13 June 2024
293-24

Approval Report – Proposal P1028

Infant Formula

Food Standards Australia New Zealand (FSANZ) has prepared and assessed a proposal to revise and clarify standards in the Australia New Zealand Food Standards Code relating to the regulatory framework, composition, labelling, category definitions and representation of infant formula products.

On 26 April 2023, FSANZ sought submissions on two draft variations and published an associated report. FSANZ received 34 submissions.

After having regard to the submissions received and the relevant matters as set out in this report, FSANZ approved the draft variations on 4 June 2024. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 13 June 2024.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991*.

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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Supporting documents

The following documents which informed the assessment of this proposal are available on the FSANZ website.

SD1 Regulatory Intent
SD2 Decision Regulation Impact Statement

Executive summary

Proposal P1028 – Infant Formula was prepared to review the regulatory requirements for infant formula products set by the Australia New Zealand Food Standards Code (the Code). The objective of the proposal was to ensure the regulation of infant formula products remained safe and suitable, while accounting for the latest scientific evidence, market developments, changes in the international regulatory context and updated Australian and New Zealand policy guidance. The review included the regulatory framework, definitions for product categories, nutrient composition, food additives, contaminants and labelling of infant formula products.

Food Standards Australia New Zealand (FSANZ) committed to reviewing infant formula product regulations after receiving policy guidance from the then Australia New Zealand Food Regulation Ministerial Council in May 2011. The standards for infant formula products were, on the whole, functioning adequately, however there was scope to clarify some standards, improve alignment with newly revised international benchmarks and international food regulators and consider application of the Ministerial Policy Guideline on the Regulation of Infant Formula Products (ANZFRMC, 2011).

Proposal P1028 commenced in 2013 and was assessed under FSANZ's major procedure, requiring two rounds of statutory public consultation. The review of regulatory requirements for infant formula products aligned as closely as possible with both the priority objectives of the *Food Standards Australia New Zealand Act 1991* as well as the ministerial policy guidance.

Due to the complexity of the proposal, seven rounds of public consultation were undertaken to support this work, with a total of 36 public reports released for comment. The Proposal also involved eight independent risk assessments; five commissioned consumer research studies; four consumer literature reviews and two label surveys. Over 40 stakeholder workshops and targeted consultations were also held from 2022 to 2024. Each of the above, together with the comments and submissions received, informed FSANZ's assessment.

The 1st statutory Call For Submissions (CFS) was issued in April 2022 and the 2nd was issued in April 2023. The 2nd included two proposed draft variations and an associated report, detailing the rationale for the proposed measures contained in each variation. FSANZ received 34 submissions in response to the latter. Each submission received was considered as part of our assessment.

The proposed draft variations were amended after further consideration and new evidence, including the submissions received.

For the reasons set out in this report, FSANZ approved the amended draft variations, which are at Attachment A and B. The first approved draft variation amends Standard 2.9.1. The second makes consequential amendments to seven other Standards and five Schedules in the Code. The related explanatory statements are at Attachment C.

This report provides a summary of the regulatory decisions made as a result of this Proposal and the reasons for those decisions. Key changes made by the approved draft variations are summarised below.

Standard 2.9.1—Infant formula products

Division 1 Preliminary

- To take effect after a 60 month transition period during which a product may comply with either the Code in force without the variations or the Code as amended by the variations.
- Renamed the Infant Formula Products for Special Dietary Use (IFPSDU) category as Special Medical Purpose Product for infants (SMPPi) with a new definition for SMPPi.

- Amended the regulatory framework to clearly separate infant formula and follow-on formula requirements from SMPPi.
- Amended the definitions for infant formula products, infant formula and follow-on formula to ensure each definition captures the respective products they represent.

Division 2 Compositional requirements for infant formula and follow-on formula

- Amended Division 2 to prescribe compositional requirements for infant formula and follow-on formula.
- Amended general compositional requirements for infant formula and follow-on formula such as permissions relating to energy, macronutrients, minerals, vitamins, electrolytes and nutritive substances.
- Added compositional limits for fluoride content of powdered, concentrated and ready-to-drink formulas.
- Added a requirement that the protein source for infant formula and follow-on formula must only be derived from one or more of the following proteins - cow milk, goat milk, sheep milk, soy protein isolate or a partially hydrolysed protein of one or more of these.
- Added a requirement that infant formula and follow-on formula must not contain added fructose and/or added sucrose, unless manufactured from partially hydrolysed protein where the fructose or sucrose is added as a source of carbohydrate and does not exceed 20% of available carbohydrates in the formula.
- Follow-on formula and infant formula have the same compositional requirements except for the protein minimum, vitamin D maximum, calcium maximum, iron minimum, choline minimum, inositol minimum and L-carnitine maximum.

Division 3 Labelling and packaging requirements for infant formula and follow-on formula

- Amended Division 3 by modifying existing requirements and adding new requirements relating to the labelling of infant formula and follow-on formula.
- Retained most labelling requirements for infant formula and follow-on formula, such as the prescribed name, the warning statement about ‘breast milk is best’, required statements about age, print size of warning statements, storage instructions and the application of general labelling requirements in Part 1.2 of the Code.
- Introduced requirements for product differentiation to require infant formula and follow-on formula to be differentiated from each other and from other foods by the use of text, pictures and/or colour.
- Varied the statement of protein source to require the specific animal or plant source of protein to be included in the name of the food, on the front of the package.
- Introduced an optional format for declaring added vitamins and minerals in the statement of ingredients.
- Simplified separate ‘follow instructions exactly’ warning statements for powdered, concentrated and ready-to-drink formulas to a single warning statement applicable to all product types. Added new directions for preparation and use specifying not to change proportions of powder/concentrate or to dilute ready-to-drink formula or add other food to any product type.
- Amended requirements for the nutrition information statement including what must be provided in the statement and introduced a new requirement for a prescribed form of the statement.
- Introduced requirements for the voluntary use of stage numbers.

- Retained existing prohibited representations and added further prohibitions on information relating to other foods and ingredients, the protein source and the words 'partially hydrolysed'.
- Removed labelling permissions for making low lactose and lactose free representations on infant formula and follow-on formula labels.

Division 4 Special medical purpose product for infants

- Amended Division 4 to prescribe requirements for SMPPi including sale, nutrition composition and labelling.
- Added a restriction on sale that limits the sale of SMPPi to a medical practitioner, dietitian, medical practice, pharmacy, responsible institution or majority seller of that product.
- Introduced compositional requirements for SMPPi that replicate the baseline composition of infant formula. Retained existing Code provisions that allow deviation from the prescribed compositional requirements if necessary to achieve the product's intended medical purpose or if it would otherwise prevent the sale of the product.
- Introduced a new labelling framework for SMPPi that specifies:
    - applicable general labelling requirements in Parts 1.2 and 1.5 of the Code (for example a name or description to indicate the true nature of the food)
    - required statements and declarations (for example the product must be used under medical supervision, the medical purpose of the product).
    - new labelling requirements for ingredients, date marking and nutrition information, inner packages and transportation outers and for SMPPi to be differentiated from other products.
    - a specific prohibition on claims made about SMPPi, unless expressly permitted.
    - permitted a lactose free claim on SMPPi.
    - retained prohibited representations that apply to infant formula and follow-on formula.

Schedule 29—Special purpose foods

- Amended compositional requirements for infant formula, follow-on formula and SMPPi, such as associated maximums, minimums, permitted forms, quality scores, units of expression, conversion factors, equivalents, ratios and nutrient interactions for energy, macronutrients, minerals, vitamins, electrolytes and nutritive substances.
- Prescribes the required format of the nutrition information statement including headings, subheadings, order, names and acronyms, base units of expression, units of measurement and bold text.

Standard 1.1.2—Definitions used throughout the Code

- Amended definitions that were revised, repealed or inserted into Standard 2.9.1, to ensure definitions are consistently applied throughout the Code.

Standard 1.2.3—Information requirements – warning statements, advisory statements and declarations

- Amended requirements to refer to SMPPi as the new infant formula product category.

Standard 1.3.1—Food additives

- Amended the requirements for carry-over of food additives to apply to foods other than infant formula products.

Standard 1.5.1—Novel foods

- Amended the definition for novel foods to note that the presence of a food as a SMPPi or in a SMPPi does not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of this section.
- Amended the requirements for sale of a novel food to ensure that unless there is express permission a novel food must not be added to infant formula products.

Standard 2.9.2—Food for infants

- Amended references to Schedule 29 to ensure compositional requirements are correctly captured.

Standard 2.9.3—Formulated meal replacements and formulated supplementary foods

- Amended references to Schedule 29 to ensure compositional requirements are correctly captured.

Standard 2.9.5—Food for special medical purposes

- Amended references to Schedule 29 to ensure compositional requirements are correctly captured.

Schedule 8—Food additive names and code numbers (for statement of ingredients)

- Added dl-Alpha-tocopherol, potassium hydroxide and sodium hydroxide to the food additive names and code numbers listed in the Schedule.

Schedule 15—Substances that may be used as food additives

- Amended requirements for food additives, including revision of condition statements and variation to Maximum Permitted Levels for infant formula products.

Schedule 19—Maximum levels of contaminants and natural toxicants

- Added separate maximum levels for aluminium in the following groups: infant formula, follow-on formula and special medical purpose product for infants (other than special medical purpose product for infants formulated for pre-term infants), soy-based infant formula products and special medical purpose product for infants formulated for pre-term infants.
- Reduced the maximum level for lead in infant formula products.

Schedule 25—Permitted novel foods

- Amended the condition statements for dried marine micro-algae (Schizochytrium sp.) rich in docosahexaenoic acid (DHA), oil derived from marine micro-algae Schizochytrium sp. (American Type Culture Collection (ATCC) PTA-9695) and oil derived from marine micro-algae (Ulkenia sp.) rich in docosahexaenoic acid (DHA) to clarify they may be added to infant formula products in accordance with Standard 2.9.1.
- Amended the condition statements for oil derived from marine micro-algae (Schizochytrium sp.) rich in docosahexaenoic acid (DHA) to clarify it is only permitted for use in infant formula products in accordance with Standard 2.9.1.
- Amended condition statements for isomalto-oligosaccharide and rapeseed protein isolate to clarify that they must not be added to infant formula products.
- Added trehalose as a novel food with a condition that it may be added to infant formula products only as a cryo-preservative for L(+) lactic acid producing microorganisms.

FSANZ's assessment of the costs and benefits of these measures is summarised in this report, including the Decision Regulation Impact Statement (DRIS) in Supporting Document 2. FSANZ's assessment is that benefits of the regulatory changes will exceed costs and the changes – if approved – will achieve the objectives of the proposal. The primary benefit of the proposal is the expected health improvements for formula-fed infants, which are anticipated to be significant when considered at a population level. FSANZ also notes that the improved international regulatory alignment is likely to provide industry with longer-term cost savings and increased regulatory certainty.

In summary, Standard 2.9.1 will continue to regulate infant formula products. The requirements set by the Code for infant formula products will continue to protect the public health and safety of vulnerable Australian and New Zealand infants by ensuring infant formula products remain safe and suitable as a breast milk substitute. The amendments provide regulatory clarity and account for changes in the latest scientific evidence, market developments, international regulations and updated Australian and New Zealand policy guidance. The amendments also ensure reasonable information is provided to caregivers to enable them to appropriately access and differentiate products and make an informed choice.

Abbreviations and glossary

Abbreviation or term	Meaning
ARA	Arachidonic acid
ASCIA	Australasian Society of Clinical Immunology and Allergy
CFS	Call for submissions
cfu	Colony-forming units
CHO	Carbohydrate
Code	Australia New Zealand Food Standards Code
Codex	Codex Alimentarius Commission
CP	Consultation paper
CSO	Community Service Obligations
DHA	Docosahexaenoic acid
EC	European Commission
EFSA	European Food Safety Authority
EPA	Eicosapentaenoic acid
EU	European Union
FAO	Food and Agriculture Organization
FoF	Follow-on formula
FSANZ	Food Standards Australia New Zealand
FSMP	Food for special medical purposes
FuF	Follow-up formula
FuFOI	Follow-up formula for Older Infants
g	Gram
GMP	Good manufacturing practice
GUL	Guidance upper level
IFP	Infant formula products
IFPSDU	Infant formula products for special dietary use
INC	Infant Nutrition Council
JECFA	Joint WHO/FAO Expert Committee on Food Additives
kg	Kilogram
kJ	Kilojoule
L	Litre
LAM	Lactic acid-producing microorganisms
µg	Microgram
MAIF Agreement	Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement
mg	Milligram

Abbreviation or term	Meaning
ML	Maximum level
MPL	Maximum permitted level
NHMRC	National Health and Medical Research Council
NRV	Nutrient reference value
NIP	Nutrition information panel
NIS	Nutrition information statement
NS	Not specified
PKU	Phenylketonuria
PSA	Pharmaceutical Society of Australia
SD	Supporting document
SMPPi	Special medical purpose product for infants
US	United States of America
WHO	World Health Organization
WTO	World Trade Organization

1 The Introduction

1.1 The proposal

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

Infant formula products are primarily regulated through Standard 2.9.1 and Schedule 29 of the Australia New Zealand Food Standards Code (the Code) and have the most prescriptive requirements of any food category. Other standards in the Code also contain provisions for infant formula products, such as those relating to definitions, food additives, contaminants, labelling, novel foods and microbiological limits.

Proposal P1028 – Infant Formula aimed to revise and clarify standards relating to infant formula products in the Code. In addition to the assessment criteria prescribed by the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) (see section 6), the following regulatory objectives were considered in the assessment of this proposal:

- protection of infant health and safety
- provision of information to enable informed choice and ensure caregivers are not misled
- consistency with advances in scientific knowledge
- industry innovation and/or trade is not unduly hindered.

1.2 Reasons for preparing the proposal

FSANZ committed to reviewing infant formula product regulations after receiving policy guidance from the then Australia New Zealand Food Regulation Ministerial Council in May 2011. Revision and clarification of the relevant standards in the Code works to ensure that infant formula products remain safe and suitable, account for market developments and reflect changes in the international regulatory context.

The aim of this proposal was to set revised standards covering composition, labelling and representation of infant formula products that:

- protect the health and safety of formula-fed infants (0 to <12 months) by specifying compositional requirements that support normal growth and development of infants and clearly indicate which foods and substances require pre-market assessment
- require adequate information be provided to ensure their safe preparation and use and enable parents and carers to make an informed choice
- are readily understood and able to be implemented by food manufacturers
- are enforceable by jurisdictions
- have regard to the Ministerial Policy Guidelines on the Regulation of Infant Formula Products; the Intent of Part 2.9 of the Food Standards Code - Special Purpose Food; and Nutrition, Health and Related claims
- align with relevant international and overseas regulations, as appropriate in the Australian and New Zealand context.

1.3 Procedure for assessment

This proposal was assessed under the Major Procedure requirements of the FSANZ Act, which requires two rounds of statutory calls for submissions (CFS). These were completed in 2022 and 2023 (FSANZ 2022a; FSANZ 2023a).

This approval report provides a record of all consultation undertaken and subsequent decisions. Summary tables of the issues that were raised in submissions to the 2nd CFS and our responses to those issues are provided in Appendix 3. More detail on specific issues raised by submitters is in section 0 of this report. Additional targeted consultation with stakeholders was also undertaken prior to finalisation of the approval report.

1.4 Decision

As explained, in April 2023, FSANZ sought public submissions on two draft variations: the Food Standards (Proposal P1028 – Infant Formula) Variation and the Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation. For the purposes of this report these draft variations are referred to as the ‘2nd CFS proposed variation’.

For the reasons listed in this report, including the Supporting Documents, FSANZ approved each variation with amendments.

For the purposes of this report, the approved draft variations are referred to as follows: the Food Standards (Proposal P1028 – Infant Formula) Variation is referred to as the 'primary variation'; and the Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation is referred to as the 'consequential variation'.

The primary variation amends Standard 2.9.1 Infant formula products. The consequential variation amends Schedule 29, Standard 1.1.2, Standard 1.2.3, Standard 1.3.1, Standard 2.9.2, Standard 2.9.3, Standard 2.9.5, Schedule 8, Schedule 15 and Schedule 25.
The primary variation is at Attachment A. The consequential variation is at Attachment B. Both variations will take effect on gazettal, with a five year transitional arrangement (see section 7). The related explanatory statements are at Attachment C. An explanatory statement is required as each variation is a legislative instrument which, if approved, will be included on the Federal Register of Legislation.

The versions of the 2nd CFS proposed variations on which submissions were sought are at Attachments D and E.

In recognition of the extensive nature of the amendments made by the approved draft variations, SD1 provides a detailed outline of each amendment and the regulatory intent behind that amendment.

The intent of this document is to complement the explanatory statement at Attachment C. FSANZ has also produced summary tables that collate and detail the current requirements in the Code against the requirements in the approved draft variations to assist in identifying the amendments made by each variation. Summary tables for nutrient composition, food additives and labelling can be found at Appendix 1.

2 Overview of the proposal to date

2.1 Current regulatory environment

2.1.1 Australian and New Zealand standards

Australian and New Zealand food laws require food for sale to comply with relevant provisions in the Code. The Code provisions that set requirements for infant formula products range across eight standards and five schedules. These provisions include requirements for definitions, food additives, contaminants and natural toxins, novel foods, nutrient composition and labelling that relate to infant formula products.

Standard 1.1.1 requires food for sale, including infant formula products, to comply with composition, labelling and other requirements set by the Code. That Standard also prohibits food for sale from being or containing certain substances unless expressly permitted by the Code.

Standard 2.9.1 currently provides requirements for the composition and labelling of infant formula products. The standard is organised into six divisions:

- Division 1 deals with preliminary matters.
- Division 2 sets out general compositional requirements for infant formula products.
- Division 3 sets out compositional requirements for infant formula and follow-on formula.
- Division 4 sets out compositional requirements for infant formula products for special dietary use.
- Division 5 sets out labelling and packaging requirements for infant formula products.
- Division 6 sets out guidelines for infant formula products. The guidelines are not legally binding.

Since gazettal in 2016, specific amendments have been made to the requirements in Standard 2.9.1, as detailed in Table 1. Proposal P1028 aims to comprehensively revise the regulatory requirements for infant formula products.

Table 1: Applications and proposals relating to the regulation of infant formula products

Permission or change to infant formula regulation
A0563 – Medium Chain Triglycerides in Infant Formula
A0594 – Lutein as a nutritive substance in infant formula
P0306 – Addition of Inulin / FOS & GOS to Food
A1055 – Short-chain fructo-oligosaccharides
A1074 – Minimum L-histidine in Infant Formula Products
A1155 – 2′-FL and LNnT in infant formula and other products
A1173 – Minimum protein in follow-on formula
A1233 – 2′-FL in infant formula
A1251 – 2′-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products
A1253 – Bovine lactoferrin in infant formula products

Permission or change to infant formula regulation
A1265 – 2′-FL DFL, LNT, 6′-SL sodium salt and 3′-SL sodium salt for use as nutritive substances in infant formula products
A1277 – 2′-FL from GM *Escherichia coli* K-12 (gene donor: *Helicobacter enhydrae*) in infant formula products

2.1.2 International standards

Internationally, requirements for infant formula products can vary, however most global standards are developed with reference to the Codex standards. Codex and overseas regulations from the European Union (EU), the United States of America (US) and Asian countries are particularly relevant for the trade of products to and from Australia and New Zealand.

It is important to note that there is no global benchmark for the regulations of infant formula products. Each international jurisdiction has its own legislation. While some jurisdictions may adopt Codex standards, Codex is not considered a global regulation and is technically a guideline. In addition, the EU regulations are reflective of one jurisdiction.

To assist trade, it is preferable for regulations to be harmonised where appropriate as much as possible between countries and consistent with the Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT) of the World Trade Organization (WTO). Support for this is provided in both the FSANZ Act and the Ministerial Policy Guideline on the Regulation of Infant Formula Products.

Codex Alimentarius

Codex Alimentarius, through the Codex Committee for Nutrition and Special Dietary Uses (CCNFSDU), updated its infant formula standard in 2007 to include new provisions in section B of that standard for formula for special medical purposes intended for infants. Section B sets out the composition, quality, labelling and safety requirements by referencing the requirements for infant formula in section A of that standard, where appropriate. It also draws on the Codex provisions for labelling of food for special medical purposes (FSMP) (Codex CXS 180-1991; Codex 1991). In recent years, the Codex Committee has revised the Codex Standard for Follow-up Formula for older infants and products for young children (Codex CXS 156-1987; Codex 1987; Codex 2023a).

Codex CXS 156-1987 was adopted by the Codex Alimentarius Committee (CAC) in late 2023 and the related food additive provisions were considered by the Codex Committee on Food Additives (CCFA) at the CCFA53 meeting held in March 2023.

European Union

In 2016 the European Commission Directive revised 2016/127 – Infant Formula and Follow-on Formulae (European Commission 2016a). The EU regulates special purpose infant formulas as food for special medical purposes specifically designed for infants. Specific compositional and information requirements for infant formula for special medical purposes are set out in Commission Delegated Regulation 2016/128 (European Commission 2016b). This includes a requirement for the nutritional composition of FSMP for infants to be based on that of infant and follow-on formula, except where necessary for the intended purpose of the product.

Specific comparison between international standards and regulations and the Code have been considered throughout the assessment for this proposal including a comprehensive

review of overseas approaches to the addition of substances to infant formula (FSANZ 2016f, Attachment A3).

2.2 P1028 assessment reports

FSANZ has undertaken iterative assessment on all issues. These were detailed and published with previous consultation papers (CP) in 2016, 2017 and 2021 for the statutory CFS in 2022 and 2023. Across the reports (noted below) FSANZ has undertaken risk assessment and risk management on regulatory decisions to meet statutory requirements.

Risk assessments were completed across a number of topics. Details of each were published in the above-mentioned papers and CFS, all of which are publicly available online. Conclusions from the risk assessments were considered in the two statutory CFS and informed the decision to approve the draft variations. The risk assessments noted below have been complemented and considered in light of new evidence provided via submissions to the CPs and CFSs.

The risk assessments included:

- Nutrition assessment (FSANZ 2016d; FSANZ 2016e)
- Safety & Food Technology - Risk profile of contaminants in infant formula (FSANZ 2016f)
- Microbiological Safety Assessment of Powdered Infant Formula (FSANZ 2016f)
- Food additives safety assessment (FSANZ 2021a)
- Microbiology risk assessment: L(+) lactic acid producing microorganisms (FSANZ 2021c)
- Microbiological safety of powdered infant formula: Effect of storage temperature on risk (FSANZ 2021d)
- Nutrition assessment (FSANZ 2021g)
- Microbiological safety of powdered infant formula: Effect of water temperature on risk (FSANZ 2022c)
- Labelled composition available on the retail market in Australia and New Zealand (FSANZ 2016c)
- Analysis of Current Stage Labelling and Proxy Advertising Practices of Infant Formula Products in Australia and New Zealand (FSANZ 2023f).

Consumer research was also undertaken and underpinned all risk management assessments. This included literature reviews and commissioned research.

Literature reviews

- Rapid evidence assessment on infant formula preparation, perceptions and label use (FSANZ 2016f)
- Consumer research in relation to safe preparation and use of infant formula (FSANZ 2021e)
- Consumer research on infant formula labelling (FSANZ 2022f).
- Rapid systematic evidence summary on infant formula stage labelling and proxy advertising (FSANZ 2023e).

Commissioned research

- Infant Formula Use and Decision Making Study (InFormD) Australian and New Zealand consumers' perceptions, understanding and use of labelling information on infant formula products. Part A: Infant formula purchase decisions (Malek 2016a)
- Infant Formula Use and Decision Making Study (InFormD) Australian and New Zealand consumers' perceptions, understanding and use of labelling information on infant formula products. Part B: Infant formula preparation (Malek 2016b)
- Infant formula information use and preferences: an online survey of Australian and New Zealand caregivers (Malek 2017)
- Investigating changes to labelling information on infant formula products: Part A: Focus groups with Australian and New Zealand caregivers (Malek 2018a)
- Investigating changes to labelling information on infant formula products: Part B: Online survey of Australian and New Zealand caregivers (Malek 2018b)
- Collaboration with New Zealand Ministry of Primary Industries on research on caregiver's beliefs about the risk of improper infant formula preparation and their understanding of infant formula preparation risks (NZFS 2020).

2.3 2nd CFS conclusions

In April 2022, FSANZ issued a 1st CFS which summarised stakeholder submissions to the CPs released in 2021 (CP1, CP2 and CP3). The 1st CFS sought further views on the assessment of the Proposal and on FSANZ's preferred option for reform based on that assessment. The preferred option included amending Standard 2.9.1, Schedule 29 and other related standards and schedules. FSANZ received 33 submissions in response.

After consideration of each submission, FSANZ prepared two proposed draft variations, FSANZ then issued a 2nd CFS summarising FSANZ's assessment of the Proposal following the 1st CFS, the reasons for FSANZ's decision to prepare each draft variation and the rationale for the proposed measures contained in each variation. FSANZ sought submissions on each of the latter in order to inform a decision on whether each proposed draft variation should be rejected, approved or approved with amendments.

3 Summary of submissions to the 2nd CFS

3.1 Submissions received

FSANZ received 34 submissions to the 2nd CFS (eight government, 17 industry, nine public health/consumer) and two additional late submissions. The Australian and New Zealand governments also released a WTO notification to which we received one submission from the US.

FSANZ has carefully analysed the comments in each submission and responded to issues raised in this approval report. Where a submitter raised an issue which resulted in a change to the variation, FSANZ noted it within this report.

Table 2: Submitters to the 2nd CFS

Organisation	Abbreviation
Abbott Australasia Pty Ltd	AA
Advanced Dietitians Group	ADG
Allergy & Anaphylaxis Australia	A&AA
Australian Food and Grocery Council	AFGC
Breastfeeding Advocacy Australia	BAA
Dairy Companies Association of New Zealand	DCANZ
Danone Oceania	DAN
Department of Health Western Australia	WA DoH
Dietitians Australia	DA
DSM Nutritional Products Asia Pacific	DSM
Fonterra Co-Operative Group Limited	FCG
Gene Ethics	GE
Global Organization for EPA & DHA Omega-3s	GOED
IFF (Danisco) New Zealand	IFF
Infant Nutrition Council	INC
New Zealand Ministry of Health	NZ MoH
National Allergy Council	NAC
Nestlé	NES
New Zealand Food and Grocery Council	NZFGC
New Zealand Food Safety	NZFS
NSW Food Authority	NSWFA
Public Health Individual	PHI1
Public Health Individual	PHI2
Public Health Individual	PHI3
Public Health Services, Department of Health, Tasmania	TAS DoH
Queensland Health	QLDH
South Australia Health	SAH
Sprout Organic	SO
Synlait Milk Limited	SML
The a2 Milk Company Limited	A2M
Victorian Department of Health and Department of Energy, Environment and Climate Action	VIC DoH & DEECA
Woolworths	WW

Organisation	Abbreviation
Late comments	
ASCIA Dietitians	ASCIA
Public Health Individual	PHI4

The above submissions are publicly available on the FSANZ's website. Two additional submissions were accepted as confidential. FSANZ has considered these submissions, however cannot publish them on the FSANZ website.

3.2 Submitter comments and FSANZ responses

Submitter comments[2] and FSANZ responses, including where a change was made to a draft variation, are captured in tables in Appendix 3. The tables summarise submitter comments to the 2nd CFS and FSANZ considerations and decisions. The table, topic and page numbers are noted below. More detailed discussion about stakeholder comments on key specific issues is provided in section 4 of this report.

3.2.1 WTO Notification

In April 2023, FSANZ made a notification to the WTO for this proposal in accordance with the WTO TBT Agreement. Section 9 of Appendix 3Table 1 provides a summary of FSANZ's response to comments received from the one member country that responded. Comments received were supportive of the proposed special medical purpose product for infants (SMPPi) category with some clarification sought to ensure facilitation of trade, availability and accessibility.

To support readers, Table 3 identifies topics covered by submissions and where they can be found in Appendix 3.

Table 3 – Guide to submitter comments to the 2nd CFS and FSANZ responses in Appendix 3

Topic	Page Number
Section 1: General comments	146
Section 2: Definitions	152
Section 3: Regulatory framework	161
Section 4: Nutrient composition	177
Section 5: Novel foods	204
Section 6: Food technology	217
Section 7: Labelling	235
Section 8: Costs and benefits and transition period	301
Section 9: WTO notification responses	323

[2] All non-confidential submissions to the 2nd CFS are available on the FSANZ website P1028 - Infant Formula | Food Standards Australia New Zealand.

4 Discussion of specific issues from the 2nd CFS

The below sections cover the key topics explored within the proposal and outline the current regulations, previous considerations, submitter comments to the 2nd CFS and FSANZ discussion and decision. Issues that are not captured in the below discussions can be found in Appendix 3 - Summary of submitter comments to the 2nd CFS and FSANZ responses or in SD1.

4.1 Regulatory framework

4.1.1 Current regulations

Infant formula products are predominantly regulated by the Code through Standard 2.9.1 which prescribes requirements for definitions, nutrient composition, preparation and storage and labelling. The Standard has six divisions with a range of functions (see section 2.1.1 and Figure 1).

Standard 2.9.1 regulates all infant formula products including infant formula (for use from newborn), follow-on formula (for use from 6 months to <12 months of age) and infant formula for special dietary use (IFPSDU). IFPSDU in Division 4 captures all specialised formulas with specific requirements depending on whether products are formulated for premature or low birthweight infants (section 2.9.1—13), for metabolic, immunological renal, hepatic and malabsorptive conditions (section 2.9.1—14), or for a specific dietary use based on a protein substitute (section 2.9.1—15).

A large proportion of the compositional requirements for infant formula products are prescribed in Schedule 29. This includes calculations, permitted nutritive substances, amino acid minimums, required amounts and permitted forms of vitamins, minerals and electrolytes, fatty acid limits and guidelines. The guidelines also include a recommended format for the declaration of nutrition information.

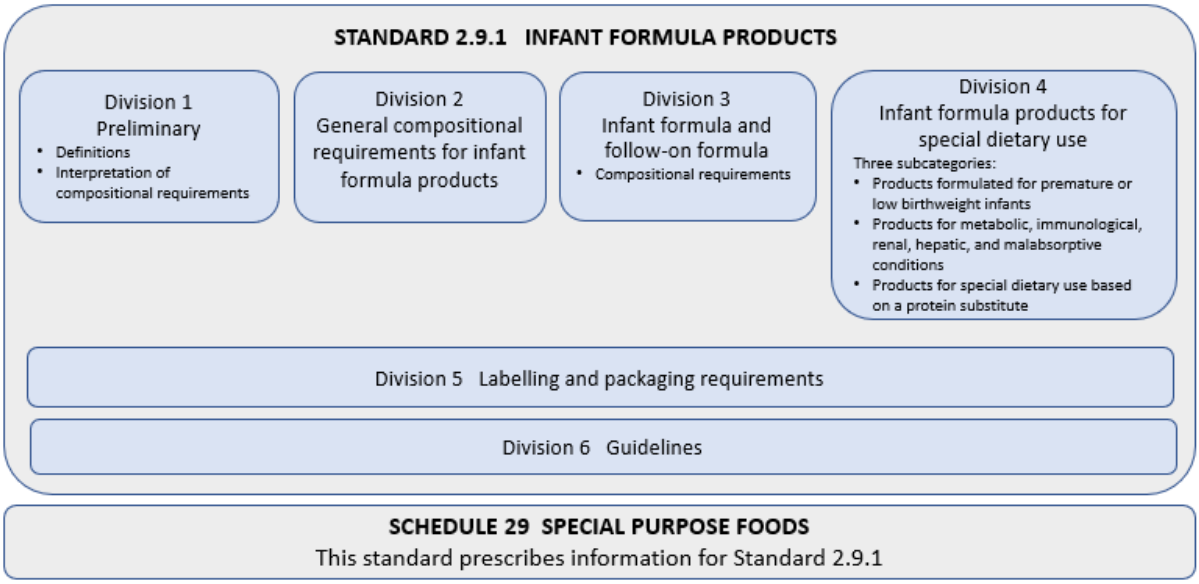

Figure 1: The structure of the current regulation for infant formula products.

Additional requirements for food additives, contaminants and natural toxicants, novel foods, definitions, nutrition information statements and information requirements applicable to infant formula products can be found throughout the Code.

4.1.2 Previous considerations

FSANZ undertook extensive consultation on the regulatory framework in relation to definitions, product categories, specialised infant formula product requirements and each Division's function.

Consultation on specialised infant formula products has explored specific issues and problems to be addressed as follows:

- Areas of regulatory uncertainty related to the broad nature of the current subcategories, the range of products in each category and related definitions. There is a lack of clarity regarding how products are categorised and what their requirements are.
- The range of available products may pose different risks depending on their specialised nature. Some IFPSDU are not safe for use by healthy infants, while others can be consumed with little risk of harm.
- Categorisation by condition is not useful as many can be used for multiple conditions.
- No consistent approach is used internationally.
- Clarity is required on the regulation of supplementary or modular products that can be used in combination with each other and/or infant formula products to meet an individual infant's special requirements.
- The current approach is not well harmonised with the EU, which is the source of most products.
- Need for greater regulation of products for transient gastrointestinal conditions through measures such as restricted sale in relation to protein modified and lactose free/low infant formula products; greater evidence to support product on market; labelling requirements to ensure caregivers are able to identify appropriate products and are not misled.

FSANZ's in-depth considerations and proposed approaches on the regulatory framework were considered in:

- Consultation Paper – Infant formula products for special dietary use (FSANZ 2017)
- Consultation Paper 3 – Regulatory Framework and Definitions (FSANZ 2021h)
- 1st Call for Submissions – Proposal P1028 (2022a)
- Supporting Document 4 – Special Medical Purpose Products for Infants (FSANZ 2022g)
- 2nd Call for Submissions – Proposal P1028 (2023a).

At the 2nd CFS FSANZ sought submissions on a proposed two-tiered framework to differentiate clearly products for healthy infants (e.g. infant formula and follow-on formula) from products for infants with special medical needs (SMPPi). Please refer to section 2 of the 2nd CFS for further details.

4.1.3 Submitter comments

Submitter comments to the 2nd CFS and FSANZ responses are captured in section 2 of Appendix 3.

4.1.4 Discussion

Standard 2.9.1 regulates infant formula products which by definition includes infant formula, follow-on formula and SMPPi. FSANZ has retained the regulatory framework proposed at the 1st and 2nd CFS which separates formula for healthy infants (infant formula and follow-on formula) from formula for infants who require specialised or medical formula. Infant formula product categories and applicable regulatory divisions are detailed in Table 4.

Table 4: Infant formula product categories

Product category	Definition	Purpose	Regulation
Formula for healthy infants			
Infant formula	means an infant formula product that is represented as: (a) a breast milk substitute for infants; and (b) satisfying by itself the nutritional requirements of infants under the age of 6 months.	To provide the sole or principal source of nourishment to infants (from).	Standard 2.9.1 Division 2 and 3
Follow-on formula	means an infant formula product that is represented as: (a) either a breast milk substitute or replacement for infant formula; and (b) being suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.	To provide the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.	Standard 2.9.1 Division 2 and 3
Formula for infants requiring dietary management for a medically diagnosed disease, disorder or condition			
Special Medical Purpose Products for infants	means an infant formula product that is: (a) represented as being: i. specially formulated for the dietary management of infants who have medically determined nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food); and ii. suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product; and iii. for the dietary management of a medically diagnosed	To provide the sole or principal source of nourishment to infants with a disease, disorder or condition.	Standard 2.9.1 Division 4

	disease, disorder or condition of an infant; and (b) intended to be used under medical supervision; and (c) not suitable for general use.		

The requirements for infant formula and follow-on formula are prescribed by Division 2 and Division 3 of Standard 2.9.1 of the primary variation.

Division 4 of the primary variation contains all regulatory requirements for specialised formulas called SMPPi. The regulation for this category includes a definition, compositional requirements, mandatory labelling requirements, restriction on sale and food additive permissions. A SMPPi is an infant formula product that is specially formulated for the dietary management of infants who have medically determined nutrient recommendations due to a medically diagnosed disease, disorder or condition. These products constitute either the sole or principal source of nourishment, are used under medical supervision and are not suitable for general use. Such products include but are not limited to extensively hydrolysed protein formulas, formulas for premature or low birth weight infants and renal formulas.

The SMPPi category does not include specialised medical products for infants that are not used as the sole or principal source of nutrition. These products include but are not limited to human milk fortifiers, modulatory formulas (for example, protein, carbohydrate or fat modulars), food thickeners and medical infant foods or semi-solid foods.

The changes to the regulation are consistent with the regulatory parameters currently in the Code and established internationally. The amended regulatory requirements proposed for SMPPi have been modelled on the existing Standard 2.9.5 – Foods for Special Medical Purposes, where appropriate. The new framework is illustrated at Figure 2.

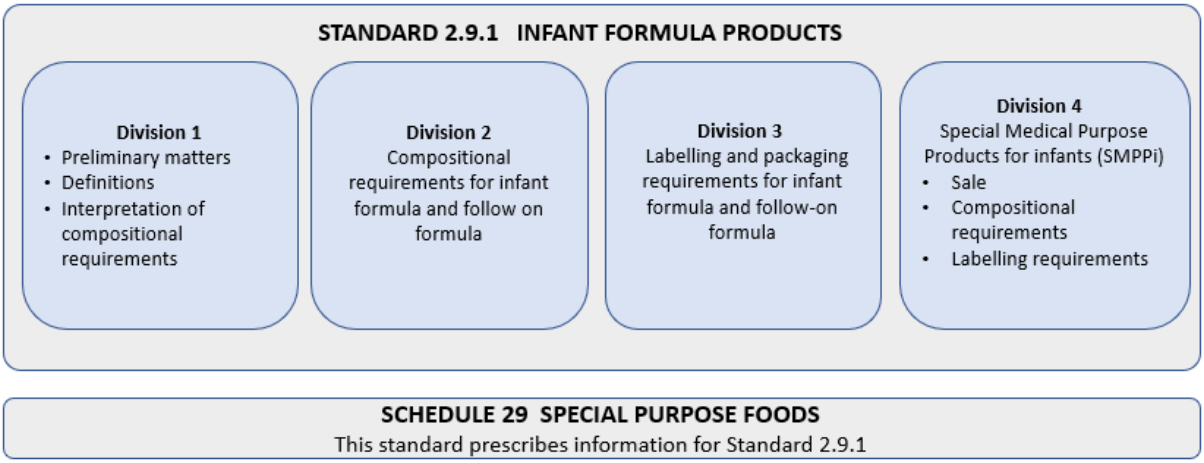

Figure 2: The structure of the amended regulation for infant formula products.

Stakeholders on the whole supported this framework. The new framework gave rise to changes across several regulatory elements including definitions, food additives permissions, nutrient composition, restriction on sale and labelling requirements. Issues related to these areas were raised in submissions to the 2nd CFS and have been addressed in this report (see section 3.2). Principal issues that stakeholders raised in response to the 2nd CFS are discussed in depth below. In addition, further information on the regulatory framework can be found in section 2 of the 2nd CFS (FSANZ 2023a).

The amendments to Schedule 29 are set out in the consequential variation. These amendments make some formatting changes to the Schedule that are required as result of other amendments that change infant formula and follow-on formula composition

requirements, specifically by setting out for each which nutritive substances are mandatory and which are optional.

L-carnitine, inositol and choline have been classified as essential and required as a mandatory addition to infant formula and are now captured in the consequential variation in new section S29—5 Vitamins, minerals, electrolytes and other substances required in infant formula and special medical purpose products for infants. This is not replicated for follow-on formula, as these substances are not considered essential in infants aged 6 – 12 months. As such these substances are captured in the consequential variation at section S29—8 Optional nutritive substances in follow-on formula. FSANZ considers that these regulatory changes provide further clarity as to which nutritive substances are mandatory and which are voluntary in infant formula and follow-on formula.

4.1.5 Decision

The principal change to the regulation of infant formula products relates to the regulatory framework, which introduces distinguishing requirements to separate formula for healthy infants from specialised formula for infants with a disease, disorder or condition.

Requirements for formulas for healthy infants (infant formula and follow-on formula) are prescribed in Division 2 and Division 3 of Standard 2.9.1. Requirements for specialised formulas (SMPPi) are confined to Division 4 of that Standard. The changes aim to modernise the Standard, provide regulatory clarity and clearly delineate the requirements for each formula category.

The primary variation removes the current Division 6 Guidelines. These Guidelines have been replaced by the Guidance Upper Limits (GULs) described in Schedule 29 and Standard 2.9.1. The amendments made by the approved variations make clear that GULs are not mandatory or binding but instead are only 'recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional needs of infants and an established history of apparent safe use. It is recommended that GULs not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of special medical purpose products for infants or due to technological reasons.

SD1 provides a more detailed outline of all the amendments, the regulatory intent and the rationale for each amendment.

FSANZ considers the changes to the regulatory framework increase clarity and thereby assist compliance.

4.2 SMPPi composition

4.2.1 Current regulations

As noted above, the Code currently categorises specialised infant formula products as IFPSDU which are regulated by Division 4 of Standard 2.9.1. There are three subsections within Division 4 which prescribe requirements for differing conditions and dietary uses:

- Section 2.9.1—13 prescribes requirements for products formulated for premature or low birthweight infants. It includes labelling requirements and the ability to deviate from the prescribed composition of infant formula products.
- Section 2.9.1—14 prescribes requirements for products formulated for metabolic, immunological, renal, hepatic or malabsorptive conditions. Again, compositional

requirements do not apply to the extent that they would prevent the sale of an infant formula product that is specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions. This subsection also captures specific requirements for food represented as lactose free and low lactose formulas including compositional parameters.

- Section 2.9.1—15 prescribes requirements for products formulated for specific dietary use based on a protein substitute. This section includes compositional requirements for energy, potential renal solute load, the addition of medium chain triglycerides and minimums and maximums for protein, fat, chromium and molybdenum.

S29—10 also prescribes a non-binding guideline maximum for manganese of 7.2 µg per 100 kJ for use in infant formula products specifically formulated to satisfy requirements for particular metabolic, immunological, renal, hepatic or malabsorptive conditions.

While current regulations for infant formula products are generally working well, government, public health and consumer advocacy groups have expressed significant concern to FSANZ about products being characterised as IFPSDU in order to make use of the more flexible labelling regulations for marketing advantages. There is concern that some of these products do not contain significant compositional changes required to manage diagnosable conditions. There is also concern that these products are, instead, targeting transient gastrointestinal conditions or claiming to address or support what would otherwise be considered normal infant behaviour or symptoms e.g. colic or constipation formula, sleepy time formula, fussy baby formula. This has the potential to create confusion for caregivers and prevent infants from receiving formula that is appropriate for them.

4.2.2 Previous considerations

The 1st and 2nd CFS proposed that SMPPi would comply with the baseline composition of infant formula, unless deviation was required for a particular medical purpose or would otherwise prevent sale of the food (as is the case now). The proposed amendments also removed all specific compositional parameters currently prescribed for IFPSDU.

4.2.3 Submitter comments

Government, industry and public health submitters responded to the 2nd CFS proposed variations. Most submitters supported the proposed intent of the SMPPi composition, however had concerns regarding:

- the drafting only capturing compositional parameters noted in S29
- the wording ‘would otherwise prevent the sale of the food’ being too broad and potentially allowing reasons other than those intended to deviate from the baseline composition
- lack of prescriptive compositional requirements based on individual medical conditions
- permissions granted for nutritive substances and novel foods being too broad and potentially posing risks to infant health
- lack of pre-market assessment requirements
- formulas with modified lactose composition not being categorised as SMPPi (this topic is discussed in section 4.4).

For further details please refer to section 3 and 4 of Appendix 3.

4.2.4 Discussion

As noted above, FSANZ is aware of the concerns regarding the proliferation of products within the IFPSDU category that make use of flexible labelling and composition requirements for marketing advantages. FSANZ is also aware of IFPSDU that do not deviate from the required composition of general infant formula or follow-on formula yet make claims regarding their formulation assisting in managing symptoms and/or conditions. This is deduced from research (Bronsky et al. 2019; Vandenplas et al. 2019; Dipasquale et al. 2020; Hegar et al. 2021) that notes formulas for transient gastrointestinal conditions (such as fussing, colic, constipation and anti-reflux) differ from infant formula due to the following compositional requirements: partially hydrolysed protein, reduced lactose content, change in lipid content and in some cases addition of thickening agents. Each of these compositional modifications can be achieved under current infant formula compositional requirements.

FSANZ expects that the clear delineation between formulas for healthy infants and formulas for special medical purposes provided in the amended regulatory framework combined with the additional risk management interventions (for example, the restriction on sale discussed below) will adequately address these issues.

The current compositional requirements for IFPSDU can be confusing. They prescribe requirements for some medical conditions, however not all special purposes fit clearly into the three subsections of Division 4. Due to the difficulties of prescribing specific compositional requirements for each medical disease, disorder or condition for infants, FSANZ has proposed, through several rounds of consultation, to not prescribe set compositional parameters for each possible medical condition. Instead, FSANZ considers the responsibility of formulating and evaluating the efficacy and suitability of varied composition lies with the manufacturers of the products, medical specialists and experts and clinical nutrition guidelines. In addition, the medical specialist supervising or managing the infant's condition also holds responsibility in selecting and prescribing the SMPPi. As per paragraph 2.9.1—50(g)(ii) (A) and (B) of the primary variation, if a SMPPi has been modified to vary from the compositional requirements of sections 2.9.1—32 to 2.9.1—41, unless provided in other documentation, it must have a statement on the label indicating the nutrient or nutrients which have been modified and whether each modified nutrient has been increased, decreased or eliminated from the food. This information is typically found in accompanying documents to the SMPPi. For further information on this topic please refer to the discussion in section 4.22.

FSANZ received considerable feedback from submitters regarding compositional deviations (especially for nutritive substances and novel foods requirements) that are not required to undergo pre-market assessment. These requirements are largely based on the FSMP requirements in Standard 2.9.5. The proposed regulation separates SMPPi from pre-market assessment requirements (in the same way FSMP currently are) and only to the extent that the permitted deviation from compositional requirements is required for a particular medical purpose. Subjecting SMPPi to pre-market assessment would introduce long delays in getting those products to sick infants who depend on them as their sole source of nutrition. FSANZ is not aware of evidence that demonstrates a safety issue with this approach, nor was any provided during the multiple rounds of public consultation on P1028. In addition, similar provisions have been in the Code for a considerable amount of time and no evidence has been provided of a problem caused by these provisions.

Government submitters suggested in consultations that the requirement in paragraph 2.9.1—42(b) of the primary variation (which prescribes that SMPPi need not comply with sections 2.9.1—32 to 2.9.1—41 to the extent that it would otherwise prevent the sale of the food) could be complemented with an additional clarification of 'subject to a FSANZ equivalent

independent assessment by a competent overseas regulatory authority'. The FSANZ Act does not clearly authorise FSANZ to include such a provision in a Standard. Nor is it apparent that such a provision would deliver the level of certainty and objectivity required of a 'Standard' by the FSANZ Act. Such a provision would also require FSANZ to define what an 'equivalent independent assessment' is and determine who is a competent overseas regulatory authority may be. FSANZ also considers the addition of this type of provision to be unwarranted, noting the lack of evidence referred to above.

