. FSANZ 2021 CP2 also considered advice from EFSA which concluded that some infants may consume amounts of vitamin D that exceed the upper intake level (EFSA 2018). Based on the above rationale FSANZ does not consider the level appropriate within the ANZ population to adopt a higher maximum. FSANZ's preferred option is to adopt the range proposed within the FSANZ 2021 CP2 of 0.25 – 0.63 µg/100 kJ for follow-on formula.

Vitamin E

FSANZ 2021 CP2 proposed adopting the Codex CXS 72-1981 vitamin E minimum and GUL (0.12 – 1.2 mg α-TE/100 kJ). This range aligns with that proposed for the Codex Draft Standard for FuFOI. Submitters to FSANZ 2021 CP2 requested that FSANZ adopt the EU 2016/127 range or minimum. Submitter comments have been discussed in section 2.2.2

above. Based on alignment with Codex CXS 72-1981 and the Codex Draft Standard for FuFOI, FSANZ's preferred option is to adopt the range of 0.12 – 1.2 mg α-TE/100 kJ for follow-on formula.

Vitamin K

FSANZ 2021 CP2 proposed retaining the vitamin K maximum of 6.5 (GUL) µg /100 kJ, which closely aligns with other international regulations, and adopting the EU 2016/127 ANNEX I vitamin K minimum. This decision was supported by all submitters to FSANZ 2021 CP2. One submitter did question whether the EU 2016/127 minimum met the AI for infants aged 7 – 12 months. The 2021 Nutrition Assessment concluded that estimated vitamin K intakes from formula containing the EU 2016/127 minimum amount exceeds half the AI value for infants aged 6 – <12 months, with the other half being met through complementary feeding. FSANZ's preferred option is to adopt the FSANZ 2021 CP2 proposed vitamin K range of 0.24 – 6.5 (GUL) µg /100 kJ for follow-up formula.

Zinc

FSANZ 2021 CP2 proposed adopting the Codex CXS 72-1981 GUL for zinc. This proposed range of 0.12 - 0.36 mg/100 kJ aligns with the Codex Draft Standard for FuFOI. Government submitters who did not support adoption of the Codex CXS 72-1981 GUL recommended that the EU 2016/127 maximum was used instead. This was on the basis that the Codex CXS 72-1981 GUL equates to infant intakes that would exceed the UL. FSANZ's 2016 Nutrition Assessment evaluated the Codex CXS 72-1981 zinc GUL and concluded that it may potentially exceed the UL, however there is no evidence of a risk to infant health from such intakes. Based on alignment with international standards for follow-on formula and the conclusions of FSANZ 2016 Nutrition Assessment and FSANZ 2021 CP2, FSANZ's preferred option is to align infant formula and follow-on formula with a range of 0.12 - 0.36 (GUL) mg/100 kJ.

Thiamin

FSANZ 2021 CP2 proposed retaining the minimum in Standard 2.9.1 (10 µg/100 kJ) and adopting the Codex CXS 72-1981 GUL (72 µg/100 kJ) for thiamin. The 2016 Nutrition Assessment previously concluded that the Codex CXS 72-1981 minimum (14 µg/100 kJ) was also appropriate for infants aged 0 – 12 months and did not pose a risk to infant health. However, 10 µg/100 kJ was more closely aligned with the EU 2016/127 regulation and received support from submissions to FSANZ 2016 CP and FSANZ 2021 CP2. Based on the 2016 Nutrition Assessment this minimum meets the nutritional needs of most infants and is consistent with breast milk concentrations. The Codex Draft Standard for FuFOI has proposed to include the same essential composition requirements for thiamin as Codex CXS 72-1981. FSANZ's preferred option is to retain the FSANZ 2021 CP2 proposed approach and prescribe a range of thiamin within follow-on formula of 10 – 72 (GUL) µg/100 kJ, and therefore aligning with infant formula.

Biotin

For biotin FSANZ 2021 CP2 proposed adoption of the EU 2016/127 minimum (0.24 µg /100 kJ) and the Codex CXS 72-1981 GUL (2.4 µg /100 kJ). This range was proposed as it aligns closely with breast milk biotin concentrations (EFSA 2014, EC SCF 2003, NHMRC 2006) and was unlikely to impact trade since products formulated for either EU 2021/127 or Codex CXS 72-1981 were accounted for within the range. The majority of the submitters to the FSANZ 2021 CP2 supported adopting the EU 2016/127 minimum, however one government submitter raised concerns regarding if the minimum needs of older infants would be met by the proposed range. FSANZ's 2021 and 2016 Nutrition

Assessments both assessed infants aged 0 – 6 and 6 – 12 months and concluded that the proposed minimum and maximum were unlikely to pose a risk to infant health. Not all submitters agreed on the maximum, while three industry submitters supported the proposed GUL, one government submitter preferred adopting the EU 2016/127 maximum. FSANZ's preferred option is to retain the proposed option from FSANZ 2021 CP2 of 0.24 - 2.4 (GUL) µg /100 kJ. The proposed range does not pose nutritional adequacy or safety risks to ANZ infants and the maximum more closely aligns with breast milk concentrations and the GUL proposed in the Codex Draft Standard for FuFOI.

Copper

FSANZ 2021 CP2 proposed adopting the Codex CXS 72-1981 permitted range for copper of 8.5 – 29 (GUL) µg /100 kJ. This closely aligns with the copper range proposed in the Codex Draft Standard for FuFOI. Opposing submitter comments were received from FSANZ 2021 CP2 on the copper range, these views are discussed within section 2.2.2 above. FSANZ retains its current position for infant formula and notes the preferred option is to adopt the range of 8.5 – 29 (GUL) µg /100 kJ for follow-on formula, based on international alignment with Codex CXS 72-1981 and the Codex Draft Standard for FuFOI and the conclusions of FSANZ 2021 CP2.

Iron

FSANZ 2021 CP2 proposed retaining the Standard 2.9.1 range of 0.2 – 0.5 mg/100 kJ as the range accounted for older infants, soy-based infant formulas, aligned with the current ANZ market and was supported by FSANZ 2016 and 2021 Nutrition Assessment conclusions. This range closely aligns with the Codex Draft Standard for FuFOI and the EU 2016/127 ANNEX II. A submitter to FSANZ 2021 CP2 supported adopting the Codex Draft Standard for FuFOI range for iron of 0.24 – 0.48 mg/100 kJ. Based on the above rationale and close alignment with the Codex Draft Standard for FuFOI, FSANZ preferred option is to retain the range of 0.2 – 0.5 mg/100 kJ.

FSANZ has given consideration to setting a separate iron range for soy based formulas. However, based on the conclusions of FSANZ 2021 CP2 and submitter comments, FSANZ's preferred option is to retain the range of 0.2 -0.5 mg/100 kJ for iron which accounts for older infants and soy-based formulas.

Calcium

For calcium FSANZ 2021 CP2 proposed to adopt the Codex CXS 72-1981 prescribed range of 12 – 35 (GUL) mg/100 kJ. This proposed option was also consulted on in 2016 to which no comments were raised by submitters. FSANZ 2021 CP2 received comments in favour of the proposed option and noted that for follow-on formula a GUL of 43 mg/100 kJ should be adopted in line with the Codex Draft Standard for FuFOI. The increased GUL was based on the increase in calcium requirements for this age group, reduced intakes of follow-up formula at this age, and noting that calcium intakes are often limited in the diets of this age group. Based on the above discussion and alignment with recent international standards, FSANZ's preferred option for follow-on formula is to prescribe a range of 12 – 43 (GUL) mg/100 kJ of calcium.