Also informing FSANZ's approach was consideration of the fact that the majority of SMPPi are imported from Europe and the US. SMPPi are not currently produced domestically in quantities or varieties that can support the diverse needs of Australian and New Zealand infants. In addition, evidence from industry submitters confirmed that importing SMPPi into the Australian and New Zealand markets does not provide commercial advantages for infant formula manufacturers. Therefore, if trade barriers were placed on this category due to a change in regulation, it is likely that the supply of these formulas would significantly decrease and/or cease all together. FSANZ considers this as a larger public health and safety risk than any other concern raised. Because of this reliance on the importation of SMPPi, FSANZ considers it crucial to allow for flexible compositional and labelling requirements so that products produced in Europe or the US are not required to reformulate or re-label before entering the Australian and New Zealand market.

FSANZ acknowledges that the amendment to Schedule 29 proposed by the 2nd CFS only captured compositional parameters. This was not the intent as the 2nd CFS clearly articulated that the composition of SMPPi should mirror the baseline composition of infant formula, except where deviation is required to achieve the product's special medical purpose. FSANZ amended the primary variation to correct this oversight. The primary variation now expressly states each compositional requirement for SMPPi within Division 4. Each requirement is set out in full in Division 4. Cross referencing between Divisions has been avoided where possible to provide further clarity.

4.2.5 Decision

Sections 2.9.1—32 to 2.9.1—41 of Division 4 set the compositional requirements for SMPPi. These mirror the compositional requirements for infant formula. Each SMPPi requirement is stated in Division 4 in full to provide regulatory clarity and assurance that each parameter must be met. The aim is to ensure that the composition of SMPPi is as close to human milk as possible.

Paragraph 2.9.1—42(1)(a) recognises the essential need to vary the composition requirements for SMPPi, depending on the medical disease, disorder or condition. It provides that SMPPi need not comply with a compositional requirement (as defined) to the extent that a variation is required to achieve the product's intended medical purpose.

For a similar reason, paragraph 2.9.1—42(1)(b) prescribes that SMPPi need not comply with a compositional requirement (as defined) only to the extent that compliance with that requirement would otherwise prevent the sale of the food.

These provisions reflect the fact that the majority of SMPPi are imported into the Australian and New Zealand market. Deviation from the Code's prescriptive compositional requirements is therefore required to reflect the differences in international regulations and standards. Subjecting SMPPi to trade barriers could discontinue the supply of these essential products to the Australian and New Zealand market and in turn risk the health and safety of vulnerable infants who depend on these products as their sole source of nutrition. As per the Food Acts in Australia and New Zealand, all food products for sale in Australia and New Zealand must be safe and suitable. This ensures that any deviation made from the compositional requirements will not pose a risk to the safety or health of

infants who require these products for the management of a specific disease, disorder or condition.

The above provisions need to be seen in the light of other provisions and requirements applying to SMPPi, such the restrictions on sale, supply of SMPPi and requirement that they be used under medical supervision.

Subsection 2.9.1—42(2) sets out what is a compositional requirement for these purposes. It is a requirement imposed by any of the following sections:

a) any of sections 2.9.1—32 to 2.9.1—41, but not section 2.9.1—35;

b) paragraph 1.1.1—10(6)(a);

c) paragraph 1.1.1—10(6)(b);

d) paragraph 1.1.1—10(6)(c).

Inclusion of paragraph 1.1.1—10(6)(a) to (c) as compositional requirements means that food additives, nutritive substances and processing aids that are not expressly permitted by the Code may still be added to and present in SMPPi when required.

The exclusion of section 2.9.1—35 from the list of compositional requirements preserves the operation of that section. It provides that a novel food may be present in a SMPPi only if and when the presence of that novel food in the product is necessary to achieve that product's intended medical purpose. This requirement has been set in line with changes to the novel foods definition and novel food permissions in infant formula products. The intent of this regulatory requirement is to ensure novel foods that are not expressly permitted for use in infant formula products will only be present in SMPPi when medically required and, noting the requirements of the Food Acts, provided that that presence does not render the SMPPi unsafe or unsuitable.

4.3 Restriction on sale

4.3.1 Current regulations

Standard 2.9.1 does not currently restrict who may sell an infant formula product.

4.3.2 Previous considerations

A restriction on sale of all SMPPI was proposed in the 2nd CFS. The proposal was to restrict sales to sale by a medical practitioner or dietitian, medical practice, pharmacy or responsible institution or a majority seller of that SMPPi. This proposal was based on the following justification:

- it will support infant health and safety by more clearly delineating products that are intended for a medical purpose (SMPPi) but still retain these products under Standard 2.9.1
- as a medical purpose product, it aligns with the sale requirements of Standard 2.9.5 – Foods for Special Medical Purpose (FSMP).

See section 2.3.6 of the 2nd CFS (FSANZ 2023a) for further details.

4.3.3 Stakeholder comments

There was mixed support for the 2nd CFS proposed variations. Most industry submitters did not support the restriction on sale proposed by the 2nd CFS proposed variations. Those submitters that did support it (government, public health and consumer advocacy groups) either supported the proposed variation fully or recommended further restrictions be placed on pharmacy and online sales as products could be purchased via these channels without any medical or dietetic guidance.

Industry submitters provided various reasons for not supporting the restriction on sale. These reasons are captured in detail within section 3 of Appendix 3 and include the following topics:

- low versus high risk products
- transient gastrointestinal conditions
- adverse health impacts
- accessibility
- inequity
- supply chain issues
- connection with healthcare professionals.

Industry submitters also recommended FSANZ conduct a thorough review of the suitability of the pharmacy sector to ensure the sale restriction would not introduce unintended, undesired or adverse consequences for infants and caregivers.

Submitters made the following points on why restricting the sale of SMPPi to pharmacies would be problematic:

- Decreased accessibility and availability of products:
  - due to limited shelf space, reduced opening hours, absence of home delivery and limited financial capability to stock all formula types
  - recent changes to the PBS may challenge the viability of small pharmacies in regional areas
  - pharmacy supply chains are two to three times slower than grocery retailer supply chains, resulting in longer lead times for product replenishment
  - pharmacies are heavily regulated and restricted by set location rules.
- Increased cost of products:
  - according to industry submitters, products sold at pharmacies can cost on average 6% more in Australia and 3% more in New Zealand than the same formula product sold in the grocery channel. This difference would be expected to increase further due to the decrease in competition.
- The restriction on sale could break the point of contact between healthcare professionals and the consumer, if the consumer feels that they only need to speak to someone in the pharmacy, rather than get a clinical diagnosis from their healthcare professional.

These comments are specific to the pharmacy setting and do not extend to other responsible institutions. Industry submitters noted the above points may also cause caregivers unnecessary stress.

4.3.4 Pharmacy sector targeted consultation

After receiving the above comments FSANZ consulted with five key pharmacy stakeholders in Australia and New Zealand, including:

- The Pharmacy Guild of Australia
- Pharmaceutical Society of Australia
- Pharmaceutical Society of New Zealand
- Rural Pharmacists Australia
- Chemist Warehouse.

The targeted consultation found unanimous support from the pharmacy sector to restrict the sale of SMPPi, due to the need for them to be used under medical supervision and the risks associated with misuse of the products. The targeted consultation also provided evidence which addressed the concerns of industry submitters responding to the 2nd CFS proposed variations. This evidence is provided below.

Community pharmacies

There are 5901 community pharmacies in Australia. On average, every person visits a community pharmacy 18 times each year (across metropolitan, rural and remote locations). Community pharmacies are the most frequently accessed and most accessible health destination, with over 333.2 million individual patient visits annually. More than 2100 pharmacies open after-hours, including weekends and public holidays.

In capital cities, 97% of people have access to at least one pharmacy within a 2.5 km radius, while in the rest of Australia 66% of people are within 2.5 km of a pharmacy.

Pharmacies in Australia and New Zealand are bound by section 90 of the *National Health Act 1953* and the *Medicines Act 1981*, respectively. These requirements extend to ownership, location and compliance. In particular the Pharmacy Location Rules in Australia set out the location-specific criteria that registered pharmacists must meet to obtain approval. The Pharmacy Location Rules remain consistent with the overall objective of the National Medicines Policy to improve the health outcomes of all Australians through access to and quality use of medicines.

There are more than 900 community pharmacies in New Zealand. They are also subject to rigorous approval processes, which also aim to achieve the above objective.

Pharmacists

Registered pharmacists are healthcare professionals that specialise in preparing and dispensing medications. Pharmacy is a heavily regulated profession.

In Australia the practice of pharmacy is governed by states and territories. Every pharmacy has to be registered with the pharmacy authority and must have a pharmacist on site at all times. Pharmacists must act within the Pharmaceutical Society of Australia (PSA) Code of Ethics and Professional Practice Standards.

In New Zealand the *Medicines Act 1981* defines a pharmacist as a health practitioner who is registered with the Pharmacy Council of New Zealand as a practitioner of the profession of pharmacy.

Pharmacists can offer tailored advice on pharmaceutical products and medicine, as well as encourage caregivers to seek further medical advice from a doctor or dietitian before purchasing a formula product. Pharmacists have a comprehensive understanding of patient care and the matrix environment in which allied health professionals operate in.

Accessibility and availability

The above legislated requirements ensure pharmacies are appropriately located throughout metropolitan and regional areas across both Australia and New Zealand.

Targeted consultation confirmed that many pharmacies are open weekends, after hours and public holidays. This can vary in rural and remote areas, however this variance would also extend to grocery retailers.

Some regional or rural areas may only have a general store, however given the prices and limited shelf and storage space it would be unlikely for caregivers to purchase formula from these stores or for these stores to stock SMPPi.

While most pharmacies operate through physical stores, more recently they are also implementing e-commerce services which allow caregivers to purchase products online and arrange home delivery. Rural consumers typically seek online purchases and order more often than metropolitan consumers, which allows those without close access to a pharmacy to make required purchases.

Supply

Pharmacies are bound by Community Service Obligations (CSO) which require the following delivery timeframes to be met if placed within the cut-off time:

- 24 hour delivery time for city, metropolitan and regional areas
- 72 hour delivery time for rural and remote areas.

Pharmacies order the majority of infant formula products through distributors bound by the CSO. In addition, most pharmacies will have a primary wholesaler and secondary wholesaler account to try and mitigate stock shortages. There are also some exceptions where products are ordered directly from a manufacturer.

The targeted consultation noted that pharmacists are well connected to their communities and understand patients' product needs including when product renewal is required. Pharmacies treat the replenishment of infant formula products in the same manner they do medicine, which has an increased level of urgency and priority, in comparison to general commodities stocked in the grocery channels.

Stock

The majority of pharmacies already stock infant formula products and in particular specialised formulas (SMPPi). Storage and temperature control are highly regulated in pharmacies, supporting safe supply of the product.

Pharmacies have smaller amounts of shelf space when compared to major grocery retailers. Because of this, the number of units of each product in stock at any given time may be limited. However, the targeted consultation confirmed that if a specific formula type is required, pharmacists are willing to order the product in and it can be delivered within 24 hours. In addition, pharmacies are also able to arrange home delivery for patients where

required. If there is a need for the ongoing stock of a product, pharmacists will arrange this to support the needs of their community. Stock selection and replenishment is based on community and patient needs.

Pharmacists are skilled at rationing products and ensuring those who need the products receive it. This was demonstrated on numerous occasions during the COVID pandemic where potential shortages of prescription and over-the-counter medication and general healthcare products were identified and managed early. The unique pharmacy supply chain as well as greater understanding of the needs of the communities they serve, ensures consumers who need these products are prioritised.

The changes to the sale of SMPPi may lead to pharmacies reassessing their SKUs and stock levels and focusing more on specialised formulas, rather than general infant formula products.

In addition, pharmacy point of sale systems are used for stock management, including ordering, monitoring stock on hand and rate of sale to ensure stock holdings are sufficient.

Cost

The targeted consultation found that manufacturers typically set the price strategy for products, however there would be strong price competition from large pharmacies and in metropolitan areas. In addition, the pharmacy groups noted that pharmacies do not price gouge.

Resources

During the targeted consultation FSANZ asked what could be done to further support the pharmacy sector during the transition period.

It was recommended that FSANZ develop resources in consultation with pharmacy stakeholders to educate pharmacists about the new regulations. In the 2nd CFS submissions, stakeholders also requested materials that pharmacists can provide to caregivers to explain the changes. Education materials would also be useful for outlets that currently stock particular products but will no longer be allowed to.

Stakeholders also indicated there are several existing channels that would be ideal for communicating the changes within the sector. These include webinars, newsletter updates and annual pharmaceutical society conferences.

Targeted consultation conclusion

The evidence provided through the targeted consultation supported FSANZ's decision to restrict the sale of SMPPi to a medical practitioner or dietitian, a medical practice, pharmacy or responsible institution (as defined), or a majority seller of that SMPPi.

4.3.5 Consumer evidence

In considering the restriction on sale for SMPPi, FSANZ reviewed consumer evidence from a previous FSANZ systematic literature review (FSANZ 2022f), submissions to the 2nd CFS and additional information. The findings from the best available evidence indicates:

- Estimates on the use of specialised infant formula in Australia range from one study reporting 6% of formula-fed infants used soy, lactose free, reflux, goat or comfort formulas, to another source reporting 52% of formula-fed infants used organic,

extensively or partially hydrolysed protein, milk other than standard cow's milk, or formulas marketed as premium or for specific infant medical issues.

- Caregivers may interpret normal unsettled periods and infant behaviours such as crying, sleep-waking, posseting and gassiness to be concerns that could be addressed through a specialised formula.
- Between 57% and 79% of caregivers serving infant formula seek medical advice about infant formula use. However, only 19% seek this advice *prior to commencing* formula feeding.
- Approximately half (53%) of those using premium or specialised formulas sought advice from a health professional about formula feeding. However only 48% of premium or specialised formula users sought any advice (medical or other sources) *prior to starting* formula.
- There has been rapid growth in the sale of specialised formulas that are marketed to address sensitivities and allergies, which does not appear to align with international epidemiological prevalence data.
- Broader research on allergy prevalence in the community suggests self-reported food allergy overestimates prevalence relative to clinically diagnosed prevalence.
- There are concerns that lactose free and low lactose formulas are being inappropriately recommended and used for infants with cow's milk protein allergy. However, there is a lack of empirical research on such use.

FSANZ Literature Review

A FSANZ literature review considered evidence published between January 2003 and September 2019 on how caregivers perceive and decide to use SMPPi (see section 5; FSANZ 2022f).

Utilisation of SMPPi

The literature review highlighted an online survey of a nationally representative sample of 501 Australian mothers of infants who had been formula fed between zero and 12 months, commissioned by the Infant Nutrition Council (INC) (Jigsaw 2015). The examples given of specialised formula in the questionnaire included soy, lactose free, reflux, goat and comfort formulas. The results showed that 6% of these infants had been fed specialised formulas. There was no evidence found on the use of specialised formulas in New Zealand.

Reasons for using SMPPi

The INC survey found that 40% of those who reported changing formulas (n = 221) did so because their 'baby was unwell with current [formula]' (Jigsaw 2015). While this question was not specifically about changing to SMPPi, it suggested that a large proportion of caregivers may view changing formulas as a way to address medical concerns. In Australian and New Zealand focus groups conducted by Malek (2018a), caregivers indicated they would use formulas designed for specific nutrition or health outcomes when they had a clear infant health outcome to attend to (e.g. needing to increase infant weight, micronutrient deficiencies, gut issues). These two studies align with international evidence highlighted in the literature review which suggest that caregivers may believe problems experienced by their infant are due to the formula they are consuming and that changing to a specialised formula may address those concerns (Dykes et al. 2012; Huang et al. 2013; Parry et al. 2013). In contrast to this, in one US focus group study, breastmilk was perceived to be unchanging and thus not able to be altered to address specific issues (Parry et al. 2013).

Seeking medical advice

The literature review did not identify any evidence on whether consumers sought medical advice regarding their decisions to use specialised formulas. However, section 6 provided insight into medical advice sought for formula use more broadly (FSANZ 2022f).

In the INC survey (Jigsaw 2015), 57% percent of mothers who used formula reported they had sought information about formula from a healthcare practitioner (e.g. their general practitioner or midwife). Among mothers who introduced formula in the first three months of the infant's life, 62% sought advice from a healthcare practitioner (Jigsaw 2015). A survey of 270 Australian mothers of six-month old infants found that 77.5% had received advice on formula feeding from a medical professional (Appleton et al. 2020). These studies asked about receiving advice around infant formula (including use, preparation and storage advice), rather than specifically about advice on the type or brand of formula to provide. Evidence from the US suggests that around half of mothers discuss their choice of formula with a doctor (Huang et al. 2013). However, this rate was not specific to caregivers considering a specialised formula (who may be more likely to consult a doctor).

Qualitative interviews with 24 Australian caregivers found that formal medical advice was often received after the infant had started using formula products, as healthcare professionals were sometimes hesitant to provide advice prior to formula feeding commencing (Appleton et al. 2018). The study also noted that initial decisions to formula feed or change formula are sometimes made hastily (Appleton et al. 2018). This was in contrast to an Australian and New Zealand online discussion forum study with 137 participants, which found that caregivers typically gather information on whether they should use formula and what product other caregivers recommend, pre-purchase (Yockney and Comfort 2013).

One qualitative study from the UK (Dykes et al. 2012) identified that healthcare professionals believed that caregivers struggled with infants going through normal unsettled or difficult periods. They noted that some caregivers would seek out interventions, which health professionals considered unnecessary, to address these problems. These included introducing follow-on formula or complementary foods (solids) earlier than recommended, seeking a diagnosis to explain the problem (e.g. lactose intolerance) and seeking a prescription for medicine or specialised formula to address the problem (Dykes et al. 2012).

Evidence from stakeholders

Through the 2nd CFS, stakeholders raised additional consumer evidence pertaining to the restriction on sale for SMPPi as outlined below.

Common infant behaviours perceived as feeding problems

A paper from the 2023 Lancet Breastfeeding Series (the Lancet Series) identified that caregivers often misconstrue common infant behaviours as signs of feeding problems (Pérez-Escamilla et al. 2023). This conclusion was drawn from a systematic review (Vilar-Compte et al. 2022) of 22 studies which assessed the influence of baby behaviours perceived as problematic (including crying, sleep-waking and posseting) on infant feeding decisions during the first 6 months of life (including self-reported milk insufficiency, breastfeeding duration and introduction of formula). The review identified that unsettled infant behaviours, especially persistent crying, can lead caregivers to believe that specialised formulas are needed (Vilar-Compte et al. 2022). This finding was primarily based on a United States study of 189 breast feeding and 184 formula feeding infants (Forsyth et al. 1985). The study found that 25% (45) of those initially formula fed switched to a specialised formula, while 11% (21) of those who were initially breast fed switched to standard infant formula,

before switching again to a specialised formula. Specialised formulas in this study included soy protein and casein hydrolysate formulas. About one-quarter (26%) of mothers who had changed to a specialised formula believed that problems experienced by their infant (including excessive crying, colic, vomiting, diarrhoea, spitting, constipation or feeding difficulties) were due to an allergy to cow's milk protein. Furthermore, mothers of infants who were switched to specialised formulas due to 'non-specific' complaints which often do not have a clear cause (including crying, colic, spitting up, constipation and difficulties with feeding and sleeping) were significantly more likely to believe these problems were due to a 'disease or illness' (30%) compared to those who reported these problems but did not change to a specialised formula (9%) (Forsyth et al. 1985). As this study was undertaken in the United States 38 years ago, the findings may not be generalisable to current Australian and New Zealand populations. The Vilar-Compte et al. (2022) review included two Australian studies, however neither of these specifically considered outcomes relating to the uptake of specialised formulas.

A second paper in the Lancet Series investigated marketing strategies used by the commercial milk formula industry globally (Rollins et al. 2023). This paper drew on national survey data, company reports, case studies, methodical scoping reviews and two multi-country research studies (Rollins et al. 2023). Rollins et al. (2023) stated that commercial milk formula is often marketed as a solution to caregivers' concerns about normal infant behaviours, including sleeping patterns, fussiness, flatulence and crying. However, the study did not specifically identify any examples of such marketing in the Australian and New Zealand market. Rollins et al. (2023) also noted rapid growth in sales of specialised formulas that are marketed to address sensitivities and allergies, which does not appear to align with epidemiological prevalence data from the United Kingdom (Van Tulleken 2018; Venter et al. 2008).

A study undertaken by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) reported similar findings from Mexico (WHO 2022). The study, which included desktop reviews, marketing analyses, interviews, focus groups, phone diaries and surveys, noted that allergies and food intolerances were an emerging issue for caregivers. They identified a move toward low lactose/lactose free and hydrolysed formulas, which were marketed as suitable for babies experiencing common digestive issues, such as gassiness (World Health Organisation 2022).

Inappropriate use of specialised formulas

Several submitters also noted concerns drawn from their clinical experience regarding low lactose/lactose free formulas being inappropriately recommended to or used for infants with cow's milk protein allergy. The authors of two published studies also expressed the view that lactose intolerance is often confused with cow's milk protein allergy by clinicians and caregivers (Di Constanzo et al. 2018; Walsh et al. 2016). However, neither of these studies empirically investigated this issue and stakeholders note there is a lack of literature on the topic.

FSANZ's literature search

FSANZ also undertook a search of the literature to identify any additional evidence around caregiver purchasing decisions for SMPPi, including seeking of medical advice.

SMPPi and medical advice

A survey of 153 Australian caregivers with infants aged 0–6 months who were fully or partially formula fed found that while 79.2% had received advice from a health professional about formula feeding, only 18.9% received this advice before commencing with formula

(Appleton et al. 2022). This question was about seeking information on formula feeding in general, not specifically about the type or brand of formula they were planning to use. Those who had received advice from a health professional were more likely to have started formula when their infant was younger (median 7 days) relative to those who had not received advice from a health professional (median 21 days) ($p = 0.013$). Those who were mixed feeding had 3.8 times higher odds of seeking any advice (medical or other sources) than those only using formula (Appleton et al. 2022).

Approximately half (52%) of participants fed their infant a 'premium or specialised' formula, which included 'organic, extensively or partially hydrolysed protein, milk other than standard cow's milk and those marketed as premium or for specific infant medical issues, such as reflux' (Appleton et al. 2022, p 911). About half (52.5%) of those using 'premium or specialised' formulas had sought advice from a health professional in the past, compared with 47.5% of those using standard formulas. However, only 47.9% of 'premium or specialised' formula users sought any advice (medical or other sources) *prior to starting formula*, relative to 52.1% of those using standard formula. The differences in seeking advice between standard and 'premium or specialised' formula users were not statistically significant (Appleton et al. 2022).

The most common sources of medical advice were Child and Family Health Nurses (49.7%), General Practitioners (48.3%), midwives (42.9%) and pharmacists or pharmacy staff (21.5%). However, non-medical sources of advice were more common, including the formula tin (96.6%), family (62.4%), friends (60.1%) and formula websites (30.9%) (Appleton et al. 2022).

Appleton et al. (2022) also asked about the reasons why caregivers chose specific types or brands of formula in an open ended question. The most common reason was that the formula was recommended (53%), either by a health professional (31% of those citing recommendations as a reason), the birthing hospital used it (27%), or from family, friends or social media (21%). A further 21% did not state the source of the recommendation. Infant and health behaviour was the second most common reason (28%), being either related to infant health reasons (e.g. 'because she doesn't throw it up') (73% of those citing this reason), because the infant 'likes it' (22%), or related to infant behaviour (e.g. 'the low lactose in it has helped my baby be less agitated and happier') (7%) (Appleton et al. 2022, Supplementary Table 1). Marketing attributes (14%), perceived quality (13%), trial and error (10%), previous use (9%), ingredients (7%) and pragmatic reasons (5%) were other reported reasons behind formula type and brand choices (Appleton et al. 2022).

Importantly, this study was based on a small sample, recruited through social media channels and three metropolitan centres operated by a single family health service provider in NSW. Participants were almost entirely mothers (99.3%) and 47.4% had a university education. Thus, the results may not be generalisable to the broader population.

Allergy self-diagnosis

Broader research on allergy prevalence in the community suggests that self-reported food allergy generally overestimates prevalence, as patients or caregivers may mistake 'coincidence, toxic reactions, food poisoning, enzyme deficiencies, irritant contact reactions, food aversion or "food intolerance" for food allergy' (Tang and Mullins 2017, p. 257). For example the self-diagnosed prevalence of IgE-mediated cow's milk protein allergy in Australia has been estimated to be 10 times higher than clinically proven prevalence identified in blinded and controlled challenge trials (Crittenden and Bennett 2005).

4.3.6 Discussion

After careful consideration of submissions received, targeted consultation with the pharmacy sector and review of consumer evidence, the approach to the restriction on sale remains unchanged. The primary variation will restrict the sale of all SMPPi. Sale will be limited to sale by a medical practitioner or dietitian, medical practice, pharmacy or responsible institution or a majority seller of that SMPPi. A responsible institution is defined in the Code as a hospital, hospice, aged care facility, disability facility, prison, boarding school or similar institution that is responsible for the welfare of its patients or residents and provides food to them (noting that not all listed responsible institutions under the Code definition will be applicable to the supply of SMPPi). A majority seller is defined in the Code as a person who, during any 24 month period, sold a SMPPi to a medical practitioner, dietitian, medical practice, pharmacy or responsible institution and those sales represent more than one half of the total amount of that SMPPi sold by the person during that 24 month period. This restriction is aligned with the sale requirements of Standard 2.9.5. As SMPPi are a medical purpose product for a very vulnerable population, FSANZ considers a restriction on sale an important and appropriate risk mitigation strategy.

If a sale restriction was not applied, SMPPi would be the only medical purpose product in the Code not subject to a restriction on sale. Such a regulatory outcome would not reflect the level of risk associated with the consumption of medical purpose products by healthy infants. Due to the compositional variance between SMPPi and infant formula, the consumption of these medical products by healthy infants could lead to serious issues related to impaired growth and development and have further unknown lifelong consequences. This is particularly concerning in light of consumer evidence suggesting that many caregivers may not seek medical advice prior to feeding their infant a specialised infant formula.

Following targeted consultation with the pharmacy sector, FSANZ is satisfied that caregivers will continue to have good access to SMPPi through pharmacy channels. Pharmacy stakeholders have confirmed their ability to manage additional products, including the ability to source specific products at short notice based on community needs. FSANZ notes that some products may be more difficult for some consumers to access given the lower density and reduced opening hours of pharmacies relative to supermarkets. However, FSANZ considers that the highly regulated geographical network of pharmacies, including those accessible via e-commence, provides appropriate access, as it currently does for essential medicines. SMPPi use under medical supervision provides an additional safeguard in ensuring that infants have continued access to the formula if they require it as the sole or principal source of nutrition. Any issues relating to access and availability can be handled by the treating medical professional through direct contact with the majority seller or pharmacy.

While the discussion in section 4.2 is solely focused on pharmacies and their sale of SMPPi, it is important to note that the restriction on sale permits other healthcare practitioners and responsible institutions to sell these products (as noted above). Therefore, these products will also be accessible and available from sources other than the pharmacy sector. In some instances, infants with a disease, disorder or condition are started on a particular SMPPi within the hospital setting and the continued supply of this formula is organised by the overseeing medical practitioner or dietitian. This practice is also commonly applied in rural and remote areas, where dietitians organise routine supply of a particular formula directly from the supplier.

FSANZ disagrees with industry concerns that the restriction on sale would break the point of contact between healthcare professionals and consumers. FSANZ considers the restriction on sale will instead strengthen this relationship as the products will need to be purchased from a healthcare setting. In addition, FSANZ does not agree with the suggestion that if a consumer sees a pharmacist they will not see another healthcare practitioner, whether it be a

dietitian or doctor. Pharmacists are allied health professionals who understand and respect the importance of multidisciplinary care. It is inaccurate to suggest that pharmacists will not encourage consumers to seek further medical advice or assistance.

Within the rural setting, pharmacies and responsible institutions may not be as accessible as in metropolitan areas due to barriers such as travel distance. While FSANZ acknowledges this, there are many other avenues for seeking advice about caring for infants within the rural setting. Regardless of where they live, infants' health is generally monitored via routine health checks and screening tests. This might be with a child health nurse, a general practitioner or other medical professional. Therefore, caregivers will have opportunities to discuss infant formula products with suitable healthcare practitioners.

Based on the evidence provided in targeted consultation, FSANZ does not anticipate issues related to accessibility, availability and cost will have direct effect on caregiver and infant wellbeing. FSANZ also notes that while the restriction on sale is a large regulatory change, it is being implemented over a five year transition period which allows ample time for all stakeholders (manufacturers, sellers, consumers, healthcare professionals) to adapt to the change. FSANZ also will work with jurisdictions to provide comprehensive information for consumers and industry about the regulatory changes.

The proposed sale restriction will only affect specialised formulas currently sold in the grocery retail channel, which are typically formulas for transient gastrointestinal conditions such as diarrhoea, constipation, colic and regurgitation. FSANZ noted in the 2nd CFS that we are not aware of other specialised formulas currently sold in the grocery retail channel and did not receive any evidence from consultation to suggest otherwise. FSANZ is cognisant that the majority of products that will be regulated as SMPPi are prescription-based and/or are on the Pharmaceutical Benefits Scheme.

FSANZ notes that infant formula and follow-on formula are currently positioned alongside formulas for transient gastrointestinal medical conditions on some supermarket shelves in Australia and New Zealand. This physical proximity and placement on supermarket shelves would conceal the medical purpose of the SMPPi and the need for it to be used under medical supervision. In addition, industry submissions to the 1st CFS mentioned formulas for transient gastrointestinal conditions should be used under medical supervision. Based on this and their specific purpose to assist with a condition, FSANZ considers these products appropriately fit the SMPPi definition and should be subject to a sale restriction consistent with all other medical foods. FSANZ considers physical separation in conjunction with sale in pharmacies and/or responsible institutions would adequately protect the health of infants and allow consumers access to medical advice when purchasing formulas for medical diseases, disorders or conditions.

Stakeholders have noted that a restriction on sale is not consistent with overseas regulations and requirements. However, retail channels operate substantially differently overseas, where pharmacies can be located inside supermarkets and grocery stores. FSANZ also notes the restriction on sale posed by the primary variation would not affect the import or export market of these products.

As discussed in section 4.3.5, there has been rapid growth in the sales of specialised formulas internationally. This finding is also supported by industry data (IQVIA[3]) provided in

[3] Data from report by IQVIA titled – *Impact Analysis on Restriction of SMPPi Sale* produced for the Infant Nutrition Council and provided to FSANZ in response to the 2nd CFS. The data only includes products available for sale in supermarkets and pharmacies. Products only available in medical settings under the status quo are excluded from this list (such as prescription only products and PBS/pharmacy supported products). Note that FSANZ did not seek clarification on what products are included in the 'milk allergy' category.

response to the 2nd CFS. In Australia, sales of specialised formula have increased by an average of approximately 7% per year over the last two years. Almost all of the additional sales of specialised formula have been made in the grocery channel, with pharmacy sales not experiencing significant growth. In 2023, 10% of all infant formula products sold in Australia were specialised (non-PBS) formula. The growth in sales was largely driven by milk allergy products, the largest category of specialised formulas by sales in Australia. Sales of products for sensitivities or intolerances have also increased. In New Zealand, sales of specialised formula increased by approximately 7.5% from 2022 to 2023. Sales grew in pharmacies and remained flat in the grocery channel. The increase in pharmacy sales is reportedly due to the recent expansion of a major chain of retail pharmacies in New Zealand. In 2023, 3% of all infant formula products sold in New Zealand were specialised (non-pharmacy) formula products. Sales of milk allergy products increased by almost 50% over the year and sales of colic and constipation products increased by almost 25%. Sales of sensitivity and intolerance products also grew. Sales of reflux and anti-regurgitation products (the largest category by sales in New Zealand) decreased slightly. FSANZ is unaware of an increase in the prevalence of cow's milk protein allergy in Australian or New Zealand infants, however is cognisant that self-reported food allergy overestimates prevalence and that symptoms such as excessive crying, colic, vomiting, diarrhoea, spitting, constipation or feeding difficulties are incorrectly attributed to an allergy to cow's milk protein.

FSANZ considers the growth of the SMPPi market in Australia and to a lesser extent in New Zealand, evidences a clear need for further regulatory parameters to ensure normal infant behaviours are not targeted by marketing suggesting such behaviours require unnecessary dietary intervention. While on the one hand there is a demonstrated need for flexible regulations regarding the composition and labelling of SMPPi to ensure products can continue to be imported, the same is not required from a sales perspective. The restriction on sale does not affect international markets, import or export or as explained above, access by those who depend on these products. However, it ensures the regulation within the domestic market of Australia and New Zealand is well balanced between flexibility and risk proportionate requirements.

The restriction on sale for Standard 2.9.5 has been in place for over 12 years and has been seen to be working effectively. Issues regarding access and availability have not been raised in relation to that Standard and FSANZ has not needed to amend or vary that requirement. FSANZ has sought evidence through multiple rounds of public and targeted consultation regarding claims that this same restriction would result in significant issues if implemented for SMPPi, however no evidence has been provided to substantiate this.

4.3.7 Decision

FSANZ's decision is to restrict the sale of SMPPi to a medical practitioner or dietitian, a medical practice, pharmacy or responsible institution or a majority seller of that special medical purpose product for infants. This requirement can be found at subsection 2.9.1—31 of the primary variation.

It is also important to note:

- The data is a moving annual total (MAT), so each year of data ends on 27 May e.g. the 2023 data is for the year ending 27 May 2023.
- The data is heavily rounded, so the percentages should be used with caution, especially in NZ where sales numbers are very small relative to Australia.
- There was no data provided on the trend in pharmacy SMPPi sales.

4.4 Low lactose and lactose free formula

4.4.1 Current regulations

The current Standard 2.9.1 regulates products based on low lactose or lactose free under Division 4 *Infant formula products for special dietary use*. Subsection 2.9.1—14 covers products for metabolic, immunological, renal, hepatic and malabsorptive conditions and under *special requirements for food represented as lactose free and low lactose formulas* contains specific representation, labelling and composition requirements as follows:

(3) A compositional or labelling requirement of this Standard, other than a requirement that relates to lactose content, applies to an infant formula product that is represented as lactose free formula or low lactose formula.

(4) If the formula is represented as lactose free, it must contain no detectable lactose.

(5) If the formula is represented as low lactose, it must contain no more than 0.3 g lactose/100 mL of infant formula product.

(6) For the labelling provisions, if a label contains a claim that the infant formula product is lactose free, low lactose or words of similar import:

(a) the name of food must include the following:

(i) for a formula represented as lactose free—the words 'lactose free'; and

(ii) for a formula represented as low lactose—the words 'low lactose'; and

(b) the following statements are required:

(i) the amount of lactose expressed in g/100 mL; and

(ii) the amount of galactose expressed in g/100 mL.

4.4.2 Previous considerations

At the 1st CFS, the proposed creation of the new category of SMPPi meant that the existing category of IFPSDU and its associated subcategories would be removed. Also at the 1st CFS, FSANZ proposed to categorise formulas that deviated from the baseline infant formula or follow-on formula composition by only having modified protein and/or lactose free/low lactose content as infant formula as they were intended to address transient gastrointestinal conditions linked to poor digestion of protein or lactose. FSANZ did not intend to set a definition for this proposed subcategory for modified infant formula products, but proposed that the characteristics of these products would include modified protein and/or lactose compositional parameters only.

At the 2nd CFS, FSANZ clarified this approach. For the reasons set out in the 2nd CFS, the 2nd CFS proposed variations (subsection 2.9.1—21) proposed the following requirements if a label represents that an infant formula is lactose free or low lactose:

- If lactose free, the words 'lactose free' must be included in the statement of the name of the food
- If low lactose, the words 'low lactose' must be included in the statement of the name of the food
- If lactose free or low lactose, the average quantity of lactose and galactose, expressed in grams, must be included in the statement of nutrition information.

4.4.3 Submitter comments

Government, industry and public health submitters responded to the 2nd CFS proposed variations, of which none supported the draft variation at the 2nd CFS, as proposed.

SMPPi with restricted sale

Government and public health submitters did not support the 2nd CFS proposed variations as they considered that low lactose and lactose free formula should be categorised as SMPPi with the associated restrictions on sale.

The following reasons were provided by these submitters:

- Low lactose and lactose free formula are required for a medical purpose. By categorising these as SMPPi they can be labelled with the specific medical purpose and will be used only when medically necessary.
- Caregivers of infants that likely have cow's milk protein allergy that is not yet diagnosed may mistakenly purchase low lactose or lactose free formula.
- Seeking advice from a health professional before introducing SMPPi can prolong breastfeeding duration.
- Specialised formulas attract a higher price so caregivers may inadvertently pay more for a specialised formula the infant does not require.
- Replacing lactose, the largest provision of carbohydrate energy in human milk with other carbohydrate sources for no reason moves away from human milk composition. This cannot be considered ethical or safe for vulnerable infants.
- It is important to consider increasing rates of infant obesity in the context of increasing use of low lactose and lactose free formula and later onset obesity associated with low lactose formula.
- There is a lack of longitudinal studies on growth and development outcomes of infants fed low lactose or lactose free formula.

One of these submitters considered it important to retain the ability for soy-based formula, which may be represented as lactose free, to be positioned as infant formula, therefore not having restricted sale.

Remove low lactose from sale

A government submitter did not support the 2nd CFS proposed variations as they considered that low lactose and lactose free formula were rarely required for an extended period of time. The submitter suggested that there is no aetiological requirement for low lactose infant formula and there should be a transition to removing these from the food supply.

SMPPi without restricted sale

Most industry submitters supported the 2nd CFS proposed variations as they considered that low lactose and lactose free formula are low risk and should remain as infant formula products but requested extended labelling provisions for lactose intolerance. Alternatively they proposed that low lactose and lactose free formula could be categorised as SMPPi but should be exempt from the restriction on sale.

Labelling

Industry submitters did not support the restriction for the condition 'lactose intolerance' to be labelled on standard formula. They suggested it be permitted similarly to 'lactose free' or 'low lactose' so it did not constitute a prohibited claim, or alternatively have extended labelling (e.g. a statement 'for babies with lactose intolerance'). One industry submitter commented that existing labelling requirements are inappropriate i.e. products could not be truly 'lactose

free' and 'low lactose' products may present a potential safety issue for lactose intolerant infants. While industry submitters supported the requirement at 2nd CFS for 'lactose free' and 'low lactose' to be included with the name of the food on the front of the package of infant formula, they opposed the restriction for these terms elsewhere on the label.

A government submitter also stated it will need to be clear that low lactose and lactose free formulas are not indicated for lactose intolerance. This submitter commented that some overarching advisory [statement] indicating that low lactose and lactose free formula are rarely required for an extended period will need to be considered.

Health professional, government and individual submitters recommended 'lactose free' and 'low lactose' formula be subject to a labelling statement such as 'not suitable for infants with cow's milk allergy' because of the importance of clearly distinguishing between formula suitable for lactose intolerance and formula suitable for infants with cow's milk protein allergy. Further, a government submitter and a health professional submitter stated the inclusion of 'lactose free' or 'low lactose' with the name of the food was viewed as information typically deemed as a nutrition content claim, which is inconsistent with the Ministerial Policy Guideline on the Regulation of Infant Formula Products (MPG 2011).

4.4.4 Discussion

FSANZ previously proposed that low lactose and lactose free products would be categorised as general infant formula and/or follow-on formula, instead of a specialised formula subject to sale and use under medical supervision. However, through industry submissions to the 2nd CFS, FSANZ has learnt that 'low lactose' and 'lactose free' representations are unlikely to be used by manufacturers of dairy-based formula for two reasons.

Firstly, as analytical methods have progressed and evolved to detect very small amounts of lactose present in a product, infant formula manufacturers are not able to achieve the no detectable amount required by the Code to represent a dairy-based infant formula as lactose free.

Secondly, the current Code stipulates that formulas represented as low lactose must have no more than 0.3 g lactose/100 mL of the formula. However, Codex and EU regulations do not set conditions for a similar claim for infant formula and/or follow-on formula. FSANZ has learnt from industry submitters that 'low lactose' is not used as it does not convey the purpose of the product. Industry have commented that they formulate products for lactose intolerance, however the lactose cut point for 'low lactose' is too high for the treatment of lactose intolerance. Thus, in a clinical setting, a product represented as 'low lactose' would not be recommended for the dietary management of infants with lactose intolerance.

FSANZ has confirmed via consultation that lactose modified products are formulated for the dietary management of lactose intolerance. However it is important to note that clinically diagnosed lactose intolerance is likely extremely rare in infants (Heyman 2006; TRCHM 2018; Mattar et al. 2012). Despite this, a common rationale for purchasing such products is that the infant is presumed to be lactose-intolerant. Evidence suggests however that elimination of lactose from infants' diet is disadvantageous for the development of a healthy gut microbiome (Di Costanzo and Berni Canani 2019). To support consumer decision making and reduce the potential risk of unnecessary use of lactose modified formula, FSANZ considers these formulas fit better under the SMPPi category and proposes to remove the 'low lactose' and 'lactose free' compositional and labelling requirements for infant formula and follow-on formula. As the SMPPi category already allows for compositional deviation, no additional requirements would be needed in Division 4 relating to composition.

FSANZ has also considered how existing labelling requirements in Division 4 would apply to lactose modified products as SMPPi. As for all SMPPi, labelling requirements relating to the true nature of the food, statements indicating the medical purpose and, if applicable, any statements about precautions or contradictions associated with consumption of the product, will apply.

An explicit labelling provision to permit a claim that a SMPPi is 'lactose free' will be required because SMPPi will be prohibited from making nutrition content claims. FSANZ has inserted a new provision to permit SMPPi to be sold as 'lactose free' subject to the condition that it contains no detectable lactose (section 2.9.1—47 of the primary variation). FSANZ notes the requirement differs from the EU regulatory approach for a 'lactose free' statement for infant formula and follow-on formula, which includes a threshold i.e. a lactose free claim may be made if lactose content in the product is not greater than 2.5 mg/100 kJ (Article 9(2) of EU 2016/127; European Commission 2016a). However, the primary variation is consistent with the existing regulatory approach in the Code for adult FSMP (section 2.9.5—14(2)) and the generic conditions for 'lactose free' claims for all foods (see the table to section S4—3), which take account of Australian Competition and Consumer Commission (ACCC) and New Zealand Commerce Commission (NZCC) views that consumers are likely to consider 'free' means zero. FSANZ acknowledges the challenges associated with making a 'lactose free' claim for dairy-based formula given the sensitivity of analytical methods as noted above, however the claim could be used for soy-based SMPPi. Additionally, manufacturers can formulate SMPPi suitable for lactose intolerance and include a statement indicating this is the medical purpose.

Explicit requirements to declare the amount of lactose and galactose in the NIS when a lactose free claim is made are not needed for SMPPi. SMPPi manufacturers are able to provide information on sub-group nutrients of carbohydrate if the declaration of that information is necessary for the use of the SMPPi for its intended medical purpose (paragraph 2.9.1—51(1)(d) of the primary variation). Nutrition information requirements are purposefully more flexible for SMPPi to ensure the continued supply of imported products.

FSANZ does not agree that an advisory statement indicating low lactose and lactose free formula are rarely required for an extended period is warranted. Regulating lactose free formula as SMPPi means these products will be managed by a medical professional and will be required to provide a statement indicating the medical purpose in addition to other required statements. SMPPi manufacturers must include a statement indicating any precautions or contraindications associated with the consumption of the food, if applicable. In response to submitter comments that 'lactose free' in the name of the food constitutes a claim and is inconsistent with infant formula policy guidance, an explicit historical permission in the Code meant its use was not incompatible with the existing claim prohibition[4] or the Ministerial Policy Guideline on the Regulation of Infant Formula Products (MPG 2011). Going forward, a similar explicit permission will apply to lactose modified products regulated as SMPPi.

No conditions have been set for 'low lactose' because, as noted above, FSANZ has been advised that low lactose formulas are not suitable for lactose intolerant infants and this representation is not used by formula manufacturers.

[4] Paragraph 2.9.1—24(1)(f) in Standard 2.9.1 Infant formula products and paragraph 1.2.7—4(b) of Standard 1.2.7 Nutrition, health and related claims.

4.4.5 Decision

FSANZ's decision is to regulate lactose modified formulas as SMPPi under Division 4 of Standard 2.9.1. Provisions relating to lactose free and low lactose standard formulas and permitting lactose related claims for infant formula and follow-on formula will be removed from Division 3.

Labelling requirements in Division 4 SMPPi will apply to lactose modified formula. An additional provision will apply so that a 'lactose free' claim may be made if a SMPPi contains no detectable lactose (section 2.9.1—47 of the primary variation).

4.5 Partially hydrolysed protein

FSANZ has considered the regulatory requirements for partially and extensively hydrolysed proteins throughout P1028. This issue is connected with the definition for protein substitute in Standard 2.9.1 and in turn the IFPSDU subcategory of 'products for specific dietary use based on a protein substitute'.

4.5.1 Current regulations

Section 2.9.1—15 permits an infant formula product to be based on a protein substitute, The term 'protein substitute' is defined in section 1.1.2—2 to mean (a) L-amino acids, (b) the hydrolysate of one or more of the proteins on which an infant formula product is normally based, or (c) a combination of L-amino acids and the hydrolysate of one or more of the proteins on which an infant formula product is normally based. The definition of protein substitute was introduced in the last revision of infant formula regulations (Proposal P93 – Review of Infant Formula; FSANZ 2002) to allow for partial or extensive protein hydrolysates used in specialised formulas at the time.

The current standard does not differentiate between specialised products based on a protein substitute that are safe for consumption by healthy infants and those that are intended for sick infants and could be unsafe for healthy infants.

4.5.2 Previous considerations

At the 1st CFS, for the reasons listed in that report, FSANZ proposed an amendment to the regulatory framework which aimed to separate infant formula and follow-on formula from specialised formulas by creating clear definitions for each product category. In addition, it was noted that infant formula and follow-on formula could have modified protein and lactose content. This 'modified' category was not a proposition to define a new subcategory for modified infant formula products, instead it was intended to provide clarity to the regulation and labelling of a low risk modified protein source in infant formula products. The intent of the proposed option at the 1st CFS was that products based on partial hydrolysis of one or more of the proteins on which infant formula is normally based (i.e. the current definition in Standard 2.9.1), would continue to be permitted as infant formula or follow-on formula (not SMPPi) as long as they met all other compositional requirements for infant formula or follow-on formula.

For the reasons stated therein, the 2nd CFS proposed variations categorised partially hydrolysed protein formula as infant formula and follow-on formula, with the intent of the regulation outlined in the 1st CFS being retained. These products were to be subject to specific requirements to label as 'partially hydrolysed' as per section 2.3.5 of the 2nd CFS (FSANZ 2023a).

4.5.3 Submitter comments

FSANZ received comments from government, industry and public health submitters on this issue. Most of the submitters supported the 2nd CFS proposed variations. One submitter supported partially hydrolysed protein being permitted for use in infant formula and follow-on formula recommended further consideration of labelling restrictions to prevent inappropriate representation as 'pseudo-medical' products. Further comments regarding labelling of partially hydrolysed protein infant formula are included in section 3 of Appendix 3.

Some government and public health submitters did not support the 2nd CFS proposed variations. These submitters considered that partially hydrolysed protein does not have a functional purpose and is not required by healthy infants. A submitter noted that the Australasian Society of Clinical Immunology and Allergy (ASCIA) does not recommend using partially hydrolysed protein infant formula for the dietary management of allergy, noting that extensively hydrolysed protein or amino acid based infant formula products are used for infants with cow's milk protein allergy.

Some government submitters recommended that criteria be developed to differentiate partially hydrolysed protein formulas from extensively hydrolysed products for SMPPi.

4.5.4 Discussion

To more closely align with the digestibility and composition of human milk and to provide choice in the infant formula options available to caregivers, the Code allows for certain compositional factors to be manipulated. This includes protein type and level of hydrolysis, as well as the ratio and type of fat and carbohydrate. Since the 1980s, the Code has permitted infant formula based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants. This includes protein hydrolysates as a safe protein source in infant formula products. Current research supports the use of protein hydrolysates in infant formula products to provide options for better digestibility (Vandenplas et al. 2019; Meyer et al. 2015).

There is no internationally agreed definition for partial protein hydrolysis in the context of infant formula products and it is not possible to categorise and define formulas according to particle size. Prescribing a degree of hydrolysis would be out of step with international jurisdictions and thus potentially creating a trade barrier. For Code purposes, the differentiation between partially hydrolysed and extensively hydrolysed protein will be made by the food additives needed to produce a functional, stable product for infants, e.g. their use of additional thickeners and stabilisers that would not be permitted for infant formula and follow-on formula. That is, if a product is based on a protein source that is hydrolysed to the degree that higher levels or more intense thickeners or other additives are needed, then these will no longer be suitable for healthy infants. Further it would be categorised as SMPPi.

FSANZ considers partially hydrolysed formulas to be an alternative protein source for digestibility. In contrast, extensively hydrolysed formulas are specially formulated and used by medical practitioners as part of a suite of options for the management of cow's milk protein allergy and other varying conditions. See section 4.6 for further discussion. Partially hydrolysed protein is not intended to be used for any medical purpose and as such, FSANZ does not consider it an ingredient that can have associated claims nor is it considered a SMPPi.

4.5.5 Decision

FSANZ has decided to retain its position at the 2nd CFS. Notwithstanding the lack of clarity in the current definition for protein substitute, infant formula products based on a protein hydrolysate have been used in specialised formulas since the 1980s and permitted in the Code since commencement of the current standard. FSANZ does not consider removing that permission for products that meet all other requirements and restrictions is warranted. The permission to include partially hydrolysed protein in infant formula and follow-on formula is considered to be safe and in line with overseas regulations and safety assessments (Commission Delegated Regulation (EU) 2016/127 (European Commission 2016a), EFSA 2020b).

Infant formula and follow-on formula containing partially hydrolysed proteins must meet the composition requirements including all restrictions on the use of food additives (i.e. the restricted use of thickeners will apply). For further discussion on labelling of hydrolysed protein see section 4.15 of this report. SMPPi may also include partially hydrolysed proteins although they would be able to deviate from the base composition of infant formula and follow-on formula to address a medical disease, disorder or condition of an infant.

4.6 Extensively hydrolysed protein

4.6.1 Current regulations

The current requirements for extensively hydrolysed formulas are outlined in section 4.5.1 of this report.

4.6.2 Previous considerations

At the 1st CFS, for the reasons stated in that report, FSANZ proposed to permit extensively hydrolysed protein as an ingredient in SMPPi, where required to address a medical condition, disease or disorder. The exclusion of extensively hydrolysed protein in infant formula and follow-on formula was to be controlled by the prescribed protein sources and differences in food additive permissions for infant formula, follow-on formula and SMPPi.

FSANZ retained the above approach in the 2nd CFS for the reasons stated in that report. Further information relating to SMPPi is outlined in section 4.2 of this report.

4.6.3 Submitter comments

None of the public health submitters supported the 2nd CFS proposed variations on the issue of extensively hydrolysed protein. Most of the submitters recommended that to be able to classify a product as extensively hydrolysed formula, there should be a definition relating to either specific peptide size (Dalton) or proven hypo-allergenicity in clinical trials.

Submitters noted that there could be an influx of extensively hydrolysed protein formula imported from the US and the EU because there are currently only two extensively hydrolysed formulas on the market in Australia and one of these will soon be discontinued. Submitters noted research that indicates there is wide variability in the extent of hydrolysed proteins between formulas and some may not be appropriate for an infant with cow's milk protein allergy. They considered that without a definition of extensively hydrolysed formula, the potential influx of imports could increase risk. This in turn could increase prescriptions for amino acid formula and increase costs to Medicare in Australia.

Some submitters stated that infant formula that has had two of the three macronutrients extensively modified (extensively hydrolysed protein and lactose free) poses a theoretical and unknown risk to infants and requires investigation to ascertain safety.

4.6.4 Discussion

FSANZ does not expect the variations to result in an influx of inappropriate products available on the Australian and New Zealand market as suggested by submitters. This is because the proposed amendments clearly stipulate requirements for labelling, composition, sale and food additives. In addition, SMPPi are produced in small batches, provide little commercial advantages to manufacturers and pose reputational risk to manufacturers if they are not safe and suitable. FSANZ also clarified that according to the ASCIA Guide for Milk Substitutes in Cow's Milk Allergy[5], there are currently three infant formulas on the Australian market that contain extensively hydrolysed protein (with one of those soon to be discontinued).

In regard to labelling, SMPPi will be required to include a name or description of the product sufficient to indicate its true nature and have a statement indicating the medical purpose of the product which may include a disease, disorder or medical condition for which the product has been formulated (paragraph 2.9.1—50(c) of the primary variation).

If the extent of protein hydrolysis makes the formula inappropriate for the use in the treatment of cow's milk protein allergy, paragraph 2.9.1—50(b) (of the primary variation) states that SMPPi are required to have a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food (see section 4.4.4). In addition, the formula must state a name or description sufficient to indicate the true nature of the food and which medical disease, disorder or condition it is formulated for.

Products formulated for cow's milk protein allergy that do not have an acceptable level of protein hydrolysis would be breaching the requirements of the Food Acts. The Food Acts in each state and territory require all food – which includes infant formula products– to be safe and suitable, irrespective of Code requirements.

The variations will require any extensively hydrolysed formula to be used under medical supervision. Medical practitioners and dietitians are supported by peak professional bodies, such as ASCIA, which provide advice and resources on which formulas are suitable and supported by substantiated evidence.

4.6.5 Decision

For the reasons stated in the discussion above, FSANZ retained its position from the 2nd CFS. FSANZ considers it inappropriate to provide a definition of extensively hydrolysed protein (e.g. dalton size) within the SMPPi category as it is out of step with international jurisdictions and would produce a potential trade barrier for a vulnerable population. Australian and New Zealand infants rely on the availability of these products from overseas manufacturers (see section 4.2 on SMPPi) and it is thus not appropriate for FSANZ to introduce a regulation out of step with these jurisdictions.

There are no prescriptive requirements in the primary or consequential variation relating to extensively hydrolysed protein. Instead, the primary variation states that as per paragraph 2.9.1—42(a) SMPPi can deviate from the composition requirements prescribed by sections 2.9.1—32 to 2.9.1—41 when and to the extent required to achieve the product's intended medical purpose.

[5] https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Guide_CMA_Milk_Substitutes_2023.pdf

4.7 Protein source

FSANZ has reviewed the protein source requirements for infant formula products. As infant formula products are formulated for a particularly vulnerable population and with an increasing variety of products available on the market, FSANZ has considered the safety associated with new proteins potentially being used in infant formula products.

4.7.1 Current regulations

Standard 2.9.1 does not currently prescribe specific protein sources that may be used in infant formula products.

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

4.7.2 Previous considerations

FSANZ has consulted on the protein source for infant formula products within the 2016 (FSANZ 2016a), 2021 (FSANZ 2021f), 2022 (FSANZ 2022a) and 2023 (FSANZ 2023a) consultations. Throughout the consultations mixed stakeholder views were raised regarding the need for a prescriptive protein source list, the protein sources that should be permitted and the requirements for pre-market assessment.

At the 1st CFS, for the reasons stated in that report, FSANZ proposed the protein source be restricted to cow milk protein, goat milk protein, protein hydrolysates of one or more proteins normally used in infant formula and soy protein isolate.

FSANZ retained the above approach in the 2nd CFS for the reasons stated in that report FSANZ also proposed adding sheep milk protein to the above list of permitted protein sources in infant formula products.

4.7.3 Submitter comments

Government and industry submitters responded to the proposed approach at the 2nd CFS.

Most of the government submitters noted their support for prescribing protein sources that have undergone pre-market assessment or that have a history of safe use within the infant population. Some did not support the inclusion of sheep milk as a permitted protein source.

Industry submitters opposed restricting protein sources to an explicit list of permitted sources. One submitter commented that prescribing protein sources is not aligned with the Ministerial Policy Guideline and Codex CXS 72-1981 (Codex 1981) and that removal of plant-based options inhibits the transition to more sustainable diets.

4.7.4 Discussion

Prescribed protein sources

FSANZ maintains the view that prescribing permitted protein sources in infant formula products is warranted for the reasons stated in section 4.4.4 of SD2 to the 2nd CFS (FSANZ 2023c). FSANZ considers that prescribing protein sources will increase regulatory clarity in the Code and mitigate potential health and safety risks by ensuring that the protein used in infant formula products is nutritionally adequate as well as being safe for vulnerable consumers.

Protein sources not included in the prescribed list, as well as any protein fractions that have been synthesised, extracted and/or concentrated above their background levels in existing ingredients in infant formula products will be required to undergo pre-market assessment before being permitted in infant formula products.

Sheep milk protein

The primary variation includes sheep milk protein as a permitted protein source in infant formula.

This decision was based on the equivalent composition of sheep, cow and goat milks; sheep milk's highly comparable composition with human milk; the inclusion of sheep milk within New Zealand infant feeding guidance; and its history of use within the New Zealand population. After consideration of the evidence, including submissions received, FSANZ considers the justification to include sheep milk protein as a permitted protein source as stated in the 2nd CFS stands. See section 4.4.4 of SD2 to the 2nd CFS (FSANZ 2023c).

Rice and pea protein

A submission to the 2nd CFS requested that FSANZ consider providing permission for additional plant-based protein sources in infant formula and follow-on formula, specifically rice and pea protein which are currently available on the Australian and New Zealand market. Rice and pea protein can be used as a protein source within SMPPi, for infants with conditions. Based on the limited evidence available, no demonstrated safe history of use and potential allergen risk, FSANZ does not support these formulas being permitted outside of specialised use.

While FSANZ acknowledges the investment of manufacturers in developing plant-based infant formula products, FSANZ has limited evidence to support the use of pea and rice proteins in infant formula and their role in supporting normal infant growth and development.

As noted above, manufacturers may apply to FSANZ for permission to add plant-based protein sources to infant formula products through the pre-market assessment process by submitting an application to FSANZ.

4.7.5 Decision

For the reasons stated above, FSANZ decided to maintain the approach at the 2nd CFS, as follows:

- to prescribe the protein sources that are permitted for infant formula products, specified to be 'cow milk protein, goat milk protein, sheep milk protein, soy protein isolate and partially hydrolysed protein of one or more of these specified proteins' and

- any protein sources outside of those specified above will be required to undergo a pre-market assessment through FSANZ.

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

4.8 Carbohydrate source

4.8.1 Current regulations

Standard 2.9.1 does not currently prescribe carbohydrate source.

Codex CXS 72-1981 (Codex 1981) permits the addition of glucose as a source of carbohydrate and notes that *'lactose and glucose polymers should be the preferred source of carbohydrate in formula based on cow's milk protein and hydrolysed protein'* with a total carbohydrate limit of 3.3 g/100 kJ. Codex CXS 156-1987 (Codex 1987) prescribes limits on sucrose and fructose and notes these sources should not be added, unless needed as a carbohydrate source and must not exceed 20% of available carbohydrates.

EU 2016/127 (European Commission 2016a) prescribes a positive list of permitted carbohydrate sources which includes lactose, maltose, sucrose, glucose, glucose syrup or dried glucose syrup, malto-dextrins, pre-cooked starch and gelatinised starch.

Table 5: Current regulations for carbohydrate sources

Carbohydrate source	Units	Standard 2.9.1		Codex CXS 72-1981		Codex Draft Standard for FuFOI		EU 2016/127	
		Min	Max	Min	Max	Min	Max	Min	Max
Carbohydrate	g/100 kJ	NS	NS	2.2	3.3	2.2	3.3	2.2	3.3
Lactose	g/100 kJ	NS	NS	NS	NS	NS	NS	1.1	NS
Sucrose	% CHO[1]	NS	NS	NS^	NS^	NS	20*	NS	20
Glucose	% CHO[1]	NS	NS	NS^	NS^	NS	20*	NS	0.5 g/100 kJ
Glucose syrup or dried glucose syrup	g/100 kJ	NS	NS	NS	NS	NS	NS	NS	0.2
Pre-cooked starch and/or gelatinised starch	% CHO[1]	NS	NS	NS	NS	NS	30	NS	30

*Notes: ^should be avoided; *sucrose and fructose combined; [1] total carbohydrate; NS: not stated*

4.8.2 Previous considerations

In 2021 and 2022, FSANZ proposed adopting limits on sucrose and fructose aligned with Codex CXS 72-1981 (Codex 1981). This was based on safety concerns cited by government submitters, the outcome of FSANZ's safety assessment conducted in 2002 (ANZFA 2002) and by international requirements that came into place in 2020 including EU 2016/127 (European Commission 2016a) and Codex CXS 72-1981 (Codex 1981).

At the 2nd CFS, for the reasons stated in that report, the proposed option was to prohibit the addition of sucrose and/or fructose to infant and follow-on formula, unless needed as a carbohydrate source in formula manufactured from protein hydrolysates and provided the sum of the added fructose and/or sucrose does not exceed 20% of available carbohydrates in the formula.

4.8.3 Submitter comments

Government, industry and public health submitters responded to the proposed approach at the 2nd CFS, with mixed views on the permission. Industry submitters supported the intent of the 2nd CFS proposed variations, however requested clarification regarding incidental presence of sucrose and fructose where residual fructose at small levels may be 'added' as part of the inulin-type fructans. Industry submitters also noted that the 2nd CFS proposed variations set a higher standard than the Codex guidance through use of 'must not contain' language compared to 'should not' in Codex.

In addition, some submitters requested the introduction of a specified carbohydrate amount and minimum lactose level of 53.6 g/L for infant formula.

4.8.4 Discussion

Prescribed list of carbohydrate sources

After having regard to all evidence, including submissions, FSANZ's view remains that the Code should not set a list of permitted carbohydrate sources, however should prescribe restrictions on carbohydrate sources that are not naturally occurring in breast milk. FSANZ did not receive any additional evidence to the 2nd CFS that substantiated prescribing an extensive list of permitted carbohydrates, similar to the EU 2016/127.

Minimum and maximum carbohydrate levels

As explained in section 4.1.3 in SD2 to the 2nd CFS (FSANZ 2023c), the amount of carbohydrate within infant formula products, regulated by Standard 2.9.1, is self-limiting and dependant on the energy, protein and fat content of the product. Total carbohydrate content is calculated by difference based on the prescribed range of fat and protein and the energy density. Indeed the minimum amount of carbohydrate set in EU 2016/127 (European Commission 2016a) is based on such a calculation (EFSA 2014). Setting a minimum and maximum range for carbohydrate is inconsistent with the principle of minimal effective regulation.

Restriction on fructose and sucrose

Sucrose and fructose are not naturally occurring in breast milk, and therefore should not be added to infant formula and follow-on formula. When added in excess there are associated safety concerns (ANZFA 2002a). This requirement is present within the EU 2016/127 (European Commission 2016a), Codex CXS 72-1981 (Codex 1981) and Codex CXS 156-1987 (Codex 1987).

The EU 2016/127 allows the addition of added fructose and/or added sucrose to formulas based on partially hydrolysed protein. This is allowed in international regulations and standards in order to mask the bitter taste of these formulas (EFSA 2014).

The addition of sucrose and fructose is typically subject to additional requirements that control the amount added and the purpose of addition. For example, the addition must be as a source of carbohydrate and the sum of fructose and/or sucrose in the formula should not exceed 20% of available carbohydrates. This allows fructose and/or sucrose to be added to partially hydrolysed protein formulas where required, in amounts that do not pose risk to the health and safety of infants.

Following submissions to the 2nd CFS, FSANZ has also considered an exemption for sucrose and fructose present as a result of the addition of inulin-type fructans or the use of a

substance as a processing aid. FSANZ acknowledges that clarity is needed regarding the residual presence of sucrose and fructose resulting from the use of other permitted substances. FSANZ did not intend for the restriction to extend to substances that already have express permissions in the Code for infant formula products.

FSANZ also acknowledges that the text of the relevant provisions in the primary variation is more restrictive than the text used in Codex (ie, 'must not' as opposed to 'should not'). This is due to the difference in function of each document. As Codex is a guidance document rather than a legislative instrument, the language used can be less prescriptive. In contrast, the purpose of the Code is to set mandatory requirements in relation to food for the purposes of the Food Acts. A provision that uses the phrase 'should not' does not set a mandatory requirement.

4.8.5 Decision

Having regard to the evidence, and for the reasons stated in this report, FSANZ has decided to:

- Not specify a minimum or maximum amount of carbohydrate within infant formula and follow-on formula.
- Prohibit the presence in infant formula and follow-on formula of added fructose and/or added sucrose subject to two exceptions,
- Permit formula manufactured from partially hydrolysed protein to contain added fructose and/or added sucrose, provided that it is added to provide a source of carbohydrate and the sum does not exceed 20% of available carbohydrates in the formula.
- Permit the presence in infant formula and follow-on formula of added fructose and/or added sucrose that is present as a result of inulin-type fructans and/or processing aids present in accordance with the Code.

The above amendments are made in subsection 2.9.1—5 (3) and 2.9.1—5 (4.) of the primary variation.

See also the explanation in in SD1 – Regulatory Intent.

4.9 Vitamin D in follow-on formula

4.9.1 Current regulations

Schedule 29 prescribes the range of vitamin D to be 0.25–0.63 µg/100 kJ for both infant formula and follow-on formula.

4.9.2 Previous considerations

At the 1st CFS, for the reason stated in that report, FSANZ proposed to retain the current range for vitamin D as it closely aligns with Codex CXS 72-1981 (Codex 1981), it is the most appropriate range for the Australian and New Zealand population and was supported by all submissions to FSANZ 2021 CP2 (FSANZ 2021f).

FSANZ retained the above approach in the 2nd CFS for the reasons stated in that report. FSANZ noted that this range is wide enough to be achievable in product formulation and manufacturing.

4.9.3 Submitter comments

The submitters that responded to the 2nd CFS proposed variations (government and industry) did not support it as it did not align with the Codex Draft Standard FuFOI (now Codex CXS 156-1987) and EU Annex II. Submitters recommended that the maximum should be aligned with the Codex and EU maximum for follow-on formula of 0.72 µg/100 kJ. The rationale for their position is summarised in section 4 of Appendix 3.

4.9.4 Discussion

In SD2 to the 2nd CFS (FSANZ 2023c), FSANZ reiterated early considerations to retain the vitamin D range of 0.25–0.63 µg/100 kJ on the basis that no safety concerns had been identified with using this range, it aligns closely with international regulations and standards and is wide enough to be achievable in product formulation and manufacturing. While the evidence for vitamin D ULs has not changed since our previous consideration, FSANZ acknowledges that compliance with both EU regulations and the Code requires a narrower vitamin D range (0.48–0.63 µg/100 kJ), thus making meeting technological requirements difficult.

FSANZ notes the discussion in SD2 to the 1st CFS regarding the European Food Safety Authority (EFSA) revising the UL for older infants from 25 µg/day to 35 µg/day in 2018 (FSANZ 2022d). EFSA notes that older infants consuming both follow-up formula containing the maximum amount of vitamin D of 3 µg/100 kcal (0.72 µg/100 kJ) and fortified foods would not exceed the UL. FSANZ also notes that the addition of vitamin D is not permitted in infant foods in Australia and New Zealand and there are limited fortification permissions for foods for the general population, thus further reducing the likelihood of exceeding safe levels.

In addition, FSANZ acknowledges that the National Health and Medical Research Council (NHMRC) nutrient reference values (NRVs) for vitamin D require review. While the NHMRC is undertaking a rolling review of nutrients, a review of vitamin D is not currently scheduled.

4.9.5 Decision

After consideration of the evidence (including submissions received), and for the reasons stated above, FSANZ decided to increase the vitamin D maximum from 0.63 µg/100 kJ to 0.72 µg/100 kJ in follow-on formula.

4.10 Novel foods and nutritive substances

4.10.1 Current regulations

Subsections 1.1.1—10(5) and 1.1.1—10(6) require that unless expressly permitted in the Code, novel foods and nutritive substances must not be added to food for sale. Standard 1.1.1 in effect requires these foods to undergo pre-market assessment in order to be permitted to be added to food, including infant formula products. Novel foods permitted to be added to infant formula products are listed in section S25—2. Nutritive substances permitted to be added to infant formula products are listed in section S29—5.

4.10.2 Previous considerations

In 2016, FSANZ proposed that a review of the novel food and nutritive substance provisions should be included in P1028 to address issues around definitions, category overlap between novel foods and nutritive substances and nutritive substances that are naturally present in ingredients.

The approach proposed in the 1st CFS was to consider any new requirements for novel foods and nutritive substances in infant formula products as part of the broader review of these substances for all food categories under Proposal P1024 – Revision of the Regulation of Nutritive Substances and Novel Foods (FSANZ 2017b). FSANZ also proposed no change to the regulatory status quo, which was a general prohibition on the addition of novel foods or nutritive substances to infant formula products unless these were expressly permitted through an application or proposal.

At the 2nd CFS, in line with the views put forward by FSANZ in the 1st CFS, the 2nd CFS proposed variations did not include any further changes to pre-market assessment requirements for novel foods and nutritive substances in infant formula products. However, in recognition of submitter views presented at the 1st CFS, and for the reasons stated in that report, FSANZ proposed several changes in the 2nd CFS to improve regulatory clarity for the regulation of novel food and nutritive substances in infant formula products.

4.10.3 Submitter comments

The changes proposed in the 2nd CFS are described in section 5 of Appendix 3 of this report.

Government and industry submitters responded to the proposed approaches in the 2nd CFS for novel foods and nutritive substances in infant formula products. One government submitter opposed FSANZ's approach to not include any overall changes to pre-market assessment requirements for novel foods and nutritive substances in infant formula and recommended an amendment instead.

Government and industry submitters also responded to the proposed approaches in the 2nd CFS for novel foods and technologies in SMPPi. The majority of these submitters supported the proposed approach, that is for paragraph 1.1.1—10(6)(f) relating to novel foods to not apply to SMPPi. Several others disagreed or suggested amendments, for the reasons summarised in section 5 of Appendix 3. A government submitter supported the intent of the provision, however opposed the 2nd CFS proposed variations, citing concerns that the proposed drafting would allow ingredients and components produced by cell culture or precision fermentation to be added to SMPPi without pre-market assessment.

A range of general comments were also received on FSANZ's proposed approach to consider the broader role of nutritive substances and novel foods as part of Proposal P1024 – Revision of the Regulation of Nutritive Substances and Novel Foods (FSANZ 2017b). Some of these submitters supported FSANZ's proposed approach, while others raised concerns citing reasons outlined in section 5 of Appendix 3.

4.10.4 Discussion

This section summarises FSANZ's response to the above submissions. A detailed response is set out in section 5 of Appendix 3

Deferral of Proposal P1024

FSANZ notes that the deferral of Proposal P1024 is out of scope for P1028.

FSANZ considers the amendments to subsection 1.5.1—3(2) will provide appropriate regulation of these ingredients in infant formula products.

FSANZ notes the current provisions of the Code, in effect prohibit new substances from being added to infant formula products unless expressly permitted (e.g. requiring premarket assessment).

Pre-market assessment requirements and nutritive substances

The Code imposes pre-market assessment requirements for infant formula products. Subsections 1.1.1—10(5) and 1.1.1—10(6) of the Code, for example, require that a food for sale – including an infant formal product - must not consist of, or have as an ingredient or a component, a novel food, a food used as a nutritive substance[6], food produced using gene technology, food additive or processing aid, unless expressly permitted by the Code (note, this list is not all of the ingredients listed in the subsections, but are the substances most likely to be relevant to infant formula). Ingredients or components in the categories listed in these provisions require an application to change the Code.

After consideration of submissions, FSANZ's view remains that, for the reasons stated in the 2nd CFS, Standard 1.1.1 of the Code provides appropriate safeguards for the vulnerable infant population and for enforcement purposes. We consider any additional clauses in Standard 2.9.1 to set out the pre-market assessment requirements to be unnecessary duplication. FSANZ also notes the number of recent applications for nutritive substances added to infant formula products as evidence that the current pre-market assessment requirements work.

Several submitters commented on the role of the Advisory Committee Novel Foods (ACNF) in considering new substances for infant formula products. The ACNF members include representatives from the jurisdictions and FSANZ. The ACNF's purpose is to provide advice to FSANZ on whether a particular food is a novel food for Code purposes and therefore requires premarket assessment. ACNF views or opinions are not those of FSANZ. Nor are ACNF opinions legally binding or a formal safety assessment. Additionally FSANZ notes that the ACNF was established prior to the 2011 Policy Guideline on Infant Formula Products. The Policy Guideline established the intent for all new substances and ingredients in infant formula to undergo a pre-market safety assessment[7] and that substances subject to pre-market assessment should have a substantiated beneficial role or a technical role.

[6] A definition for 'used as a nutritive substance' is given in section 1.1.2—12. Permissions for the use of nutritive substances other than vitamins and minerals in infant formula products are listed in section S29—5.
[7] Under specific policy principle i), relative to principles (d) and (e) and specific policy principle j).

4.10.5 Decision

Novel foods in SMPPi

For the reasons stated in this report, FSANZ decided to retain the approach proposed in the 2nd CFS subject to certain amendments.

The consequential variation provides that a novel food may be present in a SMPPi for retail sale only when and to the extent to achieve the product's intended medical purpose. Further explanation of FSANZ's decision on permissions for novel foods in SMPPi is in section 4.2.

The consequential variation differs from the 2nd CFS proposed variations. FSANZ amended the latter as set out below.

Proposed new subsection 1.5.1—2 (2) was amended to provide that the use of a novel food in an SMPPi does not 'constitute history of safe consumption'. This is the same approach taken by the Code for FSMP.

Proposed new subsection 1.5.1—3 was amended to make clear that an infant formula product for retail sale may consist of, or have as an ingredient or a component, a novel food only if that presence is expressly permitted by section S25—2.

Further detail and rationale for both these amendments can be found in SD1.

Amendments to Schedule 25

The consequential variation's amendments to Schedule 25 differ from the amendments to that Schedule proposed by the 2nd CFS. These differences are explained below.

The consequential variation amends the novel food permissions listed in the table to section S25—2 for the following substances: Dried marine micro-algae (Schizochytrium sp.) rich in DHA; Oil derived from marine micro-algae (Schizochytrium sp.) rich in DHA; and Oil derived from marine micro-algae (Ulkenia sp.) rich in DHA. The amendment now adds a condition to each permission stating that the substance 'may be added to infant formula products in accordance with Standard 2.9.1'. This will provide the express permission now required by proposed new subsection 1.5.1—3(2) (see above). As explained above, that subsection now requires the presence of each of these substances – as a novel food – to be expressly permitted by the table to section S25—2. New subsection 1.5.1—3(1) will permit these substances to continue to be added to other foods and products.

The consequential variation will also amend the novel food permission listed in the table to section S25—2 for Oil derived from marine micro-algae Schizochytrium sp. (American Type Culture Collection (ATCC) PTA-9695). The amended permission will provide that that substance – as a novel food - is 'only permitted for use in infant formula products in accordance with Standard 2.9.1. The effect will be that proposed new section 1.5.1—3 will restrict the use of that novel food only to infant formula products. This is consistent with Application A1124 (FSANZ 2017) which added this permission to Schedule 25.

The above amendments will not change the permitted uses for each of the substances.

Each permission or use has already been assessed and approved by FSANZ in accordance with the relevant legislation. As such, FSANZ did not reassess the latter in P1028.

4.11 Lactic Acid Producing Microorganisms

4.11.1 Current regulations

Section 2.9.1—6 provides the following permission for lactic acid producing microorganisms (LAM):

> *L(+) lactic acid producing microorganisms may be added to infant formula product.*

4.11.2 Previous considerations

In the 1st CFS, FSANZ proposed to retain the existing permission for the addition of LAM in infant formula products in Standard 2.9.1 but to clarify that LAM may only be added for acidification purposes. This was based on the conclusion that clarifying the current permission to indicate the purpose of use (for acidification) would align with the original intent of the permission and would provide regulatory certainty around the addition of microorganisms to infant formula products. At the same time, FSANZ proposed to clarify the permission to indicate that only non-pathogenic or non-toxigenic microorganisms could be used.

Based on submitter comments to the 1st CFS, FSANZ understood that the proposed option to restrict the existing permission 'for acidification' would significantly disrupt the availability of domestically and internationally manufactured infant formula products. Large reformulation costs, decreased product availability (possibly permanent), or a large influx of applications to FSANZ seeking permissions would all be factors that would be potentially detrimental to Australian and New Zealand infants requiring infant formula products.

FSANZ considered that alignment with the Codex standards for infant formula and follow-on formula[8] was also justified within the objectives of this proposal (see discussion in section 5.3.2 of the 2nd CFS; FSANZ 2023a) and further justified retaining the existing permission. Therefore, at the 2nd CFS, FSANZ reconsidered its approach and the proposed variations retained the current permission which permits LAM to be added to infant formula products as a substance with no regulatory definition. This did not include the addition of specific strains as probiotics, which FSANZ considered would be new permissions for addition of novel foods or nutritive substances to the Code. The retention of the current permission included restrictions on labelling such that, as there is no specific permission to add LAM as a nutritive substance or novel food, inclusion of LAM in the nutrition information statement (NIS) would be prohibited. Further restrictions that apply are outlined below.

Labelling of LAM in infant formula products

In the 1st CFS, FSANZ proposed that generic ingredient labelling requirements would continue to apply to infant formula products (see section 2 in SD3 to the 1st CFS; FSANZ 2022e). LAM added as an ingredient would be listed in the statement of ingredients. As per section 1.2.4—4, ingredients are to be declared using their common name, a name that describes the true nature of the ingredient, or a generic name (if any) specified in Schedule 10. This approach was maintained in the 2nd CFS.

At the 2nd CFS, FSANZ specified how the content and format of the NIS would be mandated for infant formula and follow-on formula. The 2nd CFS proposed variations included the requirement for substances 'used as a nutritive substance' (as defined in section 1.1.2—12 of the Code) to be declared under the subheading 'Additional' when voluntarily added (subsection 2.9.1—26(3) of the 2nd CFS proposed variations). Further, these proposed

[8] Codex – Clause 3.2.4 of CXS72-1981 states that "Only L(+) lactic acid producing cultures may be used"; for infant formula and formulas for special medical purposes intended for infants.

variations prohibited any other information in the NIS that was not expressly provided for in the Code (subsection 2.9.1—25(4) of the 2nd CFS proposed variations).

As noted above, while the Code permits the addition of LAM to infant formula products, they have not been explicitly approved for use as a nutritive substance or as a novel food. Other than inulin-type fructans, galacto-oligosaccharides or a combination of these, the 2nd CFS proposed variations specified only those permitted substances used as a nutritive substance must be declared in the NIS if they are used voluntarily in infant formula and follow-on formula. Additionally, as novel foods are added as ingredients rather than added for a nutritive purpose, they would not be permitted to be declared in the NIS.

FSANZ also indicated the existing prohibition for nutrition content and health claims would apply to LAM (section 5.3.4 in the 2nd CFS; FSANZ 2023a). This meant a reference to LAM outside the statement of ingredients and a reference to 'probiotics' anywhere on the label, would be prohibited.

Other restrictions that apply to LAM in infant formula products

At the 2nd CFS, FSANZ noted the following other restrictions that currently apply to the use of LAM in infant formula products that were retained in the proposed variation:

- The current Standard 2.9.1 provides that only microorganisms producing the L(+) form of lactic acid are permitted.
- Paragraphs 1.1.1—10(5)(c) and (6)(g) of Standard 1.1.1 require that, unless expressly permitted, a food for sale must not be a *food produced using gene technology*, or have as an ingredient or component of a *food produced using gene technology*. This requirement is applicable to all infant formula products and any food, ingredient or component produced using gene technology must be assessed for safety through FSANZ pre-market assessment before it can be sold in Australia and New Zealand.

There was no change proposed for these Code requirements as applied to infant formula products.

4.11.3 Submitter comments

Both government and industry submitters responded to FSANZ's proposed retention of the LAM permission with some government and most industry submitters supporting FSANZ's approach. Support cited that it aligned with international regulations and standards, was a risk-based approach and provided sufficient regulatory clarity. Some government submitters either opposed retaining the permission or supported clarification in the Code that LAM be added as an ingredient for acidification purposes and not declared in the NIS, as well as a lack of alignment with the policy guidance. It was also suggested that a rapid review process for the consideration of specific strains be used for individual permissions of LAM rather than maintaining one open permission. Further discussion is summarised in section 5 of Appendix 3 of this report.

4.11.4 Discussion

After consideration of submissions, FSANZ decided to maintain the position proposed by the 2nd CFS . It did so for the following reasons:

- FSANZ has found no safety concerns with retaining the current permission. FSANZ considers it important to note submitter concerns regarding case reports of infections associated with dietary supplementation of LAM in infants with underlying clinical complications. FSANZ considers that the infants identified in the 2021 risk assessment

(SD2 of CP1; FSANZ 2021c) would not be consuming infant formula formulated for the general population, but instead would be consuming SMPPi. SMPPi are used in clinical settings, under medical supervision and with ingredients that have an evidenced, medical need. In addition, the requirement of pre-market assessment for the use of specific strains as novel foods or nutritive substances provides further safety assurance in conjunction with this permission.

- Recognition of the long history of safe use consistent with the Ministerial Policy Guideline and ubiquity in products currently on market.
- Alignment with Codex.
- Removal of, or amendment to, the permission (i.e., clarification of LAM's use for acidification purposes only) would cause a large reformulation cost to industry (for minimal benefit), loss of products from the market (possibly permanently) and potentially a large influx of applications to FSANZ seeking permission to add LAM to infant formula products. FSANZ considers the cost of reformulation outweighs any benefit that might arise from removal of the permission.
- Labelling requirements are based on permissions for use. LAM is currently added as an ingredient and must be listed in the statement of ingredients in accordance with section 1.2.4—4. Paragraph 2.9.1—28(1)(j) of the primary variation prevents LAM from being mentioned elsewhere on the package (see section 4.19).
- Permitted novel food ingredients must be declared in the statement of ingredients and cannot appear elsewhere on the label of infant formula or follow-on formula. While FSANZ notes the definition of novel food refers to microorganisms, including probiotics, as a category of novel foods (section 1.1.2—8), this does not confer a permission for a specific novel food to be used as a nutritive substance.

4.11.5 Decision

FSANZ has retained the current permission to permit LAM in infant formula products which includes restrictions on labelling and claims such that any indication of this purpose is not permitted unless approved for that purpose (i.e. used as a nutritive substance).

This permission does not permit the addition to infant formula products of specific strains as probiotics. The latter would constitute addition of a substance used for a nutritive purpose for which an express permission would be required.

4.12 Food technology

The food technology aspects related to infant formula products for this proposal extend to permissions for use of food additives, maximum levels of contaminants and processing aids.

For the reasons set out in the 2nd CFS, FSANZ proposed variations to set permissions for the use of food additives and processing aids in infant formula products – including SMPPi - and proposed maximum levels of contaminants in such products.

After consideration of submissions and for the reasons stated in the 2nd CF and this report, FSANZ decided to approve the proposed measures subject to certain amendments.

FSANZ amended the permissions for food additives and contaminant maximum levels for infant formula products.

No issues were raised relating to the use of processing aids in the production of infant formula products. Three submitters noted support for retaining the current permissions in the Code. For further details on processing aids please see section 6 of Appendix 3.

4.13 Food additive permissions

FSANZ developed a risk management framework to guide consideration of the risk management approach for food additives. The primary objective is protection of infant health and safety. Additionally FSANZ considered harmonisation with international regulations and standards. This is consistent with the need to have regard to the promotion of consistency between domestic and international food standards, where appropriate (FSANZ Act 1991 section 18(2)(b)).

FSANZ has updated the food additive permissions for infant formula products to align as best as possible with relevant international regulations and standards, especially Codex standards and EU Regulations. As a part of the harmonisation process, FSANZ has considered the available evidence on safety and technological function of the food additives.

FSANZ has aimed to align food additive permissions with relevant Codex Standards on the basis of MPG 'Regulation of Infant Formula Products' under Additional Policy Guidance states that:

> *The regulation of infant formula products in Australia and New Zealand should be consistent to the greatest extent possible with:*
>
> • *Relevant World Health Organization agreements; and*
> • *Relevant World Trade Organization agreements, Codex standards and guidelines.*

SMPPi are generally not produced in Australia and New Zealand, but are mainly imported from Europe in small quantities, as specialised products. Consistency with European regulations, where appropriate, is therefore critical to ensure a continued supply of essential products for vulnerable infants. Such infants have specific physical or physiological conditions, diseases or disorders and such products are often the infant's sole source of nutrition.

Food additives used in nutritive preparations added to infant formula products

The issue of permitting some food additives in nutritive preparations that are then added to infant formula products was raised in submissions during consultation.

The 2nd CFS proposed variations to remove the 'carry-over principle' permission for infant formula products. The reasons for removal are stated in the 2nd CFS (see section 3.2 of SD1 for the 2nd CFS (FSANZ 2023b)). Removing carry-over permissions for food additives is consistent with Codex and the EU regulations. As well it is consistent with the principle that food additive use should be minimised in products for infants who are a vulnerable population. After careful consideration of submissions received, FSANZ maintained its position on this issue. The consequential variations do not permit food additive 'carry-over' for infant formula products.

Submitters noted that, to ensure consistency with Codex and EU regulations for food additives, express permissions were required in the Code for the use of food additives in nutritive preparations added to infant formula products.

Codex CXG 10-1979 (Codex 1979), Part D permits the five food additives listed in that standard to be used as nutrient carriers in preparations added to infant formula products. FSANZ has noted in earlier reports for this proposal that unlike in Codex, substances that are carriers are not food additives for the purposes of the Code but are processing aids.

The five food additives in Codex CXG 10-1979 (Codex 1979) are listed in section S16—2 of the Code and are permitted for use as food additives at levels consistent with good manufacturing practice (GMP) . Food additives permitted at GMP are also permitted as generally permitted processing aids by subsection 1.3.3—4(2) of the Code. Therefore all five substances are generally permitted by the Code for use as processing aids (including as carriers).

Information relevant for permissions of substances in the Code are:

- the technological function and purpose of adding the substance to infant formula products
- whether the substance is added as a nutrient carrier and if that is the case it is functioning as a processing aid
- whether its technological purpose is that of a food additive (as listed in Schedule 14), examples of technological purposes are: antioxidant, anti-caking agent, emulsifier and stabiliser.

After consideration of submissions, FSANZ decided to amend the consequential variations to provide express permissions for six substances to be used as food additives in nutritive preparations added to infant formula products. Reasons for that decision included providing regulatory clarity, international alignment and the principle that substances that have a technological function as a food additive should be expressly permitted in the Code. A summary of these amendments and permissions is provided in Table 6.

Table 6: Substances used in nutritive preparations added to infant formula products

Substance (INS #)	CXG 10-1979 (MPL, mg/kg)	EU regulations (mg/L)	FA/PA	Code amendment (MPL, mg/L)
Sodium ascorbate (301)	75, coating nutritive preparations containing PUFA	75, coating nutritive preparations containing PUFA	FA	75, coating nutritive preparations containing PUFA
Calcium citrates (333)	No permission	0.1, as calcium	FA	0.1, as calcium, may only be added as part of a nutrient preparation
Gum arabic (acacia) (414)	10	10 (carry-over in final product)	FA	10, may only be added as part of a nutrient preparation
Mannitol (421)	10	3, carrier for vitamin B_{12}	PA	Not added since carrier (PA)
Silicon dioxide (551)	10	10,000 mg/kg in nutrient preparations	FA	Already added, 10 mg/L, may only be added as part of a nutrient preparation
Starch sodium octenyl succinate (1450)	100	100 (vitamin preparations) 1,000 (PUFA preparations)	FA	100, may only be added as part of a nutrient preparation 1,000, may only be added to PUFA preparations

INS: International Numbering System; MPL: maximum permitted level; FA: food additive; PA: processing aid; PUFA: polyunsaturated fatty acid

4.13.1 dl-alpha-tocopherol (INS 307c)

Current regulations

The Code does not expressly permit the addition of - tocopherol, d-alpha (307a) and tocopherol, dl-alpha (307c) - to food, including infant formula products. The Code does permit the use of 307b tocopherols concentrate, mixed as a food additive in infant formula products subject to an MPL of 10 mg/L.

Codex CXS 156-1987 permits tocopherols concentrate, mixed (307b) in follow-on formula with a higher MPL of 30 mg/L than the Code. CXS 156-1987 also permits the use of the other tocopherols 307a and 307c, along with 307b – either singly or in combination, for use in follow-on formula, with this same MPL.

Previous considerations

At the 2nd CFS, FSANZ proposed not to add permission for an alternative tocopherol, dl-alpha- tocopherol (INS 307c). A reason was that it is not currently permitted in the Code for any food classes.

Submitter comments

Industry submitters requested FSANZ reconsider its proposed approach of not permitting the use of dl-alpha-tocopherol (307c) in infant formula products.

Submitters noted that since dl-alpha-tocopherol is captured by EU regulations for infant formula products (as E307) at 10 mg/L, alignment should be sought.

Other submissions noted that there is general permission for tocopherol (INS 307) in food classes 0 (preparations of food additives) and 2 (Edible oils and oil emulsions) in the Code. FSANZ notes that this is not a permission for use in infant formula products, but is in response to FSANZ's statement in the 2nd CFS that 307c is not permitted in any food class in the Code. It was noted that INS 307 captures 307c, specifically due to the European specifications of food additives Commission Regulation (EU) No 231/2012 (European Commission 2012). This contains a specification for E307 as alpha-tocopherol with a synonym of dl-alpha-tocopherol. The European specifications are a primary source of specifications in Schedule 3. FSANZ accepted the argument proposed by submitters that there is permission for 307c captured by the general term 307 in some food classes in the Code. Therefore it changed its earlier decision and reconsidered the specific tocopherol 307c for use in infant formula products. This required FSANZ undertaking a safety assessment.

Discussion

FSANZ conducted a specific safety assessment which is provided as Appendix 2. The assessment concluded that the dl-alpha-tocopherol is safe and suitable as an alternative form of tocopherol as a food additive to be added to infant formula products.

Decision

For the reasons stated in this report, FSANZ decided to permit the use of dl-alpha-tocopherol (INS 307c) in infant formula products with the MPL of 10 mg/L within Schedule 15. The consequential variation was amended accordingly. The permission is the same as for tocopherols concentrated, mixed (307b). INS 307c has also been permitted for follow-

on formula subject to a MPL of 30 mg/L, which is consistent with the permission for 307b and Codex CXS 156-1987.

4.13.2 Calcium citrates (INS 333)

Current regulations

Calcium citrates are not currently permitted in the Code for infant formula products. However, they are permitted in the EU Regulations in food class 13.1.5.1 (equivalent to SMPPi) at quantum satis (meaning 'no maximum level is specified' and is equivalent to GMP).

Previous considerations

At the 2nd CFS, for the reason stated in that report, FSANZ's proposed approach was to add calcium citrates at GMP in SMPPi to align with EU Regulations.

Submitter comments

Industry submissions noted that the proposed permission for use of calcium citrate as a food additive in nutrient preparations for SMPPi (food class 13.1.1) should also refer to the plural form. Submissions noted that the European specification for food additives, EU Regulation 231/2012 (European Commission 2012), has specifications for all three forms of calcium citrate therefore it is appropriate to refer to the plural form of calcium citrates in the permissions.

Discussion

This EU regulation is a primary source of specifications in Schedule 3.The food additive is technologically justified for use in nutrient preparations, with the functional class of acidity regulator or stabiliser. FSANZ accepts that to be consistent with EU regulations it should include the permission listed above in the consequential variation.

Decision

Calcium citrates has been permitted in all infant formula products (food class 13.1) with a MPL of 0.1 mg/L as calcium. This permission is accompanied by a condition statement that notes the permission is only for use in a nutrient preparation. The consequential variation also amends the food additive name to reflect the use as plural form 'calcium citrates' not singular 'calcium citrate' in SMPPi (food class 13.1.1).

4.13.3 Xanthan gum (INS 415)

Current regulations

Xanthan gum is not currently permitted in the Code for infant formula products, consistent with both Codex and EU Regulations. However, it is permitted in the Codex and EU Regulations for products equivalent to SMPPi, but with MPL and condition statements.

Previous considerations

At the 2nd CFS, FSANZ proposed to include two different permissions for this food additive in SMPPi (food class 13.1.1) in order to achieve alignment with Codex CXS 72-1981 (Codex 1981) and EU regulations (Regulation (EC) No 1333/2008, food class 13.1.5.1).

Submitter comments

Industry submitters suggested that it would be simpler to only have one permission with one MPL and one condition statement. This view was also supported by one government submitter as it makes it simpler both for enforcement agencies and for industry.

Some submitters also noted that since the 2nd CFS, EFSA's re-evaluation of the food additive had been released (EFSA 2023b).

Discussion

The EFSA opinion concluded that xanthan gum is safe for infants below 16 weeks at a concentration of up to 1200 mg/L. FSANZ has assessed the recent EFSA opinion and supports its conclusions.

Decision

FSANZ decided to permit xanthan gum for use as a food additive in SMPPi subject to a MPL of 1200 mg/L. FSANZ set one such permission with one MPL and one condition statement. This permission is subject to a condition that use is permitted 'only in a product that is based on hydrolysed protein, amino acids or peptides. This is consistent with Codex Standards and EU regulations.

4.13.4 Diacyltartaric and fatty acid esters of glycerol (INS 472e)

Current regulations

The Code currently permits the use of diacyltartaric and fatty acid esters of glycerol (INS 472e) in IFPSDU based on a protein substitute with a MPL of 400 mg/L.

Neither Codex or EU regulations permit the use of diacyltartaric and fatty acid esters of glycerol (INS 472e) in infant formula products.

Previous considerations

FSANZ has previously requested usage data and justification for retaining the permission. As no evidence had been provided, FSANZ proposed at the 2nd CFS to remove the above permission from the Code.

Submitter comments

Industry submitters to the 2nd CFS requested that INS 472e be permitted for use as a food additive in SMPPi, subject to an MPL of 2500 mg/L. This request was not accompanied by substantiated evidence demonstrating safety and technological justification for the proposed use at the higher MPL compared to the current permission and MPL of 400 mg/L. Information was provided in the submission that the food additive is technologically justified for use as an emulsifier for use with amino acid-based infant formula product in general but not for why a higher MPL was required.

Discussion

FSANZ has requested usage data and justification for retaining the permission on multiple occasions, however no information on actual use or an acceptable technological justification and safety information had been provided.

FSANZ responded to an industry submission request to maintain the permission in section 3.3.10 of SD1 of the 2nd CFS (FSANZ 2023b). FSANZ 's response was that the reference to permission of the food additive in the US Code of Federal Regulations (CFR), Chapter 21 section 184.1101, does not mention infant formula products but only the food category 'fats and oils' so it is not relevant to this proposal. Industry separately noted that the permission had been in the Code for use in infant formula products for many years. However, since no new relevant information was received to the earlier submission to the 1st CFS (discussed in 2nd CFS) FSANZ did not support maintaining the current permission.

The industry submission to the 2nd CFS did provide more technological justification and information on earlier Joint WHO/FAO Expert Committee on Food Additives (JECFA) and EFSA safety assessments of the food additive to support its request to not remove the current permission but to actually increase the MPL for use in SMPPi. The JECFA and EFSA assessments indicate a high ADI so supporting the claim that it is safe for the proposed use. That is not the issue that FSANZ is primarily concerned with which is that no new supportive information was provided justifying why an increase in the MPL was required and justified as being both safe and justified. In addition, no actual use levels were provided.