Iodine

For iodine FSANZ 2021 CP2 proposed to align the minimum amount with EU 2016/127 (3.6 µg/100 kJ) and retain the maximum in Standard 2.9.1 (10 µg/100 kJ). The proposed maximum was opposed by eight industry submitters and one government submitter. Eight industry submitters preferred adoption of the Codex CXS 72-1981 prescribed range

(2.5 – 14 µg/100 kJ), whereas the government submitter preferred alignment with the EU 2016/127 maximum (6.9 µg/100 kJ). The proposed minimum was opposed by the eight industry submitters, however was supported by two government submitters. The FSANZ 2016 Nutrition Assessment concluded that the Codex CXS 72-1981 prescribed range would be unlikely to pose risk to infant health, for both 0 - 6 and 6 - 12 months and was appropriate for ANZ infants. Based on the above, FSANZ's preferred option is to align with the Codex CXS 72-1981 and the proposed Codex Draft Standard for FuFOI by applying the proposed prescribed range (2.5 – 14 µg/100 kJ) for infant formula also to follow-on formula. This range also closely aligns with the EU's follow-on formula range for iodine.

Selenium

For selenium FSANZ 2021 CP2 proposed a minimum of 0.48 µg/100 kJ and aligning with the EU 2016/127 maximum of 2.0 µg /100 kJ. The proposed maximum was supported by one government submitter and was opposed by five industry submitters. The industry submitters supported alignment with the Codex CXS 72-1981 and Codex Draft Standard for FuFOI GUL of 2.2 µg /100 kJ. The FSANZ 2016 Nutrition Assessment concluded that the Codex CXS 72-1981 GUL was unlikely to pose a risk to infant health and the 2021 Nutrition Assessment noted that for breast milk concentrations equivalent to 2.2 µg/100 kJ were not associated with adverse effects. Based on the above discussion, FSANZ's preferred option is to retain the proposed minimum of 0.48 µg /100 kJ and increase the maximum to 2.2 µg /100 kJ.

3.3.3 Preferred composition

Table 3.3.3 Preferred micronutrient composition for follow-on formula

Nutrient	Unit	P1028 follow-on formula	P1028 infant formula	Standard 2.9.1 (follow-on formula)	Codex CXS 72-1981	Codex Draft Standard for FuFOI	EU 2016/127 ANNEX I	EU 2016/127 ANNEX II
Vitamin A	µg RE/100 kJ	14 – 43	14 – 43	14 – 43	14 – 43	18 – 43	16.7 – 27.2	16.7 – 27.2
Niacin	µg /100 kJ	70 – 360*	70 – 360*	130 - NS	70 – 360*	72 – 359*	100 – 360	100 – 360
Vitamin B6	µg /100 kJ	8.5 – 45*	8.5 – 45*	9 – 36	8.5 – 45*	8 – 42*	4.8 – 41.8	4.8 – 41.8
Vitamin B12	µg /100 kJ	0.025– 0.36*	0.025–0.36*	0.025 – NS	0.025–0.36*	0.02 - 0.36*	0.02 – 0.12	0.02– 0.12
Vitamin C	mg/100 kJ	1.7 – 17*	1.7 – 17*	1.7 – NS	2.5 – 17*	2.4 – 17*	0.96 – 7.2	0.96 – 7.2
Vitamin D	µg /100 kJ	0.25 – 0.63	0.25 – 0.63	0.25 – 0.63	0.25 - 6	0.24 – 0.72	0.48 – 0.6	0.48 – 0.72
Vitamin E	mgα-TE/100kJ	0.12 – 1.2*	0.12 – 1.2*	0.11 – 1.1	0.12 – 1.2*	0.12 – 1.2*	0.14 – 1.2	0.14 – 1.2
Vitamin K	µg /100 kJ	0.24 – 6.5*	0.24 – 6.5*	1 – NS	1 – 6.5*	0.96 – 6*	0.24 – 6	0.24 – 6
Zinc	mg/100 kJ	0.12 – 0.36*	0.12 – 0.36*	0.12 – 43	0.12 – 0.36*	0.12 – 0.36*	0.12 – 0.24	0.12 – 0.24
Thiamin	µg /100 kJ	10 – 72*	10 – 72*	10 – NS	14 – 72*	14 – 72*	9.6 – 72	9.6 – 72
Biotin	µg /100 kJ	0.24 – 2.4*	0.24 – 2.4*	0.36 – NS	0.4 – 2.4*	0.36 – 2.4*	0.24 – 1.8	0.24 – 1.8
Copper	µg /100 kJ	8.5 – 29*	8.5 – 29*	14 – 43	8.5 – 29*	8 – 29*	14.3 – 24	14.3 - 24
Phosphorus	mg/100 kJ	6 – 24*	6 – 24*	6 – 25	6 – 24*	6 – 24*	6 – 21.5	6 – 21.5
Magnesium	mg/100 kJ	1.2 – 3.6*	1.2 – 3.6*	1.2 – 4.0	1.2 – 3.6*	1.2 – 3.6*	1.2 – 3.6	1.2 – 3.6
Folic acid	µg /100 kJ	2.5 – 12*	2.5 – 12*	2 – NS	2.5 – 12*	2.4 – 12*	3.6 – 11.4	3.6 – 11.4
Sodium	mg/100 kJ	5 – 14	5 – 14	5 – 15	5 – 14	4.8 – 14	6 – 14.3	6 – 14.3
Chloride	mg/100 kJ	12 – 38	12 – 38	12 – 35	12 – 38	12 – 38	14.3 – 38.2	14.3 – 38.2
Potassium	mg/100 kJ	14 – 43	14 – 43	20 – 50	14 – 43	14 – 43	19.1 – 38.2	19.1 – 38.2
Pantothenic acid	µg /100 kJ	96 – 478*	96 – 478*	70 – NS	96 – 478*	96 – 478*	100 – 480	100 – 480
Manganese	µg /100 kJ	0.25 – 24*	0.25 – 24*	0.24 – 24*	0.25 – 24*	0.24 – 24*	0.24 – 24	0.24 – 24
Riboflavin	µg /100 kJ	14.3 – 119*	14.3 – 119*	14 – NS	19 – 119*	19 – 120*	14.3 – 95.6	14.3 – 95.6
Iron	mg/100 kJ	0.2 – 0.5	0.2 – 0.5	0.2 – 0.5	0.1 – ~	0.24 – 0.48	0.07 – 0.31	0.14 – 0.48
Calcium	mg/100 kJ	12 – 43*	12 – 35*	12 – NS	12 – 35*	12 – 43*	12 – 33.5	12 – 33.5

Iodine	µg /100 kJ	2.5 – 14*	2.5 – 14*	1.2 – 10	2.5 – 14*	2.4 – 14*	3.6 – 6.9	3.6 – 6.9
Selenium	µg /100 kJ	0.48 – 2.2*	0.48 – 2.2*	0.25 – 1.19	0.24 – 2.2*	0.48 – 2.2*	0.72 – 2	0.72 – 2

* = GUL NS = not specified ~ = levels may be determined by national authorities

3.4 Ratios

3.4.1 Stakeholder views

No issues were received during FSANZ 2021 CP2 relating to ratios present within follow-on formula nutrition composition.