FSANZ therefore decided not to agree with the request to increase the MPL as requested but not justified. However, because the industry submitter had noted that the food additive is used as an emulsifier in certain SMPPi FSANZ concluded that it was still appropriate to maintain the current permission. It separately notes there is information provided in the submission that it is safe and justified for the current permission.

Decision

For the reasons stated above, FSANZ decided to retain the current permission in the Code for SMPPi (food class 13.1.1) at the MPL of 400 mg/L.

4.13.5 Sucrose esters of fatty acids (INS 473)

Current regulations

Sucrose esters of fatty acids are not currently permitted in the Code for infant formula products, consistent with Codex standards. It is permitted in EU Regulations for infant formula products and SMPPi (food classes13.1.1 and 13.1.5.1). Both permissions have a MPL of 120 mg/L and the same condition statement of 'only for products containing hydrolysed proteins, peptides and amino acids.

Previous considerations

At the 2nd CFS, for the reasons stated in that report, FSANZ proposed an MPL of 120 mg/L in SMPPi, with a condition statement noting 'only in products that contain hydrolysed proteins, peptides and amino acids. This approach intended to align with the EU regulations. Due to the EU's condition statement, FSANZ has concluded the permission was only appropriate for SMPPi and not general infant formula products.

Submitter comments

Government submitters noted that EFSA's re-evaluation (EFSA 2023a) identified that sucrose esters of fatty acids are not being used in infant formula products including SMPPi in Europe and suggested the permission should be removed.

Discussion

EFSA's re-evaluation of sucrose esters of fatty acids in foods for infants below 16 weeks of age identified that manufacturers were not using sucrose esters of fatty acids in food belonging to food categories 13.1.1 and 13.1.5.1. These food categories are equivalent to infant formula products and specialised formulas in the Code (equivalent to food class 13.1 and 13.1.1 respectively in the amended Code).

FSANZ's intention at the 2nd CFS to promote international alignment, where appropriate. However, noting the findings of the EFSA re-evaluation, this is no longer the case.

Decision

For the reasons stated above, FSANZ decided not to permit the use of sucrose esters of fatty acids as food additives in SMPPi.

4.13.6 Phosphoric acid (INS 338), sodium phosphates (INS 339), potassium phosphates (INS 340) and calcium phosphates (INS 341)

Current regulations

Phosphoric acid, sodium phosphates, potassium phosphates and calcium phosphates are not permitted in the Code for use in infant formula products. However, sodium, potassium and calcium phosphates are permitted for use at GMP in many other food classes.

Codex CXS 72-1981 permits the use of sodium phosphates and potassium phosphates in infant formula products, including specialised formulas.

EU regulations permit phosphoric acid, sodium phosphates and potassium phosphates for use in infant formula products (food class 13.1.1) at a MPL of 1000 mg/L as P_2O_5 (equivalent to 450 mg/L as phosphorus). The EU regulations also permit phosphoric acid and sodium, potassium and calcium phosphates for use in SMPPi equivalent (food class 13.1.5.1) at a MPL of 1000 mg/L as P_2O5 (equivalent to 450 mg/L as phosphorus).

For Codex and the EU Regulations the permission for infant formula products (food class 13.1) is linked to limits for sodium, potassium and phosphorus.

Previous considerations

For the reasons stated in the 2nd CFS FSANZ had proposed a variety of different food additive permissions for these substances. A reason was consistency with Codex CXS 156-1987 and EU regulations.

Submitter comments

A number of industry submissions requested FSANZ reconsider its proposed permissions in infant formula products, in particular for follow-on formula, for phosphoric acid (INS 338) and the other phosphates, sodium phosphates (INS 339), potassium phosphates (INS 340) and calcium phosphates (INS 341).

The main request from industry submissions was that FSANZ should add permissions for follow-on formula to be consistent with Codex CXS 156-1987. They also noted that if the food additives are safe and suitable and technologically justified for infant formula then they

should also be appropriate for follow-on formula. It was further noted that the same nutrient preparations may be used for both infant formula and follow-on formula.

Discussion

FSANZ has reconsidered the position provided in section 3.3.4 of SD1 of the 2nd CFS (FSANZ 2023b). FSANZ also noted section 3.4 of SD1 of the 2nd CFS which was addressing the amended CXS 156-2987 as it was finalising the 2nd CFS. This was to align as most appropriate the updated CXS 156-1987 with the Code in relation to follow-on formula.

The 2nd CFS proposed variations permit phosphates in infant formula, aligning with EU Regulations. However, the proposed variation did not extend the permission to follow-on formula due to the difference in age ranges between the Code (6-12 months) and the EU Regulations (6-36 months). In addition, there are also provisions for sodium phosphates and potassium phosphates in infant formula products in CXS 72-1981. However, there are not any provisions for these phosphates in follow-up formula within CXS 156-1987. Therefore the 2nd CFS proposed variation did not add permissions for use in follow-on formula.

FSANZ notes that within the Code the age limit for follow-on formula of 6-12 months is captured within the infant formula age limit (0-12 months) and does not extend past 12 months, unlike other international regulations and standards.

As noted previously, FSANZ considers that these phosphates are both safe and technologically justified for infant formula consumed by infants aged 0-12 months. As this age range already covers that of follow-on formula, FSANZ considers it is appropriate to apply the same food additive permissions.

FSANZ's explanations and conclusions in relation to the permission of phosphates being both safe and technologically justified for infant formula are provided within section 3.3.4 of SD1 of the 2nd CFS (FSANZ 2023b) as noted above.

Decision

FSANZ decided to permit the use of phosphates (INS 338, 339 and 340) as food additives in follow-on formula, consistent with permissions for infant formula. The condition statement 'Not for follow-on formula' proposed for food class 13.1 at the 2nd CFS was removed from the consequential variation.

Summary of food additive amendment post 2nd CFS

Table 7 provides a summary of amendments made by the consequential variation to Schedule 15 of the Code that were not proposed at the 2nd CFS.

Food additive permissions operate in a hierarchical manner in the Code (consistent with Codex and EU regulations). That is, permissions in food class 13.1 also apply to the subclass 13.1.1 unless explicitly stated not to apply or where different permissions are provided to the subclass (explained in section S15—2).

Table 7: Food additive amendments that differ from those proposed at 2nd CFS

Food additive (INS #)	Infant Formula Products Food class 13.1 (MPL mg/L)	SMPPi Food class 13.1.1 (MPL mg/L)
Sodium ascorbate (301)	75, only for use in coating of nutrient preparations containing polyunsaturated fatty acids	Consistent with 13.1
dl-alpha-tocopherol (307c)	10, for IFP 30, for FoF	10
Calcium citrates (333)	0.1, as calcium, may only be added as part of a nutrient preparation.	Amend to plural, calcium citrate**s**
Gum arabic (acacia) (414)	10, may only be added as part of a nutrient preparation	Consistent with 13.1
Xanthan gum (415)	-	1200, only in a product that is based on hydrolysed protein, amino acids or peptides
Phosphoric acid (338)	450, for use in infant formula and follow-on formula	-
Sodium phosphates (339)	450, for use in infant formula and follow-on formula	-
Potassium phosphates (340)	450, for use in infant formula and follow-on formula	-
Diacyltartaric and fatty acid esters of glycerol (472e)	-	400 Default, consistent with current Code permission, no justification to increase MPL provided
Sucrose esters of fatty acids (473)	-	Remove permission of 120
Starch sodium octenyl succinate (1450)	100, may only be added as part of a nutrient preparation 1000, may only be added as part of a polyunsaturated fatty acid preparation	Consistent with 13.1

INS: International Numbering System; IFP: infant formula products; FoF: follow-on formula; MPL: maximum permitted level; SMPPi: special medical purpose product for infants
- = no change

4.14 Contaminants

The 2nd CFS proposed variations proposed maximum levels (MLs) of contaminants in infant formula products. The rationales were set out in section 4 of SD1 for the 2nd CFS (FSANZ 2023b).

4.14.1 Lead

The 2nd CFS proposed variations lowered the ML for lead in infant formula products from 0.02 mg/kg to 0.01 mg/kg. A reduction in the ML was proposed in SD1 for the 1st CFS (FSANZ 2022b) and CP1 2021 (FSANZ 2021a).

No submissions were received on this issue in response to the 2nd CFS.

FSANZ approved the consequential variation with the above ML for lead.

4.14.2 Aluminium

Current regulations

Aluminium can be present in food as a result of its natural occurrence in the environment, leaching from food contact materials and the use of aluminium-containing food additives.

Paragraph 2.9.1—8(c) of the Code currently prescribes the following MLs for aluminium: not more than 0.1 mg/100 mL in soy based infant formula products; not more than 0.05 mg/100 mL in other infant formula products; and not more than 0.02 mg/100 mL in pre-term formula.

The higher ML for aluminium in soy-based infant formula products was set during Proposal P93 as evidence suggested that the lower limit for formula (0.05 mg/100 mL) may not be achievable for soy protein isolate (ANZFA 1999b). Codex does not specify an ML for aluminium in infant formula products.

Previous considerations

FSANZ at the 2nd CFS proposed to reduce the aluminium ML for soy-based infant formula products from 1 mg/kg to be the same as for milk-based infant formula products (i.e., 0.5 mg/kg). See SD1 for the 2nd CFS (FSANZ 2023b). As explained in the latter, the justification for this reduction was infant safety and to ensure levels of aluminium are as low as reasonably achievable.

Submitter comments

A number of industry submissions restated their opposition to reducing the ML for soy-based infant formula products and provided confidential evidence to support their submissions. A central argument was that soy-based infant formula product manufacturers may not be able to consistently meet the lower ML and, as such, the supply of such products could not be guaranteed to always be compliant, which would impact availability.

The submitters stated that the current ML for aluminium in soy-based infant formula products is adequate to ensure these products are safe for infants to consume. They note it is consistent with the JECFA Provisional Tolerable Weekly Intake and that there is no aluminium ML in Codex or EU regulations.

A submitter also queried whether there was an unintended gap in aluminium MLs for all infant formula products. Specifically the submitter questioned whether the ML for ‘infant formula and follow-on formula’ was intended to also capture SMPPi that are not formulated for pre-term infants.

Discussion

Soybeans naturally contain aluminium due to accumulation in the soybean plant from the soil. Natural levels of aluminium can vary depending on the season and location. The data provided indicated that soy-based infant formula products are typically able to meet the reduced ML, however seasonal variation does affect this on some occasions.

FSANZ has retained the ML for pre-term formulas (captured within the SMPPi category) of 0.02 mg/100 mL due to the increased vulnerability of pre-term infants.

Decision

After further consideration, and for the reasons stated above, FSANZ has decided to:

- set an ML for aluminium of 1.0 mg/kg for soy-based infant formula products
- set an ML for aluminium of 0.5 mg/kg for infant formula, follow-on formula and special medical purpose product for infants (other than special medical purpose product for infants formulated for pre-term infants)
- set an ML for aluminium of 0.2 mg/kg for special medical purpose product for infants formulated for pre-term infants.

Each is reflected in the consequential variation.

4.15 Protein source statement

4.15.1 Current regulations

Paragraph 2.9.1—23(1)(a) requires infant formula product labels to contain a statement of the specific source, or sources, of protein in the product. Standard 2.9.1 specifies requirements for the quality and quantity of protein in infant formula products but does not prescribe the protein source. The original intent of the protein source statement was to provide clarity for caregivers to be able to make informed choices and be consistent with Codex guidelines.

Paragraph 2.9.1—23(1)(a) requires the mandatory statement about protein source to be located immediately adjacent to the name of the product. Standard 1.2.1 requires infant formula products to be labelled with the name of the food (see paragraph 1.2.1—8(1)(a)) and section 1.2.2—2 specifies that the name of the food is the prescribed name, if the food has a prescribed name. Section 2.9.1—17 states that ‘Infant formula’ and ‘Follow-on formula’ are prescribed names.

The Code does not specify where the prescribed name and by association, the protein source statement should be located on the label, or their format.

There are no labelling requirements in the Code relating to ‘partially hydrolysed’ formula.

4.15.2 Previous considerations

Protein source statement

In the FSANZ 2021 CP1 (FSANZ 2021a), FSANZ proposed to clarify the source of protein in the labelling of infant formula products. FSANZ noted it had observed the following statements on labels: ‘whey partially hydrolysed protein from cow’s milk’, ‘alpha-lactalbumin enriched whey protein concentrate from cow’s milk’, ‘soy protein isolate’, ‘lactoferrin protein’, ‘Casein (or Whey) dominant based on cow’s milk protein’, ‘whey casein balanced’, ‘100% whey protein’, ‘extensively hydrolysed cow’s milk protein’, ‘a unique and premium whey and casein blend’.

Based on views of government and public health submitters that such references were potential claims and consumer research suggesting caregivers lack understanding of protein fractions and look for the protein origin, FSANZ’s proposed approach at the 1st CFS (FSANZ 2022b) was to clarify that the ‘source’ of protein referred to the origin of the protein (e.g. cow’s milk) and not the protein fractions (e.g. whey protein or casein). FSANZ considered the protein origin (e.g. cow’s milk, goat's milk) was more appropriate because it aligns with international regulations and standards and provides clearer information to caregivers.

This approach was maintained at the 2nd CFS (FSANZ 2023d).

Co-location of protein source statement with the name of the food

In FSANZ 2021 CP1 (FSANZ 2021a), FSANZ proposed to maintain the requirement for the co-location of the protein source statement and the name of the product.

Further, FSANZ proposed to clarify:

- the 'name of the product' is the prescribed name ('Infant formula'); and
- the protein source statement adjacent to the prescribed name is not required every time the prescribed name occurs on the label.

Following consideration of submitter views, EU regulations, Codex and FSANZ's observations of industry practice, FSANZ's proposed approach at the 1st CFS (FSANZ 2022b) was to:

- maintain the requirement for the co-location of the protein source statement with the name of the food; and
- clarify the co-located protein source statement and name of the food needs to appear in a prominent position just once on the label.

FSANZ considered the approach would ensure the information is more visible to caregivers of infants with allergies and intolerances and assist them in making product comparisons. The requirement for a prominent position aligned with Codex and provided flexibility for manufacturers, rather than prescribing a location.

At the 2nd CFS (FSANZ 2023d), FSANZ agreed with submitter comments that it would be inappropriate to refer to 'prominent' in the context of location in the proposed variation, given the Code refers to prominence in the context of contrasting distinctly with the background of the label (subsection 1.2.1—24(1) General legibility requirements). Therefore, the 2nd CFS proposed variations explicitly required the name of the food and the protein source statement to be co-located on the front of the package.

Further, protein source information was permitted in the statement of ingredients for consistency with generic ingredient name requirements, while prohibiting other references to protein source elsewhere on the label.

Partially hydrolysed formula

In the 1st CFS (FSANZ 2022b), FSANZ noted that infant formula and follow-on formula could have modified protein content, such as partially hydrolysed. This 'modified' category was not a proposition to define a new subcategory for modified infant formula products, instead it was intended to provide clarity to the regulation and labelling of a low risk modified protein source in infant formula products. Further information on this can be found in section 4.5.

FSANZ's preliminary view was to require the words 'partially hydrolysed' on the label of infant formula to inform caregivers of the nature of the modification and to distinguish partially hydrolysed products from unmodified infant formula or follow-on formula. No location was proposed for these words, however it was noted some manufacturers referred to 'partially hydrolysed' in the protein source statement.

At the 2nd CFS (FSANZ 2023d), following consideration of submitter comments, consumer evidence and the existing nutrition content and health claim prohibition, FSANZ proposed

that if the infant formula label represented the product as partially hydrolysed, the words 'partially hydrolysed' would need to be used immediately adjacent to the statement of protein source (e.g. *Partially hydrolysed Infant Formula based on cow's milk*). Follow-on formula could not be represented as 'partially hydrolysed'. It was also proposed that the words 'partially hydrolysed' or any word or words having the same or similar effect, could not be used on an infant formula label except in a statement of ingredients, or when used adjacent to the statement of protein source. FSANZ proposed the word 'protein' would be prohibited on the label except for a reference in a statement of ingredients or as required in the NIS.

4.15.3 Submitter comments

Protein source statement

Some public health and government submitters supported the approach at the 2nd CFS to clarify that the 'source' of protein referred to the origin of the protein (e.g. cow milk) and not the protein fractions (e.g. whey protein or casein). Industry submitters did not support the proposed variation because they considered it was necessary to include information about the type of cow milk proteins (e.g. A2 beta casein protein) to inform caregivers.

Co-location of protein source statement with the name of the food

Industry submitters considered there should be no restriction on the location of the protein source statement. Some government submitters commented that partially hydrolysed proteins should only be referred to in the statement of ingredients. These submitters stated there was no scientific justification to refer to partially hydrolysed protein in the name of the food and considered the information would not assist caregivers to make informed choices.

Partially hydrolysed formula

Industry submitters and one government submitter supported FSANZ's proposed approach at the 2nd CFS to require the words 'partially hydrolysed' if the infant formula label represented the formula as partially hydrolysed. However, when referring to the example in the 2nd CFS proposed variations, an industry submitter suggested the words 'partially hydrolysed' would be better placed within the protein source statement (e.g. *Infant Formula from partially hydrolysed cow milk*).

Other government and public health submitters did not support the approach and proposed the requirement be removed because it would not support informed choice and the presence of the words would infer hydrolysed proteins are of benefit to infants. Government submitters also commented there should be no claims permitted that imply there is an associated health effect.

Industry submitters did not support prohibiting the words 'partially hydrolysed' on follow-on formula labels as some follow-on formula contain partially hydrolysed protein as a protein source and labelling would provide for informed choice. Industry submitters also did not support a prohibition on the use of the words 'partially hydrolysed' outside the ingredient list and protein source statement (paragraph 2.9.1—29(1)(l) in the 2nd CFS proposed variations).

See section 7 of Appendix 3 for responses to other submitter comments.

4.15.4 Discussion

Protein source statement

The 2nd CFS addressed views about protein fractions, such as 'A1 beta casein protein', rather than the specific animal or plant source(s) of protein appearing in the protein source statement (issue A.12, Table 4, part A of SD3; FSANZ 2023d). Consumer evidence indicates caregivers lack understanding of protein fractions and look for the protein origin (see section 5.6.4 of the FSANZ 2021 CP1 (FSANZ 2021a)). Furthermore, FSANZ considers that, in accordance with the intent of the Policy Guideline on the Regulation of Infant Formula Products (MPG 2011), other protein fractions or isolates must undergo a pre-market assessment as a nutritive substance before they are permitted for addition and declaration (section 4.1 in the 2nd CFS; FSANZ 2023d). FSANZ is permitting a voluntary declaration for whey and casein in the NIS (see section 3.4 of SD3 to the 1st CFS for the consumer evidence and discussion on this issue)(FSANZ 2022b). The regulatory approach is consistent with Codex standards for infant formula and follow-up formula and enables caregivers to differentiate between products that contain animal- or plant-derived protein, partially hydrolysed protein, or a combination thereof.

If a product differs from another infant formula or follow-on formula because of a type of protein that is added for the dietary management of a medically diagnosed disease, disorder or condition of an infant, then it would be a SMPPi and would be subject to relevant compositional and labelling requirements and a restriction on sale (see sections 4.2, 4.3, 4.21 to 4.24 and Attachment A primary variation).

Co-location of protein source statement with the name of the food

FSANZ considers the co-location requirement as a balance between existing requirements in Standard 2.9.1, current policy settings relating to the prohibition of claims[9] and consumer evidence indicating caregivers of infants with allergies and intolerances find it useful when making purchase decisions (section 4, Part A of SD3 to the 2nd CFS; FSANZ 2023d). The protein source statement located with the name of the food and permission to use the protein source in the statement of ingredients will enable caregivers to differentiate between products and make informed choices.

Further, FSANZ has previously stated that it views a requirement to co-locate the information 'prominently' (now explicitly on the front of the package) is not inconsistent with Codex (section 4, Part A of SD3 to the 2nd CFS; FSANZ 2023d). Unless expressly permitted, nutrition information outside the NIS and the statement of ingredients is considered a nutrition content claim. This is consistent with Codex and the EU, which refer to requirements for mandatory nutrition declaration while also prohibiting nutrition claims elsewhere on the label (section 6.2 of SD3 to the 1st CFS; FSANZ 2022e).

Partially hydrolysed formula

The intent of the drafting at the 2nd CFS was to distinguish between infant formula (0–12 months) represented as partially hydrolysed (currently those infant formula that reference medical conditions e.g. 'colic') and infant formula that is not represented as such (see section 8 of SD3 to the 2nd CFS; FSANZ 2023d). However, FSANZ agrees with submitter comments that the 2nd CFS proposed variations specified partially hydrolysed protein is a permitted

[9] FSANZ noted previously that the issue of voluntary nutrition content claims was extensively considered and consulted on as part of Proposal P293 Nutrition, health and related claims (FSANZ 2016g). The decision to retain the claim prohibition for infant formula under that proposal was considered consistent with the Policy Guideline on Nutrition, Health and Related Claims (MPG 2003) and the Policy Guideline on the Regulation of Infant Formula Products (MPG 2011).

protein source for both infant formula and follow-on formula (subsection 2.9.1—6(1)) and that this information should also be required in the protein source statement of follow-on formula whenever partially hydrolysed protein is used (rather than relying on it if the product label represents that the formula is partially hydrolysed). Further, it may be misleading to caregivers if this information was omitted from the protein source statement.

FSANZ also agrees there was a disconnect between the specific protein source and the words 'partially hydrolysed' in the 2nd CFS proposed variations. The primary variation in Attachment A clarifies the intent that the partially hydrolysed protein is derived from one or more of the following proteins: cow milk, goat milk, sheep milk or soy protein isolate. The changes made to the 2nd CFS proposed variations are as follows:

- A Note has been added to the requirement for the specific animal or plant source of protein to be included in the name of the food (subsection 2.9.1—20(1)) to signpost the permitted sources of protein in section 2.9.1—6(1).
- The words 'partially hydrolysed' are now required to be used immediately adjacent to the protein source (subsection 2.9.1—20(2)). This change clarifies the words 'partially hydrolysed' are linked to the specific animal or plant source or sources of protein, rather than to the protein source statement as a whole. The effect is that the words may appear within the protein source statement.

  The example to this requirement has also been updated to reflect this intent (e.g. *Infant formula based on partially hydrolysed cow milk*) (example to subsection 2.9.1—20(2)).

FSANZ notes government and public health submitter views that the words 'partially hydrolysed' should not be required in the protein source statement (if used in the formula) or permitted at all on the label. However, FSANZ considers that given partially hydrolysed protein is safe for healthy infants to be used as a permitted protein source in infant formula products (see section 4.5 of this report) and 'partially hydrolysed' refers to an attribute of the protein source and not a health effect, there should be a reference on the label to its presence in a formula. This approach will enable caregivers to compare the protein source statement across products, thereby supporting informed choice. As discussed above, FSANZ has amended the declaration requirements to be based on use, rather than when a product is represented as 'partially hydrolysed'. Products will have to be positioned as SMPPi to be able to refer to 'anti-reflux' etc as the medical purpose. The words 'partially hydrolysed' will be required in the name of the food and are also permitted to be in the statement of ingredients but not in the NIS.

The word 'milk'

In response to submitter comments to the 2nd CFS, FSANZ has amended 2nd CFS proposed variations to permit the use the word 'milk' outside the statement of ingredients and the protein source statement (see section 4.19 of this report).

As part of this consideration, FSANZ has added a new provision to clarify the required protein source statement must not use the word 'milk' as the sole descriptor of the protein source (subsection 2.9.1—20(3) of the primary variation). The word 'milk' does not describe the protein source adequately for caregivers to make an informed choice and it does not reflect the proteins cow milk, goat milk and sheep milk listed in subsection 2.9.1—6(1). Examples of non-compliant protein source statements have been provided in the primary variation to reflect the intent.

A Note has been added to the prohibition for use of the word 'milk' as the sole descriptor of the protein source (Note to subsection 2.9.1—20(3) of the primary variation) to direct the reader to the permission for the separate use of the word 'milk' elsewhere on the label and in

addition to a protein source statement (sub-paragraph 2.9.1—28(1)(j)(i) of the primary variation).

4.15.5 Decision

For the reasons stated in this report, FSANZ's decision is to:

- Require the specific protein source (e.g. cow milk) to be included in the statement of protein source (subsection 2.9.1—20(1) of the primary variation).
- Require the protein source statement to be included in the statement of the name of the food on the front of the package (subsection 2.9.1—20(1) of the primary variation).

  The primary variation clarifies that protein source information is permitted in the statement of ingredients for consistency with generic ingredient name requirements. Other references to protein source are prohibited elsewhere on the label (subparagraph 2.9.1—28(1)(k) of the primary variation).
- For partially hydrolysed protein used as a permitted protein source:
  - require the words 'partially hydrolysed' in the protein source statement, irrespective of whether the infant formula or follow-on formula is represented as partially hydrolysed (subsection 2.9.1—20(2) of the primary variation).
  - the words 'partially hydrolysed' must be used immediately adjacent to the specific plant or animal protein source and included in the statement of the name of the food on the front of the package.
  - The words 'partially hydrolysed' may also be used in the statement of ingredients (subparagraph 2.9.1—28(1)(j)(ii) of the primary variation).
- Prohibit the word 'milk' as the sole descriptor of the protein source in the protein source statement (subsection 2.9.1—20(3) of the primary variation). The separate use of the word 'milk' is permitted elsewhere on the label and in addition to in a protein source statement.

4.16 Age-related statements

4.16.1 Current regulations

Paragraph 2.9.1—19(4)(a) of the Code requires a statement on infant formula labels indicating the infant formula product may be used from birth.

Paragraph 2.9.1—19(4)(b) requires a statement on follow-on formula labels indicating that the infant formula product should not be used for infants aged under the age of 6 months.

Paragraph 2.9.1—19(4)(c) requires a statement on infant formula product labels (except pre-term formula) indicating it is recommended that infants from the age of 6 months should be offered foods in addition to the infant formula product.

4.16.2 Previous considerations

FSANZ's proposed approach at the 1st CFS (FSANZ 2022b) was to maintain the requirement for the age statements for infant formula and follow-on formula as currently required in the Code.

This approach was maintained at the 2nd CFS (FSANZ 2023d), noting that in the proposed variation the words 'infant formula product' were changed to 'infant formula' and/or 'follow-on

formula' as appropriate. FSANZ also proposed the age statements relating to the use of infant formula and follow-on formula must be on the front of the package (and immediately adjacent to stage numbers (if used)—see section 4.20) to ensure the information is prominent while not preventing the statements from appearing more than once on the label.

4.16.3 Submitter comments

While the requirement to have the age-related statements on product labels was supported by some public health, government and industry submitters, each of the statements attracted comments from government and industry submitters (see section 7 of Appendix 3).

Some government submitters referred to the imprecise and inconsistent way that manufacturers currently indicate the recommended age ranges for their product/s. Industry submitters did not support the specific wording to be used on follow-on formula, requesting clarification that a positive statement can be used such as 'from 6 months' and for examples of compliant statements to be provided. Government submitters also suggested a positive statement be co-located with the stage number on the front of the package and that follow-on formula should display two required statements about the appropriate age.

Industry submitters suggested the wording for the statement recommending when infants should be offered food be modified to include the word 'around' i.e. 'around 6 months'.

Industry submitters supported the proposed approach for requiring age statements (relating to use of infant formula and follow-in formula) on the front of the package as this aligns with current practice. Suggestions from government submitters included recommending the statements be:

- required to be in a prominent position on the front of the package
- required to be elsewhere on the label and co-located with required warning statements.

4.16.4 Discussion

FSANZ notes the regulatory approach for age statements is consistent with EU regulations. For infant formula, article 6(2)(a) of EU 2016/127 requires a statement that the product is suitable for infants from birth when they are not breastfed. For follow-on formula, article 6(3)(a) requires a statement that the product is suitable only for infants over the age of six months (European Commission 2016a).

FSANZ's regulatory intent is to ensure follow-on formula is not introduced before six months of age. This is consistent with section 9.6.4 in Section A of CXS 72-1981 (Codex 1981), section 8.5.6 in section A of CXS 156-1987 (Codex 2023a), Article 6(3)(a) of EU 2016/127 and domestic infant feeding guidance (NHMRC 2012; Ministry of Health 2021).

The age statement for follow-on formula (paragraph 2.9.1—21(2)(b) of the primary variation) is also consistent with Codex and EU regulations where the wording of the required statement is not prescribed and does not specify a particular age range e.g. 'from 6 months' or '6–12 months'.

The definition of 'follow-on formula' is also relevant, i.e. in section 2.9.1—3 of the primary variation, 'follow-on formula' in part means 'being suitable to constitute the principle liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months'.

The required statement is one that indicates that follow-on formula should not be used for infants aged under the age of six months. Similar to the other required age statements in paragraphs 2.9.1—21(2)(a) and (c) of the primary variation, the wording of the statement is

not prescribed. FSANZ considers label statements such as ‘from six months’ or ‘6–12 months’ meet the intent of the required statement.

Regarding the use of the phrase ‘around 6 months’, FSANZ considers the current wording that ‘the follow-on formula should not be used for infants aged under the age of 6 months’ is appropriate to support infant feeding guidance, noting the wording of the statement is not prescribed (see previous discussion on FSANZ’s rationale in section 8.12.3 of SD1 to the 1st CFS; FSANZ 2022b).

Regarding the required statement about offering foods in addition to infant formula and follow-on formula from the age of six months (section 2.9.1—21(2)(c) of the primary variation), FSANZ notes this regulatory approach is consistent with section 9.6.4, Part A of Codex CXS 72-1981, which specifies ‘Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker and in any case from the age over six months’ (Codex 1981).

Regarding the location of the statements on the label, FSANZ considers that co-locating age-related statements and stage numbers (if used)(see section 4.20 on stage labelling) on the front of the package is sufficient to ensure that caregivers can differentiate between infant formula and follow-on formula (see previous discussion on FSANZ’s rationale in section 9.5.4.2 of SD3 to the 2nd CFS; FSANZ 2023d).

Mandating age statements to appear elsewhere on the label, for example co-locating age information with warning statements, would be more onerous than international standards or another jurisdictions regulations. FSANZ considers the provision in subsection 2.9.1—21(4) of the primary variation indicating the age statement may appear more than once on the label is sufficient and will assist caregivers to identify appropriate products. Similar to manufacturers being able to refer to the prescribed name ‘Infant formula’ or ‘Follow-on formula’ elsewhere on the label, age statements and stage numbers may also appear elsewhere on the label. The primary variation (section 2.9.1—15) also requires the label on infant formula or follow-on formula to differentiate that infant formula or follow-on formula from other foods by the use of text, pictures and/or colour (see section 7 in Appendix 3). As such, there will be sufficient information and formatting measures to enable caregivers to differentiate between different infant formula products.

FSANZ has considered submitter comments about providing examples of compliant statements in the Explanatory Statement. FSANZ has provided information in SD1 to indicate the regulatory intent of these provisions and considers there is no need for a Note in the primary variation as recommended by some submitters.

FSANZ does not agree that two separate statements on follow-on formula about the appropriate age is required. The additional statement suggested by government submitters that ‘the follow-on formula may be used from the age of six months’ is not as clear as the current drafting, while the existing statement indicating that the formula should not be used under the age of six months accurately conveys the intent. Further, a requirement for another statement would pose an unnecessary regulatory burden on industry.

FSANZ does not agree that a change to the proposed variation is needed to require the statements be placed in a *prominent position* on the front of the package. As noted in section 3.4.1 of the 2nd CFS (FSANZ 2023d), FSANZ considers that mandating the location as the front of the package is consistent with current industry practice, ensures the information is accessible for caregivers and provides regulatory certainty for manufacturers and enforcement agencies. Additionally, determining what ‘prominent position’ means for implementation and enforcement purposes, could be problematic.

4.16.5 Decision

For the reasons stated in this report, FSANZ's decision is to maintain the current approach for requiring age-related statements (subsection 2.9.1—21(2) of the primary variation). As proposed in the 2nd CFS, the age-related statements referred to in paragraphs 2.9.1—21(2)(a) and (b) of the primary variation must be on the front of the package (subsection 2.9.1—21(3) of the primary variation). Age-related statements about the use of infant formula and follow-on formula must be immediately adjacent to stage numbers on the front of the package (if the latter are used) (subsection 2.9.1— 27(2) of the primary variation).

The wording of the age-related statements is not prescribed and the statements may appear more than once on the label (subsection 2.9.1—21(4) of the primary variation).

4.17 Declaration of nutrition information – base unit of expression

4.17.1 Current regulations

Paragraph 2.9.1—21(1)(a) of the Code requires the declaration of energy, macronutrients, vitamins and minerals and other specified nutrients using the per 100 mL base unit of expression. No other base units of expression are mandated.

Subsection S29—10(3) of Schedule 29 sets out the Guideline format for a nutrition information table. The Guideline specifies the mandated base unit is for per 100 mL of made up formula and indicates an additional column may be used for either per 100 g of powder or per 100 mL of liquid concentrate (as sold). The Guideline is not legally binding and there is no explicit permission to include an additional column for these base units of expression.

4.17.2 Previous considerations

FSANZ's proposed approach at the 1st CFS (FSANZ 2022b) was to only permit the base unit of expression (per 100 mL as reconstituted) in the NIS. This was based on little stakeholder interest in mandating additional base units, that most product labels in the domestic market typically only used per 100 mL as reconstituted and a view that other base units may be less familiar to caregivers. Further, most submitters agreed that base units relating to energy values could not be used by caregivers for comparative purposes and health professionals have access to this information directly from companies.

The 2nd CFS proposed that the '*unit quantity' (defined in subsection 1.1.2—2(3)) of the food expressed in per 100 mL was required nutrition information in the NIS (paragraph 2.9.1—25(1)(a) of the 2nd CFS proposed variations). The 2nd CFS also proposed that the NIS must not include a unit quantity other than per 100 mL (paragraph 2.9.1—26(2)(f) of the 2nd CFS proposed variations).

4.17.3 Submitter comments

One public health and one government submitter supported the proposed approach. Submissions are summarised in section 7 of Appendix 3.

Industry submitters and one government submitter did not support the restriction of base units to per 100 mL. Submitters commented that this does not align with Codex CXS 72-1981 or regulations used in the EU and US. Some domestic products are sold in smaller markets that align with Codex. Therefore, prohibiting information permitted by Codex could result in their withdrawal from sale and present a public health issue. This issue was also raised through the WTO notification. One industry submitter requested a table be added to the

Code to demonstrate how to display nutrient information per 100 g as sold to ensure consistency across labels.

4.17.4 Discussion

FSANZ acknowledges submitter comments on this issue and agrees the approach proposed at the 2nd CFS would be detrimental to those Pacific Island countries that have adopted Codex labelling requirements and rely on imported infant formula and follow-on formula. FSANZ also notes the guideline NIS format currently suggests the voluntary addition of per 100 mL (as sold) or per 100 g (as sold) are permitted as base units, although these Guidelines are not legally binding and there is no explicit permission in the standard for other base units to be used. FSANZ has therefore introduced a permission so that per 100 g powder or per 100 mL concentrated liquid (as sold) may be used in the NIS in addition to the mandatory per 100 mL when reconstituted. The NIS format is now prescribed for per 100 mL prepared formula with an example provided for the optional addition of per 100 g powder or 100 mL liquid concentrate to the NIS (see S29—10 and 10A of the primary variation).

References to '*unit quantity' in the 2nd CFS proposed variations have been removed in the primary variation. This amendment has been made as the primary variation requires one base unit of expression (per 100 mL) for the information in the NIS (paragraphs 2.9.1—24(3), (4) and (5)), whereas 'unit quantity' is defined in subsection 1.1.2—2(3) to mean more than one base unit of expression (i.e. for a food that is a solid or semi-solid food—100 grams; for a food that is a beverage or other liquid food—100 millilitres).

FSANZ has clarified that base units (i.e. quantities) other than those specified in the nutrition information declaration requirements are not permitted (for example, a base unit that is based on energy values).

4.17.5 Decision

For the reasons stated in this report, FSANZ has decided that the nutrition information in subsections 2.9.1–24(3) to (5) of the primary variation must be expressed in per 100 mL of formula and the formula must be reconstituted according to the directions on the package, if applicable (paragraph 2.9.1—24(6) of the primary variation). Manufacturers can also choose to display nutrition information based on the quantities per 100 g powder (as sold), or per 100 mL concentrated liquid (as sold) (paragraph 2.9.1—24(7) of the primary variation). Nutrition information expressed using an 'as sold' base unit must be located in a separate column to the right of the column that contains mandatory nutrition information expressed per 100 mL as reconstituted (subsection 2.9.1—25(7) of the primary variation).

The NIS must not contain any other information, which would include another base unit, unless expressly provided elsewhere in the Code (paragraph 2.9.1—24(8) of the primary variation).

4.18 Declaration of nutrition information – fatty acid acronyms and names for certain vitamins

4.18.1 Current regulations

The Code does not include declaration requirements or permissions for nutrient acronyms in the NIS. The current Guidelines in subsection S29—10(3) display a NIS that includes two micronutrients with number notations (vitamin B_6 and vitamin B_{12}). This example NIS format is not legally binding.

4.18.2 Previous considerations

Section 3.3 of SD3 to the 1st CFS (FSANZ 2022e) discussed FSANZ's proposed approach for a prescribed format for the NIS. This included a list of substances and the units of measurement in which they should be declared.

The following provisions were included in the 2nd CFS proposed variations:

Fatty acids

Paragraph 2.9.1—26(2)(e) specified that nutrients and subgroup nutrients are stated 'using the names and units of measurement specified in that table for that nutrient or subgroup.' The specified table was the table to section S29—10.

The table to section S29—10 included the full names for the permitted fatty acids (docosahexaenoic acid, eicosapentaenoic acid and arachidonic acid). A Note to the table specified these fatty acids 'only needed to be included when stated in accordance with subsection 2.9.1—25(2)'. This subsection stated that if these substances are present, the NIS 'may include the average quantity of that substance (including any naturally-occurring amount), expressed in milligrams or grams'.

Vitamins

Paragraph 2.9.1—26(2)(e) required nutrients and subgroup nutrients to be stated 'using the names and units of measurement specified in that table for that nutrient or subgroup'. The specified table was the table to section S29—10.

The table to section S29—10 did not include the option to use number notations for niacin, pantothenic acid, riboflavin, or thiamin. This approach was consistent with the guideline NIS in subsection S29—10(3) of the current Code.

4.18.3 Submitter comments

Industry submitters broadly supported the proposed approach for the use of nutrient terms. A government submitter supported the chosen terminology based on consumer research. Another noted that prescribing names and units of measurement will make it easier for caregivers to compare products.

Industry submitters did not support restrictions on common terms, acronyms/abbreviations and additional contextual information. Specifically, they considered caregivers may be more familiar with common terms and abbreviations for long-chain polyunsaturated fatty acids (docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and arachidonic acid (ARA)) and vitamins than scientific names. An industry submitter noted this is especially applicable for those with a non-English-speaking background.

These submitters requested acronyms be permitted in addition to the scientific name. One industry submitter referred to research by Laszlo and Federmeier (2007a and 2007b) to argue that familiar acronyms can help caregivers find the information they need more so than unfamiliar scientific terms. Another industry submitter suggested that permitted fatty acid acronyms could be listed within S29–10.

Industry submitters stated that the suggested permission to include the acronyms should also apply to linolenic acid and alpha linoleic acid. One industry submitter requested that linolenic acid and alpha linoleic acid be permitted in the NIS because they are currently declared on product labels and it would provide continuity of labelling.

There was industry support for the number notations to be voluntarily permitted in addition to scientific names, particularly for Niacin (B_3), Pantothenic acid (B_5), Riboflavin (B_2) and Thiamin (B_1).

Industry and government submitters made comments that did not support the 2nd CFS proposed variations regarding the format of the NIS. Submissions questioned the choice of units for vitamins A and E. The government submitter also suggested changing the unit for niacin.

See section 7 of Appendix 3 for submitter comments.

4.18.4 Discussion

Fatty acids

Acronyms

Focus groups with 136 Australian and New Zealand caregivers (Malek et al. 2019) identified that caregivers were generally unfamiliar with both the full names and abbreviations of ingredients in nutrient content claims on infant formula. While not asked to compare familiarity with nutrient abbreviations and full names directly, participants in the study reported finding both abbreviations and full names of ingredients difficult to understand and thus not influential in their purchasing decisions for infant formula.

An industry submitter cited two studies (Laszlo and Federmeier 2007a; Laszlo and Federmeier 2007b) to suggest that acronyms are favoured over full word strings in reading development. However, these studies found that familiar acronyms were more recognisable than unfamiliar acronyms when neither conform to rules governing word formation, as measured by accuracy in identifying missing letters (Lazlo and Federmeier 2007a) and using electrophysiology (Laszlo and Federmeier 2007b). Acronyms were less recognisable than words or ‘pseudowords’ which followed word formation conventions (Laszlo and Federmeier 2007a). Thus, these studies do not suggest that familiar acronyms are favoured over words, nor do they provide evidence around the familiarity of the acronyms in question.

FSANZ is not aware of any evidence comparing whether acronyms or full scientific nutrient names are more familiar or useful to caregivers, with available consumer evidence suggesting that both are generally unfamiliar. However, FSANZ considers that allowing the use of the acronyms DHA, EPA, ARA may provide additional information for caregivers while giving industry some flexibility in how voluntary fatty acid declarations are made.

While allowing the optional use of acronyms introduces potential for inconsistencies between product labels, the full name of the fatty acid will always be present and indented under the subheading ‘long chain polyunsaturated fatty acids’ and under ‘fat’. Any inconsistencies between product labels would therefore be minor. Permission to declare the fatty acids in the NIS means they would not be considered to be nutrient content claims.

Condition for voluntary declaration of fatty acid acronyms

As noted above, the 2nd CFS proposed variations permitted the optional declaration of the fatty acids ‘docosahexaenoic acid’, ‘eicosapentaenoic acid’ and ‘arachidonic acid’ in the NIS. However, it did not specify whether one or all of the fatty acids must be declared if used, although the latter was the intent. If only one fatty acid is optionally declared (e.g. ‘docosahexaenoic acid (DHA)’), it may give caregivers the impression that this sub-group nutrient is specifically added to the formulation as a point of difference from other infant

formula products. This could be perceived as a nutrition content claim. FSANZ has clarified that the voluntary declaration of the fatty acids requires them to all be declared together in the NIS.

Linoleic acid and α-linolenic acid

FSANZ notes that linoleic acid and α-linolenic acid are declared on some product labels in the marketplace. However, there is currently no explicit permission or requirement for these fatty acids to be included in the NIS.

FSANZ stated in section 3.4 of SD3 to the 1st CFS that listing linoleic acid and α-linolenic acid is unnecessary given the compositional requirement for all infant formula products to contain these essential fatty acids (FSANZ 2022e). Linoleic acid and α-linolenic acid have established minimum and maximum limits (paragraph 2.9.1—7(1)(c) of the primary variation).

In comparison, FSANZ previously noted DHA, EPA and ARA were permitted to be present in infant formula and follow-on formula via Schedule S29—4 of the 2nd CFS proposed variations. FSANZ has now clarified these substances are a part of the required composition (section 2.9.1—7(1) of the primary variation), however they can be present due to being synthesised from linoleic acid and α-linolenic acid (Ponnampalam et al. 2021).

As DHA, EPA and ARA are regulated in the primary variation through the use of ratios (paragraphs 2.9.1—7(1)(c) to (f)) and a maximum limit for DHA (table to section S29-4), rather than specified minimum and maximums, including information about these fatty acids on infant formula and follow-on formula may assist health professionals. In particular, in a clinical setting when there may be a need to calculate total fatty acid content from the formula when combined with other supplementary products.

FSANZ has therefore maintained its position such that linoleic acid and α-linolenic acid are not permitted to be included in the NIS.

Vitamins

Some vitamins are better known by their number notation than their scientific name e.g. vitamins B_6 and B_{12} are more commonly used names than ‘Pyridoxine’ and ‘Cobalamin’, respectively. Other vitamins are more commonly referred to by their scientific names e.g. ‘Biotin’, ‘Folate’.

FSANZ has observed some variation regarding how vitamins are declared on product labels and the use of number notations. For example, the B vitamin Niacin has been declared as ‘Vitamin $B_{3'}$, ‘Niacin’, ‘Niacin (Vitamin B_3)’ or ‘Niacin B_3’.

Although industry submitters supported the voluntary use of number notations alongside the scientific name, FSANZ considers this will lead to inconsistencies between product labels and may make label comparisons more difficult for caregivers. FSANZ has therefore amended the 2nd CFS proposed variations to require the full names and number notations for the four B vitamins noted specifically by industry submitters. The table to section S29—10 in the primary variation now specifies these vitamins must be declared as follows: Niacin (B_3), Pantothenic acid (B_5), Riboflavin (B_2) and Thiamin (B_1).

FSANZ considers it is unnecessary to change the declarations for vitamin B_6 or vitamin B_{12} to require them to be identified as ‘Pyridoxine’ and ‘Cobalamin’ respectively, as caregivers are more likely to be familiar with the numbered designation. Declarations for biotin and folate will not be changed to ‘Biotin (B_7)’ and ‘Folate (B_9), respectively, for similar reasons.

The table to section S29—10 in the 2nd CFS proposed variations specified that vitamins A and E must be declared in micrograms (µg). Some industry submitters suggested changing the units for vitamin E to mg α-TE and the units for vitamin A to µg RE to align with the NHMRC NRVs and support health professionals to use the NIS. FSANZ maintains its position as summarised in SD3 to the 2nd CFS (see item B.4 in Table 5; FSANZ 2023d), that the primary purpose of the NIS is to provide nutrition information to caregivers in a manner that enables product comparisons and informs choice. The use of micrograms is also consistent with how other vitamins are declared and are more likely to be familiar to consumers.

A government submitter suggested changing the unit for vitamin E to milligrams (mg). This change is appropriate given manufacturers are using either milligrams (or tocopherol equivalents), rather than micrograms as indicated in the Guideline NIS format so would be familiar to caregivers. FSANZ notes the use of milligrams would also enable easier compliance with the compositional requirements for vitamin E.

FSANZ agrees the unit of measurement for niacin should be micrograms. This change would ensure consistency in the units of measurement for all B vitamins. Further, determining compliance with compositional requirements (that are also in micrograms) would be easier for manufacturers. FSANZ also notes that micrograms is being used on the majority of infant formula and follow-on formula labels so would be familiar to caregivers.

4.18.5 Decision

For the reasons stated in this report, FSANZ has decided that if the fatty acids DHA, EPA and ARA are voluntarily declared in the NIS, the acronyms may be included. If the acronyms are used, they must be added in brackets immediately after the mandatory full name (paragraph 2.9.1—25(6)(d) of the primary variation). If the manufacturer chooses to declare these fatty acids, all three must be included in the NIS (subsection 2.9.1—24(5) of the primary variation). Linoleic acid and α-linolenic acid are not permitted to be declared in the NIS.

Numbered notations for niacin, pantothenic acid, riboflavin and thiamin will be required as part of the name that must be declared in the NIS. The notation must be provided in brackets immediately following the name as declared and appear as subscript (paragraph 2.9.1—25(2)(e) of the primary variation and the table to section S29—10 of the consequential variation).

Vitamin E will be required to be expressed in milligrams and niacin will be required to be expressed in micrograms in the NIS (paragraph 2.9.1—25(2)(e) of the primary variation and the table to section S29—10 of the consequential variation).