3.4.2 Discussion

LA : ALA ratio

The linoleic acid to α-linolenic acid ratio is aligned across all regulations noted below in Table 3.4.3. All submitters to the FSANZ 2021 CP2 supported the approach for retaining the ratio of no less than 5 to 1 and no more than 15 to 1 in infant formula. FSANZ proposes to also retain this ratio for follow-on formula.

3.4.3 Preferred composition

Table 3.4.3 Preferred ratios for follow-on formula

Nutrient	Unit	P1028 follow-on formula	P1028 infant formula	Standard 2.9.1 Schedule 29	Codex CXS 72-1981	Codex Draft Standard for FuFOI	EU 2016/127 ANNEX I	EU 2016/127 ANNEX II
LA:ALA	ratio	5:1 - 15:1	5:1 - 15:1	5:1 - 15:1	5:1 - 15:1	5:1 - 15:1	NS	NS
Ca:P	ratio	1:1 – 2:1	1:1 – 2:1	1:1 – 2:1	1:1 – 2:1	1:1 – 2:1	1:1 – 2:1	1:1 – 2:1
Vitamin E : fatty acids	ratio	0.5mg : 1g - NS	0.5mg : 1g - NS	0.5mg : 1g - NS	0.5mg : 1g - NS	0.5mg : 1g - NS	NS	NS

3.5 Other nutritive substances

3.5.1 Stakeholder views

Table 3.5.1 Other nutritive substance issues raised by stakeholders

Issue & CP2 proposed approach	Raised by	FSANZ proposed response
Permit choline, Inositol and L-Carnitine as voluntary addition instead of mandatory additions. (currently voluntary)	4 submissions (4 industry)	After assessment, FSANZ's preferred option is to permit choline, inositol and L-Carnitine as optional ingredients within follow-on formula for the reasons stated below.
L-Carnitine minimum (0.29 mg/100 kJ)	1 submissions (1 industry)	After assessment, FSANZ's preferred option is to adopt a minimum of 0.3 mg/100 kJ for L-Carnitine within follow-on formula for the reasons stated below.
L-Carnitine as maximum not a GUL (GUL)	1 submissions (1 industry)	After assessment, FSANZ's preferred option is to set a maximum or GUL for follow-on formula for the reasons stated below.

3.5.2 Discussion

FSANZ considers that for fluoride, nucleotides, lutein and 2'-FL (alone or in combination with LNnT) it is appropriate for follow-on formula to align with the nutrient composition ranges proposed for infant formula. Further discussions on these nutrients can be found within section 2.5 above.

Taurine

Codex CXS 72-1987 includes provision for the addition of taurine at a maximum of 3 mg/100 kJ and similarly the EU 2016/127 (ANNEX I and ANNEX II), and Codex Draft Standard for FuFOI at 2.9 mg/100 kJ, with no minimum. FSANZ has proposed to retain its current permission for taurine of 0.8 – 3 mg/100 kJ within infant formula. Based on international harmonisation, FSANZ's preferred option is to also retain the permission for taurine as an optional ingredient within follow-on formula with a range of 0.8 - 3.0 mg/100 kJ.

Choline

Standard 2.9.1 currently permits choline as an optional ingredient in infant formula products at a range of 1.7 – 7.1 mg/100 kJ. FSANZ has proposed to increase the maximum to a GUL of 12 mg/200 kJ for infant formula. The Codex Draft Standard for FuFOI also permits choline as an optional ingredient with a GUL of 12 mg/100 kJ. The EU 2016/127 regulation for follow-on formula does not include any addition of choline on the basis of the EFSA recommendation that there is no need to add choline to follow-on formula (EFSA, 2014). FSANZ's preferred option, is to permit choline as an optional ingredient with a GUL of 12 mg/100 kJ in follow-on formula consistent with the maximum permitted for infant formula. This preferred option aligns with the Codex Draft Standard for FuFOI and the maximum levels prescribed by Codex STAN 72-1981.

Myo-inositol

Standard 2.9.1 currently permits inositol as an optional ingredient in infant formula products at a range of 1.0 – 9.5 mg/100 kJ. FSANZ has proposed to retain this range in infant formula. The addition of myo-inositol is not specified within EU 2016/127 for follow-on formula, however the addition to infant formula is mandatory under Codex CXS 72-1981, EU 2016/127 and the proposed infant formula nutrient composition for Standard 2.9.1. EFSA has recommended that sometimes the addition of optional substances, such as myo-inositol, are not necessary in the composition of follow-on formula as they can be synthesised endogenously and provided for by other foods in the complementary diet (EFSA, 2014). FSANZ's preferred option, which aligns with Codex CXS 156-1987, is to permit myo-inositol as an optional ingredient with a GUL of 9.5 mg/100 kJ in follow-on formula.

L-Carnitine

Standard 2.9.1 currently permits L-carnitine as an optional ingredient in infant formula products at a range of 0.21 – 0.8 mg/100 kJ. FSANZ has proposed a range of 0.3 – 0.8 (GUL) mg/100 kJ in infant formula. L-Carnitine is currently not specified within follow-on formula regulations, including Codex Draft Standard for FuFOI and EU 2016/127 ANNEX II. The Codex Draft Standard for FuFOI notes that L-carnitine 'levels may need to be determined by national authorities'. Both the EU Scientific Committee on Food (SCF) (2003) and EFSA (2014) recommend that L-carnitine not be mandatory for follow-on formula due to the addition of other complementary food sources and endogenous synthesis in older infants (EU SCF 2003, EFSA 2014). As there is evidence supporting the need for L-carnitine in infant formula, FSANZ's preferred option is to permit L-carnitine within follow-on formula, as

a voluntary substance, at a minimum level of 0.3 mg/100 kJ in line with infant formula. No maximum level is proposed.

3.5.3 Preferred composition

Table 3.5.3 Other nutritive substances for follow-on formula

Nutrient	Unit	P1028 follow-on formula	P1028 infant formula	Standard 2.9.1 (Schedule 29)	Codex CXS 72-1981	Codex Draft Standard for FuFOI	EU 2016/127 ANNEX I	EU 2016/127 ANNEX II
Choline	mg/100 kJ	NS – 12*	1.7 – 12*	1.7 – 7.1	1.7 – 12*	NS – 12*	6 – 12	NS
Myo-inositol	mg/100 kJ	NS – 9.5*	1.0 – 9.5*	1.0 – 9.5	1.0 – 9.5*	NS – 10*	0.96 – 9.6	NS
L-Carnitine	mg/100 kJ	0.3 - NS	0.3 – 0.8	0.21 – 0.8	0.3 – NS	~	0.3 - NS	NS
Taurine	mg/100 kJ	0.8 – 3	0.8 – 3	0.8 – 3	NS - 3	NS – 2.9	NS – 2.9	NS – 2.9
Lutein	µg/100 kJ	NS	NS	1.5 - 5	NS	NS	NS	NS
2′-O-fucosyllactose ^	mg/100 kJ	NS - 96	NS - 96	NS - 96	NS	NS	NS	NS
Nuceltodies								
Adenosine-5′-monophosphate	mg / 100 kJ	NS - 0.38	NS - 0.38	0.14 – 0.38	~	~	NS – 0.36	NS – 0.36
Cytidine-5′-monophosphate	mg / 100 kJ	NS - 0.6	NS - 0.6	0.22 – 0.6	~	~	NS – 0.60	NS – 0.60
Guanosine-5′-monophosphate	mg / 100 kJ	NS - 0.12	NS - 0.12	0.04 – 0.12	~	~	NS – 0.12	NS – 0.12
Inosine-5′-monophosphate	mg / 100 kJ	NS - 0.24	NS - 0.24	0.08 – 0.24	~	~	NS – 0.24	NS – 0.24
Uridine-5′-monophosphate	mg / 100 kJ	NS - 0.42	NS - 0.42	0.13 – 0.42	~	~	NS – 0.42	NS – 0.42
Total free nucleotide 5'-monophosphates	mg / 100 kJ	NS - 3.8	NS - 3.8	NS - 3.8	~	~	NS - 1.2	NS - 1.2

NS = Not specified * = GUL ~ = Levels may need to be determined by national authorities.
^ A combination of 2′-O-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

3.5.3.1 Proposed composition once reconstituted

Fluoride

After assessment, FSANZ's preferred option is to set a compositional limit for fluoride of 24 µg/100 kJ when prepared ready for consumption and to remove the labelling statements relating to dental fluorosis in paragraph 2.9.1—23(1)(b). This limit is not set out in the above composition table as it will be addressed within paragraph 2.9.1—23(2)(a). This is based on the conclusions of FSANZ 2021 CP2.

4. Part C: Infant Formula Products

Issues discussed in Part C of this SD relate to infant formula products, as defined in the CFS as: 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.

4.1 Permitted Forms for Infant Formula Products

4.1.1 Stakeholder views

Table 4.1.1 Permitted form issues raised by stakeholders

Issue & CP2 proposed approach	Raised by	FSANZ response
Pantothenic acid (permit D-panthenol, calcium D-pantothenate, and sodium D-pantothenate as forms for pantothenic acid but not DL-panthenol)	2 submissions (2 industry)	After consideration of submissions, FSANZ's preferred option remains unchanged. See discussion below for further information.
Vitamin D (Retain permissions for vitamin D_2 and vitamin $D_{3)}$	4 submissions (2 industry, 2 government)	Industry submitters agreed with the proposed approach. Government submitters did not agree with the proposed approach to retain vitamin D2 as a form of vitamin D. For the reasons stated in CP 2016 and in CP2 and below, FSANZ's preferred option is to retain permission for vitamin D2 and vitamin D3.
Niacin (Not to permit nicotinic acid for use in infant formula)	4 submissions (3 industry, 1 government)	Submitters agreed with maintaining the current requirement of preformed niacin. Most submitters did not support the non-alignment with Codex CXS 156-1987 with nicotinic acid. For the reasons stated in FSANZ 2016 Nutrition Assessment, in CP2 and below, FSANZ's preferred option is to not permit nicotinic acid for use in infant formula
Copper (Permit cupric carbonate)	0 submissions	No submissions were received on this proposed approach. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Magnesium (Permit magnesium hydroxide carbonate, magnesium hydroxide and magnesium salts of citric acid)	0 submissions	No submissions were received on this proposed approach. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Potassium (Permit potassium L-lactate)	0 submissions	No submissions were received on this proposed approach. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.

Zinc (Permit zinc lactate and zinc citrate (zinc citrate dehydrate or zinc citrate trihydrate))	0 submissions	No submissions were received on this proposed approach. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Iron (Permit ferric citrate, ferrous bisglycinate and ferrous sulphate)	0 submissions	No submissions were received on this proposed approach. After assessment, FSANZ's preferred option is to retain the CP2 approach for the reasons stated below.
Folic Acid (Permitted forms of folate/folic acid were not addressed in CP2)	1 submission (1 industry)	One industry submitter suggested calcium L-methylfolate should be a permitted form of folic acid, particularly within SMPPi. Under the new regulatory framework for SMPPi, permitted forms can be added where needed to address a specific disease, disorder or medical condition. After consideration of submissions, FSANZ's preferred option remains unchanged.

4.1.2 Discussion

Pantothenic acid

FSANZ 2021 CP2 proposed to permit D-panthenol, calcium D-pantothenate, and sodium D-pantothenate as forms for pantothenic acid but not DL-panthenol which is consistent with EU 2016/127 direction. Two industry submitters commented on the proposed approach and did not agree with not aligning with Codex CXS 156-1987 which allows DL-panthenol.

FSANZ 2016 Nutrition Assessment considered this issue and identified that the physiological activity of the DL form of panthenol is half of the D-isomer. Due to its decreased activity FSANZ does not consider it an adequate form of pantothenic acid, in comparison with the other permitted forms discussed within FSANZ 2021 CP2. Therefore, FSANZ's preferred option is to not permit DL-panthenol.

Vitamin D

FSANZ 2021 CP2 proposed to retain permission for vitamin D_2 and vitamin D_3. This was on the basis that FSANZ's 2016 Nutrition Assessment concluded that both forms are equally effective in raising 25-hydroxyvitamin D (25OHD) concentration.

Four submitters (two industry and two government) commented on the proposed option. Industry submitters agreed with the proposed approach. Government submitters did not agree with the retention of Vitamin D_2 as a form of vitamin D, suggesting that a review of literature indicates that D_3 is more effective in its ability to raise 25-hydroxyvitamin D status.

2016 Nutrition Assessment concluded that in addition to both forms being equally effective in raising 25OHD concentration, use of vitamin D_2 would be unlikely to pose a risk to infant health. Additional assessment examined whether any human clinical trials published from 2015 to 2018 compared the efficacy of vitamin D_2 and vitamin D_3 in raising serum 25OHD concentrations. No clinical studies involving infants were identified from the literature search.

Also, during the revision of the Codex Draft Standard for FuFOI, it was concluded that the requirement for vitamin D should encompass both vitamin D_2 and vitamin D_3.

Based on the 2016 Nutrition Assessment and the conclusions from the revision of the Codex Draft Standard for FuFOI on permitted forms for this nutrient, FSANZ's preferred option is to retain permission for vitamin D_2 and vitamin D_3.

Niacin

FSANZ 2021 CP2 proposed to not permit nicotinic acid for use in infant formula. Four submitters (three industry and one government) commented on the proposed approach. Some submitters did not support the non-alignment with Codex CXS 72-1981 by not permitting nicotinic acid.

The FSANZ 2016 Nutrition Assessment concluded that as nicotinamide is less toxic and serves the same biological function as nicotinic acid, it is preferable to use nicotinamide rather than nicotinic acid in infant formula. Therefore, although nicotinic acid is used as a form of niacin in infant formula in Codex CXS 72-1981, it does not meet this assessment criteria and it was concluded that use of this form may pose a risk to infant health.

Therefore, based on the FSANZ 2016 Nutrition Assessment, FSANZ's preferred option is to not permit nicotinic acid for use in infant formula.