4.19 Prohibited representations – ingredients

4.19.1 Current regulations

The Code does not contain an express prohibition for ingredients to be referenced outside the statement of ingredients, or the NIS (if relevant).

4.19.2 Previous considerations

FSANZ's proposed approach at the 1st CFS (section 6.3 in SD3; FSANZ 2022e) was to only permit information about ingredients in the statement of ingredients (except for ingredients, such as nutritive substances, that are required to be declared in the NIS).

This approach was maintained at the 2nd CFS (item B.15 in Table 5 of SD3; FSANZ 2023d). The 2nd CFS proposed variations prohibited information relating to ingredients except for in a statement of ingredients or a declaration or statement expressly permitted or required by the Code (paragraph 2.9.1—29(1)(j)). The word 'milk' was captured as ingredient information and thus prohibited.

A Note was also added to the section on prohibited representations for infant formula and follow-on formula, which included the ingredient information prohibition (Note to subsection 2.9.1—29(1) of the 2nd CFS proposed variations), which cross referenced provisions in Standard 1.2.7 relating to the prohibition of nutrition content and health claims for infant formula product.

4.19.3 Submitter comments

The word 'milk'

Industry submitters objected to the proposed restrictions on using the word 'milk'. Some manufacturers use the term in provenance statements or to describe their protein source, which they say does not imply nutrition or health benefits. Of these submitters, some suggested the prohibition would impair informed choice and others indicated it would be extremely detrimental for the competitiveness of the domestic infant formula industry in export markets.

Prohibited representations about other ingredients

Industry submitters did not support the prohibition for representations about ingredients generally. They indicated the proposed regulatory approach does not align with other national and international regulatory approaches, which only prohibit nutrient and health claims. One industry submitter commented that not being able to accurately provide information about the quality and performance of a product's ingredients and their purpose is misleading to caregivers. Another indicated that, in some cases, extra information is needed to give a true and accurate representation of their ingredients. As the term 'ingredient' is not defined in the Code, one industry submitter highlighted the fact that this introduces uncertainty to the scope of the prohibition.

One industry submitter considered that the proposed Note which cross referenced the prohibited claims in Standard 1.2.7, should be sufficient to address FSANZ's concerns about implied nutrition content and health claims without the need for an explicit prohibition. Submitters requested clarity about whether statements made about ingredients generally were permitted, such as 'sustainably-sourced ingredients'.

See section 7 of Appendix 3 for submitter comments.

4.19.4 Discussion

The word 'milk'

FSANZ understands from submitter feedback that manufacturers use the word 'milk' in provenance-related statements such as 'made with New Zealand milk' and that these statements are considered important value propositions and are commonly used on the label of products (particularly for New Zealand-made products).

Given the potential significant impact on trade, FSANZ has decided to exempt the use of the word 'milk' from the prohibition for information relating to ingredients. FSANZ considers an explicit exemption is also justified because 'milk' does not refer to the specific animal source (e.g. cow milk, goat milk, sheep milk in subsection 2.9.1—6(1) of the primary variation),

which must be declared in the statement of protein source (subsection 2.9.1—20(2) of the primary variation).

Further, the Code does not regulate provenance-related statements or country of origin labelling; these types of representations are regulated by consumer protection legislation.

Prohibited representations about other ingredients

International alignment

FSANZ acknowledges there are differences between the regulatory approach proposed in the 2nd CFS and some overseas regulations. Some of these differences are not new (e.g. compared to previous EU regulations which permitted certain nutrition content and health claims (Commission Directive 2006/141/EC and amending Directive 1999/21/EC; European Commission 2006a), nutrition content and health claims have always been prohibited on infant formula and follow-on formula in the Code).

Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997; Codex 1997) specify that nutrition claims and health claims should be consistent with national nutrition policy and national health policies. In the development of Standard 1.2.7 under Proposal P293 – Nutrition, health and related claims (FSANZ 2012d), FSANZ had regard to the Policy Guideline on Nutrition, Health and Related Claims (MPG 2003) and other relevant information. The outcome was that nutrition content and health claims are prohibited on infant formula products. The prohibition relies on the definition of 'claim', which refers in part to express or implied statements about a property of food which are not mandatory in the Code. An ingredient may be a property of a food. The Ministerial Policy Guideline on the Regulation of Infant Formula Products was published in 2011 and reaffirmed the prohibition of claims on infant formula products in Specific Policy Principle n (MPG 2011).

Article 1(2) of World Health Assembly (WHA) Resolution 58.32 (World Health Assembly 2005) refers to the specific resolution 'to ensure that nutrition and health claims are not permitted for breast-milk substitutes, except where specifically provided for in national legislation'. FSANZ does not consider there is an inconsistency between Code requirements and the WHA resolution 58.32. FSANZ considers the Ministerial Policy Guideline on the Regulation of Infant Formula Products (MPG 2011) signals the intent of the prohibition for information about ingredients other than in a statement of ingredients or where otherwise permitted or required and notes this approach is supported by government and health professional submitters.

European Regulation (EC) 1924/2006 on nutrition and health claims (European Commission 2006b) made on foods applies to infant formula and follow-on formula regulated under EU 2016/127 (which prohibits such claims). Article 2(5) of EC 1924/2006 provides that *'health claim' means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health*. It is conceivable that an ingredient may be a 'constituent' of a food.

Consumer evidence

Research into consumer perceptions of ingredient claims on infant formula products had mixed results (FSANZ 2022f). Some caregivers in qualitative research reported disregarding ingredient-related claims, as they do not understand the purpose of the specific ingredient being claimed, or they considered claims in general to be a marketing tactic. However for others, ingredient-related claims influenced perceptions of infant formula and follow-on formula, leading them to consider it more favourably and influencing product choices. Ingredient claims relating to 'fish oil' or 'organic' were reported as being influential to

caregivers in Australian and New Zealand research (see section 6.3 of SD3 in the 1st CFS (FSANZ 2022e) and Attachment 1 to that SD3 (FSANZ 2022f)).

FSANZ acknowledges this consumer evidence did not look at consumer understanding of the broader term 'ingredients' nor did it specifically ask participants about claims referring to the 'ingredients' e.g. all natural ingredients. However, FSANZ considers the finding that ingredient information is either confusing to caregivers or influential in their purchase decisions is valid, particularly when the ingredient may be present in different products but 'called out' on the label of one product.

Quality and performance characteristics and purpose

Government submitters noted at the 1st CFS (section 6.3 of SD3; FSANZ 2022e) that specific policy principles for labelling and advertising in the Policy Guideline on Infant Formula Products capture ingredients in addition to nutrients and nutritive substances. As discussed above, consumer evidence suggests that while some caregivers may find ingredient claims helpful, others may be misled and have a more favourable view of infant formula in response to such claims. In accordance with specific policy principle (n), FSANZ considers this potential for caregivers to be misled from ingredient claims needs to be addressed in the Code.

FSANZ therefore considers information about ingredients (including LAM – see section 4.11) should only appear in the statement of ingredients, except for the word 'milk' which may be used elsewhere on the label (as discussed above), or a declaration or statement that is expressly permitted or required in the Code (e.g. nutritive substances required to be declared in the NIS).

Definition of ingredient

FSANZ has addressed the reasons why it considers a definition of ingredient is unnecessary in Table 5 to SD3 of the 2nd CFS (FSANZ 2023d). FSANZ notes the ordinary meaning of 'ingredient' applies across the Code and considers it is unnecessary to define 'ingredient' for this purpose.

Statements about 'ingredients' generally

The primary variation does not prohibit general statements made about ingredients, for example 'high quality ingredients' or 'sustainably sourced ingredients'. The intent is to prohibit references to specific ingredients, whereas these statements do not refer to specific ingredients and the Code does not regulate such matters. The word 'ingredient' is not prohibited.

Need for explicit prohibition on ingredient information

FSANZ acknowledges the submitter comment regarding the Note in the 2nd CFS proposed variations to Standard 1.2.7 claim prohibitions as being sufficient (now appears as a Note to Division 3 in the primary variation). FSANZ noted in section 6.3.5 of SD3 to the 1st CFS (FSANZ 2022e) that the definition of 'claim' refers to a property of food, which may be an ingredient. However, FSANZ considers a separate, express prohibition for information relating to ingredients is warranted for regulatory clarity (paragraph 2.9.1—28(1)(j) of the primary variation).

4.19.5 Decision

For the reasons stated in this report, FSANZ has decided the label on a package of infant formula or follow-on formula must not contain information relating to ingredients, except for:

- use of the word ‘milk’; or
- a reference in a statement of ingredients; or
- a reference in a declaration or statement expressly permitted or required by the Code.

See paragraph 2.9.1—28(1)(j) of the primary variation.

4.20 Stage labelling

4.20.1 Current regulations

There are no requirements or conditions in the Code relating to the use of stage labelling.

4.20.2 Previous considerations

The labelling issues of line marketing (subsequently referred to as stage labelling) and proxy advertising were first raised by submitters to the FSANZ 2012 CP (FSANZ 2012a) but were not considered further until the 1st CFS (FSANZ 2022e) when the scope of Proposal P1028 was extended to include follow-on formula.

At the 1st CFS, FSANZ discussed stage labelling and proxy advertising and noted stage numbers are used by caregivers to identify age appropriate products for infants but that age information is considered most important for product differentiation.

Following consideration of submitter comments, consumer evidence, a market survey, Codex guidelines, the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF agreement) (Department of Health and Ageing 2022) and other relevant information, at the 2nd CFS (FSANZ 2023d), FSANZ proposed:

- the number ‘1’ for infant formula and the number ‘2’ for follow-on formula would be permitted for use on the label to help caregivers identify that the product is infant formula or follow-on formula, respectively
- if used, the number must appear on the front of the package of the product and be located immediately adjacent to the age statement
- use of the number for the purposes of identifying a product is infant formula or follow-on formula would be prohibited elsewhere on the label.

These conditions were prescribed in section 2.9.1—28 of the 2nd CFS proposed variations.

4.20.3 Submitter comments

Permission

Submitters had mixed views on permissions for stage labelling, with some industry and government submitters supporting the proposed approach and some public health and government submissions having opposing views.

Reasons for not supporting stage number labelling included:

- it sets up a progressive feeding regime that suggests there are nutritional benefits in moving from stage 1 to stage 2 and acts as a marketing strategy for continued use of products (government and public health submitters)
- the approach will encourage line marketing practices as nutrition content claims and health claims are permitted for stage 3 and 4 products (government submitters)
- evidence shows caregivers are confused by stage number labelling and can misinterpret the function of the labelling (government submitter)
- evidence suggests the labelling can lead to the unnecessary use of products (government submitter)
- both infant formula and follow-on formula have virtually the same ingredients (government submitter)
- the labelling is a violation of the WHO Marketing Code (public health submitter).

One government submitter suggested FSANZ consider stage labelling and product differentiation together to counter progressive feeding regimes. For example, prohibiting the use of numbers on stage 3 and 4 products would break the links with infant formula and follow-on formula products.

Submitter comments are in section 7 of Appendix 3.

Location and format

One government submitter strongly supported the proposed requirement for stage labelling to appear adjacent to the age statement information.

Two government submitters did not support the proposed location. One of these submitters viewed the proposed approach as potentially encouraging continuation of formula feeding beyond infancy and early childhood. These submitters suggested the size of the stage labelling should be mandated so it is less prominent than age information (e.g. smaller font size than the age information) and therefore minimises the impact of marketing.

Prohibited representation

One government submitter supported the proposed prohibition of numbers to identify infant formula and follow-on formula except as required in the 2nd CFS proposed variations (see section 4.20.2). One government submitter requested more detail be added to the prohibition to specify sequential stage letters or numbers.

Industry submitters objected to the restriction on the use of stage numbers for a variety of reasons including:

- use of stage numbers on other parts of the package promotes informed choice by supporting product differentiation
- caregivers do not make purchasing decisions solely on information on the front of the package
- some brands use the same product name across multiple stages so the stage number is the main way to distinguish the products
- prescribing the location of stage numbering is inconsistent with international standards.

4.20.4 Discussion

Permission

The labelling regulatory approach for infant formula and follow-on formula in the primary variation includes:

- the requirement to co-locate the stage number (if used) with the relevant age statement (subsection 2.9.1—27(2))
- strengthened provisions for product differentiation (which include the use of stage numbers)(section 2.9.1—15)
- a prohibition for information relating to another product (proxy advertising)(paragraph 2.9.1—28(1)(c) and
- emphasising the existing prohibition of nutrition content, health claims and therapeutic claims for infant formula products in Standard 1.2.7 through a Note to Division 3.

The permission for nutrition content and health claims and the voluntary use of stage numbers on toddler milks (stage 3) and 'growing up' milks (stage 4) is out of scope for Proposal P1028. Similarly, the use of such products by healthy young children when they are intended to address inadequate dietary requirements is also out of scope.

Consumer evidence

Most of the studies and recent reviews cited by submitters were captured in either the rapid systematic evidence summary in the 2nd CFS (M&C Saatchi World Services 2022; Romo-Palafox et al. 2020; Cattaneo et al. 2015) (FSANZ 2023e) or the literature review to the 1st CFS (Berry et al. 2011)(FSANZ 2022f).

Studies not previously captured include Rollins et al. (2023), Baker et al. (2023) and Richter et al. (2022). Rollins et al. (2023) provides a detailed overview of marketing strategies used by commercial formula product companies. Baker et al. (2023) uses political economy research to understand the social, political and economic reasons for the low rates of breastfeeding worldwide. While these studies discuss the occurrence of stage labelling, they do not note any empirical evidence on consumer understanding or behaviour in response to such labelling.

Richter et al. (2022) looked at the influence of claims on toddler milks (e.g. 'brain development' and 'immunity-related' claims) on consumer perceptions, intentions and beliefs about the toddler milk product. The study suggests that claims on toddler milk can influence consumer perceptions and purchase intentions for toddler milk. It does not demonstrate that

the influence of toddler milk claims are transferred to infant formula products as a result of stage labelling and line marketing. However, findings from previous literature reviews indicate that some caregivers who see advertisements for toddler milk believe they have seen advertisements for infant formula products, or associate claims seen in toddler milk adverts with infant formula products (Berry et al. 2010; Berry et al. 2012). However, FSANZ notes the issue of claims on toddler milks is out of scope for P1028.

Composition

Follow-on formula is specifically formulated for infants aged 6–12 months. Because of this it is not suitable for use in infants aged under six months. Compositional differences are required because follow-on formula is not intended as a sole source of nutrition and infants aged from six months have different nutritional needs (for example, higher iron requirements). FSANZ therefore disagrees with the submitter comment that the composition of infant formula and follow-on formula are similar and considers that being able to differentiate the products with stage labelling is appropriate.

WHO Marketing Code

Marketing practices related to infant formula and follow-on formula are controlled by voluntary codes of practice (MAIF Agreement and the INC Code of Practice for the Marketing of Infant Formula in New Zealand (see section 9.1 of SD3 to the 2nd CFS)(FSANZ 2023d)). These codes of practice have incorporated the relevant principles of the WHO International Code of Marketing of Breast-milk Substitutes (the WHO Code) (WHO 1981) through the oversight of Australian and New Zealand governments.

In section 9.3.1 of SD3 to the 2nd CFS (FSANZ 2023d), FSANZ outlined how guidance to the current MAIF Agreement specifies that, in relation to the front of the package/label, 'the use of text, numbers on the label (additional to that required in Standard 2.9.1) to further assist consumers in the identification of age appropriateness of the infant formula product, such as Stage 1 or Stage 2 or the number 1 or 2, is acceptable'.

The findings of the Rapid Systematic Evidence Summary undertaken by FSANZ support this guidance (Attachment 1 to SD3 to the 2nd CFS; FSANZ 2023e).

Location and format

The conclusion from the market survey conducted by FSANZ (see section 9.5.3 of SD3 to the 2nd CFS; FSANZ 2023d) stated the majority of infant formula products included stage labelling that was either both larger and more prominent, or larger and just as prominent as the associated age information.

Despite stage labelling being commonly in a larger font than age labelling, findings from the Rapid Systematic Evidence Summary indicate Australian and New Zealand caregivers generally understand that each formula stage has a specific nutrient composition designed to meet the needs of children of a certain age. Additionally, evidence indicates stage numbers assist caregivers in differentiating products and that they use them together with age statements to make product choices (Attachment 1 to SD3 of the 2nd CFS; FSANZ 2023e).

FSANZ considers co-locating the stage and age information label elements on the front of the package is sufficient to ensure caregivers can differentiate between formula products. Additionally, product differentiation requirements have been strengthened by requiring that infant formula or follow-on formula must be differentiated from each other and other foods by the use of text, pictures and/or colour (subsection 2.9.1—15 of the primary variation) and by

prohibiting information about another product from being on the label of infant formula or follow-on formula (paragraph 2.9.1—28(1)(c) of the primary variation).

The evidence which indicated stage labelling and related marketing may encourage caregivers to continue formula feeding beyond infancy and early childhood came from other countries. It is unclear whether this occurs in Australia and New Zealand, however this issue is not in scope of Proposal P1028.

Prohibited representation

The current version of the MAIF Agreement permits a stage number specific to the product itself on the back of the package (e.g. stage 1 on an infant formula product label). The review of the MAIF Agreement was published in April 2024, however a government response is pending (Department of Health and Ageing, 2024). FSANZ's market survey (see section 9.5.3 of SD3 to the 2nd CFS; FSANZ 2023d) noted that nearly 40% of products included stage labelling on the back-of-pack.

Opposition from government and health professional submitters to the proposed provision to permit stage labelling was, in part, based on existing industry practice of proxy advertising (e.g. referencing stage 2 or stage 3 products on the label of a stage 1 infant formula). However, FSANZ had prohibited proxy advertising on infant formula and follow-on formula in the 2nd CFS proposed variations. This prohibition has not changed (see paragraph 2.9.1—28(1)(c) of the primary variation). Stage labelling for toddler milks (stage 3) and 'growing up' milks (stage 4) is not in scope of P1028.

International standards (Codex) or overseas regulations (EU) are silent on the use of stage numbers for the purpose of product differentiation, while the Codex Standard for Follow-up Formula for Older Infants (2023a) prohibits numbers in relation to proxy advertising.

Consumer evidence indicates age statements and stage numbers are used by caregivers to differentiate between products. Mandatory age statements may appear more than once on the label (via subsection 2.9.1—21(4) of the primary variation). FSANZ considers it is reasonable to also permit stage numbers to appear elsewhere on the label (in addition to the front of the package) to provide more information to assist caregivers to make appropriate product choices. FSANZ has therefore amended the 2nd CFS proposed variations to permit the stage number to appear elsewhere on the label (see subsection 2.9.1—27(3) of the primary variation). However, FSANZ has not extended the co-location requirement for age statements and stage numbers as it is not always practical for this information to appear together elsewhere on the label.

Paragraph 2.9.1—29(1)(n) of the 2nd CFS proposed variations, relating to the prohibition of a number used to identify that the product is infant formula or follow-on formula, except where required with age-statements in accordance with section 2.9.1—28 in the primary variation, has been removed as it is now redundant.

4.20.5 Decision

For the reasons stated above, FSANZ has decided that the number '1' may be used on the label on a package of infant formula and the number '2' may be used on the label on a package of follow-on formula to identify for consumers that the product is infant formula or follow-on formula, respectively.

If the number '1' or '2' is used for this purpose:

- The number must appear on the front of the package of the product and be located immediately adjacent to the relevant age statement. For infant formula, this is the statement indicating the infant formula may be used from birth. For follow-on formula, this is the statement indicating the follow-on formula should not be used for infants aged under six months.
- The number may appear elsewhere on the label in addition to the requirement for it to be located on the front of the package.

See section 2.9.1—27 of the primary variation.

4.21 Prohibited representations – SMPPi

4.21.1 Current regulations

Subsection 2.9.1—24 of Standard 2.9.1 provides the prohibited representations that apply to an infant formula product, including an infant formula product for special dietary use.

4.21.2 Previous considerations

FSANZ's proposed approach at the 1st CFS (FSANZ 2022g) was to not apply the existing prohibited representations for infant formula products to SMPPi. Many of these were considered inappropriate for highly specialised products for use under medical supervision which are not marketed to caregivers of healthy infants.

Submitter responses to this approach were mixed and led FSANZ to further assess whether the prohibited representations currently provided for infant formula products should apply to SMPPi (see section 12 in SD3 to the 2nd CFS; FSANZ 2023d).

At the 2nd CFS, following assessment, FSANZ proposed the following prohibited representations would apply to SMPPi (section 2.9.1—35 of the 2nd CFS proposed variations):

- a picture of an infant
- the word 'humanised' or 'maternalised' or any word or words having the same or similar effect
- the words 'human milk oligosaccharide', 'human identical milk oligosaccharide' or any word or words having the same or similar effect
- the abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect'
- information relating to another food.

The 2nd CFS proposed variations included a Note to section 2.9.1—35 to indicate that the existing prohibition for an infant formula product from making a nutrition content claim, health claim or therapeutic claim in Standard 1.2.7 would apply to SMPPi.

4.21.3 Submitter comments

Industry and government submitters did not support the prohibited representations proposed for SMPPi in the 2nd CFS proposed variations. Industry submitters stated the proposed approach was inconsistent with EU regulations, whereas the government submitter recommended other specified prohibited representations for infant formula and follow-on formula should apply.

Industry submitters also recommended removing the prohibition relating to another food because it may have clinical implications.

The government submitter recommended an explicit prohibition for claims instead of the proposed Note, given the 2nd CFS proposed variations specified that Part 1.2 of the Code does not apply to SMPPi unless the contrary intention appears and a Note to Standard 1.2.7 is ambiguous and not enforceable.

See section 7 of Appendix 3 for submitter comments.

4.21.4 Discussion

International alignment

At the 2nd CFS, FSANZ considered the following prohibited representations in the current standard were consistent with EU Regulation EU 2016/128 (European Commission 2016b):

- a picture of an infant (paragraph 2.9.1—24(1)(a))
- a picture that idealises the use of infant formula product (paragraph 2.9.1—24(1)(b))
- the word 'humanised' or 'maternalised' or any word or words having the same or similar effect (paragraph 2.9.1—24(1)(c)).

FSANZ notes the prohibition relating to a picture that idealises the use of infant formula product was omitted in error in the 2nd CFS proposed variations and should apply to SMPPi for consistency with the EU Regulation. The primary variation therefore includes this prohibited representation (section 2.9.1—45(b)), however, the wording has been amended to reflect Article 8(2) of EU 2016/128, which prohibits 'pictures or text which may idealise the use of the product'.

Following further consideration, FSANZ acknowledges the prohibition relating to the word 'humanised' or 'maternalised' (or similar) has no direct counterpart in Article 8 of the EU Regulation. FSANZ has therefore removed this prohibition to avoid a potential trade restriction that would prevent the importation of SMPPi, which could have negative public health impacts.

FSANZ does not agree with industry submitter recommendations to remove the prohibited representations about human milk oligosaccharide (HiMO and HMO terminology and abbreviations) proposed in the 2nd CFS. These submitters commented that these prohibitions are not consistent with international regulations. However, as FSANZ has previously discussed, the Ministers' decision to permit the addition of HMO substances to all infant formula products (including infant formula for special dietary use) in Application A1155 was subject to the prohibition of HiMO and HMO labelling terminology (FSANZ 2019). The permission for addition will be reviewed within five years from gazettal of A1155[10] (see section 12.3 in SD3 to the 2nd CFS; FSANZ 2023d).

FSANZ is not aware of evidence that HMOs treat certain medical conditions. As such, there is no need for HMOs to be listed as a property or characteristic which makes the food

[10] Australia and New Zealand Ministerial Forum on Food Regulation meeting 27 November 2020 https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/forum-communique-2020-November27

appropriate for a medical purpose and therefore there is no reason for SMPPi to be labelled differently to infant formula and follow-on formula in relation to HMO.

Prohibited representations for infant formula and follow-on formula should apply to SMPPi

A government submitter recommended the following prohibited representations that apply to infant formula and follow-on formula should also apply to SMPPi:

- words claiming that the formula is suitable for all infants
- information relating to the nutritional content of human milk.

FSANZ does not agree with this recommendation for reasons previously noted (see section 12.3 in SD3 to the 2nd CFS; FSANZ 2023d). The specialised nature of SMPPi means they are not intended to replicate human milk and they often need to describe nutrient modifications that make the product suitable for a particular medical condition. FSANZ notes the main supply region for SMPPi, the EU, does not include these prohibitions in its regulations (European Commission 2016b).

FSANZ also considers it is highly unlikely that SMPPi manufacturers would provide such words or information on their product labels, as SMPPi are required to display mandatory statements such as 'use under medical supervision' and identify the medical disease, disorder or medical condition for which the food has been formulated. The sale of these products is also restricted so there is less opportunity for caregivers to be misled that SMPPi are appropriate for healthy infants.

Information relating to another food

FSANZ agrees with submitter comments that prohibited representations relating to another food as proposed in the 2nd CFS, may inadvertently capture other food products that may be clinically appropriate for use in conjunction with SMPPi (e.g. human milk).

SMPPi are required to be used under medical supervision and given the specialised nature of these products, it would be inappropriate (and unlikely) that SMPPi would refer to infant formula or follow-on formula on their labels. The requirement would also likely impose a trade barrier. FSANZ has therefore removed this requirement.

Explicit prohibition for claims

FSANZ agrees with the government submitter that the use of a Note is ambiguous and may not achieve the policy intent that nutrition content and health claims made about a SMPPi are prohibited. It is unclear whether a non-legally binding Note as proposed would override paragraph 2.9.1—30(b)(i) of the 2nd CFS proposed variations, which stated that unless the contrary intention appears, Part 1.2 of Chapter 1 (labelling and other information requirements) do not apply to a SMPPi. For regulatory clarity, FSANZ has removed the Note and included an explicit prohibition for nutrition content and health claims and therapeutic claims (section 2.9.1—46 in the primary variation).

4.21.5 Decision

FSANZ's decision is that the following prohibitions will apply to SMPPi:

- a picture of an infant

- a picture or text that idealises the use of special medical purpose product for infants
- the words ‘human milk oligosaccharide’, ‘human identical milk oligosaccharide’ or any word or words having the same or similar effect
- the abbreviations ‘HMO’ or ‘HiMO’ or any abbreviation having the same or similar effect.

See section 2.9.1—45 of the primary variation.

FSANZ has decided to include an explicit prohibition for nutrition content and health claims and therapeutic claims. See section 2.9.1—46 of the primary variation.

4.22 Mandatory statements – SMPPi

4.22.1 Current regulations

Products formulated for premature or low birth weight infants are required to have a warning statement ‘Suitable only for pre-term infants under medical supervision’ (paragraph 2.9.1—13(2)(a)).

Products for metabolic, immunological, renal, hepatic and malabsorptive conditions must include the following statements on the label (paragraphs 2.9.1—14(2)(b) to (d) and paragraph 2.9.1—14(6)(b)):

- the infant formula product is suitable for infants with these conditions (if other compositional requirements are met)
- the product is not suitable for general use and should be used under medical supervision
- the condition, disease or disorder for which the product has been specially formulated
- the nutritional modification, if any, which have been made to the product
- the amount of lactose and galactose, if an infant formula product is represented as lactose free or low lactose.

Other mandatory statements, such as warning statements, age statements and statements of protein source and dental fluorosis also apply to IFPSDU as they do for infant formula and follow-on formula.

4.22.2 Previous considerations

Statement indicating the nutrient or nutrients which have been modified

At the 1st CFS (FSANZ 2022g), FSANZ proposed to apply the mandatory statements and declarations currently required for adult FSMP in section 2.9.5—10(1), to SMPPi, given these foods are both formulated for a special medical purpose. This included the statement indicating the nutrient or nutrients which have been modified (subsection 2.9.5—10(1)(g)(ii)(A)).

This approach was maintained in the 2nd CFS (FSANZ 2023a). The 2nd CFS proposed variations (section 2.9.1—38(1)(g)(ii)(A)) specified that a statement indicating the nutrient or nutrients which have been modified was required if the food:

- is represented as being suitable for use as a sole source of nutrition and

- has been modified to vary from the compositional requirements for SMPPi in section 2.9.1—32 of the proposed variation such that the content of one or more nutrients falls short of the prescribed minimum or exceeds the prescribed maximum (if applicable).

Required warning statements, advisory statements and other mandatory labelling information

Other FSMP requirements that were proposed to apply to SMPPi at the 1st CFS (FSANZ 2022g) included:

- Advisory statements about:
  - bee pollen, aspartame ('contains phenylalanine'), guarana ('contains caffeine'), propolis, quinine, cola beverages, unpasteurised egg products and unpasteurised milk in items 1, 4, 6 or 9 of the table to section S9—2 and
  - excess consumption of listed polyols and polydextrose in subsection 1.2.3—2(2).
- The warning statement in subsection 1.2.3—3 relating to royal jelly.

As FSANZ received no submitter comments about the required statements, these were maintained in the 2nd CFS proposed variations (subsections 2.9.1—38(2) and (3)).

4.22.3 Submitter comments

Industry submitters did not support the requirement for a statement indicating the nutrient(s) which have been modified because the number of nutrients varies significantly in some products; variations for certain nutrients are not required to be declared under some overseas regulations (so labels will not reflect them); the requirement would pose a trade barrier for imported product; and the information is only particularly relevant to health professionals and could be provided off-label.

Government submitters queried whether the advisory statements relating to bee pollen, aspartame, guarana, propolis, quinine, cola beverages, unpasteurised egg products and unpasteurised milk were applicable to SMPPi. One industry submitter did not support the advisory statement relating to excess consumption of listed polyols and polydextrose as it was inconsistent with international regulatory requirements.

4.22.4 Discussion

Statement indicating the nutrient or nutrients which have been modified

As noted above, the 2nd CFS proposed variations required a statement indicating the nutrient or nutrients which have been modified, consistent with adult FSMP requirements. However, FSANZ agrees there are compositional differences between SMPPi and adult FSMP. SMPPi is required to meet the baseline composition for infant formula (in sections 2.9.1—32 to 2.9.1—41 of the primary variation), which is the most prescriptive formula food regulated by the Code. However, SMPPi need not comply with these compositional requirements to the extent that a variation is required to achieve the product's intended purpose or would otherwise prevent the sale of the food (an alignment with international regulations)(subsection 2.9.1—42 in the primary variation).

There are 61 nutrient requirements for SMPPi, which have associated maximums, minimums, sources, quality scores, units of expression, conversion factors, equivalents, ratios and nutrient interactions. In comparison, FSMP that provide the sole source of nutrition only have 27 nutrient requirements, most of which only have an associated minimum requirement.

FSANZ acknowledges a statement on the product label of SMPPi detailing all modifications would be significantly onerous. FSANZ also notes some SMPPi are sold in small packages for use in clinical facilities. Applying the same FSMP requirements to SMPPi is therefore not fit for purpose and may not fit on a product label.

FSANZ has therefore permitted the statement to be provided in other documentation (subsection 2.9.1—50(g)(ii)(A) of the primary variation).

Required warning statements, advisory statements and other mandatory labelling information

FSANZ agrees the following advisory statements and warning statement proposed in the 2nd CFS are not relevant because these foods and substances would not be added to SMPPi:

- items 1, 4, 6 or 9 of the table to section S9—2 relating to several advisory statements, including those about bee pollen and caffeine
- subsection 1.2.3—2(2) relating to listed polyols and polydextrose
- the warning statement in section 1.2.3—3 relating to royal jelly.

FSANZ has therefore removed the requirement for these statements to apply to SMPPi.

The provision for declarations required by section 1.2.3—4 (relating to listed foods that are allergens) has been retained (paragraph 2.9.1—50(h) of the primary variation).

4.22.5 Decision

FSANZ's decision is to permit the information indicating the nutrient or nutrients which have been modified to be provided in other documentation about the product if it is not provided on the label of a package of SMPPi (subsection 2.9.1—50(g)(ii)(A) of the primary variation).

Requirements for advisory statements required by items 1,4,6 or 9 of the table to section S9—2 and the warning statement required by subsection 1.2.3—2(2), have been removed. However, other advisory statements relating to allergens required by section 1.2.3—4 have been retained (paragraph 2.9.1—50(h) of the primary variation).

4.23 Nutrition information – SMPPi

4.23.1 Current regulations

IFPSDU are subject to the same nutrition information requirements that are required for infant formula and follow-on formula. Section 2.9.1—21 requires a statement of nutrition information (NIS) that includes:

- the average energy content expressed in kJ/100 mL
- the average amount of protein, fat and carbohydrate expressed in g/100 mL
- the average amount of each vitamin or mineral and any other permitted nutritive substance expressed in weight/100 mL (including any naturally occurring amount) and
- if added, the average amount of inulin-type fructans, galacto-oligosaccharides or a combination of these, expressed in weight/100 mL.

There is also a requirement to declare the proportion of powder or concentrate required to reconstitute the formula according to directions (for powdered or concentrated formula) and a declaration of the weight of one scoop.

Section 4.2 of Codex CXS 180-1991 Standard for the Labelling of and Claims for Foods for Special Medical Purposes (Codex 1991) applies to FMSP intended for infants and is given effect by Part B section 9.3 of Codex CXS 72-1981 (Codex 1981).

In particular, Codex CXS 180-1991 specifies that:

- Information on the amounts of protein, carbohydrate and fat in the food shall be expressed in g per 100 g or per 100 ml as sold, as well as per specified quantity of the food suggested for consumption. Information on the amounts of essential and non essential amino acids and/or essential fatty acids may be expressed similarly in metric units as appropriate (section 4.2.3).
- Information on osmolality or osmolarity and/or on acid-base balance shall be given when appropriate (section 4.2.6).

Regulation EU 2016/128 (European Commission 2016b) requires as a mandatory declaration for FSMP:

- The amount of components of protein, carbohydrate, fat and/or of other nutrients and their components, the declaration of which would be necessary for the appropriate intended use of the product (Article 9(1)(b)).
- Information on the osmolality or the osmolarity of the product where appropriate (Article 9(1)(c)).

4.23.2 Previous considerations

At the 1st CFS, FSANZ considered the applicability of nutrition information requirements for FSMP in section 2.9.5—13 to SMPPi. This approach was based on the need for label information to facilitate the safe and effective use of SMPPi and to be flexible to ensure their continued supply (section 3.2.2 in SD4 to the 1st CFS; FSANZ 2022g).

FSANZ's proposed approach was to:

- Apply nutrition information requirements in paragraph 2.9.5—13(a) and subparagraphs 2.9.5—13(b)(i) and (ii) to SMPPi, which require nutrition information be expressed per given amount of food in relation to the minimum or average energy content; and the minimum amount or average quantity of protein, fat and carbohydrate; and any vitamin, mineral or electrolyte that has been used as a nutritive substance in the food.
- Not apply nutrition information requirements in subparagraphs 2.9.5—13(b)(iii) and (iv), which require the declaration of any substance used as a nutritive substance listed in the table to section S29—20, as well as declaring the amount of any other substance in respect of which a nutrition content claim has been made. These subparagraphs were excluded because the table to section S29—20 is specific to FSMP composition and nutrition content claims are prohibited on infant formula products, including SMPPi.
- Add a general requirement to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose.

Submitters to the 1st CFS that commented on this issue noted their support for this approach.

Nutrition information requirements for SMPPi, that were based on FSMP requirements as proposed at the 1st CFS, were set out in subsection 2.9.1—41(1) of the 2nd CFS proposed variations. The intent in the 2nd CFS was to require the presence of energy and certain substances to be declared while providing flexibility for variations in the nutrition information.

4.23.3 Submitter comments

Industry submitters did not support the proposed nutrition information requirements, stating it does not align with international regulations. The effect would be to prohibit certain nutrition information that is permitted on shared international labels, including:

- amounts of essential and non-essential amino acids and/or essential fatty acids
- osmolality or osmolarity and/or on acid-base balance
- the components and/or modification of proteins, fats or carbohydrates or other nutrients whereby its presence is appropriate for the product's intended medical purpose.

One industry submitter proposed amendments to allow for all nutritive substances to be included in the NIS (rather than those that are only added as proposed in paragraph 2.9.1—41(1)(c) of the 2nd CFS proposed variations), including those that are present to achieve the product's intended medical purpose.

See section 7 of Appendix 3 for submitter comments.

4.23.4 Discussion

SMPPi are low volume products that are predominantly imported from the EU. Given they are produced in low volumes, manufacturers use shared labels for different markets.

Codex standards and EU regulations expressly require nutrition information about macronutrient components when their declaration is appropriate, however the specified text differs. Codex (Codex 1991) refers to essential and non-essential amino acids and/or essential fatty acids, whereas the EU regulation (European Commission 2016b) refers to components of protein, carbohydrate, fat and/or of other nutrients and their components. Both regulations require information about osmolality or osmolarity where appropriate, however only Codex specifies the declaration of acid-base information where appropriate.

FSANZ acknowledges submitter comments that the 2nd CFS proposed variations:

- do not provide sufficient clarity relating to permissions for subgroup nutrients (e.g. fatty acids, amino acids) to be declared in the NIS and
- omit specific permissions for nutritional attributes (e.g. osmolality/osmolarity).

The lack of clarity and omissions may present a trade barrier and interrupt the supply of imported SMPPi.

FSANZ agrees it is important to align with these international regulations and standards to permit this additional nutrition information on product labels and therefore ensure the importation of SMPPi continues. A new provision has therefore been added to permit this additional information if it is necessary for the use of the SMPPi for its intended purpose (paragraph 2.9.1—53(1)(d) of the primary variation).

4.23.5 Decision

FSANZ's decision is to permit the declaration of the following additional nutrition information, if the declaration is necessary for the use of the SMPPi for its intended medical purpose:

- information on sub-group nutrients of protein, fat and/or carbohydrate
- osmolality and osmolarity
- acid-base balance.

See paragraph 2.9.1—53(1)(d) of the primary variation.

4.24 Supplier name and address – SMPPi

4.24.1 Current regulations

General requirements for the supplier name and address in section 1.2.2—4 apply to IFPSDU.

4.24.2 Previous considerations

Under the proposed regulatory framework at the 1st CFS, FSANZ considered the applicability of FSMP labelling requirements in Standard 2.9.5 to SMPPi (FSANZ 2022g).

FSANZ proposed the FSMP labelling requirements for transportation outers in subsection 2.9.5—17 (and given effect through paragraph 2.9.5—8(4)(a)) would apply to SMPPi and the generic requirements for the name and business address in section 1.2.2—4 would not apply (see section 3 in SD4 to the 1st CFS; FSANZ 2022g). The intent was to permit Australian or New Zealand supplier information for SMPPi to be provided in accompanying documentation, as imported products usually include overseas supplier information on the physical label.

One government submitter opposed this approach. However, FSANZ indicated it was maintaining the approach for the reasons stated in Table 7 of SD3 to the 2nd CFS.

The 2nd CFS proposed variations therefore set labelling requirements for SMPPi in a transportation outer that were consistent with provisions for adult FSMPs (section 2.9.1—43 of the proposed variation). This included the requirement that if packages of SMPPi are contained in a transportation outer (as defined in subsection 1.1.2—2(3)), the name and address of the supplier (as specified in section 1.2.2—4) must be:

- contained in a label on the transportation outer; or
- contained in a label on a package of the food for sale and clearly discernible through the transportation outer; or
- provided in accompanying documentation.

4.24.3 Submitter comments

Government submitters did not support the approach that SMPPi be exempt from the requirement for the name and address of the supplier on the physical label. They considered the provision of this information on a transportation outer was ineffective for enforcement in the case of a recall and would not be available for caregivers. One government submitter considered that over stickering supplier information would outweigh the potential risks to infants of a delayed recall.

See submitter comments in section 7 of Appendix 3.

4.24.4 Discussion

FSANZ acknowledges submitter concerns, however, does not consider it necessary to mandate the provision of supplier information on the physical label.

FSANZ is aware that imported SMPPi typically have shared international labels for multiple countries where free label space is extremely limited and it is common practice for supplier information to be provided off-label. The regulatory approach proposed in the 2nd CFS (see section 4.24.2) provides SMPPi manufacturers with flexibility so that products imported for the domestic market do not need to be relabelled.

As noted previously, the provision for providing supplier information is consistent with the requirements for adult FSMPs. During the development of Standard 2.9.5, information sought from industry confirmed that imported adult FSMP do not always have the Australian or New Zealand supplier details on each package. Industry submitters commented that requiring this information on individual packages of FSMP would impose a significant cost burden due to re-labelling for the domestic market for the reasons discussed above e.g. shared labels for multiple countries (section 2.1.3 in SD3 to the Final Assessment Report (FAR) for Proposal P242 Food for Special Medical Purposes; FSANZ 2012c). SMPPi are labelled in the same manner. More recent advice from industry has indicated SMPPi manufacturers are unlikely to change their labels because the size of the Australian and New Zealand market is too small.

As part of its consideration of adult FSMP regulation, FSANZ considered that other labelling elements (name of the food, lot identification and date mark) would provide adequate information in the case of a food recall. Restricting the locations from which FSMP are permitted to be sold was considered helpful for assisting the tracing of products. FSANZ considered this approach was consistent with reducing the cost burden associated with re-labelling this category of foods, while maintaining adequate identification (section 2.2.2 in SD3 to the Final Assessment Report for Proposal P242; FSANZ 2012c). FSANZ considers this approach is applicable to SMPPi, given the sale of these products will also be restricted.

As noted previously, the majority of SMPPi are low volume, highly specialised products imported from the EU, with a few that are imported from the US. SMPPi manufacturers follow stringent production methods to ensure their products are safe for vulnerable infants to consume. There are few manufacturers of SMPPi and they are generally the same manufacturers that make adult FSMP. SMPPi are made available to pharmacies through specific wholesalers in Australia and New Zealand. FSANZ is unaware of any individual pharmacies choosing to import products directly from overseas countries.

Given these products are sourced through known wholesalers, it is not necessary for the name and address of the supplier to be on the physical product label. Further, highly specialised products are required to be used under medical supervision and the majority of products are only available under prescription. Should a recall occur, the pharmacy will be able to rely on customer records. Pharmacies must also comply with their own regulations and reporting measures.

In targeted consultation following the publication of the 2nd CFS, a government submitter suggested a requirement for over-stickering of imported product labels before they are sold. This issue was also noted in submitter comments to the 2nd CFS (see section 4.24.3).

FSANZ notes subsection 1.2.1—22(2) of the Code states that ‘a person who sells a food that is packaged, or deals with a packaged food before its sale, may re-label the food if the label

contains incorrect information, by placing a new label over the incorrect one in such a way that: the new label is not able to be removed; and the incorrect information is not visible'.

FSANZ considers requiring such a provision to over-sticker SMPPi would be onerous and costly for the supplier, although there is nothing to preclude suppliers from voluntarily doing so. Further, FSANZ considers setting such a specific requirement is unnecessary as there are other risk management measures that can be relied upon during a recall (e.g. other labelling elements, pharmacy records and known wholesalers of SMPPi).

In regard to domestically manufactured SMPPi, FSANZ understands these products would include an Australian supplier name and address on the physical label and be made available through the same wholesale suppliers as for imported products.

4.24.5 Decision

FSANZ has decided that if packages of SMPPi are contained in a transportation outer, the name and address of the supplier must be:

- contained in a label on the transportation outer; or
- contained in a label on a package of the food for sale and clearly discernible through the transportation outer; or
- provided in accompanying documentation.

See subsection 2.9.1—55 of the primary variation.

5 Risk communication

5.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a comprehensive communication strategy to this proposal.

The 1st CFS was open from 4 April to 17 June 2022, with 32 submissions received. The 2nd CFS was open from 26 April to 7 July 2023 with 34 submissions received. Submissions were also called through six public consultations in 2012, 2016, 2017, 2021, 2022 and 2023, each focusing on different aspects of the regulation of infant formula products. Further information is detailed in section 1.6 and Table 1.6.1 of the 2nd CFS. Targeted consultation with stakeholders was also undertaken at a number of stages throughout the proposal. Subscribers, interested parties and members of the public were notified about the public consultations via the FSANZ Notification Circular, media releases, FSANZ's social media channels and Food Standards News.

In its assessment and finalisation of this proposal, FSANZ had regard to all submissions received. FSANZ acknowledges the time taken by individuals and organisations to make a submission. All comments are valued and contribute to the rigour of our assessment.

5.2 World Trade Organization (WTO)

As members of the WTO, Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

Amendments in the Code to update the regulation of infant formula products may have a significant effect on international trade due to differences in labelling and composition and in turn require manufacturers to reformulate and update labels specifically for the Australia and New Zealand markets. For this proposal, FSANZ made a notification to the WTO in accordance with the WTO Agreement on Technical Barriers to Trade. Comments were received from one member nation and these are addressed in section 9 of Appendix 3.

In accordance with Australia and New Zealand's obligations, FSANZ has developed an addendum to the initial WTO notification and this will be notified to the WTO after gazettal.

6 FSANZ Act assessment requirements

When assessing this proposal and in the development of the approved draft food regulatory measure, FSANZ had regard to the following matters in Section 59 of the FSANZ Act:

- whether costs that would arise from the variation outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation (paragraph 59(a))
- whether other measures (available to the FSANZ or not) would be more cost-effective than the variation (paragraph 59(b))
- any relevant New Zealand standards (paragraph 59(c))
- any other relevant matters (paragraph59(d)).

FSANZ's consideration of the above matters is summarised below.

6.1 Consideration of costs and benefits and preparation of a Decision RIS

In assessing the proposal, FSANZ had regard (as required by paragraph 59(a) of the FSANZ Act) to whether the costs that would arise from the proposal outweigh the direct and indirect benefits.

FSANZ also met impact analysis requirements applying to national standards setting bodies.[11]

A Decision Regulation Impact Statement (RIS) has been prepared (provided as SD2) and contains FSANZ's analysis of both:

- the costs and benefits, as required by the FSANZ Act
- broader impact analysis questions, to meet impact analysis requirements.

The Office of Impact Analysis has assessed the quality of the regulatory impact analysis in the Decision RIS as compliant with impact analysis guidelines, containing an adequate level of analysis that is commensurate with the significance of the impacts.

This section summarises the key impacts of the primary and consequential variations. For the full analysis, refer to SD2 – Decision RIS.

[11] The requirements are described within the Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies

6.1.1 Decision RIS findings – benefits exceed costs, objectives of the proposal achieved

The Decision RIS concluded that option 2 (the final set of variations) is the best option (relative to the status quo), because it:

- is expected that benefits will exceed costs, see below discussion on:
  - who is impacted and how
  - break-even analysis
- has been subject to comprehensive consultation with stakeholders
- achieves the objectives of the proposal, which are:
  - the protection of infant health and safety
  - the provision of information to enable informed choice and ensure caregivers are not misled
  - consistency with advances in scientific knowledge
  - industry innovation and/or trade is not unduly hindered.

6.1.2 Who is impacted and how

Table 8 lists all major impacts identified, by stakeholder group. They key impacts are described in the following sections.

Table 8: Major costs and benefits, by group

Formula fed infants and their carers	
Benefits	Health improvements from products that better meets infants' development needs
	Net improvement in the ability to compare and choose products, removal of misleading claims
	Better advice at point of sale for specialised products which could result in both improved health outcomes and avoidance of unnecessary costs if specialised formula is not desirable or needed
	Clearer instructions on product labels leading to reduced risk of unsafe preparation
Infant formula industry	
Benefits	Improved international harmonisation increasing cost efficiencies of manufacturing[12]
	Improved regulatory certainty
	Increased sales (SMPPi, pharmacies)

[12] These cost savings may flow through the supply chain, potentially reducing costs for retailers and/or carers. The savings may be passed on in part or in full.