4.1.3 Preferred composition

Table 4.1.3 Preferred permitted forms for infant formula products

Nutrient	Change Proposed (Y/N)	Proposed Approach	Standard 2.9.1 (Schedule 29)
Pantothenic Acid	Yes	D-panthenol, calcium D-pantothenate, sodium D-pantothenate as new forms in addition to existing permissions	Calcium pantothenate, dexpanthenol
Vitamin D	No	Vitamin D_2, vitamin D_3 and vitamin D (cholecalciferol-cholesterol)	Vitamin D_2, vitamin D_3 and vitamin D (cholecalciferol-cholesterol)
Niacin	No	Niacinamide (nicotinamide)	Niacinamide (nicotinamide)
Copper	Yes	Cupric carbonate as a new form in addition to existing permissions	Copper gluconate, cupric sulphate, cupric citrate
Magnesium	Yes	Magnesium hydroxide carbonate, magnesium hydroxide and magnesium salts of citric acid as new forms in addition to existing permissions	Magnesium carbonate, magnesium gluconate, magnesium oxide, magnesium phosphate dibasic, magnesium phosphate tribasic, magnesium sulphate
Potassium	Yes	Potassium L-lactate as a new form in addition to existing permissions	Potassium bicarbonate, potassium carbonate, potassium chloride, potassium citrate, potassium glycerophosphate, potassium gluconate, potassium hydroxide, potassium phosphate, dibasic, potassium phosphate, monobasic, potassium phosphate, tribasic
Zinc	Yes	Zinc lactate and zinc citrate (zinc citrate dehydrate or zinc citrate trihydrate) as new forms in addition to existing permissions	Zinc acetate, zinc chloride, zinc gluconate, zinc oxide, zinc sulphate
Iron	Yes	Ferric citrate, ferrous bisglycinate and ferrous sulphate as new forms in addition to existing permissions	Ferric ammonium citrate, ferric pyrophosphate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferrous succinate, ferrous sulphate

Choline	Yes	Choline, choline citrate and choline hydrogen tartrate as new forms in addition to existing permissions	Choline chloride and choline bitarate
L-Carnitine	Yes	L-carnitine hydrochloride and L-carnitine tartrate as new forms in addition to existing permission	Does not permit other forms of L-carnitine
Inositol	Yes	Refer to inositol as myo-inositol	Inositol

4.2 Vitamin and Mineral Supplementation

4.2.1 Stakeholder views

FSANZ received comments and additional information (including recent research) on vitamin and mineral supplementation in infants following FSANZ 2016 CP. Nine submitters (four industry, four government, one health professional) provided information in response to the four questions posed. These are summarised in 4.2 below.

Table 4.2.1 Vitamin and mineral supplementation issues and information raised by stakeholders

Comments	Submitter
General comments	
Supported maintaining as a voluntary statement, or considered existing non-regulatory guidance is sufficient. Further communication more broadly should be a matter for health care professionals and relevant health authorities to consider. Noted some brands currently include the information.	Industry
Stated that FSANZ should consider: • the amount of vitamins and minerals provided by infant formula, given minimum level meets the needs of virtually all healthy infants and infant formula usually provide more than this. • the position provided by EFSA NDA and ESPGHAN that excess amounts of substances can be a burden on infant systems.	Government
Evidence on prevalence of vitamin and mineral preparation use by ANZ infants	
Provided information regarding presentation at the 2016 Dietitians Association of Australia conference on the prevalence of supplement use in Australia. Using data from the 2011 Australian Health Survey, which showed: • Sample size 742 infants • 8% females and 6% males aged 0-12 months used vitamin supplements.	Government
Suggested prevalence information could be sourced from pharmacists or through a survey of Therapeutic Goods Administration (TGA) registered or Medsafe products appropriate for infants.	Industry
Prevalence of vitamin and mineral preparation use in formula-fed infants versus breastfed infants	
Vitamin D: - Supplementation might be provided to breastfed infants as different jurisdictions screen infants for different vitamin and mineral deficiencies, and may suggest ways to address deficiencies identified. - Studies provided evidence for routine vitamin D supplementation (Grant 2013; Munns 2006; Wheeler 2015). - Supplementation recommendations exist overseas (e.g. American Academy of Paediatrics). - Prevalence may be more relevant for breastfed infants as several evidence based recommendations exist for some subgroups of infants (NHMRC 2012, MoH 2008).	Industry
Advice given by health care professionals and/or state and territory government agencies on whether vitamin and mineral supplementation is needed for infants	
From health care professional perspective, supplementation is not indicated unless there are insufficiencies (e.g. vitamin D or iron).	Health care professional
Specific medical advice is recommended for supplementation as per principles outlined in NHMRC Infant Feeding Guidelines (2012).	Government
New Zealand Ministry of Health Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2): includes advice that full-term breastfed or formula fed infants should not require supplements.	Government
Individual advice is provided in clinical situations, e.g. clinical deficiency or for at risk groups (e.g. preterm or dark skinned infants).	Government
Government endorsed websites providing information on infant feeding do not state whether or not supplementation should be given.	Government
Paediatric dietitians and maternal and child health care nurses have indicated supplements would not normally be recommended for infants unless there is a specific reason to do so (e.g. high risk vitamin D deficiency).	Government

Comments	Submitter
Supplementation may not be driven by health care professionals' advice. An Australian study indicated largest reported information source for infant feeding was relatives and friends (78%), with 69% seeking health care professional advice. Television and internet were also significant information sources (Newby R, et al., 2015).	Government
Supplementation is not needed for healthy infants (either breastfed or formula-fed).	Industry
Unaware of any national guidelines for vitamin/supplementation for formula-fed infants.	Industry
Cost and trade implications of mandating advice regarding vitamin and mineral preparations on infant formula packages	
Prescribed label changes will require revised artwork and cost.	Industry
The requirement would be inconsistent with international regulations and could cause a trade barrier.	Industry

4.2.2 Discussion

Current regulations

The *Guidelines for infant formula products* in subsection 29—10(2) of Schedule 29 include a *Guideline on advice regarding additional vitamin and mineral supplementation* that states:

> *Manufacturers are recommended to provide an advice in the label on a package of infant formula product to the effect that consumption of vitamin or mineral preparations are not necessary.*

As this is guidance only, infant formula companies can choose whether to provide this advice on their product labels. FSANZ is not aware of any international or overseas regulations that require or recommend infant formula product labels to include advice about use of vitamin or mineral preparations for infants.

Previous consideration

FSANZ 2016 CP noted that this advice had been part of both the Australian and New Zealand Regulations prior to the joint Code. The need for this advice was reviewed during Proposal P93, at which time it was determined the advice would assist in protecting against the risk of toxicity arising from excessive vitamin and mineral intakes. At that time it was decided to retain the advice as a voluntary addition to labels, because it could constitute a technical barrier to trade if mandated (ANZFA 2002). Thus it was included in the Guidelines to the Standard to encourage infant formula product companies to display this information on product labels.

FSANZ reviewed a range of products available on the ANZ market in the FSANZ 2016 CP. The majority of products did not include the advice on labels. FSANZ noted in 2016 that there was limited data on dietary supplement intake of ANZ infants. It was noted however, that there were a number of vitamin and mineral preparations designed specifically for infants available from pharmacies in ANZ. Based on the available evidence (refer to Attachment A2.2 to SD2 of FSANZ 2016 CP2), no conclusion could be reached about the likely prevalence of caregivers directly adding vitamins and minerals to infant formula in ANZ. FSANZ posed several questions to submitters seeking information about: the prevalence of vitamin and mineral preparation use by ANZ infants, data on intake levels of vitamins and minerals, advice given by healthcare professionals about vitamin and mineral supplementation and the cost and trade implications of mandating this advice on infant formula product packages.

Relevant evidence

Limited evidence was identified on the prevalence of vitamin and mineral preparation use by infants in ANZ. FSANZ did not identify any additional data on the prevalence in ANZ, however some data from the US Feeding Infants and Toddlers Studies was obtained. In a 2002 study (Briefel et al 2006), 4.9% of infants aged between 4 - 5 months (n=624) had taken a supplement, while 14.5% of infants aged between 6 - 11 months had taken a supplement in a 24 hour recall period. Most infants were given one type of supplement, commonly a multivitamin and/or mineral supplement.

In 2016, 23% of infants aged between 0 - 5.9 months (n=600) had taken a supplement in a 24 hour recall period, while 15% (n=902) of infants aged between 6 - 11.9 months had taken a supplement (Bailey et al 2018). The most prevalent supplement used was vitamin D, while a small number consumed vitamin E supplements. The authors report that supplements contributed to exceedance of the UL for retinol in infants aged between 9 - 11.9 months.

A Singapore study investigating infant feeding practices (infants aged between 9 – 12 months) and differences between the major ethnic groups (Chinese, Malay and Indian) reported that 20.5% of infants were given vitamin and mineral supplements in the first year of life (Toh et al 2016). The most common types given were multivitamins (9.0%) and minerals such as iron and calcium (8.4%). Individual vitamins (4.0%) e.g. vitamin A, B12, C and D were also given (Toh et al 2016). There were differences (not statistically significant) between the ethnic groups.

The respective Australian and New Zealand Infant Feeding Guidelines (NHMRC 2012; MoH 2008) advise that healthy infants, both breastfed and formula-fed, generally do not require dietary supplements, including vitamin and mineral supplements. Thus the statement that ‘consumption of vitamin and mineral preparations are not necessary’ is consistent with current best practice guidance.

As noted by submitters, there are a small number of exceptions in both countries. Vitamin D supplementation is recommended under medical supervision for some sub-groups of breastfed infants. Infants on a vegan diet can require nutritional supplements, especially iron and vitamin B12, after dietary assessment by a healthcare professional.

FSANZ has observed some infant formula products currently include the advice on their labels, although this is not common practice.

Preferred option

The original purpose of this guidance statement was to assist in protecting against the risk of toxicity arising from excessive vitamin and mineral intakes. Given the lack of evidence that this is a problem for ANZ formula fed infants, combined with the lack of voluntary use of the statement on labels, FSANZ proposes to remove the guideline on advice regarding additional vitamin and mineral supplementation (subsection S29—10(2) of Schedule 29).

4.3 Measuring scoop

4.3.1 Stakeholder views

FSANZ 2021 CP2 received 15 submissions (eight industry, five government, two health professionals) on this. All submitters who commented on this issue supported FSANZ's view not to standardise the scoop volume. However, three government submitters sought further consideration of a standardised ratio.

Table 4.3.1 Measuring scoop issues raised by stakeholders

Issue	Raised by	FSANZ response
Support a standardised ratio (e.g. one scoop to each 30 ml or 50 ml of water) for the following reasons: • to reduce risk of over and under concentration, particularly for groups with lower literacy skills • consumer evidence suggests consumers rarely recheck instructions when they change brands for cost saving reasons or when formula availability changes • case studies where changes in water ratios have led to errors and hypernatremic dehydration in infants (Leung 2009) • health professionals recommend 1 scoop per 30 ml water to allow for smaller increments to reduce risk of overfeeding • all UK infant formula brands appear to use 1 scoop per 30 ml	3 submissions (3 government)	FSANZ's preferred option is to maintain the current approach for the reasons stated below.

4.3.2 Discussion

Current regulation

Standard 2.9.1 includes three requirements relating to the presence and use of a measuring scoop. These requirements are:

- that a package of infant formula product in powdered form (excluding single serve sachets) must contain a scoop to enable the use of the product in accordance with the directions for preparation on the label (section 2.9.1—18)
- the weight of one scoop to be declared (if a powdered product), and
- the proportion of powder or concentrate required to reconstitute the formula according to directions to be declared (if a powdered or concentrated form of infant formula product) (paragraph 2.9.1—21(1)(b)).

Previous consideration

FSANZ referenced these requirements in section 5.4.3 of FSANZ 2021 CP1, however they were not specifically discussed. These requirements also received no comments from submitters during the consultation.

FSANZ did receive consumer evidence that did not support standardising the scoop volume or ratio as it would be difficult and costly to implement, and it would be inconsistent with Codex Alimentarius and other overseas regulations.

Discussion

FSANZ considers that all submitters to FSANZ 2021 CP2 supported the approach from FSANZ 2021 CP1 and that this approach aligns with international standards (Codex CXS

72-1981, EU 2016/127 and the Draft Codex Standard for FuFOI). FSANZ notes there is comprehensive guidance around the importance of preparing infant formula products as directed and it is covered in detail within both the Australian Infant Feeding Guidelines and the Healthy Eating Guidelines for New Zealand Babies and Toddlers (NHMRC 2012, MoH 2021). Further to this, FSANZ notes that prescribing a standardised ratio is not common practice internationally and would put the ANZ market out of step with Codex Alimentarius and the EU regulations. As a large portion of the ANZ market place is imported, this could create importation issues.

Standard 2.9.1 provides set compositional requirements for infant formula products and due to the prescribed compositional ranges differentiation between products is evident. Products will differ further based on individual formulation (within the compositional limits) and through the prescribed 'directions of use' which are determined by manufacturers. The reconstitution of infant formula products is also determined by manufacturers based on the products specific requirements. These requirements are discussed within SD1.

FSANZ considers the requirement for the package of infant formula to contain a scoop specific to that infant formula product is necessary, given the risk of over or under nutrition from using a different measure. There are existing labelling provisions that also address this risk, including that requirement for a direction instructing that if a package contains a measuring scoop, only the enclosed scoop should be used (see section 7.2 of SD1) and a warning statement to not change the proportions of powder (or concentrate) except on medical advice (see section 7.7 of SD1). Declaring the weight of the scoop and the amount of water needed to prepare the formula is important information for the general population to aid correct preparation. This information, and information about the proportion of powder or concentrate, is also useful for health professionals when calculating the nutritional value of the formula when reconstituted according to directions on the label.

Further to this, as the weight of the scoop is not standardised across infant formula products it is difficult to prescribe a standardised ratio due to varying dilution recipes. As noted in FSANZ 2012 the weight of a measuring scoops for infant formula products can vary largely in size between brands due to bulk density and energy density, where one scoop can be equal to 30, 50 or 60 mL of powdered formula depending on the product. The weight of the scoop noted above will further vary the amount of water the formula is ideally reconstituted with to deliver the optimum level of nutrition. While a standardised ratio may provide consistency across infant formula products, there is not clear consumer evidence that supports this. FSANZ also notes that prescribing a standardised ratio would likely incur technological difficulties and be costly to implement.

There is also a lack of evidence to demonstrate that a standardised ratio would address the issues raised in regard to FSANZ 2021 CP2.

4.3.3 Preferred option

Based on the above discussion, FSANZ's preferred option is 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.

4.4 Modified Formulas

Following the 2021 consultation, FSANZ reconsidered the regulatory framework and definitions for infant formula products. This included a review of the classification of infant formula, follow-on formula and specialised infant formula products. The CFS outlines the regulatory framework and definitions within sections 2 and 3.