	Costs	Reformulation costs[13] Relabelling costs[13] Loss of sales (SMPPi, supermarkets) Transition costs (for example, increased calls to hotlines)
Government		
	Benefits	Improved ability to enforce standards Savings in health care expenses
	Costs	Some small costs of adapting to new standards

6.1.3 Key benefit of proposal – health improvements for formula-fed infants

The most significant benefit of this proposal is improved health outcomes for infants, primarily resulting from improved infant formula composition in line with scientific developments since the current set of standards were implemented. These health improvements are lifelong, given the vital role nutrition plays early in an infant's life.

Due to a lack of data and the technical complexity of calculating health benefits, the value of the benefit could not be quantified.

However, the benefits are expected to be significant when considered at a population level.

6.1.4 Benefit per infant required to break-even on the quantified costs

Because the benefits could not be quantified, FSANZ has performed a break-even analysis.

This is the benefit per infant required for the changes to at least break-even on the quantified costs (which are discussed below).

FSANZ has calculated that society will only need to receive a benefit of approximately A$26–27 per infant to break-even on the quantified costs[14].

FSANZ considers it likely that this quantum of benefit will be achieved, especially given the lifelong nature of the health benefits arising from this proposal.

6.1.5 Key costs for industry – reformulating and relabelling products

The total quantified cost of this proposal is a one-off cost to the infant formula industry of A$46–48 million.

This represents the cost of:

- reformulating affected infant formula products – A$44 million one-off cost
- relabelling affected infant formula products – A$2–4 million one-off cost.

The other major cost of this proposal is the restriction on sale.

[13] These cost increases may flow through the supply chain, potentially increasing costs for retailers and/or carers. The cost increases may be passed on in part or in full.

[14] This is calculated by dividing the total quantified cost of the proposal by the number of infants expected to be born and fed infant formula (exclusively or in combination with breastmilk) over the first 10 years of the change in the standards. Refer to SD2 for more information.

The restriction on sale will result in some retailers (primarily supermarkets) losing the ability to sell SMPPi. The loss of sales will be mitigated where consumers switch to purchasing general infant formula. Any lost sales for supermarkets will be gained by pharmacies and other responsible institutions.

The net impact to the industry overall of restricting sale could not be quantified. The impact will depend on the relative profit margins of specialty products (sales of which may reduce) compared to general infant formula products (sales of which may increase).

The above costs may be passed on to consumers in full or in part in the form of higher prices, however the extent that manufacturers will or be able to pass on the costs is unknown.

6.1.6 Short term industry costs may be offset by longer term cost savings

These short-term one-off costs could be offset by potential longer-term costs savings for industry (which may also be passed on to consumers) arising from greater alignment with international standards and increased regulatory certainty.

6.2 No other measures that are more cost effective

Paragraph 59(b) of the FSANZ Act required FSANZ to have regard to whether other measures (available to FSANZ or not) would be more cost-effective than the proposal.

FSANZ considers that there are no other measures that would be more cost-effective.

6.3 No other relevant New Zealand standards

Section 59(c) of the FSANZ Act required FSANZ to have regard to any relevant New Zealand Standards when developing this proposal.

This proposal proposes to amend the current joint Australia New Zealand standards that regulate infant formula products. There are no other relevant New Zealand standards.

6.4 Any other relevant matters

Paragraph 59(c) of the FSANZ Act required FSANZ to have regard to any other relevant matters when assessing the proposal.

Other relevant matters are considered in the following section.

6.5 Subsection 18(1) objectives

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

6.5.1 Protection of public health and safety

Infant formula products are the only safe and suitable alternative to breast milk. Standard 2.9.1 and Schedule 29 (and other related standards) set specific compositional and labelling requirements to ensure this. The primary and consequential variations approved by FSANZ aim to update these standards where appropriate or necessary to ensure products remain safe. Where relevant, FSANZ assessed scientific evidence related to the protection of the health and safety of infants who consume infant formula products. The conclusions (listed

throughout the 1st and 2nd CFS and SDs) underpin the risk management options and the primary and consequential variations to the Code.

6.5.2 The provision of adequate information relating to food to enable consumers to make informed choices

Existing labelling requirements in Divisions 4 and 5 of Standard 2.9.1 have been reviewed and varied where appropriate to ensure adequate information is provided to consumers to enable informed choices.

6.5.3 The prevention of misleading or deceptive conduct

FSANZ has reviewed and varied existing labelling requirements in Standard 2.9.1 to reduce the potential for misleading or deceptive conduct.

6.6 Subsection 18(2)

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ used an internationally-accepted risk analysis framework in our decision making and the best available scientific evidence to assess this proposal. This approach took into account the importance of the role of formula as a potential sole source of nutrition and the vulnerability of the formula-fed infant population. Where evidence was lacking, particularly in relation to consumer behaviour, FSANZ commissioned or undertook research reviews and utilised these reviews in the assessment.

In addition to FSANZ's formal risk assessment, the risk analysis component comprised:

- Microbiological safety of powdered infant formula: Effect of water temperature on risk (Attachment to SD1, 1st CFS; FSANZ 2022c)
- Microbiology risk assessment of L(+) lactic acid producing microorganisms, which evaluated relevant, appropriately designed studies, including clinical trials, case reports, other relevant epidemiological studies and studies evaluating safety (SD2, CP1; FSANZ 2021c)
- Microbiological safety assessment of powdered infant formula which used the risk assessment model developed by the FAO/WHO to estimate the relative risk that the main microbiological hazard identified—*Cronobacter* spp. (formerly known as *Enterobacter sakazakii*)—poses to infants from intrinsically contaminated powdered infant formula (SD3, CP1; FSANZ 2021d)
- Food additive safety assessment, which included evaluation against Joint FAO/WHO Expert Committee on Food Additives (JECFA) recommendations, food additive permissions in Codex and the EU regulation (SD1, CP1; FSANZ 2021b)
- Comparative nutrition assessment of compositional requirements in the Code and Codex Alimentarius Standard 72-1981 Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex STAN 72-1981; Codex 1981) (SD1 Attachment A1.1, 2016 CP; FSANZ 2016d)
- Comparative nutrition assessment of compositional requirements in the Code and those set by the European Commission Delegated Regulation (EU) 2016/127 (European Commission 2016a) (SD1, CP2; FSANZ 2021g)

- Comparative nutrition composition assessment of the Code, Codex STAN 72-1981 and EU 2016/127 against substances naturally present in human milk.

The risk management component comprised:

- Analysis of current stage labelling and proxy advertising practices of infant formula products in Australia and New Zealand (Attachment 2 to SD3, 2nd CFS; FSANZ 2023f)
- Consideration of risk assessment conclusions (1st CFS, 2nd CFS, approval report)
- Consideration of costs and benefits (SD5; 1st CFS; FSANZ 2022h), Impact Analysis (SD4, 2nd CFS; FSANZ 2023g) and Decision Regulation Impact Statement (approval report, 2024)
- Rapid Systematic Evidence Summary on Infant Formula Stage Labelling and Proxy Advertising (Attachment 1 to SD3, 2nd CFS; FSANZ 2023e)
- Consumer research on caregiver's beliefs about the risk of improper infant formula preparation and their understanding of infant formula preparation risks (NZFS, 2020)
- Consumer research in relation to safe preparation and use of infant formula (SD4, CP; FSANZ 2021e)
- Consumer research on infant formula labelling (Attachment to SD3, 1st CFS; FSANZ 2022f)
- Labelled composition available on the retail market in Australia and New Zealand (Appendix 1, CP; FSANZ 2016c)
- Consumer research in relation to safe preparation and use of infant formula (SD4, CP1; FSANZ 2021e)
- Consumer evidence review on the restriction on sale of SMPPi (approval report, 2024).

- **the promotion of consistency between domestic and international food standards**

A primary objective of this proposal is to align with international regulations where appropriate and safe Codex is the main regulator to which FSANZ has compared requirements. Where relevant, alignment with Codex, along with other international regulations is referenced throughout this assessment.

- **the desirability of an efficient and internationally competitive food industry**

The primary and consequential variations will clarify and update current standards and align with international standards where appropriate and safe. This supports efficiency and competitiveness in the food industry.

- **the promotion of fair trading in food**

Any amendment to the standards that regulate the infant formula product industry can have implications for domestically manufactured products in both the domestic and international markets and for internationally manufactured products for the domestic market.

Potential implications to the Australian and New Zealand domestic markets are detailed in SD2, section 6.1 of this report and section 8 of Appendix 3.

For international markets, FSANZ has obligations as a member of the WTO to identify any potential trade issues, see section 5.2 and section 9 of Appendix 3 for details.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

FSANZ had regard to the policy guideline on the Regulation of Infant Formula Products in the assessment of this proposal. The policy guideline includes specific policy principles relating to composition, labelling and advertising, as well as overarching principles. The section below summarises the assessment against these specific policy principles for the proposed changes to all eight standards and five schedules associated with P1028.

Table 9: P1028 assessment against specific policy principles

Specific Policy Principles	Assessment
Overarching principles	
(a) The regulation of infant formula products should recognise that breastfeeding is the normal and recommended way to feed an infant.	FSANZ has acknowledged in its public reports that breastfeeding is the recommended way to feed an infant, however 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.
(b) The regulation of infant formula products should not be inconsistent with the national nutrition policies and guidelines of Australia and New Zealand that are relevant to infant feeding.	In reviewing the requirements for infant formula products in Standard 2.9.1, FSANZ has had regard to: • Australian Infant Feeding Guidelines • Healthy Eating Guidelines for New Zealand Babies and Toddlers • Australian and New Zealand NRVs. • Healthy Eating Guidelines for New Zealand Babies and Toddlers (0-2 years old) These documents are cited where relevant in the 1st and 2nd CFS, approval report and relevant SD[i]s.
(c) The regulation of infant formula products should be based on risk analysis, taking into account the vulnerability of the population for whom they are intended and the importance of these products in the diets of formula-fed infants.	Infants are recognised as a vulnerable population group, hence infant formula products continue to be tightly regulated in the Code. FSANZ used an internationally accepted risk analysis framework in our decision making. This takes into account the importance of the role of formula as a potential sole source of nutrition and the vulnerability of the formula-fed infant population. See section 6.6 for details on FSANZ's risk analysis.
Composition	
(d) The composition of infant formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole	FSANZ's 2016 Nutrition Assessment evaluated the best available scientific evidence on physiological, metabolic and biochemical processes that underlie normal growth and development in infants. This included evidence obtained from reports published by key review panels, published primary research and other vitro evidence and infant trials relevant to the Australian and New Zealand (ANZ) population.

Specific Policy Principles	Assessment
source of nutrition up to six months of age. AND (e) The composition of follow-on formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical or functional outcomes) of healthy full term breastfed infants at the appropriate age when follow-on formula used as the principal source of liquid nourishment in a progressively diversified diet.	The 2016 Nutrition Assessment also evaluated the Codex STAN 72-1981 provisions for each nutrient against a set of criteria. The assessment criteria were as follows: • origin of the current standards • recommendations of key expert bodies • comparison with human milk concentrations • estimation of intakes and comparison with Australia and New Zealand NRVs for adequate and excess intakes • physiological, biochemical or functional outcomes • identification of new or emerging scientific evidence. The 2021 Nutrition Assessment built on the 2016 Nutrition Assessment and evaluated the EU 2016/127 provisions for each nutrient against a set of criteria. The assessment criteria were as follows: • outline of the scientific basis of the current standards • comparison with human milk concentrations, focusing on Australia and New Zealand populations • comparison with EFSA (2014) recommendations and FSANZ (2016) proposed levels • estimation of intakes and comparison with Australia and New Zealand NRVs for adequate and excess intakes (non Australia and New Zealand NRVs were used in circumstances when an Australia and New Zealand value was not available) • other relevant factors unique to the nutrient of interest such as the impact of manufacturing or other nutrients on the nutrient's bioavailability, history of apparent safe use, or the Australia and New Zealand infant or maternal population • when a potential risk was identified based on comparisons to human milk concentrations and NRVs, a review of scientific evidence which focused on primary research published after the FSANZ 2016 assessment and on Australia and New Zealand populations • if a potential risk was identified, a comparative assessment of the risk associated with the compositional requirements of the Code and Codex STAN 72-1981 was conducted. Both nutrition assessments evaluated evidence based on infants aged 0–12 months. Normal growth and development was considered through the FSANZ 2016 and 2021 nutrition assessments, noting measures of growth relate to both safety and favourable health effects. Given the complexities and ethical challenges in infant feeding research, FSANZ notes that comparisons of anthropometric measures (length, weight, head circumference) should consider control and intervention groups as well as intervention groups and

Specific Policy Principles	Assessment
	breastfed reference group. The assessment included infant studies which assessed growth concluding that there are no negative impacts on physical growth throughout infancy. The above assessments concluded that the proposed composition for infant formula products is safe, suitable for the intended purpose and will achieve as closely as possible the normal growth and development of healthy full term exclusively breastfed infants when infant formula is used as the sole source of nutrition for up to six months of age and continued use for up to 12 months of age alongside complementary feeding.
(f) The essential composition of infant formula and follow-on formula should be prescribed in regulation and must satisfy the nutritional requirements of infants.	Proposal P1028 – Infant Formula has reviewed and approved updated essential composition and voluntary permissions for infant formula and follow-on formula. As noted above, the FSANZ 2016 and 2021 nutrition assessments concluded that the proposed composition satisfies the nutritional requirements of Australia and New Zealand infants and ensures normal growth and development.
(g) Compositional requirements for infant formula and follow-on formula products should only be mandated in regulation where there is sufficient evidence to demonstrate that they are safe and essential for normal growth and development of infants.	See comments for specific policy principles (d), (e) and (f).
(h) The composition of breast milk should be used as a primary reference for determining the composition of infant formula and follow-on formula.	FSANZ's 2016 and 2021 nutrition assessments used human milk as the primary reference for determining compositional requirements of infant formula products (FSANZ 2016; FSANZ 2021). Further to this, comparison of human milk from Australian and New Zealand mothers was used where available.
(i) Pre-market assessment, relative to principles (d) and (e), should be required for any substance proposed to be used in infant formula and follow-on formula that: i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or ii. has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.	Policy principle (i) sets the requirements for pre-market assessment for any new substance proposed to be used in infant formula and follow on formula. With regard to pre-market assessment requirements, all infant formula products sold in Australia and New Zealand must meet the applicable composition and labelling requirements of general foods set out in the Code. This includes the requirements in subsections 1.1.1—10(5) and 1.1.1—10(6) of the Code, which require that a food for sale must not consist of, or have as an ingredient or a component, a novel food, a food used as a nutritive substance[15], food produced using gene technology, food additive or processing aid, unless expressly permitted by the Code. There has been no change to these requirements via Proposal P1028. FSANZ has reviewed the current compositional requirements and no new substances are proposed to be added. In response to stakeholder feedback, FSANZ has

[15] A definition for 'used as a nutritive substance' is given in section 1.1.2—12. Permissions for the use of nutritive substances other than vitamins and minerals in infant formula products are listed in section S29—5.

Specific Policy Principles	Assessment
	made several changes to Standard 1.5.1 Novel Foods and Schedule 25 permissions to improve regulatory clarity for the regulation of novel food and nutritive substances in infant formula products.
(j) Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated beneficial role in the normal growth and development of infants or children, or a technological role, taking into account, where relevant, the levels of comparable substances in breast milk. A substance's role in normal growth and development is substantiated where there is appropriate evidence to link the physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood. Particular caution should be applied by the Authority where such links are less clear.	See comments for specific policy principle (i).
Labelling and advertising	
(k) The labelling and advertising of infant formula products should be consistent with the World Health Organization International Code of Marketing of Breast Milk Substitutes (*WHO Marketing Code*) as implemented in Australia and New Zealand.	FSANZ has reviewed existing generic requirements in Part 1.2 of the Code (e.g. labelling of ingredients, lot identification) and specific requirements in Standard 2.9.1 (e.g. directions for preparation and use, prohibited representations) that are consistent with the WHO Marketing Code. FSANZ is proposing: • these labelling requirements primarily remain unchanged • minor changes to some provisions to assist caregivers' understanding and use of infant formula products. Proposed changes for certain directions for preparation and use (including a new direction), a warning statement to follow instructions exactly and clarifications to the protein source statement are detailed in SD1 to the 1st CFS (FSANZ 2022b). FSANZ is also proposing a consistent, prescribed format for declaring nutrition information and clarifications for ingredient declarations and certain nutrient declarations to assist caregivers when making product choices and for regulatory certainty regarding prohibited representations as detailed in SD3 to the 1st CFS (FSANZ 2022e) and across the 2nd CFS and this approval report.
(l) The labelling and advertising of infant formula products should not represent those products as an equivalent to, or better than, breast milk.	Existing provisions in section 2.9.1—24 Prohibited representations are proposed to be retained.

Specific Policy Principles	Assessment
(m) The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products.	See comments for specific policy principle (k).
(n) The Authority should: i. ensure that the prohibitions and restrictions on nutrient content, health, therapeutic and prophylactic claims in the Food Standards Code are clear and effective for infant formula products; and ii. consider whether the current labelling regime is leading to consumers being misled about the quality or effectiveness of an infant formula product.	The existing prohibition for nutrition content claims and health claims for infant formula products remains unchanged. Additional labelling considerations relevant to policy principle (n) include prescribing the format of the nutrition information statement to clearly indicate mandatory nutrition information and permitted optional nutrients and substances. FSANZ is also proposing whey and casein and certain polyunsaturated fatty acids that are currently permitted by Standard 2.9.1, may be declared as additional nutrition information to assist health professionals, however the format of these declarations would be prescribed.
Infant formula products for special dietary uses	
(o) IFPSDU must be safe, suitable and meet the nutritional requirements to support the growth, development and dietary management of the infants for whom they are intended.	See comments for specific policy principles (d), (p) and (q).
(p) The composition of IFPSDU should be based on appropriate scientific evidence.	FSANZ has proposed that IFPSDU, now re-classified as SMPPi, may deviate where required to achieve the product's intended medical purpose or would otherwise prevent the sale of the food. Care must be taken by food businesses to formulate products for specific dietary uses. Proposed changes are discussed across the 1st and 2nd CFS and this approval report and associated SDs.
(q) The labelling and advertising of IFPSDU should clearly specify the special dietary or medical uses for which the product is intended.	FSANZ has mostly aligned specific labelling requirements for SMPPi with requirements in Standard 2.9.5. These provisions include requirements for a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated. Proposed changes are discussed in SD4 to the 1st CFS (FSANZ 2022g; FSANZ 2023a, approval report, 2024).

Specific Policy Principles	Assessment
The regulation of infant formula products in Australia and New Zealand should be consistent to the greatest extent possible with: • relevant World Health Organization agreements; and • relevant World Trade Organization agreements, Codex standards and guidelines.	A primary purpose of the proposal is to align Standard 2.9.1 and Schedule 29 with international standards or overseas regulations, where appropriate and safe. Comparison with Codex standards and EU regulations has been described throughout the 1st and 2nd CFS, associated SDs and this approval report is cited where relevant. This includes relevant international regulations for infant formula and FSMP including: - Commission regulation 1274/2013 - EU 13.1.5.1 EU Regulations food category - European regulations for FSMP, Commission Delegated Regulation 2016/128 - US Infant formula Act - Codex Alimentarius Standards for Infant Formula and Formulas for Special Medical Purposes Intended for Infants: Codex Stan 72-1981 and Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes Codex Stan 180-1991 - Alignment with the Australian and New Zealand government's commitments to the World Health Organisation's (WHO) Code of Marketing of Breast-milk Substitutes.

FSANZ has also had regard to the policy guideline on the intent of Part 2.9 – Special Purpose Foods of the Code. The policy guideline includes specific policy principles for standards contained within Part 2.9 of the Code.

Table 10: P1028 assessment against specific policy principles on the Intent of Part 2.9

Specific Policy Principles	Assessment
a) Special purpose foods should be targeted to specific population groups who meet the criteria outlined in the policy guideline.	Special purpose foods relevant to this application are infant formula products including infant formula, follow-on formula and SMPPi. Infant formula and follow-on formula are the only safe and nutritious substitute for breast milk for infants who are not breastfed. For this reason they are regulated as special purpose foods with the most prescriptive requirements of any food category to ensure the protection of public health and safety of the vulnerable infant population. 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 infant formula or follow-on formula is not suitable.

Specific Policy Principles	Assessment
b) The composition of special purpose food should be consistent with the intended purpose.	Compositional requirements are based on the assumption that infant formula is used as the sole source of nutrition while follow-on formula constitutes the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months. The composition of SMPPi is based on the essential composition of infant formula and only deviates where required to achieve the product's intended medical purpose or would otherwise prevent the sale of the food.
c) Adequate information should be provided, including through labelling and advertising of special purpose foods.	The proposed labelling requirements for infant formula products are detailed in SD1 (FSANZ 2022b), SD3 (FSANZ 2022e) to the 1st CFS, SD3 to the 2nd CFS (FSANZ 2023d) and this report. These requirements will enable consumers to make informed purchasing decisions. Labelling information provided on SMPPi must also facilitate the safe and effective use of these products with infants whose medical conditions make them more vulnerable than healthy infants. The proposed labelling requirements for SMPPi are detailed within SD4 to the 1st CFS (FSANZ 2022g) specifically and further in the 2nd CFS, associated SDs and this approval report.
d) Consideration, where appropriate, should be given to application of controls to restrict access to a special purpose food on the basis of risk to public health and safety.	Access to infant formula products on the market is currently not restricted. In the proposed regulation, sale of SMPPi will be restricted to be sold to a consumer, other than from or by a medical practitioner or dietitian, a medical practice, pharmacy or responsible institution (defined in the Code) or a majority seller of that special medical purpose product for infants. SMPPi are to be used under medical supervision. Proposed changes are detailed across the 1st and 2nd CFS, the approval report and associated SDs.

7 Transitional arrangements

The primary and consequential variations are subject to transitional arrangements outlined in section 4 of the primary variation. These transitional arrangements will extend to all amendments to the Code made by P1028 including all standards and schedules appearing in both the primary and consequential variations. To assist with understanding and interpreting these changes, FSANZ has prepared a Regulatory Intent report and Explanatory Statement (see SD1 and Attachment C).

In developing these transitional arrangements, FSANZ considered the complex and diverse regulatory changes proposed. FSANZ also considered the range of products on the market required to adopt the proposed labelling and composition requirements, the costs and practicalities of transition for industry, stakeholder views, precedents for transitional arrangements and other relevant FSANZ proposals and applications. FSANZ also acknowledges that the primary and consequential variations for P1028 represent some of the largest regulatory changes the agency has proposed to date and understands the complexities associated with infant formula and its use as sole source of nutrition for a vulnerable population.

After significant consultation and consideration of similar proposals (e.g. P242), the approved variations provide for a five year transitional arrangement, commencing on the gazettal date. During that five year period, infant formula products may be sold if they comply with either the Code as in force (as if the variation had not taken effect) or the Code as amended by the approved variations. Products must comply fully with one version of the Code or the other. They cannot pick and choose individual permissions from either versions of the Code. After the transition period, all infant formula products available in the Australia and New Zealand markets would need to comply with the Code as amended. FSANZ notes that during the transition period, this could mean that two similar products (one complying with the old standard and the other complying with the new) could be sold at the same time. FSANZ will work with retailers to assist in reducing confusion for consumers who are choosing between these products (see section 8.2 for more details). However, this approach has previously been applied to other major changes to the Code. Of which, no apparent problems have been caused.

With these arrangements, the default standard transition arrangements provided by section 1.1.1—9 of the Code will not apply, as this only provides for a 12 month stock-in-trade period for variations commencing on the date of gazettal. Further, FSANZ is not proposing to apply a separate, additional two year stock-in-trade period sought by some submitters to the 1st CFS. This is because a five year transition period inclusive of stock-in-trade provides more flexibility to manufacturers and food businesses. Allowing manufacturers and food businesses to comply with either the Code as currently in force or with the Code as amended by the approved variations provides opportunity for individualised reformulation and labelling changes that are fit for purpose for each manufacturer. These transitional arrangements also take account of stock-in-trade and the fact that the changes will be affecting products with a longer shelf life (up to 24 months).

FSANZ also notes that as infant formula products currently on the Australia and New Zealand market are already safe and suitable, allowing the proposed time for industry to comply with the current standard poses no risk to the health of infants.

A five year transition period would allow sufficient time for industry to adopt new labelling and composition requirements and minimise costs associated with labelling changes and reformulation, whereas a transition period greater than five years would unreasonably delay optimum nutrition to infants and the provision of information to consumers.

In summary, FSANZ approves a five year transition period for infant formula products that will take effect on the date of gazettal. A more detailed discussion of the rationale and background to this decision can be found in section 11 of the 2nd CFS (FSANZ 2023a). Further details on FSANZ's assessment of potential impact of these transitional arrangements are outlined in the Decision RIS (SD2), section 9.5.

8 Implementation and review

FSANZ is committed to providing support to all affected stakeholders during the implementation of the P1028 amendments. The following section outlines how FSANZ will assist with implementation and evaluation of the changes.

8.1 Reporting and consultation

Proposal P1028 has been developed in conjunction with some of the most extensive consultation ever undertaken by FSANZ. Over its history, 36 public report documents have been released, eight open public stakeholder forums and 30 targeted stakeholder meetings have been held throughout Australia and New Zealand and regular communications have

been ongoing with interested stakeholders as either groups or individuals. FSANZ has also regularly reported to intergovernmental, parliamentary, jurisdictional and formalised liaison groups, presented at conferences and other such forums both domestically and internationally and provided regular written updates and web-based material. Further, FSANZ has a statutory requirement to publicly notify consultation documents for consideration by the public at large. These reports are made available on the FSANZ website, media releases are issued and subscribers to FSANZ standards development processes are also advised directly by email.

8.2 Communication

In addition to consultation and to support the implementation of the P1028 amendments, FSANZ has developed a communication plan which will commence post gazettal.

Further, the Marketing in Australia of Infant Formula (MAIF) Agreement restricts marketing of infant formula products to the public and health workers. It is thus expected that FSANZ will support the provision of information about P1028 changes to these stakeholders. Communication materials will aim to provide clarity for consumers, industry, health practitioners, pharmacies and jurisdictions on the key amendments and how they will impact each stakeholder. All of this is in line with requests from stakeholders in the 2nd CFS who asked for FSANZ to provide communication plans and resources (see submitter tables in Appendix 3) and to collaborate with jurisdictions to disseminate information about the regulatory changes.

FSANZ has a number of channels available to reach target audiences and disseminate products and messages, including the FSANZ subscription service, the FSANZ website, social media and attendance at meetings, events and conferences. Other organisations can also assist in providing information to complement and strengthen initiatives to increase public awareness of the changes to the relevant Standards. FSANZ will work cooperatively with these organisations to ensure consistency of information and to maximise the effectiveness of available resources.

8.3 Educational resources

In accordance with paragraph 13(1)(i) of the FSANZ Act, one of FSANZ's functions is to develop, in co-operation with the states and territories, food education initiatives, including the publication of information to increase public awareness of food standards and food labels. Such initiatives can increase consumer knowledge and understanding by providing information on how to interpret and apply food labelling and help to create a supportive environment whereby consumer choices are possible or easier for individuals and communities. As part of the communication plan, FSANZ will - in co-operation with the jurisdictions - produce and disseminate educational resources (e.g. factsheets) to stakeholders to assist with the implementation of these regulatory changes.

This approval report also contains summary tables in Appendix 2 designed to allow manufacturers to identify the nutrient composition, food additive and labelling regulatory changes in a quick and simple format. In addition, FSANZ has developed a Regulatory Intent report (SD1) intended to assist explain the decisions made under P1028. This document is available for use by government agencies and manufacturers.

FSANZ has also provided individual responses in the summary tables (at Appendix 3) in response to submissions relating to the need for resources and educational materials.

8.4 Enforcement

Enforcement and interpretation of the Food Acts that apply the Standards and give them legal force is the responsibility of the jurisdictions. In Australia, this is the responsibility of the states and territories. The Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) is responsible for the inspection and sampling of imported food. In New Zealand, enforcement is monitored by the Ministry for Primary Industries. Enforcement will be subject to the individual operations of each jurisdiction.

Issues in relation to fair trading or other aspects, such as weights and measures, will be the responsibility of the respective agencies including the Australian Competition and Consumer Commission (ACCC), jurisdictional fair trading offices and trade measurement offices. The above activities will be augmented by the actions of self-regulatory agencies such as the self-regulatory Ad Standards in Australia, which investigates complaints in relation to advertising content. In New Zealand, the Advertising Standards Authority is the self-regulatory body that administers a code for food advertising.

9 Evaluation and monitoring

The primary responsibility for actively monitoring and evaluating food standards lies with the jurisdictional governments that have adopted those standards as part of their food laws. Further, jurisdictions via representation on the Food Ministers' Meeting, develop the policy principles for food standards including infant formula standards and it is appropriate that they have responsibility for reviewing the outcomes of the standards against these principles.

In the case of an issue, agencies with responsibility for food policy could act alone to evaluate or monitor the standards, or agencies could act jointly through the Food Regulation Standing Committee (FRSC). FRSC provides advice to food ministers on food regulation issues, which can then result in FSANZ taking action. Typically, this would be through a proposal, which will involve an independent evaluation of the standards.

It is also possible for non-government entities (for example, academics, public health groups or industry) to evaluate the standards and then submit an application to change the Code (including the infant formula standards). FSANZ would then consider this application, perform an independent assessment (in the same way this proposal was assessed) and if appropriate, amend the standards.

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Appendix 1 - Summary Tables

Nutrient composition for infant formula products

Table 11: Comparison between existing and new infant formula and SMPPi nutrient composition requirements

SMPPi are required to comply with the same compositional as infant formula, except where deviation is required to achieve the product's special medical purpose.

Nutrient	Unit	Existing provisions		Provisions in the variations at Attachment A and B	
		Min	Max	Min	Max
Energy	kJ/L	2500	3150	2510	2930
Total fat	g/100 kJ	1.05	1.5	1.1	1.4
Linoleic acid (LA)	mg/100 kJ	-	-	90	335*
Linoleic acid (LA)^	% total fatty acid	9	26	-	-
α-Linolenic acid (ALA)	mg/100 kJ	-	-	12	NS
α-Linolenic acid (ALA)^	% total fatty acid	1.1	4	-	-
Long chain omega 6 series fatty acids (C≥20)^	% total fatty acid	NS	2	-	-
Long chain omega 3 series fatty acids (C≥20)^	% total fatty acid	NS	1	-	-
Arachidonic acid^	% total fatty acid	NS	1	-	-
Erucic acid^	% total fatty acid	NS	1	NS	1
Docosahexaenoic acid (DHA)^	mg/100 kJ	-	-	NS	12
Trans fatty acid^	% total fatty acid	NS	4	NS	4
Phospholipids^	mg/100 kJ	NS	72	NS	72
Protein (milk)	g/100 kJ	0.45	0.7	0.43	0.72
Protein (soy)	g/100 kJ	-	-	0.54	0.72
Gluten		No detectable gluten		No detectable gluten	
L-amino acids					
Histidine	mg/100 kJ	10	NS	10	NS
Isoleucine	mg/100 kJ	21	NS	22	NS
Leucine	mg/100 kJ	42	NS	40	NS
Lysine	mg/100 kJ	30	NS	27	NS
Cysteine	mg/100 kJ	-	-	9[1]	NS
Cysteine & cysteine total	mg/100 kJ	6	NS	-	-
Methioine	mg/100 kJ	-	-	6[1]	NS
Cysteine, cysteine & methionine total	mg/100 kJ	19	NS	-	-
Phenylalaine	mg/100 kJ	17	NS	19[1]	NS
Phenylalanine & tyrosine total	mg/100 kJ	32	NS	-	-
Threonine	mg/100 kJ	19	NS	18	NS
Tryptophan	mg/100 kJ	7	NS	8	NS
Tyrosine	mg/100 kJ	-	-	18[1]	NS
Valine	mg/100 kJ	25	NS	22	NS
Vitamins					
Vitamin A	µg RE/100 kJ	14[2]	43[2]	14	43
Vitamin B_6	µg/100 kJ	9	36	8	42*
Vitamin B_{12}	µg/100 kJ	0.025	0.17*	0.02	0.36*
Vitamin C	mg/100 kJ	1.7	5.4*	1.7	17*
Vitamin D	µg/100 kJ	0.25	0.63	0.24	0.63
Vitamin E	mg α-TE/100 kJ	0.11[5]	1.1[3]	0.14	1.2*
Vitamin K	µg/100 kJ	1	5*	0.24	6*
Biotin	µg/100 kJ	0.36	2.7*	0.24	2.4*
Niacin	µg/100 kJ	130	480*	72	359*
Riboflavin	µg/100 kJ	14	86*	14.3	120*
Pantothenic acid	µg/100 kJ	70	360*	96	478*
Folic acid	µg/100 kJ	2	8*	2.4	12*
Thiamin	µg/100 kJ	10	48*	10	72*
Minerals					
Calcium	mg/100 kJ	12	33*	12	35*
Magnesium	mg/100 kJ	1.2	4	1.2	3.6*
Iron	mg/100 kJ	0.2	0.5	0.14	0.48
Phosphorus	mg/100 kJ	6	22* and 25	6	24*
Manganese	µg/100 kJ	0.24	24	0.24	24*

Nutrient	Unit	Existing provisions		Provisions in the variations at Attachment A and B	
		Min	Max	Min	Max
Zinc	mg/100 kJ	0.12	0.43	0.12	0.36*
Copper	µg/100 kJ	14	43	8	29*
Iodine	µg/100 kJ	1.2	10	2.4	14*
Selenium	µg/100 kJ	0.25	1.19	0.48	2.2*
Chromium	µg/100 kJ	NS	2[4]	-	-
Molybdenum	µg/100 kJ	NS	3[4]	-	-
Electrolytes					
Sodium	mg/100 kJ	5	15	4.8	14
Chloride	mg/100 kJ	12	35	12	38
Potassium	mg/100 kJ	20	50	14	43
Essential and nutritive substances					
Choline	mg/100 kJ	1.7^	7.1^	1.7	12*
Inositol	mg/100 kJ	1^	9.5^	1	10*
L-carnitine	mg/100 kJ	0.21^	0.8^	0.3	0.8*
Fluoride	µg/100 kJ	-	-	NS	17 (powdered/ concentrated) 24 (RTD)
2′-fucosyllactose^	mg/100 kJ	NS	96	NS	96
3′-sialyllactose sodium salt^	mg/100 kJ	NS	8	NS	8
6′-sialyllactose sodium salt^	mg/100 kJ	NS	16	NS	16
2′-fucosyllactose + difucosyllactose^	mg/100 kJ	NS	96	NS	96
2′-fucosyllactose + lacto-N-neotetraose^	mg/100 kJ	NS	96[5]	NS	96[5]
Taurine^	mg/100 kJ	0.8	3	NS	2.9
Lutein^	µg/100 kJ	1.5	5	1.5	5.
Lactoferrin^	mg/100 kJ	NS	40	NS	40
lacto-N-neotetraose^	mg/100 kJ	NS	32	NS	32
Inulin-type fructans^	mg/100 kJ	NS	110	NS	110
Galacto-oligosaccharides^	mg/100 kJ	NS	290	NS	290
Nucleotides					
Adenosine-5′-monophosphate^	mg/100 kJ	0.14	0.38	NS	0.36
Cytidine-5′-monophosphate^	mg/100 kJ	0.22	0.6	NS	0.6
Guanosine-5′-monophosphate^	mg/100 kJ	0.04	0.12	NS	0.4
Inosine-5′-monophosphate^	mg/100 kJ	0.08	0.24	NS	0.24
Uridine-5′-monophosphate^	mg/100 kJ	0.13	0.42	NS	0.42
Free nucleotide 5′-monophosphates^	mg/100 kJ	NS	3.8	NS	3.8
Ratios					
LA : ALA	ratio	5 : 1	15 : 1	5 : 1	15 : 1
Ca : P	ratio	1.2 : 1	2 : 1	1 : 1	2 : 1
Vitamin E : PUFA	ratio	0.5 mg : 1 g	NS	0.5 mg : 1 g	NS
Arachidonic acid^	ratio	-	-	≥DHA	NS
Eicosapentaenoic acid	ratio	NS	≤DHA	NS	≤DHA
Total long chain omega 6 series fatty acids (C≥20) : total long chain omega 3 series fatty acids (C≥20) ^	ratio	1	NS	NS	NS
Methionine : cysteine	ratio	NS	NS	2 : 1	NS
Zn : Cu	ratio	NS	15 : 1	-	-
Sources					
Protein				Cow milk protein, goat milk protein, sheep milk protein, soy protein isolate, a partially hydrolysed protein of one or more of these specified proteins	
Carbohydrate				Sucrose and/or fructose should not be added, unless they provide a carbohydrate source in infant formula or follow-on formula manufactured from partially hydrolysed protein and provided the sum of these does not exceed 20% of available carbohydrates	
Permitted forms and equivalents					
Vitamin A		*Retinol forms*: vitamin A (retinol), vitamin A acetate (retinyl		*Retinol forms*: vitamin A (retinol), vitamin A acetate (retinyl	

Nutrient	Unit	Existing provisions		Provisions in the variations at Attachment A and B	
		Min	Max	Min	Max
		acetate), vitamin A palmitate (retinyl palmitate), retinyl propionate *Provitamin A forms*: beta-carotene		acetate), vitamin A palmitate (retinyl palmitate), retinyl propionate *Provitamin A forms*: beta-carotene	
Vitamin C		L-ascorbic acid, L-ascorbyl palmitate, calcium ascorbate, potassium ascorbate, sodium ascorbate		L-ascorbic acid, L-ascorbyl palmitate, calcium ascorbate, potassium ascorbate, sodium ascorbate	
Vitamin D		Vitamin D_2 (ergocalciferol), vitamin D_3 (cholecalciferol), vitamin D (cholecalciferol-cholesterol)		Vitamin D_2 (ergocalciferol), vitamin D_3 (cholecalciferol), vitamin D (cholecalciferol-cholesterol)	
Thiamin		Thiamin hydrochloride, thiamin mononitrate		Thiamin hydrochloride, thiamin mononitrate	
Riboflavin		Riboflavin, riboflavin-5′-phosphate (sodium)		Riboflavin, riboflavin-5′-phosphate (sodium)	
Niacin		Niacinamide (nicotinamide)		Niacinamide (nicotinamide)	
Vitamin B_6		Pyridoxine hydrochloride, pyridoxine-5′-phosphate		Pyridoxine hydrochloride, pyridoxine-5′-phosphate	
Folic acid		Folic acid		Folate (excluding naturally occurring folate)	
Pantothenic acid		Calcium pantothenate, dexpanthenol		Calcium pantothenate, dexpanthenol, D-panthenol, calcium D-pantothenate, sodium D-pantothenate	
Vitamin B_{12}		Cyanocobalamin, hydroxocobalamin		Cyanocobalamin, hydroxocobalamin	
Biotin		d-biotin		d-biotin	
Vitamin E		dl-α-tocopherol, d-α-tocopherol concentrate, tocopherols concentrate (mixed), d-α-tocopheryl acetate, dl-α-tocopheryl acetate, d-α-tocopheryl acid succinate, dl-α-tocopheryl succinate		dl-α-tocopherol, d-α-tocopherol concentrate, tocopherols concentrate (mixed), d-α-tocopheryl acetate, dl-α-tocopheryl acetate, d-α-tocopheryl acid succinate, dl-α-tocopheryl succinate	
Vitamin K		Vitamin K_1 as phylloquinone (phytonadione)		Vitamin K_1 as phylloquinone (phytonadione)	
Calcium		Calcium carbonate, calcium chloride, calcium citrate, calcium gluconate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium oxide, calcium phosphate (dibasic), calcium phosphate (monobasic), calcium phosphate (tribasic), calcium sulphate		Calcium carbonate, calcium chloride, calcium citrate, calcium gluconate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium oxide, calcium phosphate (dibasic), calcium phosphate (monobasic), calcium phosphate (tribasic), calcium sulphate	
Chloride		Calcium chloride, magnesium chloride, potassium chloride, sodium chloride		Calcium chloride, magnesium chloride, potassium chloride, sodium chloride	
Chromium		Chromium sulphate		Chromium sulphate	
Copper		Copper gluconate, cupric sulphate, cupric citrate		Copper gluconate, cupric sulphate, cupric citrate, cupric carbonate	
Iodine		Potassium iodate, potassium iodide, sodium iodide		Potassium iodate, potassium iodide, sodium iodide	
Iron		Ferric ammonium citrate, ferric pyrophosphate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferrous succinate, ferrous sulphate		Ferric ammonium citrate, ferric pyrophosphate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferrous succinate, ferrous sulphate, ferric citrate, ferrous bisglycinate	
Magnesium		Magnesium carbonate, magnesium chloride, magnesium gluconate, magnesium oxide, magnesium phosphate (dibasic), magnesium phosphate (tribasic), magnesium sulphate		Magnesium carbonate, magnesium chloride, magnesium gluconate, magnesium oxide, magnesium phosphate (dibasic), magnesium phosphate (tribasic), magnesium sulphate, magnesium hydroxide carbonate, magnesium	

Nutrient	Unit	Existing provisions		Provisions in the variations at Attachment A and B	
		Min	Max	Min	Max
				hydroxide, magnesium salts of citric acid	
Manganese		Manganese chloride, manganese gluconate, manganese sulphate, manganese carbonate, manganese citrate		Manganese chloride, manganese gluconate, manganese sulphate, manganese carbonate, manganese citrate	
Molybdenum		Sodium molybdate VI		Sodium molybdate VI	
Phosphorus		Calcium glycerophosphate, calcium phosphate (dibasic), calcium phosphate (monobasic), calcium phosphate (tribasic), magnesium phosphate (dibasic), potassium phosphate (dibasic), potassium phosphate (monobasic), potassium phosphate (tribasic), sodium phosphate (dibasic), sodium phosphate (monobasic), sodium phosphate (tribasic)		Calcium glycerophosphate, calcium phosphate (dibasic), calcium phosphate (monobasic), calcium phosphate (tribasic), magnesium phosphate (dibasic), potassium phosphate (dibasic), potassium phosphate (monobasic), potassium phosphate (tribasic), sodium phosphate (dibasic), sodium phosphate (monobasic), sodium phosphate (tribasic)	
Potassium		Potassium bicarbonate, potassium carbonate, potassium chloride, potassium citrate, potassium glycerophosphate, potassium gluconate, potassium hydroxide, potassium phosphate (dibasic), potassium phosphate (monobasic), potassium phosphate (tribasic)		Potassium bicarbonate, potassium carbonate, potassium chloride, potassium citrate, potassium glycerophosphate, potassium gluconate, potassium hydroxide, potassium phosphate (dibasic), potassium phosphate (monobasic), potassium phosphate (tribasic), potassium L-lactate	
Selenium		Seleno methionine, sodium selenate, sodium selenite		Seleno methionine, sodium selenate, sodium selenite	
Sodium		Sodium bicarbonate, sodium carbonate, sodium chloride, sodium chloride iodised, sodium citrate, sodium gluconate, sodium hydroxide, sodium iodide, sodium lactate, sodium phosphate (dibasic), sodium phosphate (monobasic), sodium phosphate (tribasic), sodium sulphate, sodium tartrate		Sodium bicarbonate, sodium carbonate, sodium chloride, sodium chloride iodised, sodium citrate, sodium gluconate, sodium hydroxide, sodium iodide, sodium lactate, sodium phosphate (dibasic), sodium phosphate (monobasic), sodium phosphate (tribasic), sodium sulphate, sodium tartrate	
Zinc		Zinc acetate, zinc chloride, zinc gluconate, zinc oxide, zinc sulphate		Zinc acetate, zinc chloride, zinc gluconate, zinc oxide, zinc sulphate, zinc lactate, zinc citrate (zinc citrate dihydrate or zinc citrate trihydrate)	
Choline		Choline chloride, choline bitartrate		Choline chloride, choline bitartrate, choline, choline citrate, choline hydrogen tartrate	
L-carnitine		L-carnitine		L-carnitine,L-carnitine hydrochloride and L-carnitine tartrate	
2′-fucosyllactose		2′- fucosyllactose		2′-fucosyllactose	
3′-sialyllactose sodium salt		3′-sialyllactose sodium salt		3′-sialyllactose sodium salt	
6′-sialyllactose sodium salt		6′-sialyllactose sodium salt		6′-sialyllactose sodium salt	
2′-fucosyllactose + difucosyllactose		2′-fucosyllactose and difucosyllactose		2′-fucosyllactose and difucosyllactose	
2′-fucosyllactose + lacto-N-neotetraose		2′-fucosyllactos and lacto-N-neotetraose		2′-fucosyllactos and lacto-N-neotetraose	
Adenosine-5′-monophosphate		Adenosine-5′-monophosphate		Adenosine-5′-monophosphate	
Cytidine-5′-monophosphate		Cytidine-5′-monophosphate		Cytidine-5′-monophosphate	
Guanosine-5′-monophosphate		Guanosine-5′-monophosphate, guanosine-5′-monophosphate sodium salt		Guanosine-5′-monophosphate, guanosine-5′-monophosphate sodium salt	
Inosine-5′-monophosphate		Inosine-5′-monophosphate, inosine-5′-monophosphate sodium salt		Inosine-5′-monophosphate, inosine-5′-monophosphate sodium salt	
Uridine-5′-monophosphate		Uridine-5′-monophosphate sodium salt		Uridine-5′-monophosphate sodium salt	
Lactoferrin		Bovine lactoferrin		Bovine lactoferrin	

Nutrient	Unit	Existing provisions		Provisions in the variations at Attachment A and B	
		Min	Max	Min	Max
lacto-N-tetraose		lacto-N-tetraose		lacto-N-tetraose	
Lutein		Lutein from *Tagetes erecta L.*		Lutein from *Tagetes erecta L.*	
Inositol		Myo-inositol		Myo-inositol	
Taurine		Taurine		Taurine	
Conversion factors					
Nitrogen conversion factor (NCF) – milk proteins		6.38		6.25	
Nitrogen conversion factor (NCF) – otherwise		6.25		6.25	
Potential renal solute load (PRSL)		-		-	

NS = Not Specified * = GUL ^ = Voluntary Addition - = Substance not listed

[1] The minimum levels specified do not apply if:

- the minimum amount of combined cysteine and methionine is not less than 15 mg per 100 kJ; and the ratio of methionine to cysteine in the infant formula and follow-on formula is less than 2 to 1.
- the minimum amount of combined phenylalanine and tyrosine is not less than 37 mg per 100 kJ; and the ratio of phenylalanine to tyrosine is less than 2 to 1.

[2] Units for vitamin A in the Code are µg/100 kJ.

[3] Units for vitamin E in the Code are mg/100 kJ.

[4] Specific compositional requirements parameters have been removed for SMPPi. The SMPPi framework allows for deviations where necessary for particular diseases, disorders and conditions.

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

Table 12: Comparison between IFPSDU and SMPPi nutrient composition requirements

Nutrient	Unit	Existing provisions		Provisions in the variation at Attachment A[1]	
		Min	Max	Min	Max
Energy	kJ/L	2500 (IF)[2] 2500 (FoF)[2]	3150 (IF)[2] 3550 (FoF)[2]	-	-
Protein	g/100 kJ	0.45[2]	1.4[2]	-	-
Fat	g/100 kJ	0.93[2]	1.5[2]	-	-
Chromium	µg/100 kJ	0.35[2]	2[2]	-	-
Molybdenum	µg/100 kJ	0.36[2]	3[2]	-	-
Potential renal solute load	mOsm/100 kJ	NS[2]	8[2]	-	-
Manganese	µg/100 kJ	NS	7.2*[3]	-	-

NS = Not Specified * = GUL

[1] Specific compositional requirements parameters have been removed for SMPPi. The SMPPi framework allows for deviations where necessary for particular diseases, disorders and conditions.