FSANZ has proposed to include products which have been compositionally modified to be either low lactose/lactose free or contain partially hydrolysed protein as infant formula products. This decision was made on the basis that SMPPi are specifically formulated for a specific disease, disorder or medical condition and are prescribed under medical supervision. These formulas are also sold over the counter or via a script. Modified formulas were previously classified under the Infant Formulas for Special Dietary Uses (IFSDU), however as low lactose/lactose free and partially hydrolysed protein formulas are not effective in the clinical management of allergies and are considered low risk products they are more appropriately classified within infant formula products. This is on the basis that these formulas are modified for dietary conditions and are otherwise deemed safe for use by healthy infants.

Recent studies have re-affirmed that partially hydrolysed proteins are safe and appropriate for use in starter formulas for infants who cannot be exclusively breastfed and show no difference in growth or development when compared to infants who consume cow's milk protein formula (Vandenplas 2019, Gappa 2021). The use of partially hydrolysed formulas in the prevention of allergies is also not supported by the majority of stakeholders to FSANZ 2021 CP3 and current infant feeding guidelines, which state that only extensively hydrolysed and amino acid formulas are recommended for the dietary management of cow's milk protein allergy. The guidelines also do not differentiate between degree of hydrolysis in partially hydrolysed formulas (NHMRC 2012). Industry submitters also provided data that evidenced all currently available partially hydrolysed infant formula products on the ANZ market are based on 100% whey protein.

Low lactose/lactose free and partially hydrolysed protein formulas must meet the essential composition prescribed for infant formula products.

If a formula is represented as being low lactose, FSANZ retains the requirements that it must contain no more than 0.3 g lactose/100 mL.

The stakeholder views and labelling requirements for low lactose/lactose free and partially hydrolysed protein infant formula products are discussed in section 5.1 and 5.2, respectively, of SD3.

Attachment 1

Table 1: Infant formula products composition compared with international regulations

Nutrient	Unit	P1028 Infant formula		P1028 follow-on formula		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
Energy	kJ/L	2500	2950	2500	2950	2500	2950	2510	2930	2500	2930	2500	2930
Protein (cow)	g/100 kJ	0.43	0.7	0.43	0.7	0.45	0.7	0.43	0.72	0.43	0.6	0.38	0.6
Protein (soy)	g/100 kJ	0.54	0.7	0.54	0.7	0.5	0.7	0.54	0.72	0.54	0.67	0.54	0.67
Carbohydrates	g/100 kJ	NS	NS	NS	NS	2.2	3.3	2.2	3.3	2.2	3.3	2.2	3.3
Total fat	g/100 kJ	1.05	1.4	1.05	1.4	1.05	1.4	1.1	1.4	1.1	1.4	1.1	1.4
Linoleic acid (LA)	mg/100 kJ	90	330*	90	330*	70	330*	72	335*	120	300	120	300
α-Linolenic acid (ALA)	mg/100 kJ	12	NS	12	NS	12	NS	12	NS	12	24	12	24
Lauric + Myristic acid	% total fatty acid	NS	NS	NS	NS	NS	20	NS	20	NS	NS	NS	NS
Erucic Acid^	% total fatty acid	NS	1	NS	1	NS	1	NS	1	NS	0.4	NS	0.4
Docosahexaenoic acid (DHA)^	mg/100kJ	NS	7.2	NS	7.2	NS	0.5%[1]	NS	7*	4.8	12	4.8	12
Arachidonic acid^	% total FA	NS	1	NS	1	≥ DHA	NS	≥ DHA	NS	NS	1	NS	1
Trans fatty acid^	% total FA	NS	4	NS	4	NS	3	NS	3	NS	3	NS	3
Phospholipids^	g/L	NS	2	NS	2	NS	2	NS	2	NS	2	NS	2
Vitamin A	µg RE/100 kJ	14	43	14	43	14	43	18	43	16.7	27.2	16.7	27.2
Vitamin B6	µg /100 kJ	8.5	45*	8.5	45*	8.5	45*	8	42*	4.8	41.8	4.8	41.8
Vitamin B12	µg /100 kJ	0.025	0.36*	0.025	0.36*	0.025	0.36*	0.02	0.36*	0.02	0.12	0.02	0.12
Niacin	µg /100 kJ	70	360*	70	360*	70	360*	72	359*	100	360	100	360
Riboflavin	µg /100 kJ	14.3	119*	14.3	119*	19	119*	19	120*	14.3	95.6	14.3	95.6
Vitamin C	mg/100 kJ	1.7	17*	1.7	17*	2.5	17*	2.4	17*	0.96	7.2	0.96	7.2
Vitamin D	µg /100 kJ	0.25	0.63	0.25	0.63	0.25	0.6	0.24	0.72	0.48	0.6	0.48	0.72
Vitamin E	mg α-TE/100 kJ	0.12	1.2*	0.12	1.2*	0.12	1.2*	0.12	1.2*	0.14	1.2	0.14	1.2
Vitamin K	µg /100 kJ	0.24	6.5*	0.24	6.5*	1	6.5*	0.96	6*	0.24	6	0.24	6
Phosphorus	mg/100 kJ	6	24*	6	24*	6	24*	6	24*	6	21.5	6	21.5
Calcium	mg/100 kJ	12	35*	12	43*	12	35*	12	43*	12	33.5	12	33.5
Magnesium	mg/100 kJ	1.2	3.6*	1.2	3.6*	1.2	3.6*	1.2	3.6*	1.2	3.6*	1.2	3.6
Iron	mg/100 kJ	0.2	0.5	0.2	0.5	0.1	~	0.24	0.48	0.07	0.31	0.14	0.48
Folic acid	µg /100 kJ	2.5	12*	2.5	12*	2.5	12*	2.4	12*	3.6	11.4	2.5	12
Sodium	mg/100 kJ	5	14	5	14	5	14	4.8	14	6	14.3	6	14.3
Chloride	mg/100 kJ	12	38	12	38	12	38	12	38	14.3	38.2	14.3	38.2
Potassium	mg/100 kJ	14	43	14	43	14	43	14	43	19.1	38.2	19.1	38.2
Pantothenic acid	µg /100 kJ	96	478*	96	478*	96	478*	96	478*	100	480	100	480

Manganese	µg /100 kJ	0.25	24*	0.25	24*	0.25	24*	0.24	24*	0.24	24*	0.24	24
Zinc	mg/100 kJ	0.12	0.36*	0.12	0.36*	0.12	0.36*	0.12	0.36*	0.12	0.24	0.12	0.24
Thiamin	µg /100 kJ	10	72*	10	72*	14	72*	14	72*	9.6	72	9.6	72
Biotin	µg /100 kJ	0.24	2.4*	0.24	2.4*	0.4	2.4*	0.36	2.4*	0.24	1.8	0.24	1.8
Copper	µg /100 kJ	8.5	29*	8.5	29*	8.5	29*	8	29*	14.3	24	14.3	24
Iodine	µg /100 kJ	2.5	14*	2.5	14*	2.5	14*	2.4	14*	3.6	6.9	3.6	6.9
Selenium	µg /100 kJ	0.48	2.2*	0.48	2.2*	0.24	2.2*	0.48	2.2*	0.72	2	0.72	2
Taurine^	mg/100 kJ	0.8	3	NS	3	NS	3	NS	2.9	NS	2.9	NS	2.9
Choline	mg/100 kJ	1.7	12*	NS	12*^	1.7	12*	NS	12*^	6	12	NS	NS
Myo-inositol	mg/100 kJ	1.0	9.5*	NS	9.5*^	1.0	9.5*	NS	10*^	0.96	9.6	NS	NS
L-Carnitine	mg/100 kJ	0.3	0.8*	0.3^	NS^	0.3	NS	~	~	0.3	NS	NS	NS
Adenosine-5′-monophosphate^	mg / 100 kJ	NS	0.38	NS	0.38	~	~	~	~	NS	0.36	NS	0.36
Cytidine-5′-monophosphate^	mg / 100 kJ	NS	0.6	NS	0.6	~	~	~	~	NS	0.6	NS	0.6
Guanosine-5′-monophosphate^	mg / 100 kJ	NS	0.12	NS	0.12	~	~	~	~	NS	0.12	NS	0.12
Inosine-5′-monophosphate^	mg / 100 kJ	NS	0.24	NS	0.24	~	~	~	~	NS	0.24	NS	0.24
Uridine-5′-monophosphate^	mg / 100 kJ	NS	0.42	NS	0.42	~	~	~	~	NS	0.42	NS	0.42
Total free nucleotide 5'-monophosphates^	mg / 100 kJ	NS	3.8	NS	3.8	~	~	~	~	NS	1.2	NS	1.2
Fluoride	µg /100 kJ	NS	24	NS	24	NS	24	NS	NS	NS	24	NS	24
2′-O-fucosyllactose	mg / 100 kJ	NS	96[2]	NS	96[2]	NS	NS	NS	NS	NS	NS	NS	NS
LA:ALA	ratio	5:1	15:1	5:1	15:1	5:1	15:1	5:1	15:1	NS	NS	NS	NS
Ca:P	ratio	1:1	2:1	1:1	2:1	1:1	2:1	1:1	2:1	1:1	2:1	1:1	2:1
Vitamin E : fatty acids	ratio	0.5mg : 1g	NS	0.5mg : 1g	NS	0.5mg : 1g	NS	0.5mg : 1g	NS	NS	NS	NS	NS
Eicosapentaenoic acid	ratio	NS	≤ DHA	NS	≤ DHA	NS	≤ DHA	NS	≤ DHA	NS	≤ DHA	NS	≤ DHA

NS = Not specified * = GUL ~ = Levels may need to be determined by national authorities ^ = voluntary addition [1] = total fatty acids

[2] = A combination of 2′-O-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.

Retain restrictions on inulin-type fructans and galacto-oligosaccharides in Standard 2.9.1—7.

References

Agostoni, Carlo*; Esposito, Susanna†; Nobili, Alessandro‡ Dietary Supplements in Infants and Children: Only Beneficial?, Journal of Pediatric Gastroenterology and Nutrition: August 2016 - Volume 63 - Issue 2 - p 177-180 doi: 10.1097/MPG.0000000000001180

Australia and New Zealand Food Regulation Ministerial Council. Regulation of Infant Formula Products. 2011 Available from: Food Regulation - Policy guideline on infant formula products

Campos-Giménez E, Bénet S, Oguey Y, Martin F, Redeuil K (2018) The contribution of minor folates to the total vitamin B9 content of Infant formula and clinical nutrition products. Food Chem. 249: 91-97. https://doi.org/10.1016/j.foodchem.2017.12.061.

Casey CE, Smitt A, Zhang P (1995) Microminerals in human and animal milks. In: Jensen RG (ed) Handbook of Milk Composition. Academic Press, New York, NY, p. 622–674

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, Brussels Available online at http://ec.europa.eu/food/fs/sc/scf/out199_en.pdf

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

FSANZ (2012) Consultation Paper – Regulation of Infant Formula Products in the *Australia New Zealand Food Standards Code*. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/infant/Pages/default.aspx

FSANZ (2016) Consultation Paper – Proposal P1028 (amended 4 May 2016). Infant formula. FSANZ, Canberra. Available online at www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

FSANZ (2016b) 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 (2016c) Consultation paper – Proposal P1028. Supporting Document 1: Definitions and Nutrient Composition – Proposal P1028 Infant Formula. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

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 (2021a) Consultation Paper 1 – Food Safety and Technology. 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. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

FSANZ (2021c) 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 (2021d) Consultation Paper 3 – Regulatory Framework and Definitions. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

FSANZ (2021e) Approval Report – Application A1190 – 2'-FL in infant formula and other products. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/applications/Pages/A1190.aspx

Gappa, M; et al. (2021) Long-term effects of hydrolyzed formulae on atopic diseases in the GINI study. Allergy 2021, PMID: 33320352

Jaime J Gahche, Kirsten A Herrick, Nancy Potischman, Regan L Bailey, Namanjeet Ahluwalia, Johanna T Dwyer (2019) Dietary Supplement Use among Infants and Toddlers Aged <24 Months in the United States, NHANES 2007–2014, *The Journal of Nutrition*, Volume 149, Issue 2, February 2019, Pages 314–322, https://doi.org/10.1093/jn/nxy269

Leung C, Chang WC, Yeh SJ (2009) Hypernatremic dehydration due to concentrated infant formula: report of two cases. Pediatr Neonatol. 2009 Apr;50(2):70-3. doi: 10.1016/S1875-9572(09)60036-X. PMID: 19453082.

Lonnerdal B (2008) Intestinal regulation of copper homeostasis: a developmental perspective. Am J Clin Nutr 88(3):846S–850S

LSRO (1998) Assessment of nutrient requirements for infant formulas. Life Sciences Research Office. J. Nutr. 128(11S):2059S–2294S.

Luckock, U., Harnett, J., & Cairns, R. (2021). Vitamin and mineral supplement exposures: Cases reported to Australia's largest Poisons Information Centre, 2014–2015 to 2018–2019. *British Journal of Nutrition, 126*(12), 1788-1793. doi:10.1017/S0007114521000647

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. WHO Regional Publications European Series, No 87. Rome, 2000.

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/

NHMRC (2012) Australian Infant Feeding Guidelines – Information for Health Workers. National Health and Medical Research Council, Canberra. https://www.nhmrc.gov.au/about-us/publications/infant-feeding-guidelines-information-health-workers

Oliver, Colleen, Caitlin Watson, Elesa Crowley, Melissa Gilroy, Denise Page, Katrina Weber, Deanna Messina, and Barbara Cormack. 2020. "Vitamin and Mineral Supplementation Practices in Preterm Infants: A Survey of Australian and New Zealand Neonatal Intensive and Special Care Units" *Nutrients* 12, no. 1: 51. https://doi.org/10.3390/nu12010051

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

Vandenplas, Y; et al. (2019) Partially hydrolyzed formula in non-exclusively breastfed infants: A systematic review and expert consensus. Nutrition, 2019, 57, 268-274

WHO/FAO. Vitamin and mineral requirements in human nutrition: Report of a joint FAO/WHO expert consultation, Bangkok, Thailand, 21-30 September 1998. . 2004;World Health Organisation and Food

and Agriculture Organization of the United Nations

Yamawaki N, Yamada M, Kan-no T, Kojima T, Kaneko T, Yonekubo A (2005) Macronutrient, mineral and trace element composition of breast milk from Japanese women. J Trace Elem Med Biol 19(2-3):171–181