[2] For products based on a protein substitute.

[3] For infant formula products specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.

Table 13: Comparison between existing and new follow-on formula nutrient composition requirements

Nutrient	Unit	Existing provisions		Provisions in the variation at Attachment A and B	
		Min	Max	Min	Max
Energy	kJ/L	2500	3550	2510	2930
Total fat	g/100 kJ	1.05	1.5	1.1	1.4
Linoleic acid (LA)	mg/100 kJ	-	-	90	335*
Linoleic acid (LA)^	% total fatty acid	9	26	-	-
α-Linolenic acid (ALA)	mg/100 kJ	-	-	12	NS
α-Linolenic acid (ALA)^	% total fatty acid	1.1	4	-	-
Long chain omega 6 series fatty acids (C≥20)^	% total fatty acid	NS	2	-	-
Long chain omega 3 series fatty acids (C≥20)^	% total fatty acid	NS	1	-	-
Arachidonic acid^	% total fatty acid	NS	1	-	-
Erucic acid^	% total fatty acid	NS	1	NS	1
Docosahexaenoic acid (DHA)^	mg/100 kJ	-	-	NS	12
Trans fatty acid^	% total fatty acid	NS	4	NS	4
Phospholipids^	mg/100 kJ	-	-	NS	72
Protein (milk)	g/100 kJ	0.38	1.3	0.38	0.72
Protein (other)	g/100 kJ	0.45	1.3	0.54	0.72
Gluten		No detectable gluten		No detectable gluten	

Nutrient	Unit	Existing provisions		Provisions in the variation at Attachment A and B	
		Min	Max	Min	Max
L-amino acids					
Histidine	mg/100 kJ	10	NS	10	NS
Isoleucine	mg/100 kJ	21	NS	22	NS
Leucine	mg/100 kJ	42	NS	40	NS
Lysine	mg/100 kJ	30	NS	27	NS
Cysteine	mg/100 kJ	-	-	9[1]	NS
Cysteine & cysteine total	mg/100 kJ	6	NS	-	-
Methioine	mg/100 kJ	-	-	6[1]	NS
Cysteine, cysteine & methionine total	mg/100 kJ	19	NS	-	-
Phenylalanine	mg/100 kJ	17	NS	19[1]	NS
Phenylalanine & tyrosine total	mg/100 kJ	32	NS	-	-
Threonine	mg/100 kJ	19	NS	18	NS
Tryptophan	mg/100 kJ	7	NS	8	NS
Tyrosine	mg/100 kJ	-	-	18[1]	NS
Valine	mg/100 kJ	25	NS	22	NS
Vitamins					
Vitamin A	µg RE/100 kJ	14[2]	43[2]	14	43
Vitamin B_6	µg/100 kJ	9	36	8	42*
Vitamin B_{12}	µg/100 kJ	0.025	0.17*	0.02	0.36*
Vitamin C	mg/100 kJ	1.7	5.4*	1.7	17*
Vitamin D	µg/100 kJ	0.25	0.63	0.24	0.72
Vitamin E	mg α-TE/100 kJ	0.11[3]	1.1[3]	0.14	1.2*
Vitamin K	µg/100 kJ	1	5.0*	0.24	6*
Biotin	µg/100 kJ	0.36	2.7*	0.24	2.4*
Niacin	µg/100 kJ	130	480*	72	359*
Riboflavin	µg/100 kJ	14	86*	14.3	120*
Pantothenic acid	µg/100 kJ	70	360*	96	478*
Folic acid	µg/100 kJ	2	8.0*	2.4	12*
Thiamin	µg/100 kJ	10	48*	10	72*
Minerals					
Calcium	mg/100 kJ	12	33*	12	43*
Magnesium	mg/100 kJ	1.2	4	1.2	3.6*
Iron	mg/100 kJ	0.2	0.5	0.24	0.48
Phosphorus	mg/100 kJ	6	22* and 25	6	24*
Manganese	µg/100 kJ	0.24	24	0.24	24*
Zinc	mg/100 kJ	0.12	0.43	0.12	0.36*
Copper	µg/100 kJ	14	43	8	29*
Iodine	µg/100 kJ	1.2	10	2.4	14*
Selenium	µg/100 kJ	0.25	1.19	0.48	2.2*
Chromium	µg/100 kJ	NS	2*	-	-
Molybdenum	µg/100 kJ	NS	3*	-	-
Electrolytes					
Sodium	mg/100 kJ	5	15	4.8	14
Chloride	mg/100 kJ	12	35	12	38
Potassium	mg/100 kJ	20	50	14	43
Essential and nutritive substances					
Choline^	mg/100 kJ	1.7	7.1	NS	12*
Inositol^	mg/100 kJ	1	9.5	NS	10*
L-carnitine^	mg/100 kJ	0.21	0.8	0.3	NS
Fluoride	µg/100 kJ	-	-	NS	17 (powdered/ concentrated) 24 (RTD)
2′-fucosyllactose^	mg/100 kJ	NS	96	NS	96
3′-sialyllactose sodium salt^	mg/100 kJ	NS	8	NS	8
6′-sialyllactose sodium salt^	mg/100 kJ	NS	16	NS	16
2′-fucosyllactose + difucosyllactose^	mg/100 kJ	NS	96	NS	96
2′-fucosyllactose + lacto-N-neotetraose^	mg/100 kJ	NS	96[4]	NS	96[4]
Taurine^	mg/100 kJ	0.8	3	NS	2.9
Lutein^	µg/100 kJ	1.5	5	1.5	5
Lactoferrin^	mg/100 kJ	NS	40	NS	40
lacto-N-neotetraose^	mg/100 kJ	NS	32	NS	32
Inulin-type fructans^	mg/100 kJ	NS	110	NS	110
Galacto-oligosaccharides^	mg/100 kJ	NS	290	NS	290
Nucleotides					

Nutrient	Unit	Existing provisions		Provisions in the variation at Attachment A and B	
		Min	Max	Min	Max
Adenosine-5′-monophosphate^	mg/100 kJ	0.14	0.38	NS	0.36
Cytidine-5′-monophosphate^	mg/100 kJ	0.22	0.6	NS	0.60
Guanosine-5′-monophosphate^	mg/100 kJ	0.04	0.12	NS	0.40
Inosine-5′-monophosphate^	mg/100 kJ	0.08	0.24	NS	0.24
Uridine-5′-monophosphate^	mg/100 kJ	0.13	0.42	NS	0.42
Free nucleotide 5′-monophosphates^	mg/100 kJ	NS	3.8	NS	3.8
Ratios					
LA : ALA	ratio	5 : 1	15 : 1	5 : 1	15 : 1
Ca : P	ratio	1.2 : 1	2 : 1	1 : 1	2 : 1
Vitamin E : PUFA	ratio	0.5 mg : 1 g	NS	0.5 mg : 1 g	NS
Arachidonic acid^	ratio	-	-	≥DHA	NS
Eicosapentaenoic acid^	ratio	NS	≤DHA	NS	≤DHA
Total long chain omega 6 series fatty acids (C≥20) : total long chain omega 3 series fatty acids (C≥20)	ratio	1	NS	NS	NS
Methionine : cysteine	ratio	-	-	2 : 1	NS
Zn : Cu	ratio	NS	20 : 1	-	-
Sources					
Protein	-	-		Cow milk protein, goat milk protein, sheep milk protein, soy protein isolate, a partially hydrolysed protein of one or more of these specified proteins	
Carbohydrate	-	-		Sucrose and/or fructose should not be added, unless they provide a carbohydrate source in infant formula or follow-on formula manufactured from partially hydrolysed protein and provided the sum of these does not exceed 20% of available carbohydrates	
Permitted forms and equivalents					
Vitamin A		*Retinol forms:* vitamin A (retinol), vitamin A acetate (retinyl acetate), vitamin A palmitate (retinyl palmitate), retinyl propionate *Provitamin A forms*: beta-carotene		*Retinol forms:* vitamin A (retinol), vitamin A acetate (retinyl acetate), vitamin A palmitate (retinyl palmitate), retinyl propionate *Provitamin A forms:* beta-carotene	
Vitamin C		L-ascorbic acid, L-ascorbyl palmitate, calcium ascorbate, potassium ascorbate, sodium ascorbate		L-ascorbic acid, L-ascorbyl palmitate, calcium ascorbate, potassium ascorbate, sodium ascorbate	
Vitamin D		Vitamin D_2 (ergocalciferol), vitamin D_3 (cholecalciferol), vitamin D (cholecalciferol-cholesterol)		Vitamin D_2 (ergocalciferol), vitamin D_3 (cholecalciferol), vitamin D (cholecalciferol-cholesterol)	
Thiamin		Thiamin hydrochloride, thiamin mononitrate		Thiamin hydrochloride, thiamin mononitrate	
Riboflavin		Riboflavin, riboflavin-5′-phosphate (sodium)		Riboflavin, riboflavin-5′-phosphate (sodium)	
Niacin		Niacinamide (nicotinamide)		Niacinamide (nicotinamide)	
Vitamin B_6		Pyridoxine hydrochloride, pyridoxine-5′-phosphate		Pyridoxine hydrochloride, pyridoxine-5′-phosphate	
Folic acid		Folic acid		Folate (excluding naturally occurring folate)	
Pantothenic acid		Calcium pantothenate, dexpanthenol		Calcium pantothenate, dexpanthenol, D-panthenol, calcium D-pantothenate, sodium D-pantothenate	
Vitamin B_{12}		Cyanocobalamin, hydroxocobalamin		Cyanocobalamin, hydroxocobalamin	
Biotin		d-biotin		d-biotin	
Vitamin E		dl-α-tocopherol, d-α-tocopherol concentrate, tocopherols concentrate (mixed), d-α-		dl-α-tocopherol, d-α-tocopherol concentrate, tocopherols concentrate (mixed), d-α-	

Nutrient	Unit	Existing provisions		Provisions in the variation at Attachment A and B	
		Min	Max	Min	Max
		tocopheryl acetate, dl-α-tocopheryl acetate, d-α-tocopheryl acid succinate, dl-α-tocopheryl succinate		tocopheryl acetate, dl-α-tocopheryl acetate, d-α-tocopheryl acid succinate, dl-α-tocopheryl succinate	
Vitamin K		Vitamin K_1 as phylloquinone (phytonadione)		Vitamin K_1 as phylloquinone (phytonadione)	
Calcium		Calcium carbonate, calcium chloride, calcium citrate, calcium gluconate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium oxide, calcium phosphate (dibasic), calcium phosphate (monobasic), calcium phosphate (tribasic), calcium sulphate		Calcium carbonate, calcium chloride, calcium citrate, calcium gluconate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium oxide, calcium phosphate (dibasic), calcium phosphate (monobasic), calcium phosphate (tribasic), calcium sulphate	
Chloride		Calcium chloride, magnesium chloride, potassium chloride, sodium chloride		Calcium chloride, magnesium chloride, potassium chloride, sodium chloride	
Chromium		Chromium sulphate		Chromium sulphate	
Copper		Copper gluconate, cupric sulphate, cupric citrate		Copper gluconate, cupric sulphate, cupric citrate, cupric carbonate	
Iodine		Potassium iodate, potassium iodide, sodium iodide		Potassium iodate, potassium iodide, sodium iodide	
Iron		Ferric ammonium citrate, ferric pyrophosphate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferrous succinate, ferrous sulphate		Ferric ammonium citrate, ferric pyrophosphate, ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous lactate, ferrous succinate, ferrous sulphate, ferric citrate, ferrous bisglycinate	
Magnesium		Magnesium carbonate, magnesium chloride, magnesium gluconate, magnesium oxide, magnesium phosphate (dibasic), magnesium phosphate (tribasic), magnesium sulphate		Magnesium carbonate, magnesium chloride, magnesium gluconate, magnesium oxide, magnesium phosphate (dibasic), magnesium phosphate (tribasic), magnesium sulphate, magnesium hydroxide carbonate, magnesium hydroxide, magnesium salts of citric acid	
Manganese		Manganese chloride, manganese gluconate, manganese sulphate, manganese carbonate, manganese citrate		Manganese chloride, manganese gluconate, manganese sulphate, manganese carbonate, manganese citrate	
Molybdenum		Sodium molybdate VI		Sodium molybdate VI	
Phosphorus		Calcium glycerophosphate, calcium phosphate (dibasic), calcium phosphate (monobasic), calcium phosphate (tribasic), magnesium phosphate (dibasic), potassium phosphate (dibasic), potassium phosphate (monobasic), potassium phosphate (tribasic), sodium phosphate (dibasic), sodium phosphate (monobasic), sodium phosphate (tribasic)		Calcium glycerophosphate, calcium phosphate (dibasic), calcium phosphate (monobasic), calcium phosphate (tribasic), magnesium phosphate (dibasic), potassium phosphate (dibasic), potassium phosphate (monobasic), potassium phosphate (tribasic), sodium phosphate (dibasic), sodium phosphate (monobasic), sodium phosphate (tribasic)	
Potassium		Potassium bicarbonate, potassium carbonate, potassium chloride, potassium citrate, potassium glycerophosphate, potassium gluconate, potassium hydroxide, potassium phosphate (dibasic), potassium phosphate (monobasic), potassium phosphate (tribasic)		Potassium bicarbonate, potassium carbonate, potassium chloride, potassium citrate, potassium glycerophosphate, potassium gluconate, potassium hydroxide, potassium phosphate (dibasic), potassium phosphate (monobasic), potassium phosphate (tribasic), potassium L-lactate	
Selenium		Seleno methionine, sodium selenate, sodium selenite		Seleno methionine, sodium selenate, sodium selenite	
Sodium		Sodium bicarbonate, sodium carbonate, sodium chloride, sodium chloride iodised, sodium		Sodium bicarbonate, sodium carbonate, sodium chloride, sodium chloride iodised, sodium	

Nutrient	Unit	Existing provisions		Provisions in the variation at Attachment A and B	
		Min	Max	Min	Max
		citrate, sodium gluconate, sodium hydroxide, sodium iodide, sodium lactate, sodium phosphate (dibasic), sodium phosphate (monobasic), sodium phosphate (tribasic), sodium sulphate, sodium tartrate		citrate, sodium gluconate, sodium hydroxide, sodium iodide, sodium lactate, sodium phosphate (dibasic), sodium phosphate (monobasic), sodium phosphate (tribasic), sodium sulphate, sodium tartrate	
Zinc		Zinc acetate, zinc chloride, zinc gluconate, zinc oxide, zinc sulphate		Zinc acetate, zinc chloride, zinc gluconate, zinc oxide, zinc sulphate, zinc lactate, zinc citrate (zinc citrate dihydrate or zinc citrate trihydrate)	
Choline		Choline chloride, choline bitartrate		Choline chloride, choline bitartrate, choline, choline citrate, choline hydrogen tartrate	
L-carnitine		L-carnitine		L-carnitine,L-carnitine hydrochloride and L-carnitine tartrate	
2′-fucosyllactose		2′-fucosyllactose		2′-fucosyllactose	
3′-sialyllactose sodium salt		3′-sialyllactose sodium salt		3′-sialyllactose sodium salt	
6′-sialyllactose sodium salt		6′-sialyllactose sodium salt		6′-sialyllactose sodium salt	
2′-fucosyllactose + difucosyllactose		2′-fucosyllactose and difucosyllactose		2′-fucosyllactose and difucosyllactose	
2′-fucosyllactose + lacto-N-neotetraose		2′-fucosyllactos and lacto-N-neotetraose		2′-fucosyllactos and lacto-N-neotetraose	
Adenosine-5′-monophosphate		Adenosine-5′-monophosphate		Adenosine-5′-monophosphate	
Cytidine-5′-monophosphate		Cytidine-5′-monophosphate		Cytidine-5′-monophosphate	
Guanosine-5′-monophosphate		Guanosine-5′-monophosphate, guanosine-5′-monophosphate sodium salt		Guanosine-5′-monophosphate, guanosine-5′-monophosphate sodium salt	
Inosine-5′-monophosphate		Inosine-5′-monophosphate, inosine-5′-monophosphate sodium salt		Inosine-5′-monophosphate, inosine-5′-monophosphate sodium salt	
Uridine-5′-monophosphate		Uridine-5′-monophosphate sodium salt		Uridine-5′-monophosphate sodium salt	
Lactoferrin		Bovine lactoferrin		Bovine lactoferrin	
lacto-N-tetraose		lacto-N-tetraose		lacto-N-tetraose	
Lutein		Lutein from *Tagetes erecta L.*		Lutein from *Tagetes erecta L.*	
Inositol		Myo-inositol		Myo-inositol	
Taurine		Taurine		Taurine	
Conversion factors					
Nitrogen conversion factor (NCF) – milk proteins		6.38		6.25	
Nitrogen conversion factor (NCF) – otherwise		6.25		6.25	
Potential renal solute load (PRSL)		≤8 mOsm/100 kJ		-	

NS = Not Specified * = GUL ^ = Voluntary Addition - = Substance not listed

[1] The minimum levels specified do not apply if:

- the minimum amount of combined cysteine and methionine is not less than 15 mg per 100 kJ; and the ratio of methionine to cysteine in the infant formula and follow-on formula is less than 2 to 1.
- the minimum amount of combined phenylalanine and tyrosine is not less than 37 mg per 100 kJ; and the ratio of phenylalanine tor is less than 2 to 1.

[2] Units for vitamin A in the Code are µg/100 kJ.

[3] Units for vitamin E in the Code are mg/100 kJ.

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

Food additives for infant formula products

Table 14: Comparison between maximum permitted levels of existing and new infant formula product food additive permissions

Food additive		Existing provisions		Provisions in the variation at Attachment B		
INS	**Description**	**Infant Formula Products (13.1[1])**	**Food subclass[1] (13.1.1, 13.1.2, 13.1.3)**	**Infant Formula Products[2] (13.1)**	**FoF[3] (13.1)**	**SMPPi[4] (13.1.1)**
170	Calcium carbonates	NS	NS	NS	NS	GMP
270	Lactic acid	GMP	GMP	GMP	GMP	GMP
300	Ascorbic acid	NS	NS	NS	50	NS
301	Sodium ascorbate	NS	NS	75#	50	75#
302	Calcium ascorbate	NS	NS	NS	50	NS
304	Ascorbyl palmitate	10	10	10	50	100
307b	Tocopherols concentrate, mixed	10	10	10	30	10
307c	dl-alpha-tocopherol	NS	NS	10	30	10
308	Gamma-tocopherol	NS	NS	10	10	10
309	Delta-tocopherol	NS	NS	10	10	10
322	Lecithin	5000	5000	5000	5000	5000
330	Citric acid	GMP	GMP	GMP	GMP	GMP
331	Sodium citrates	GMP	GMP	GMP	GMP	GMP
332	Potassium citrates	GMP	GMP	GMP	GMP	GMP
333	Calcium citrate	NS	NS	0.1#	0.1#	GMP
338	Phosphoric acid	NS	NS	450	450	450*
339	Sodium phosphates	NS	NS	450	450	450
340	Potassium phosphates	NS	NS	450	450	450
341	Calcium phosphates	NS	NS	NS	NS	450
401	Sodium alginate	NS	NS	NS	NS	1000*
407	Carrageenan	NS	300 (13.1.2)	300*	300*	-
		NS	1000 (13.1.3)	-	-	1000*
410	Locust bean (carob bean) gum	1000	1000	1000	1000	5000*
412	Guar gum	1000	1000	1000*	1000*	10000*
414	Gum arabic (acacia)	NS	NS	10#	10#	10#
415	Xanthan gum	NS	NS	NS	NS	1200*
440	Pectins	NS	NS	NS	10000	2000*
						5000*
471	Mono- and diglycerides of fatty acids	4000	5000 (13.1.3)	4000	4000	5000*
472c	Citric and fatty acid esters of glycerol	NS	9000 (13.1.3)	7500* (powder)	7500* (powder)	7500* (powder)
472c	Citric and fatty acid esters of glycerol	NS	9000 (13.1.3)	9000* (liquid)	9000* (liquid)	9000* (liquid)
472e	Diacetyltartaric and fatty acid esters of glycerol	NS	400 (13.1.3)	NS	NS	400
500	Sodium carbonates	NS	NS	2000	2000	2000
501	Potassium carbonates	NS	NS	2000	2000	2000
524	Sodium hydroxide	NS	NS	2000	2000	2000
525	Potassium hydroxide	NS	NS	2000	2000	2000
526	Calcium hydroxide	GMP	GMP	2000	2000	2000
551	Silicon dioxide (amorphous)	NS	NS	10#	10#	10#
1412	Distarch phosphate	5000 (13.1.1)	25000 (13.1.3)	5000*	5000*	25000*
1413	Phosphated distarch phosphate	5000 (13.1.1)	25000 (13.1.3)	5000*	5000*	25000*

Food additive		Existing provisions		Provisions in the variation at Attachment B		
INS	**Description**	**Infant Formula Products (13.1[1])**	**Food subclass[1] (13.1.1, 13.1.2, 13.1.3)**	**Infant Formula Products[2] (13.1)**	**FoF[3] (13.1)**	**SMPPi[4] (13.1.1)**
1414	Acetylated distarch phosphate	5000 (13.1.1)	25000 (13.1.3)	5000*	5000*	25000*
1422	Acetylated distarch adipate	NS	NS	NS	5000*	25000*
1440	Hydroxypropyl starch	25000 (13.1.1)	25000 (13.1.3)	5000*	NS	25000*
1450	Starch sodium octenyl succinate	NS	NS	100[#] 1000[#]	100[#] 1000[#]	100[#] 1000[#]
				-	-	20000*

Notes:
All MPLs are expressed in mg/L.
NS = Not Specified
1 Current permissions in table to S15—5 for the specific food classes:
13.1 Infant formula products
13.1.1 Soy-based infant formula
13.1.2 Liquid infant formula products
13.1.3 infant formula products for specific dietary use based on a protein substitute
2 General relates to the new high level food class of 13.1 – Infant formula and related products, that captures all infant formula products including follow-on formula and SMPPi (noting the hierarchical approach for food additive permissions in the Code, where permissions in FC 13.1 also applies to food class 13.1.1 unless stated otherwise)
3 FoF stands for follow-on formula, being comparable to the draft Codex Follow-up Standard for older infants (6-12 months)
4 Stands for the food class of 13.1.1 – Special medical purpose product for infants
* Condition statement attached to the permission
# Only for use in nutrient preparations

Table 15: Comparison between existing and new infant formula product contaminant MLs

Contaminant	Existing provisions	Provisions in the variation at Attachment B
Acrylonitrile	all foods including infant formula products: 0.02 mg/kg	No change
Aluminium	Pre-term formula: 0.02/100 mL Soy-based formula: 0.1 mg/100 mL Others: 0.05 mg/100 mL	Move ML from Standard 2.9.1 to Schedule 19. Pre-term formula: 0.2 mg/kg Infant formula, follow-on formula and special medical purpose product for infants (excluding those formulated for pre-term infants): 0.5 mg/kg Soy-based infant formula product: ML 1 mg/kg
Arsenic	No ML	No change
Cadmium	No ML	No change
Lead	Infant formula products: 0.02 mg/kg	Infant formula products: 0.01 mg/kg
Melamine	No ML	No change
Tin & inorganic tin	All canned food: 250 mg/kg	No change
Vinyl chloride	All foods except packaged water: 0.01 mg/kg	No change
Aflatoxins B1 and M1	No ML	No change
Ochratoxin A	No ML	No change
Polycyclic aromatic hydrocarbons (PAH)	No ML	No change
Perchlorate	No ML	No change
Chloropropanol, glycidol and their esters	No ML	No change

Labelling for infant formula products

Table 16: Comparison of existing infant formula and follow-on formula labelling requirements with those in the primary and consequential variations

Existing provisions	Provisions in the primary and consequential variations at Attachments A and B, respectively
Representations about food as infant formula or follow-on formula	
A food may only be represented as an IFP if it complies with Standard 2.9.1.	Provision varied to specifically refer to food as IF or FoF.
Prescribed names	
Prescribed names 'Infant formula' and 'Follow-on formula'.	Retained.
Requirement for measuring scoop	
Requirement for measuring scoop to be in a package of powdered IFP. This requirement does not apply to single serve sachets, or packages containing single serve sachets, of formula in powdered form.	Provision varied to specifically apply to IF or FoF.
Requirement for the name of the food	
General requirement in Standard 1.2.2 Information requirements – food identification.	Retained. New provision • the name of the food (the prescribed name) must be stated on the front of the package of IF and FoF.
Requirements for warning statements	
Warning statements to follow instructions exactly, prepare bottles and teats as directed and not changing proportions/not diluting or adding anything except on medical advice. Incorrect preparation can make your baby very ill. Warning statements are listed individually by product type (e.g. powdered, concentrated and ready-to-drink).	Provision varied to: • a single warning statement applicable to all product types of IF and FOF (e.g. powdered, concentrated or ready-to-drink), about following instructions exactly, preparing bottles and teats as directed and incorrect preparation can make your baby very ill.
Warning statement 'Breast milk is best for babies'.	Retained.
Warning statement 'Breast milk is best for babies' does not apply to IF products for metabolic, immunological, renal, hepatic or malabsorptive conditions.	Provision removed, however intent retained as warning statement is not required on SMPPi (Division 4).
Requirements for directions and use	
(a) each bottle should be prepared individually.	(a) Direction varied by replacing the word 'should' with 'must'.
(b) if a bottle of made up formula is stored prior to use, it must be refrigerated and used within 24 hours.	(b) Direction varied by replacing the word 'made up' with 'prepared'.
(c) potable, previously boiled water should be used.	(c) Direction varied by adding the word 'cooled' ('previously boiled and cooled potable water') and replacing the word 'should' with 'must'.
(d) if a package contains a measuring scoop—only the enclosed scoop should be used.	(d) Direction varied by replacing the word 'should' with 'must'.
	New provisions (e) for powdered or concentrated formula—do not change proportions of the powder or concentrate or add other food except on medical advice (f) for ready-to-drink formula—do not dilute or add other food except on medical advice.
(e) formula left in the bottle after a feed must be discarded.	(g) Direction varied by adding the words 'within 2 hours' after 'discarded'.
	New provisions • directions (a), (b) and (c) do not apply to ready-to-drink formula

Existing provisions	Provisions in the primary and consequential variations at Attachments A and B, respectively
	• direction (d) does not apply to concentrated formula and ready-to-drink formula.
Required statements	
For IF—statement that IFP may be used from birth.	Provision varied by replacing the words 'infant formula product' with 'infant formula'. New provisions • the statement must appear on the front of the package • the statement may appear more than once on the label.
For FoF—statement that IFP should not be used for infants aged under 6 months.	Provision varied by replacing the words 'infant formula product' with 'follow-on formula'. New provisions • the statement must appear on the front of the package • the statement may appear more than once on the label.
Statement about recommending that infants from the age of 6 months should be offered foods in addition to the IFP. Statement does not apply to packages of pre-term formula.	Provision varied by clarifying it applies to IF and FoF only. New provision • the statement may appear more than once on the label. Provision exempting packages of pre-term formula has been removed.
Print size	
Print size is specified for warning statements, based on package net weight.	Provision varied to specifically apply to IF and FoF.
Declaration of nutrition information	
Requirement to declare energy, protein, fat, carbohydrate, vitamins, minerals, permitted nutritive substances, inulin-type fructans, galacto-oligosaccharides (or a combination of inulin-type fructans and galacto-oligosaccharides).	Retained. New provision • require choline, inositol and L-carnitine to be declared in the NIS for IF.
	New provision • permit voluntary declaration of specified fatty acids (DHA, EPA, ARA) and whey and casein in the NIS. If specified fatty acids are declared, all three fatty acids must be included and their full names must be used. Use of acronyms for specified fatty acids is optional. • if declared, these sub-group nutrients must appear in the NIS in the prescribed format.
Nutrition information declared per 100 mL made up formula; guidance indicates per 100 mL liquid concentrate or per 100 g powder also permitted.	Provision varied to require the quantity of food expressed in per 100 mL of formula and for this to be as reconstituted according to directions on the package for powdered of concentrated IFP, with the option of also expressing unit quantities in per 100 mL liquid concentrate (as sold), or in per 100 g powder (as sold).
Average energy content, average amount.	Retained average energy content. Provision varied to require the 'average quantity' for nutrients, substances and nutritive substances instead of 'average amount'. New provision • for how average quantity must be calculated.
Requirement to declare the proportion of powder or concentrate required to reconstitute the formula according to directions and the weight of one scoop for powdered formula.	Intent retained and applied to IF and FoF under new sub-heading 'Directions on preparation and use'. New provision • The direction is not permitted in the NIS.
Nutrition information must be expressed in terms of the product (powdered or concentrated) as reconstituted according to directions on the package.	Provision varied to clarify it applies to powdered and concentrated IF and FoF. New provision • information not expressly permitted or required in the NIS is not permitted.
Required form for the declaration of nutrition information	

Existing provisions	Provisions in the primary and consequential variations at Attachments A and B, respectively
Provision captured under Declaration of nutrition information. Nutrition information may be expressed in a table.	Provision varied to require nutrition information to be presented in a table. New provisions • a prescribed format for the NIS • include the title 'Nutrition Information' in bold font • subheadings 'Vitamins,' 'Minerals', 'Additional' in the NIS for IF and FoF; and the subheading 'Other nutrients' in the NIS for IF must be used • subheadings must be printed in a size of type that is the same or larger than the nutrient names in the NIS • must use the names and units of measurement specified for nutrients and subgroup nutrients • if a permitted nutritive substance, ITF or GOS declared, must be under the 'Additional' subheading for IF and FoF • choline, inositol and L-carnitine must be declared for IF under the subheading 'Other nutrients' and under 'Additional' if voluntarily declared for FoF • if specified fatty acids are voluntarily declared, all must be declared under the subheading 'Long chain polyunsaturated fatty acids' using the full name, however acronyms are optional. • number notations for niacin, pantothenic acid, riboflavin and thiamin as part of the name must be used
Storage instructions	
Storage instructions must cover the period after the package has opened.	Provision varied to apply specifically to IF and FoF.
Statements of protein source and dental fluorosis	
Statement of the specific source or sources of protein in the product must be immediately adjacent to the name of the product.	Provision varied to require the specific animal or plant source(s) of protein to be stated, to replace the word 'product' with 'food' and to specifically refer to IF and FoF. Retained requirement for protein source statement to be included in the statement of the name of the food. New provisions • as the prescribed name of the food has to be on the front of the package (see above), the protein source statement will also be on the front of the package. • the words 'partially hydrolysed' must appear immediately adjacent to the specific animal or plant source or sources of protein if the IF or FoF is derived solely or in part from a partially hydrolysed protein. The words 'partially hydrolysed' will be on the front of the package together with the protein source and the name of the food. • the protein source statement must not use the word 'milk' as the sole descriptor of the protein source.
Statements relating to dental fluorosis.	Removed.
Prohibited representations	
• a picture of an infant • a picture that idealises the use of infant formula product • the word 'humanised' or 'maternalised' or any word or words having the same or similar effect • the words 'human milk oligosaccharide', 'human identical milk oligosaccharide' or any word or words having the same or similar effect • the abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect • words claiming that the formula is suitable for all infants • information relating to the nutritional content of human milk	Retained existing prohibited representations, with the following exceptions which have been removed. • a representation that the food is suitable for a particular condition, disease or disorder • a reference in a statement relating to lactose. New provisions • Unless expressly permitted or required by the Code, the information listed below is prohibited on IF or FoF labels: – for IF, information about FoF, a SMPPi, a formulated supplementary food, or a formulated supplementary food for young children – for FoF, information about IF, a SMPPi, a formulated supplementary food or a formulated supplementary food for young children

Existing provisions	Provisions in the primary and consequential variations at Attachments A and B, respectively
• a reference to the presence of any nutrient or substance that may be used as a nutritive substance, except for a reference in a statement relating to lactose, a statement of ingredients, or a declaration of nutrition information. • a representation that the food is suitable for a particular condition, disease or disorder. • a reference to ITF or GOS except for a reference in a statement of ingredients or a declaration of nutrition information.	– except when in a statement of ingredients or when required or expressly permitted, the following information: ▪ information about the presence of ITF, GOS, a nutrient and a nutritive substance ▪ information about ingredients (except for use of the word 'milk') ▪ animal or plant sources of protein ▪ the words 'partially hydrolysed' (or any word or similar words).
Guidelines	
Guidelines for IFP in section S29—10.	Removed as section S29—10 now referenced in subsection 2.9.1—25(1).
Labelling of lactose modified products	
Requirements for lactose free and low lactose formula.	Removed permission for IF or FoF to be represented as lactose free or low lactose. Lactose modified products are regulated as SMPPi (see Table 17).
Application of certain general labelling requirements in Part 1.2 of the Code	
General legibility requirements in Standard 1.2.1.	Retained.
Food identification requirements in Standard 1.2.2.	Retained.
Warning statements, advisory statements and declarations (food allergens) in Division 3 of Standard 1.2.3.	Retained.
General requirements for statement of ingredients in Standard 1.2.4.	Retained. New provisions • permitting an optional format for declaring added vitamins and minerals that are required nutritive substances in the statement of ingredients • if optional format used, the statement of ingredients need not list the added vitamin and mineral in descending order of ingoing weight, provided that the statement of ingredients lists all added vitamins together under the subheading 'Vitamins' and lists all added minerals together under the subheading 'Minerals'.
Date marking requirements in Standard 1.2.5.	Retained.
Directions for use and storage in Standard 1.2.6.	Retained.
Prohibition for nutrition content and health claims on infant formula products in Standard 1.2.7.	New note added to signpost to existing prohibition for nutrition content and health claims for IFP in Standard 1.2.7.
Requirement for the statement 'genetically modified' in Standard 1.5.2.	Retained.
Requirement for a statement that the food ingredient is irradiated in Standard 1.5.3.	Retained.
Product differentiation	
No existing provisions.	New provision • The label on a package of IF and FoF must differentiate that IF or FOF from other foods by the use of text, pictures and/or colour.
Requirements for use of stage numbers	
No existing provisions.	New provisions • permit the use of the number '1' on IF and the number '2' on FOF to identify for consumers that the product is IF or FoF, respectively • if used, the number must appear on the front of the package and immediately adjacent to the relevant age statements for IF and FoF. • a stage number may also appear elsewhere on a label.

A summary of the labelling requirements for SMPPi is provided in Table 17. These requirements replace those in the existing Division 4 of Standard 2.9.1. The new requirements have been drawn from Standards 2.9.1 and 2.9.5 and Chapter 1 labelling requirements.

Table 173: Labelling requirements for SMPPi in the primary variation

Provisions in the primary variation at Attachment A
Application of other Standards
Division 3 of Standard 2.9.1 does not apply to SMPPi. Part 1.2 of Chapter 1 (labelling and other information requirements) does not apply to a SMPPi unless a contrary intention appears.
Representations about food as a special medical purpose product for infants
A food may only be represented as a SMPPi if it complies with Division 4 of Standard 2.9.1.
Product differentiation
A SMPPi must be differentiated from other foods (e.g. IF, FoF, formulated supplementary food for young children) using text, pictures and/or colour.
Prohibited representations
The label of a SMPPi must not contain these representations: • a picture of an infant • a picture or text that idealises the use of special medical purpose product for infants • the words 'human milk oligosaccharide', 'human identical milk oligosaccharide' or any word or words having the same or similar effect • the abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect.
Prohibited claims
Nutrition content and health claims and claims that are therapeutic in nature are not permitted on a SMPPi. Claims about a SMPPi must not refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition. The provision does not apply to a claim that is expressly permitted by the Code or a declaration that is required by an application Act.
Permitted lactose free claims
The label of a SMPPi may display a lactose free claim if the product contains no detectable lactose.
Labelling and related requirements
If a SMPPI is a food for sale in a package, it is required to bear a label with certain information (as given below). If a SMPPi is a food for sale and is in an inner package, then certain information (as given below) must be on the label. If a SMPPi is a food for sale and is in a transportation outer, then certain information (as given below) must be on the transportation outer, or the package containing the food for sale, or clearly discernible through the transportation outer. The name and address of the supplier may also be provided in accompanying documentation.
Mandatory labelling information
The following information must be on the label of a SMPPi: • a name or description sufficient to indicate the true nature of the food • lot identification • if the sale of the food for sale is one to which Division 2 or Division 3 of Standard 1.2.1 applies: – information relating to foods produced using gene technology – information relating to irradiated food • any mandatory statements and declarations (as given below) • information relating to ingredients (as given below)

Provisions in the primary variation at Attachment A
• date marking information (as given below) • directions for the preparation, use or storage of the food, if the food is of such a nature to require such directions for health or safety reasons • nutrition information (as given below). A SMPPi must also comply with legibility requirements in section 1.2.1—24.
Mandatory statements and declarations— special medical purpose products for infants
Specified statements are required on the label of a SMPPi, indicating (or where noted, describing): • to the effect that the product must be used under medical supervision • if applicable, any precautions and contraindications associated with consumption of the product • the medical purpose of the product, which may include a disease, disorder or medical condition for which the product has been formulated • describing the properties or characteristics which make the product appropriate for the medical purpose • if the product has been formulated for a specific age group—a statement to the effect that the product is intended for persons within the specified age group • whether or not the product is suitable for use as a sole source of nutrition • if the product is represented as being suitable for use as a sole source of nutrition: additional statements (unless provided in other documentation) that the food is not for parenteral use and nutrition information relating to modifications if the food product has been modified. Declarations set out in section 1.2.3—4 are also required on the label of a SMPPi.
Information relating to ingredients—special medical purpose product for infants
Information about ingredients can be provided on the label of a SMPPi using one of three specified approaches (statement of ingredients, EU requirements or information that complies with Codex (21 CFR § 101.4)).
Date marking information—special medical purpose product for infants
Information about date marking must either comply with Standard 1.2.5 or use the words ‘Expiry Date’ or similar.
Nutrition information—special medical purpose product for infants
Specified nutrition information must be provided on the label of a SMPPi, including energy, macronutrients, nutritive substances and any other substances used as a nutritive substance and added to achieve the intended medical purpose. However there is flexibility in declaring information on sub-group nutrients, osmolality and osmolarity and acid-base balance if that information is necessary for use of the SMPPi for its intended medical purpose. Information about the source or sources of protein may be stated on the label.
Labelling requirement—special medical purpose product for infants in inner package
The following information must be stated on an inner package of a SMPPi (inner package for SMPPi is defined in subsection 1.1.2—2(3)): • a name or description sufficient to indicate the true nature of the food • lot identification • any declaration that is required by section 1.2.3—4 • date marking information. Labelling information on an inner package must comply with legibility requirements in section 1.2.1—24.
Labelling requirement—special medical purpose product for infants in transportation outer
The following information must be stated either on the label of a transportation outer or on a label of a package of the food for sale, clearly discernible though the transportation outer (transportation outer is defined in subsection 1.1.2—2(3): • a name or description sufficient to indicate the true nature of the food • lot identification • the name and address of the supplier (unless it is provided in accompanying documentation).

Appendix 2 - Risk Assessment of dl-alpha-tocopherol (INS 307c) as a food additive

Submissions have requested use of dl-alpha-tocopherol (INS 307c) as a food additive in infant formula products, with an MPL of 10 mg/L.

cis not currently permitted as a food additive in infant formula products, however it is listed in section S29—7, together with several other tocopherols, as a permitted form of vitamin E in infant formula products, food for infants and food for special medical purposes.

Another form of vitamin E, tocopherols concentrate, mixed (INS 307b), is already listed in Schedule 15 (Table to section S15—5) of the Code as a food additive for infant formula products at an MPL of 10 mg/L.

Assessments by other agencies

JECFA has reviewed the safety of tocopherols as food additives and established a group ADI of 0.15–2 mg/kg bw/day for dl-alpha-tocopherol and d-alpha-tocopherol concentrate (INS 307a), singly or in combination (WHO 1987). The ADI was based on clinical experience in humans and taking into account that alpha-tocopherol is an essential nutrient.

EFSA completed a re-evaluation of tocopherol-rich extract (E 306), alpha-tocopherol (E 307), gamma-tocopherol (E 308) and delta-tocopherol (E 309) as food additives in 2015 (EFSA 2015). This review included dl-alpha-tocopherol. EFSA noted that tocopherols belong to the group of substances named vitamin E. Vitamin E is an essential vitamin and is naturally present in plant-derived foods, particularly fruit and vegetables.

EFSA concluded the available data were too limited to establish an ADI for the tocopherols. However, taking into account vitamin E is widely consumed via human food, is an essential nutrient and upper levels are not exceeded in any population group in the EU, except children in one survey from only one country, tocopherols are not of safety concern at the levels used in food. EFSA noted that the re-evaluation did not apply to infants under the age of 12 weeks, however.

Conclusion

While dl-alpha-tocopherol is not currently permitted as a food additive in infant formula products, it is already permitted to be added to infant formula products as a form of the essential nutrient vitamin E. On this basis, the addition of dl-alpha-tocopherol to infant formula products is not expected to be a safety concern, provided the total amount of vitamin E present is within the minimum and maximum amounts set out in section S29—9 of the Code.

References

EFSA (2015) Scientific Opinion on the re-evaluation of tocopherol-rich extract (E 306), α-tocopherol (E 307), γ-tocopherol (E 308) and δ-tocopherol (E 309) as food additives. EFSA Panel on Food additives and Nutrient Sources added to Food (ANS). *EFSA Journal* 13(9):4247, 118 pp. doi:10.2903/j.efsa.2015.4247

WHO (1987) Evaluation of certain food additives and contaminants. Thirtieth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series No. 751. World Health Organization, Geneva.

Appendix 3 - Summary of submitter comments to the 2nd CFS and FSANZ responses

Section 1: General comments

Comment	Submitter(s)	FSANZ response
Stakeholder views from previous consultation		
Submitters stated where they did not make comment, their position remains unchanged from comments submitted to previous statutory and non-statutory consultations. This includes in relation to nutrient composition, food additive permissions, contaminant limits and approach to optional ingredients.	VIC DoH & DEECA, DA	Noted. FSANZ has taken this into consideration when assessing the proposal.
Supports the views of the Infant Nutrition Council (INC)		
Submitters stated their support for the submission made by INC.	SML, DAN, DCANZ, A2M, AFGC, FCG	Noted. FSANZ has taken this into consideration when assessing the proposal. Where comment by the INC is indicated, comment from these additional submitters has also been included.
Inequity in the consultation process for regulation review		
This submitter stated that there is inequity in the consultation process as technical experts submit comment on a voluntary basis in their own time and they compete with industry stakeholders that have exponentially greater resources to prepare submissions.	PHI1	FSANZ notes that this is out of scope. The procedure and process for developing food standards are set by the FSANZ Act. This Proposal was conducted in accordance with the requirements of that Act. See, for example, sections 1.3, 2 and 10 of this report. To ensure stakeholders were provided with sufficient time to submit to the P1028 2nd CFS, FSANZ opened consultation for a period of ten weeks.

Comment	Submitter(s)	FSANZ response
This submitter stated that the process of food standards setting must be made more accessible to the public and be conducted at arms-length from ultra-processed food industry lobbyists.	GE	FSANZ notes that this is out of scope. The process for setting food standards is conducted in line with the requirements set out in the FSANZ Act. See response above.
Food standards-setting process		
The submitter stated that: • Australian and New Zealand food policy and regulation authorities must prioritise personal and public health and citizen wellbeing as their top priority, ahead all other issues. More independent, peer-reviewed and published scientific evidence of public health outcomes must be required for approvals of industrial, ultra-processed foods and novel ingredients with little history of safe use, for example, GMOs, NBTs, nanotechnology. • FSANZ counts ultra-processed food trade, Codex regulations and food technology innovation as beneficial to the community despite massive uncertainties about the health impacts on emerging generations of citizens. • Food regulation uses a reductionist, chemistry and food technology approach. Instead of applying the scientific model that has been used for a century as the benchmark for good scientific practice and assessment, it uses 'regulatory science' that uncritically accepts applicant's biased and incomplete data, to favour the interests of the ultra-processed food industry and its trashy products. • Safety is narrowly defined in FSANZ assessment and data gaps are filled with best guesses. • Post-approval, longitudinal, monitoring and testing for efficacy, healthfulness and compliance of the commercial products must be part of the robust regulation of the infant formula regime.	GE	Noted. As explained in this report, FSANZ assessed this Proposal and approved the primary and consequential variations in accordance with the FSANZ Act. See, for example, sections 1.3, 2 and 10 of this report. The FSANZ Act provides that 'the protection of public health and safety' is the highest objective for FSANZ in standards development. For the reasons explained in this report, FSANZ's assessment is that the primary and consequential variations meet that objective. FSANZ has used the internationally accepted risk analysis framework in making its decisions. See, for example, the risk analysis and management approach for Proposal P1028 detailed in SD6 - Assessment against the Ministerial Policy Guidelines to the 1st CFS (FSANZ 2022i). FSANZ's risk analysis used the best available scientific evidence. See, for example, section 6.6 of this report.
The submitter stated that the establishment of an independent expert working group, although not currently permitted under the FSANZ Act, would have greatly assisted FSANZ in examining the evidence and providing recommendations to the review. A working group would have supported the review in providing unbiased and expert critical review of the evidence. The submitter stated that further consideration of	WA DoH	Noted. FSANZ has undertaken extensive consultation throughout P1028, of which, has included engagement with experts. FSANZ's understanding is that the FSANZ Act does not allow for this option and notes that the FSANZ Act review is out of scope of this Proposal.

Comment	Submitter(s)	FSANZ response
potential mechanisms to explore the establishment of such expert groups in future could be considered as part of the FSANZ Act review.		
The submitter noted the work done by Australian researchers in internationally setting standards for Australian national policy that influences infant feeding on an international scale (Binns 2018, Geddes, Gridneva et al. 2021). The submitter stated that it is important that we continue to lead the world in ensuring that regulations to protect infants who are receiving products that replace breast milk are true to the evidence base and reflect only the latest scientific research.	WA DoH	Noted. For the reasons stated in this report, FSANZ is satisfied that the primary and consequential variations are 'true to the evidence base' and reflect the best available scientific research.
The submitter referred to the outcomes of the proposal if approved, outlined in the 2nd CFS, one of which is a set of revised standards that 'require adequate information to ensure their safe preparation and use and enable parents/carers to make an informed choice'. The submitter stated that the ability of parents to make informed choices was paramount and should be listed as a separate dot point to highlight this importance.	WA DoH	Noted. In addition to protection of public health and safety, the provision of adequate information relating to food to enable consumers to make informed choices is a stated objective of the FSANZ Act and an objective that that Act directs FSANZ to have regard to in developing standards for FMM approval. See, for example, 6.51 and 6.5.2 of this report.
Ultra processed foods		
The submitter stated that infant formula should be classified as ultra-processed foods, noting the following: • Governments and FSANZ need to be more proactive in advocating health and well-being that a wholesome food supply provides, which would also decrease the demand for and cost of treating diet-related illnesses later. • FSANZ approves ingredients added to infant formula products that are derived from fermentation, are genetically manipulated, or use gene edited organism that have no history of safe use. • FSANZ should resume promoting the Healthy Food Pyramid as the basis for personal and community health and well-being. • Individual ingredients are assessed in isolation from other contents of ultra-processed food concoctions. • Labelling should be required for all formula ingredients, using text rather than numbers or symbols. Those made with fermentation or other processes using	GE	FSANZ notes that infant formula is the only safe and nutritious substitute for breast milk, for infants who are not breastfed. FSANZ acknowledges that infant formula is a highly prescribed and formulated food with the most prescriptive regulation in the Code. This is because it provides the sole source of nutrition to a vulnerable population. As detailed above, in independently assessing this proposal, FSANZ acted in accordance with the FSANZ Act, including the assessment criteria prescribed by that Act. See, for example, section 6 of this report. Regarding the use of numbers rather than text, food additive numbers are based on a well-established, internationally accepted system. The FSANZ website provides an explanation for the use of a numbering system for food additives.

Comment	Submitter(s)	FSANZ response
genetically modified, other novel organisms, nanotechnology and other vanguard technologies without a history of safe use must be clearly identified as such.		Existing labelling requirements for approved genetically modified food, novel foods and irradiated foods apply to infant formula products.
The submitter recommended adopting NOVA classification category 4 with detailed explanation regarding the impact of feeding infants an ultra-processed substitute for breastmilk exclusively for six months and to 12 months with the addition of complimentary foods. The submitter recommends a warning statement should be required to identify infant formula is within this category of ultra processed products.	BAA	Noted. However, consideration of the NOVA classification system is out of scope.
Meeting the FSANZ Act requirements		
The submitter stated that FSANZ must ensure that the correct balance is struck between regulation and innovation and recommends FSANZ should consider this balance when reassessing the proposal. The submitter refers to the FSANZ commissioned report (Kollmann et. al., 2021) that highlighted that strict regulatory regimes are an important protectant of consumers however they should not be overly restrictive such that it limits the innovation of safe and suitable ideas.	DAN	In assessing this proposal, FSANZ acted in accordance with the FSANZ Act, including in terms of having regard to the objectives and criteria set by that Act. The FSANZ Act establishes three key objectives – in descending order of priority - for FSANZ in developing or reviewing food standards. These are: • protection of public health and safety • provision of adequate information relating to food to enable consumers to make informed choices • prevention of misleading or deceptive conduct. In addition, that the FSANZ Act also requires FSANZ to regard to: • the need for standards to be based on risk analysis using the best available scientific evidence • the promotion of consistency between domestic and international food standards • the desirability of an efficient and internationally competitive food industry • the promotion of fair trading in food

Comment	Submitter(s)	FSANZ response
		• any written policy guidelines formulated by the Australian and New Zealand Food Regulation Ministerial Council [now Food Ministers' Meeting] (that was established by the Food Regulations Agreement in 2000). Subject to public health and safety, where appropriate, not hindering innovation and/or trade was one of the regulatory objectives in assessing the proposal outlined in the 2nd CFS.
The submitter refers to the *New Zealand Bill of Rights Act 1990* regarding the right to freedom from discrimination. The submitter stated that caregivers should have continued right of access to infant formula product regardless of their status or circumstances and these rights would diminish if: • they are unable to freely understand the products they are buying • manufacturers are not able to educate these groups, or highlight key features of products which may be suitable for their infants • particular SKUs of infant formula disappear e.g. plant-based milks • they cannot access pharmacies to buy SMPPi • scientific innovations in infant formula products available offshore are not readily available to them because industry stops innovating locally.	DAN	Noted. An objective of P1028 in reviewing and assessing the relevant Standards to ensure adequate information relating to infant formula products is available to enable caregivers to make informed choices. FSANZ must have regard to the provision of adequate information relating to food enables consumers to make informed choices as it is also an objective of the FSANZ Act. See, for example, section 6.5.2 of this report. The restriction on sale is consistent with how medical products (FSMPs) are currently regulated in the Code and this was taken into consideration when assessing this proposal. In addition, pharmacies are not the only institution that can sell SMPPi. Further information about the issue of restricted access to SMPPi is in section 3 of this Appendix and section 4.3 of the report. FSANZ also notes that the pre-market assessment process provides industry with a clear and tangible way to innovate, that also ensures the protection of public health and safety.
Communication & education resources		
The submitter suggested that investment in quality resources by government to support breastfeeding and consumer information is required. This form of support is free from commercial interests.	DA	Noted. The National Health and Medical Research Council have and are producing and publishing the information recommended by the submitter. See the Council's Infant Feeding Guidelines and other publicly available resources.

Comment	Submitter(s)	FSANZ response
The submitter recommended a strong education programme, developed in consultation with key stakeholders to ensure consistency in messaging, once changes to the Code are in place. In relation to messaging relating to food allergy and infant formula, NAC recommended FSANZ engages with key stakeholder organisations including the National Allergy Council, ASCIA, Allergy & Anaphylaxis Australia and Dietitians Australia.	NAC	FSANZ agrees with this recommendation and will work with jurisdictions and relevant experts to develop appropriate educational resources (e.g. factsheets) to inform relevant stakeholders about changes to the Code relating to infant formula.
Taxonomy		
The submitter stated that the method of infant feeding using infant formula, which is well known not to be a complete nutritive substance, is presented as a hyphenated word 'formula-fed'. It would be preferential to demonstrate the incompleteness of this by presenting it as 'formula fed'.	WA DoH	Noted. Use of 'formula-fed' is consistent with grammatical convention and with the *Ministerial Policy Guideline on the Regulation of Infant Formula Products*.

Section 2: Definitions

Issue	Comment	Submitter(s)	FSANZ response
Definitions for infant formula products and related: *At the 2nd CFS, the draft variation proposed the following definitions:* ***Infant formula product** means a product based on milk or other edible food constituents of animal or plant origin which is represented to be nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.* ***Infant formula** means an infant formula product that is represented:* *a. as a breast milk substitute for infants; and* *b. satisfying by itself the nutritional requirements of infants under the age of 6 months.* ***Follow-on formula** means an infant formula product that is represented:* *a. as either a breast milk substitute or replacement for infant formula; and* *b. as being suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.*			
Yes, the draft variation is supported.	These submitters supported the proposed definition for infant formula products, infant formula and follow-on formula.	NZFGC, INC, FCG, NZFS, AFGC, SML, DAN, DCANZ, A2M, AFGC, FCG	Noted.
No, the draft variation is not supported.	This submitter did not support the proposed definition for infant formula and requests the following addition (identified in bold text) is included: *'satisfies by itself the nutritional requirements of infants under the age of 6 months **and as part of a diversified diet from 6 months of age**'.* This submitter notes that the proposed definition implies that after 6 months infant formula will no longer satisfy the nutritional requirements of infants.	TAS DoH	Noted. FSANZ considers that the infant formula definition in the primary variation is appropriate for the reasons stated in section 3.1.3 of the 2nd CFS (FSANZ 2023a). FSANZ also notes that the purpose of the definition is to capture and classify the product for the purpose of regulation by the Code. As follow-on formula is also regulated under Standard 2.9.1, clear delineation is needed within the definition, which is achieved through noting the difference in age groups.

Issue	Comment	Submitter(s)	FSANZ response
	This submitter requested revision of the definition for 'infant formula' to refer to *'under the age of 6 months'* (and not *'under the age of 4 to 6 months'*).	NZFS	The submitter refers to an error in 2.9.1—3 (Attachment A) where the definition indicates: ***infant formula*** means an infant formula product that is represented as: (a) a breast milk substitute for infants; and (b) satisfying by itself the nutritional requirements of infants under the age of **4 to** 6 months. FSANZ acknowledged and clarified this error within the P1028 2nd Call for Submissions - Living Document (FSANZ 2023h). The primary variation was amended to remove the bold text above from the infant formula definition.
	This submitter did not oppose the proposed definition for infant formula, however considers inclusion of '4' to be a more accurate reflection of policy guidelines feeding advice to caregivers.	FCG	FSANZ considered this issue in its assessment of P1028, see section 4 of CP3 – Regulatory framework and definition (FSANZ 2021h). FSANZ is not aware of any evidence that would warrant a change in FSANZ's position on this issue. Referral to a single maximum age allows for a more certain determination of nutritional adequacy from which to set compositional criteria. Given the confusion in the current definition, it is appropriate to clarify the maximum age for the sole use of infant formula and that subsequent use beyond its role as a sole nutritional source is intentional.
Requested removal of follow-on formula definition.	This submitter requested removal of follow-on formula given it is not recommended by Australian national infant feeding guidelines and the lack of distinction between formula for infants aged under 12 months of age.	WA DoH	International regulations including Codex and those of the EU, UK, US, Turkey, China and many in South East Asia include regulations and guidelines which prescribe separate composition for follow-on formula. To remove follow-on formula from the Code would be out of step internationally and inconsistent with a purpose of the proposal which is to align with international regulations unless safety concerns have been identified. As follow-on formula is not being removed as a product, it requires a definition to ensure effective regulation.

Issue	Comment	Submitter(s)	FSANZ response
SMPPi definition *At the 2nd CFS the draft variation defined SMPPi as:* ***special medical purpose product for infants*** *means an infant formula product that is:* *(a) represented as being:* *(i) specially formulated for the dietary management of infants who have medically determined nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food); and* *(ii) suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product; and* *(iii) for the dietary management of a medically diagnosed disease, disorder or condition of an infant; and* *(b) intended to be used under medical supervision; and* *(c) not suitable for general use.*			
Yes, the draft variation is supported.	These submitters supported the proposed definition for SMPPi.	NAC, NSWFA, NZFGC, NZFS, INC, VIC, SML, DAN, DCANZ, A2M, AFGC, FCG	Noted.
	These submitters supported the exclusion of human milk fortifiers, supplementary and modulatory products as they do not meet the definition of an infant formula product providing the sole or principal source of nourishment and should remain under Standard 2.9.5.	VIC, AFGC, INC, SML, DAN, DCANZ, A2M, FCG	Noted.
	This submitter supported no longer defining SMPPi separately from infant formula products and removal of the reference to 'partial feeding'.	AFGC	Noted.

Issue	Comment	Submitter(s)	FSANZ response
No, the draft variation is not supported and/or recommend alternative.	This submitter noted concern that the draft regulatory framework would offer industry the ability to re-label a product rather than re-formulate. This submitter considers that formula for transient gastrointestinal conditions do not fit the SMPPi definition. Dietary management of transient gastrointestinal conditions can medically be achieved without use of such products. Some conditions such as colic and reflux are medically diagnosed and provided therapeutic goods to manage (e.g., omeprazole).	NSWFA	Noted, However, while manufacturers have the prerogative to re-label and re-formulate products where they see fit, the product must still comply with the Code. The primary variation allows flexibility for the SMPPi composition. This is balanced by the labelling requirements and other risk management interventions such as the restriction on sale. It is outside of FSANZ's remit to define which gastrointestinal conditions are transient and which are not. However, FSANZ notes that if a product does not meet the definition for SMPPi specifically '*where dietary management cannot medically be achieved without use of the product'* then the product cannot be represented as a SMPPi and, if it was, could be subject to enforcement action.
	This submitter suggested including the following statement in sub-section (ii): ***'suitable for partial feeding when specifically required for the child's medical condition'.*** For example a Phenylketonuria (PKU) infant formula prescription is based on the infant's blood phenylalanine levels and are not the sole or principal liquid source.	QLDH	FSANZ 's position remains that medicalised infant formula products not used as the sole or principal source of nourishment are better regulated under Standard 2.9.5. As the regulatory requirements (labelling and composition) for SMPPi are modelled on infant formula requirements, it is not appropriate to capture partial or modulatory feeding products in the SMPPi category. These products differ too significantly to be accurately captured under the same division and/or standard. FSANZ also notes that PKU products for infants can vary in form, for example they can be prescribed as modified release tablets which should not be captured under the infant formula product regulation.
	This submitter noted that some SMPPi are for metabolic conditions which can be sole source of nutrition or supplementary for children and possibly adults. These are regulated as FSMP in the EU. This submitter recommends the addition of a note to subsection 2.9.1 – 38(f) that 'product may be used a sole source for infants but also a supplementary feed for other age groups.	DAN	FSANZ is aware that there are a small number of special medical purpose products on the market intended for use as both for the sole source of nutrition for infants and as a supplementary feed for age groups beyond 12 months of age. These products are intended for patients with metabolic conditions and are based on the composition of an infant formula. For that reasons, it is appropriate that the Code regulate these as SMPPi. If the product is formulated for a special medical purpose and intended or represented as providing the sole or principle source of nutrition to infants, it is a SMPPi. This is regardless of if it can also be used as a supplementary product for age groups beyond 12 months.

Issue	Comment	Submitter(s)	FSANZ response
	These submitters requested an addition to the definition of SMPPi (identified in bolded text): *'A Special Medical Purpose Product for infants means an infant formula product that is…* ***are formulated in accordance with scientific evidence that demonstrates the efficacy of the product in accordance with its intended medical purpose'.*** The definition needs to clearly state that the intended purpose be specified as medical purpose and that it needs to clearly demonstrate efficacy of the product in accordance with the intended purpose.	TAS DoH, VIC	This issues was considered and responded to in Table 6 of the 2nd CFS (FSANZ 2023a). After consideration of the evidence, including submissions received, FSANZ's position remains unchanged—it considers the inclusion of such statements would introduce ambiguity into the definition which in turn would undermine compliance and enforcement. Australian and New Zealand food laws already expressly require that all food sold—including infant formula products—must be safe and must be suitable. The added benefit of restating in the Code an existing requirement imposed by those Acts (i.e., through mandating that the food also 'be proven to be safe') appears unclear, noting the requirement imposed on FSANZ by paragraph 59(b) of the FSANZ Act.
	This submitter noted the revised definition means a SMPPi only needs to be *represented as* being formulated for the dietary management of infants, thereby bringing into question whether products under this category need to demonstrate an effective role in the dietary management of infants. Recommended removal of the statement 'represented as' and including additional wording to make clear only evidence-based medical products are included (definition provided).	VIC	The definition's purpose is to capture specific foods for sale for the purposes of regulation and to require such foods to comply with the specific compositional, labelling and other requirements that apply to foods that fall within that definition. The definition will apply to and capture a food for sale that is offered, advertised, held out to be or represented to a consumer – whether truthfully or falsely - to be specially formulated for the dietary management of infants who have medically determined nutrient requirements suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product for the dietary management of a medically diagnosed disease, disorder or condition of an infant. A food for sale that is represented as the above and which meets the other criteria listed in the definition of SMPPi, must then comply with each requirement listed in Division 4 for SMPPi. Those requirements are designed to ensure that the product is in fact fit for purpose, including that it can and will have an effective role in the dietary management of infants. FSANZ does not agree that the definition - and therefore the application of the above compositional, labelling and other requirements – must or should be limited only to those products that are or already have been medically or scientifically proven to be suitable for dietary management of

Issue	Comment	Submitter(s)	FSANZ response
			infants with special nutrient requirements, of a medically diagnosed disease, and to be the sole or principal liquid source of nourishment. The submitter's suggested approach would appear to require one to establish that the food for sale in issue had in fact been specially formulated for the dietary management of infants etc, rather than that the consumer had been told or led to believe that the food offered for sale was such a food. Nor does FSANZ agree that use of the phrase 'represented as' creates a circular definition. The wording 'represented as' is consistent with the definition of FSMP (section 1.1.2—5). FSANZ notes that Standard 2.9.5 also sets labelling requirements for a food for sale that is 'represented as a food for special medical purposes' (as defined) similar to those set for SMPPi, including a statement indicating the medical purpose of the food
	This submitter supported the definition for SMPPi however would prefer a simpler drafting using plain English.	AFGC	Noted. FSANZ gave careful consideration to the terms of the definition. FSANZ remains satisfied that the definition is appropriate and is sufficiently clear for compliance and enforcement purposes. See also in this regard SD1 – Regulatory Intent.
Responsible institution definition *At the 2nd CFS, responsible institution was retained as specified in section 1.1.2—2(3):* ***responsible institution*** *means a hospital, hospice, aged care facility, disability facility, prison, boarding school or similar institution that is responsible for the welfare of its patients or residents and provides food to them.*			
No, the draft variation is not supported.	This submitter did not support the proposed draft definition because it contains irrelevant institutions such as hospice, aged care facility, disability facility and boarding schools. NSWFA understands that the proposed definition mirrors the one for FSMP, however, suggests tailoring the definition to suit the context where SMPPi may be sold. This submitter proposes amendments (as indicated).	NSWFA	Noted. FSANZ acknowledges that the current definition for 'responsible institution' includes some institutions that may not always be relevant in the infant feeding context. However, the definition for 'responsible institution' is captured in Standard 1.1.2 and is used throughout the Code, including in Standard 2.9.5. In this case, amending the definition was not considered appropriate given the implications across the Code. In addition, having two definitions for the same term may create ambiguity and confusion.
	This submitter noted there should be an asterisk inserted with 'responsible institution (e.g. *responsible	NZFS	Noted. FSANZ corrected this error in the consequential variation at 1.1.2—2(3)(b).

Issue	Comment	Submitter(s)	FSANZ response
	institution), for consistency across the Code as responsible institution is a defined term.		
Infant definition *At the 2nd CFS the draft variation retained the definition of 'infant' in section 1.1.2—2(3): infant means a person under the age of 12 months.*			
No, the draft variation is not supported and/or recommend alternative	This submitter proposed highlighting this definition in section 2.9.1—3 as well. Although the definition is provided in section 1.1.2—2, this term is prevalent in Standard 2.9.1 and offers reference to other definitions (e.g. 'infant formula').	NSWFA	Noted. The current Standard 2.9.1 does not include or replicate the section 1.1.2—2 definition of 'infant' – which is the norm across the Code, including for Standards or Schedules that refer to that term multiple times (eg, Standard 2.9.2 or Schedule S25). FSANZ is not aware of any evidence that warrants a change in approach.
Soy-based formula definition *At the 2nd CFS the draft variation removed the definition for 'soy-based formula'.*			
Yes, the draft variation is supported.	These submitters supported removing this definition as the term is not used within the proposed Standard 2.9.1.	NSWFA, NZFS, AFGC, NZFGC	Noted.
Milk-based definition *At the 2nd CFS the draft variation did not define 'milk-based' although the term is used in protein and fat requirements in sections 2.9.1—6 and 2.9.1—7.*			
No, the draft variation is not supported and/or recommend alternative.	This submitter noted the term 'milk-based' is ambiguous as to what milk is referred to and recommends providing a definition or avoiding the use of this term. It is recommended that this term is replaced with the reference to relevant proteins permitted in subsection 2.9.1—6(1).	NSWFA	Noted. FSANZ amended the relevant provisions to refer to 'milk-based' and 'not milk-based', where: - milk-based means an infant formula or follow-on formula 'that is derived only from one or more of the following proteins: cow milk; goat milk; sheep milk; a partially hydrolysed protein of one or more of cow milk, goat milk and sheep milk'. - not milk-based means any other prescribed protein source that is not noted above.

Issue	Comment	Submitter(s)	FSANZ response
			This change can be seen in subsection 2.9.1—6(4) of the primary variation.
Nutrient definition *At the 2nd CFS the draft variation did not define 'nutrient' although the term is used throughout Standard 2.9.1 (and the Code).*			
No, the draft variation is not supported and/or recommend alternative.	This submitter noted the use of this term in subsection 2.9.1—26 may imply that this term refers to mandatory ingredients in the NIS as opposed to voluntary ingredients. Mandatory ingredients include nutritive substances such as vitamins, minerals and other essential substances required in sections S29—5 and S29—6. The use of the term 'nutrient' in the proposed draft subsection 2.9.1—29(3), together with 'a nutritive substance' does not provide clarity as to the difference between the two terms. This submitter recommended defining the term or avoiding the use of this term in section 2.9.1—29. Subsection 2.9.1—29(3) (and paragraph 2.9.1—29(1)(i)) could refer to the NIS requirement in sections 2.9.1—25 and 2.9.1—26 as an alternative.	NSWFA	The term 'nutrient' is used throughout the Code and is not defined in 1.1.2—3. As such, the term has and is given its ordinary meaning. The FFM endorsed this approach in P1025. Defining this term for the purposes of S29 would have implications across the Code. Setting a definition for 'nutrient' specifically for infant formula products is not feasible. The term 'nutritive substance' is also not defined, but subsection 1.1.2—12 provides a definition of 'used as a nutritive substance'. This is for the purposes of section 1.1.1—10, which defines the types of substances that must be approved through a pre-market assessment process. The definition 'used as a nutritive substance' does not define how such substances are listed in the Code. FSANZ has referred to 'nutrients' and 'sub-group nutrients' in its assessment of the nutrition declaration requirements. For example, the primary variation refers to these terms in relation to the names and units of measurements specified in the table (paragraph 2.9.1-25(2)(e)) and the subheading 'Other nutrients' that must be used in the NIS for infant formula (subparagraph 2.9.1-25(2)(d(ii)), under which choline, inositol and L-carnitine must be declared.
Removal of the term 'protein substitute' and 'preterm' *At the 2nd CFS the draft variation removed the definitions of 'protein substitute' and 'preterm'.*			
Yes, the draft variation is supported.	These submitters supported removing the definition for protein substitute' and 'preterm'.	NZFGC, AFGC, INC, SML, DAN, DCANZ, A2M, FCG	Noted.

Issue	Comment	Submitter(s)	FSANZ response
Definition of 'inner package' *At the 2nd CFS the draft variation, 2.9.1—3 defined inner package as:* ***inner package***, in relation to special medical purpose food for infants, means an individual package of the food that is: (a) contained and sold within another package that is labelled in accordance with Division 4 of Standard 2.9.1; and (b) not designed for individual sale, other than a sale by a *responsible institution to a patient or resident of the responsible institution.			
No, the draft variation is not supported.	This submitter noted an error in the draft variation (identified in bolded text below) and requests that it is amended. *'Inner package, in relation to special medical purpose* ~~***food***~~ ***product*** *for infants means…'*	NZFS	Noted. FSANZ has amended this error in the primary variation at section 2.9.1—3.
Definition of medium chain triglycerides *At the 2nd CFS the draft variation (subsection 1.1.2—2(3) removed the definition of medium chain triglycerides.*			
Yes, the draft variation is supported.	These submitters supported the removal of the definition, requested FSANZ comment in the approval report that the intent of the regulation is not to prohibit naturally occurring MCT in vegetable oils.	AFGC, INC, SML, DAN, DCANZ, A2M, FCG	FSANZ has amended the primary variation to provide clarity on the use of naturally occurring MCT in vegetable oils.
Other comments related to definitions		**Submitter(s)**	**FSANZ response**
Lactose free claims	These submitters noted that the requirements for 'lactose free' in Australia and New Zealand requires no detectable lactose. This is inconsistent with international regulations such as EU No 2016/127. Low lactose is not an accurate descriptor and impacts on consumers' ability to make informed choice.	DAN, INC, SML, DCANZ, A2M, AFGC, FCG	As discussed below, lactose modified formulas have been recategorised as SMPPi. As a result manufacturers will be able to label the products to indicate the intended medical purpose, such as for infants with lactose intolerance. The requirement for 'lactose free' to mean no detectable lactose applies across the Code. There is no intention to review this requirement through Proposal P1028. See section 4.4 for further information.

Section 3: Regulatory framework

Issue	Comment	Submitter(s)	FSANZ response
Division 4 Special medical purpose product for infants *At the 2nd CFS the draft variation prescribed:* - *A separate division for SMPPi, with stand-alone definition and separate composition, labelling and other regulatory requirements.*			
Yes, the draft variation is supported.	These submitters support the new SMPPi category.	NAC, PHI2, ASCIA, A&AA, ADG, NZFS, AFGC, NES, FCG	Noted.
Yes, the draft variation is supported.	This submitter agrees with the categorisation of SMPPi and notes they: • include any infant formula specifically formulated for the dietary management of a medically diagnosed disease disorder or condition • are intended for a medical purpose and not for use by healthy infants • are almost all exclusively imported • have limited availability, often only through hospitals or on prescription and therefore already have restricted accessibility • are very costly and often available only with subsidisation and on prescription.	INC	Noted.
No, the draft variation is not supported.	This submitter sought clarification regarding what processes will be established to ensure that products listed under the SMPPi category are and have demonstrated efficacy and safety for use for the medical condition they are formulated for. This submitter further notes that without regulation the SMPPi category will be	QLDH	This view has been previously discussed in the 2nd CFS. While the SMPPi category has flexible requirements, these products must still comply with section 2.9.1—42and Australian and New Zealand food laws.

Issue	Comment	Submitter(s)	FSANZ response
	susceptible to claiming benefit for any condition and without limitation.		Australian and New Zealand food laws already expressly require that all food sold—including infant formula products—must be safe and suitable. Any SMPPi must be suitable for its intended purpose under these laws. Responsibility for evaluating the efficacy of a new substance or changes in composition lies with the manufactures of the products and the medical professional supervising or managing the infants' condition. Subjecting each SMPPi to pre-market assessment requirements would introduce long delays in getting those products to vulnerable infants who depend on these products as their sole source of nutrition.
SMPPi – Nutrient Composition			
Yes, the draft variation is supported.	These submitters supported the composition for SMPPi deviating from the specific compositional requirements for infant formula products where required to address the product's special medical purpose. These submitters noted that this is critical in ensuring import and continued supply of these products.	NZFGC, DAN, INC, NES	Noted.
Yes, the draft variation is supported.	These submitters supported the draft variation categorising formula based on alternative proteins (such as rice) as SMPPi. These submitters noted that formula based on alternative proteins or formula for cow's milk protein allergy should undergo appropriate pre-market assessment, showing they are suitable for infant growth, development and have hypo-allergenicity data that supports their categorisation as SMPPi.	NAC, PHI2, ASCIA, A&AA	FSANZ notes that while SMPPi can deviate from the prescribed protein sources for the products' special medical purpose it still must comply with the Code and Australian and New Zealand food laws. Australian and New Zealand food laws already expressly require that all food sold – including infant formula products – must be safe and suitable. Based on this any SMPPi must be suitable for its intended purpose under these laws. Subjecting SMPPi to pre-market assessment requirements would introduce long delays in getting those products to infants that would need them. Other risk management strategies are in place to prevent misuse of these products. This includes use

Issue	Comment	Submitter(s)	FSANZ response
			under medical supervision, mandated labelling and a restriction of sale. See section 4.1 for further information.
No, the draft variation is not supported.	These submitters have noted that the draft variation in the 2nd CFS does not include reference to compositional parameters outside of Schedule 29 for SMPPi. These submitters propose adding clear provisions in section 2.9.1—32 that require SMPPi to comply with the baseline composition of infant formula.	QLDH, NZFS, NSWFA	FSANZ acknowledges that the 2nd CFS draft variations only included those substances listed in S29—5. This was not the intent of the draft variation, as the 2nd CFS noted the complete baseline composition of infant formula (macronutrients, micronutrients, energy, food additives) should only deviate in SMPPi where medically required. FSANZ has amended the primary variation at Attachment A to reflect the inclusion of all compositional parameters in Standard 2.9.1 Division 2 and all compositional requirements noted for infant formula in S29. Noting that the exception provided by 2.9.1—42 will apply to all composition parameters. Further information is at section 4.2 of this report.
No, the draft variation is not supported.	These submitters request FSANZ revise the proposed wording of 2.9.1—32(2) relating to (b) prevention of sale. The submitter considers the wording *'would otherwise prevent the sale of the food'* is too broad and reasons other than those intended could be used by a business to deviate from the baseline composition. The submitters proposed that (b) could be amended to 'subject to a FSANZ equivalent independent assessment by a competent overseas regulatory authority', or similar wording.	NZFS, NSWFA, TAS DoH, VIC DoH & DEECA	The FSANZ Act does not clearly authorise FSANZ to include such a provision in a standard. Nor is it apparent that such a provision would deliver the level of certainty and objectivity required of a 'standard' by the FSANZ Act. Such a provision would also require FSANZ to define what an 'equivalent independent assessment' is and determine who is a competent overseas regulatory authority may be. FSANZ also considers the addition of this type of provision to be unwarranted. See section 4.2 of this report. FSANZ has amended the SMPPi composition requirements to provide a clearer and tighter regulation. See section 4.2 of this report.
SMPPi – Pre-market safety assessment requirements novel foods and nutritive substances *At the 2nd CFS the draft variation (subsection 2.9.1—30(a)) notes that the following provisions do not apply to SMPPi* • paragraphs 1.1.1—10(6)(b) (foods used as nutritive substances) and 1.1.1—10(6)(f) (novel foods).			

Issue	Comment	Submitter(s)	FSANZ response
Yes, the draft variation is supported.	This submitter supported the proposed draft variation and noted that the SMPPi provisions for nutritive substances and novel foods are the same as that for FSMP. In addition, the submitter noted that SMPPi require flexibility in composition in order to allow the importation of products from the EU and continuation of supply.	DAN	Noted.
No, the draft variation is not supported.	These submitters did not support the proposed draft variation due to concerns that the width of permissions granted for nutritive substances and novel foods is too broad and may pose risks to infant health. In addition these submitters are concerned regarding the lack of pre-market assessment of new substances added to SMPPi that have not been added for a special medical purpose. These submitters have proposed the following amendments to the draft variation (identified in bolded text): 'paragraphs 1.1.1—10(6)(b) (foods used as nutritive substances) and 1.1.1—10(6)(f) (novel foods) ***where the nutritive substance or novel food is deemed medically necessary for the dietary management of the relevant condition or has been subject to an equivalent rigorous assessment for safety and suitability by an overseas regulatory authority*** Or ***where that the substance has undergone a rigorous assessment by at least one regulatory authority equivalent to FSANZ.***	NSWFA, TAS DoH, VIC DoH & DEECA	Noted. An additional subsection has been added to the primary variation at section 2.9.1—35 to specifically state that a novel food may only be added to SMPPi if required to achieve that product's intended medical purpose. Nutritive substances added to SMPPi are required to either be prescribed in the baseline composition of infant formula, required to achieve the products medical purpose or would otherwise prevent the sale of the SMPPi. FSANZ has not included the text suggested by submitters in the primary variation due to its ambiguity. See response above.
Lactose intolerance and cow's milk protein allergy			
Note that these conditions have	These submitters noted that lactose intolerance, cow's milk protein intolerance and cow's milk protein allergy were	PHI1, NAC, QLDH, ADG, INC, WA DoH	FSANZ acknowledges this comment from the submitters and notes this inaccuracy was corrected in the Living Document to the 2nd CFS (FSANZ 2023h).

Issue	Comment	Submitter(s)	FSANZ response
been incorrectly captured.	incorrectly captured within the discussion of the 2nd CFS (see section 2.3.4).		
Recommends adoption of new terminology.	This submitter recommended the Code adopt the accepted terminology outlined in the papers by Fiocchi (2022) and Boyce et al (2010) for consistent messaging to industry.	ADG	The recommendation to adopt this terminology has implications for other parts of the Code and as such, is beyond the scope of P1028. However, FSANZ has considered this terminology when discussing allergy in this report.
	The submitter noted there is commonly a lack of knowledge regarding lactose free/lactose intolerance and cow's milk protein allergy, which is noted in the research provided.	ADG	In making its decision, FSANZ had regard to the papers provided. It will also consider including them in consumer information to be developed after approval and gazettal of the standards.
Products represented as low lactose and lactose free formula *At the 2nd CFS the draft variation categorised:* • *Low lactose and lactose free formula as infant formula and are subject to the requirements noted in 2.9.1 Division 1–3.*			
No, the draft variation is not supported and/or recommend alternative.	***1. Categorisation as SMPPi*** These submitters did not support the draft variation at the 2nd CFS and instead, considered that low lactose and lactose free formula should be categorised as SMPPi. Submitters provided the following reasons: • They are required for a medical purpose, can be labelled with that purpose and only consumed when medically necessary. • Reduces chance of being purchased for an infant with cow's milk protein allergy. • Seeking advice from a health professional before introducing SMPPi can prolong breastfeeding duration.	NSWFA, QLDH, NZFS, VIC DoH & DEECA, WA DoH, PHI1, PHI2, PHI3, PHI4, NAC, ADG, DA, A&AA	After consideration of submissions, FSANZ agrees with the reasons presented and has amended the draft variation to categorise formula that have modified lactose content (for example low lactose and lactose free) as SMPPi. Further details are provided below in section 7 of this Appendix and section 4.4 of the report, including detailed comments from submitters.

Issue	Comment	Submitter(s)	FSANZ response
	• Replacing lactose moves away from breast milk composition which can be unsafe for vulnerable infants. • Research on increasing infant obesity rates and increasing use of low lactose and lactose free formula and later onset obesity associated with low lactose formula obesity. • Lack of longitudinal studies on growth and development outcomes and the relevance of insulin and glucose levels on childhood metabolic programming and exposure to sweet high GI food products. • Reduced risk of caregivers misinterpreting and identifying products. One submitter considered it important to retain the ability for soy-based formula, which may be represented as lactose free, to be positioned as infant formula, therefore not having restricted sale.		
No, the draft variation is not supported and/or recommend alternative.	***2. Categorisation as SMPPi without restricted sale*** This submitter did not support the draft variation at the 2nd CFS and instead recommended that products such as those for lactose intolerance be exempt from sale as low risk SMPPi. The submitter noted that restriction on sale has potential to be inequitable and unsafe, particularly due to limited access in rural and remote communities.	NZFGC	Noted. FSANZ does not agree that any SMPPi should be exempt from restricted sale. As lactose intolerance is a condition that requires medical supervision it is correctly captured under the SMPPi category and will have restricted sale. Further details are provided in section 4.3 and 4.4 of the report.
No, the draft variation is not supported and/or recommend alternative.	***3. Categorisation as either SMPPi without restricted sale or as infant formula and follow-on formula with extended labelling provisions*** These submitters did not support the draft variation at the 2nd CFS and instead considered that low lactose and lactose free formula are low risk and should either remain as infant formula and follow-on formula with extended labelling provisions for lactose intolerance or they should be categorised as SMPPi but be exempt from the restriction on sale.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	As above, FSANZ considers that the formulas for lactose intolerance are correctly captured as SMPPi. As formulas for lactose intolerance have significant compositional differences to infant formula and breast milk, they are not consider low risk. Categorisation as SMPPi allows for extended labelling provisions including the medical purpose and true nature of the food. Further details are provided in section 4.1, 4.3 and 4.4 of the report.

Issue	Comment	Submitter(s)	FSANZ response
	Submitters considered that regulation as infant formula was overly prescriptive and the labelling requirements were overly restrictive (e.g. not being able to label for lactose intolerance). Submitters noted that if categorised as SMPPi, that product could be labelled for lactose intolerance but considered that sale should not be restricted because it is a low risk product.		
No, the draft variation is not supported and/or recommend alternative.	***4. Remove low lactose formula from sale*** The submitter did not support the draft variation at the 2nd CFS and in addition to recommending low lactose and lactose free formula be categorised as SMPPi, they suggested that there is no aetiological requirement for low lactose infant formula and there should be a transition to removing these from the food supply.	WA DoH	FSANZ agrees that lactose modified formula should be categorised as SMPPi. Further details are provided in section 4.4 of the report.
Categorisation of infant formula products based on extensively hydrolysed protein formula *At the 2nd CFS the draft variation categorised extensively hydrolysed protein formula as a SMPPi.*			
No, the draft variation is not supported and/or recommend alternative.	These submitters did not support the draft variation at the 2nd CFS. The submitters recommended that to be able to appropriately classify extensively hydrolysed protein (eHF), there should be a definition of eHF either for a specific peptide (Dalton) size or proven hypoallergenicity in clinical trials. Submitters noted that the Australian market currently has two eHF infant formula, Aptamil Peptijunior and Nestle Alfare and the Nestle product will soon be discontinued. Because of this, Australia is likely to require more product to be imported from the EU and the US. Studies show wide variability in the extent of hydrolysed proteins between different formula, some of which are not appropriate for use by infants with cow's milk protein allergy. Submitters considered that the potential future influx of imports could increase risk if there is no definition of eHF.	NAC, PHI2, ASCIA, A&AA, ADG	FSANZ does not agree that a definition of extensively hydrolysed protein is required. FSANZ is unaware of any regulation in the EU or otherwise that defines the degree of protein hydrolysis by peptide size. FSANZ considers that creating a definition for extensively hydrolysed protein (that would apply to SMPPi) could create a trade barrier due to being out of step with international regulations. Subjecting SMPPi to potential trade barriers may affect the supply of getting these products to vulnerable infants who depend on them as their sole source of nutrition. The 2nd CFS addressed this issue in sections 2.3.1 and 2.3.3 (FSANZ 2023a). After consideration of submissions received, FSANZ's position remains unchanged. Further details are provided in this table and section 4.6 of the report.

Issue	Comment	Submitter(s)	FSANZ response
	One submitter suggested that if poorer quality eHF enters the market it may increase prescriptions for amino acid formula and increase costs to Medicare in Australia.		
No, the draft variation is not supported and/or recommend alternative.	These submitters did not support the draft variation at the 2nd CFS. These submitters stated that infant formula that has had two of the three macronutrients extensively modified (extensively hydrolysed protein and lactose free) poses a theoretical and unknown risk to infants and requires investigation to ascertain safety.	PHI1, PHI3	FSANZ notes that both of these modifications (individually or together) would result in the product being categorised as a SMPPi with appropriate risk management strategies in place to prevent their misuse. FSANZ also notes that most formula based on extensively hydrolysed protein are generally available through prescription which would also minimise the risk that the formula could be used for the wrong purpose. Further details are provided in section 4.6.
Categorisation of infant formula products based on partially hydrolysed protein *At the 2nd CFS the draft variation categorised partially hydrolysed protein formula as infant formula.*			
Yes, the draft variation is supported.	These submitters supported the draft variation at the 2nd CFS as there is no clinical indication for partially hydrolysed protein in the prevention or treatment of cow's milk protein allergy. While one of these submitters (VIC DoH & DEECA) did agree that partially hydrolysed infant formula should be classified as general purpose, they suggested further consideration is required of labelling restrictions to prevent inappropriate representation as pseudo-medical products.	ASCIA, NZFGC, INC, SML, DAN, DCANZ, A2M, AFGC, FCG, VIC DoH & DEECA	FSANZ notes this comment. See section 7 of this Appendix for discussion of labelling requirements for partially hydrolysed protein infant formula.
No, the draft variation is not supported and/or recommend alternative.	***1. No functional purpose/not suitable to treat or manage medical conditions*** These submitters did not support the draft variation at the 2nd CFS as they had concerns with the inclusion of nutritionally complete infant formula products with a modified formulation included as infant formula products for healthy infants.	QLDH, TAS DoH, DA	FSANZ notes that the evidence base does not support use of partially hydrolysed protein for prevention or treatment of allergy. Only formula based on a partially hydrolysed protein source (i.e. not extensively hydrolysed protein) may be categorised as infant formula or follow-on formula. Hydrolysing protein prior to consumption involves breaking down the protein and in turn aids

Issue	Comment	Submitter(s)	FSANZ response
	These submitters stated that partially hydrolysed protein in infant formula has no functional purpose. They questioned the evidence that partially hydrolysed formula is suitable to treat or manage any medical or health condition and noted a healthy infant would have no requirement for this type of formula. One submitter stated that ASCIA does not recommend using partially hydrolysed formula for dietary management of allergy. Infants with severe allergy such as cow's milk protein allergy are given extensively hydrolysed protein or amino acid-based infant formula products. The submitter identified new evidence that presents data that there is unsubstantiated evidence for compositions such as hydrolysed proteins or low lactose.		the digestibility, therefore such formulas are for the purpose of digestion and have a long history of use (EC SCF 2003). There are no safety concerns with the use of such formulas (see recent EFSA opinions) and removal of this permission misaligns Australia and New Zealand with Codex and EU regulations. FSANZ has not suggested that infant formula based on partially hydrolysed protein (or low lactose and lactose free protein sources) could be used to prevent or treat allergy in infants. Based on the draft variation, an infant formula product with such a purpose would be categorised as SMPPi with the appropriate risk management strategies in place for that category. Further details are provided in section 4.5.
	2. Criteria to differentiate from extensively hydrolysed protein This submitter proposed that criteria are developed that differentiates partially hydrolysed protein formula (as infant formula and follow-on formula) and extensively hydrolysed protein products for SMPPi.	QLDH	FSANZ notes that there is no internationally agreed definition for partial hydrolysis thus it would be difficult to develop criteria and remain internationally consistent. As outlined in the 2nd CFS (section 2.3.3 and Table 2; FSANZ 2023a), the categorisation of infant formula for healthy infants versus SMPPi stems from the product's ability to meet specified compositional requirements for infant formula. If an infant formula is represented as partially hydrolysed and is unable to meet general composition requirements (e.g. requires a higher level of thickeners, which is a safety issue for healthy infants), then it is SMPPi.
Restricted sale of SMPPi *At the* 2nd *CFS the draft variation proposed that the sale of SMPPi be restricted to sale to medical practitioners, dietitians, medical practice, pharmacy or responsible institution or majority seller.*			
Yes, the draft variation is supported.	These submitters supported the draft variation at the 2nd CFS regarding proposed restriction on sale for SMPPi.	NAC, A&AA, ADG	Noted.

Issue	Comment	Submitter(s)	FSANZ response
Yes, the draft variation is supported with amendments.	This submitter supported the proposed restriction on sale for SMPPi, however encouraged further restrictions be placed on pharmacy and online sales. The submitter noted that the current restriction on sale could still allow these products to be purchased without any medical or dietetic guidance or supervision and it may lead to inappropriate marketing of SMPPi. The submitter suggested for 2.9.1—31(1)(b) 'pharmacy' be removed and 'pharmacist' be used instead.	QLDH	FSANZ considers the restriction on sale proposed in the primary variation is appropriate. Regulation of e-commerce (online sales) of food is a matter for the Australian and New Zealand food laws that apply the Code. E-commerce is not within the scope of this proposal, or the remit of FSANZ. FSANZ is aware that products sold online that are to be used under a medical professional are typically accompanied by an online declaration and/or waiver that outlines this important information to caregivers at the point of purchase. FSANZ considers this suggestion as too restrictive and notes it would lead to inconsistencies in the Code between standards 2.9.1 and 2.9.5. Further details are provided in section 4.3, including detailed comments from stakeholders and discussion.
	1. Low versus high risk products These submitters did not support the draft variation at the 2nd CFS because they considered that not all current products for special dietary use are high risk. Submitters suggested that SMPPi be categorised as either low or high risk with a restricted sale exemption for low risk products for the reasons outlined below. • Products will have limited availability within pharmacies both on a geographical basis and time limits on access. • Increases to costs will potentially increase risk to infants. • There may be negative health outcomes for infants who require these products and for caregivers. • Supply chain logistic issues (see below). • Potential to be inequitable due to limited access in rural and remote communities (see below).	NZFGC, INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ does not agree that such an amendment is required. The 2nd CFS addressed the views around low and high risk formulas (section 2.3.1) and, after having regard to all submissions received, FSANZ stands by the conclusion stated in the 2nd CFS. FSANZ also notes that information provided by health professionals on products for special dietary use for transient conditions are not low risk if they are purchased for an infant with an undiagnosed cow's milk protein allergy. For this reason it is appropriate that products for special dietary use for transient conditions should also be restricted to sale in pharmacies. As the symptoms are similar for transient gastrointestinal conditions and cow's milk protein allergy, 'low risk' special dietary use products are not without risk to infants with cow's milk protein allergy (estimated prevalence 3–5%). Issues of supply chain logistics and inequity are discussed in section 4.3 of the report.

Issue	Comment	Submitter(s)	FSANZ response
	One submitter did not support the proposed trade restrictions on all SMPPi and recommended SMPPi be split into non-trade restricted SMPPi (with clear and consistent labelling) and trade restricted SMPPi (with flexible labelling) based on level of specialisation and medical need.		Further details are provided in section 4.3.
	2. Transient gastrointestinal conditions These submitters did not support the draft variation at the 2nd CFS as they did not support the restricted sale of SMPPi for products intended for transient gastrointestinal conditions, for the reasons outlined below. • Transient gastrointestinal conditions are more common than inborn errors of metabolism so many consumers will be impacted. • Transient gastrointestinal conditions are not a reason to stop breastfeeding and formula for such conditions is an intervention considered for formula-fed infants. • Submitters are unaware of misuse of products for gastrointestinal conditions or feeding problems while they have been available via grocery channels. • Gastrointestinal conditions and allergy are classified as a disease/disorder with well-defined, objective and broadly accepted diagnostic criteria in the absence of obvious structural or biochemical alterations. • The United Kingdom's National Institute for Health and Care Excellence (NICE) clinical guidelines indicate a role for products suitable for gastrointestinal conditions such as reflux. They state that for formula-fed infants with frequent regurgitation associated with marked distress, a thickened formula should be tried before alginate therapy.	NES, INC, SML, DAN, DCANZ, A2M, AFGC, FCG	For the reasons stated in section 4.3 of this report, FSANZ does not agree that a change to what was presented in the draft variation at the 2nd CFS is required. The 2nd CFS addressed the views around formula for transient gastrointestinal conditions (section 2.3.6; FSANZ 2023a) and FSANZ stands by the response provided in the 2nd CFS. There is a safety issue if products for special dietary use for transient gastrointestinal conditions are available through grocery stores where the product is more easily accessed for an infant who has an undiagnosed allergy or condition.

Issue	Comment	Submitter(s)	FSANZ response
	Submitters suggested that lower-risk SMPPi for transient gastrointestinal conditions and feeding problems be exempt from restricted sale, with proposed changes to the drafting provided. Other submitters suggested that if availability could be retained through grocery retail channels, there is support for additional clear labelling and/or compositional requirements.		
	3. Adverse health impacts These submitters did not support the draft variation at the 2nd CFS because it may cause adverse health impacts on infants who require them and caregivers. Submitters provided reasons and supporting evidence as outlined below. • Concerns about the veracity of the evidence that supports that restriction on sale will not have negative public health outcomes. • Caregivers could revert to purchasing an infant formula product which is not suitable for their infant if these products have reduced access and availability or be able to communicate modifications to the end user. This in turn could result in negative health outcomes for infants by delaying the intervention by a healthcare professional, putting extra pressure and costs on tertiary care. • When transient gastrointestinal conditions are left unmanaged, the condition will physically and mentally impact the infant and caregiver. • Limited availability and inconvenience of purchase could lead to added stress on caregivers in sourcing the most suitable product for infants.	DAN, NZFGC, INC, SML, DCANZ, A2M, AFGC, FCG	For the reasons stated in section 4.3 of this report, FSANZ does not agree that a change to what was presented in the draft variation at the 2nd CFS is required.
	4. Accessibility – suitability of pharmacy These submitters did not support the draft variation at the 2nd CFS because of concerns related to the suitability of the	NES, DAN, NZFGC, INC, WW, SML,	For the reasons stated in section 4.3 of this report, FSANZ does not agree that a change to what was presented in the draft variation at the 2nd CFS is required.

Issue	Comment	Submitter(s)	FSANZ response
	pharmacy sector to provide suitable products. Submitters provided reasons and supporting evidence as set out below. • Limiting sales will have significant impact on access—the number of pharmacies selling SMPPi will not necessarily increase, prices will go up. • Distance to travel to purchase will increase. • Products for dietary management of gastrointestinal conditions and feeding problems and allergy management will be removed from the grocery retail chain, which is concerning for rural and remote areas. • There are broadly 3300 grocery distribution points throughout Australia where products for transient gastrointestinal conditions are ranged. Removing these will significantly reduce convenience and access to these products. • Australian Federal Government changes to the PBS may challenge the viability of small regional local pharmacies, which would lead to further reduced convenience of access. • There has been a sales channel shift to the grocery retail channel since 2019 due to shopper preference. This reflects broader dynamics of shifting to grocery retail post-COVID due to availability and convenience. • Lack of accessibility is a health and safety issue for infants as demonstrated by the lack of supply in the US in 2021. It also creates stress for caregivers trying to source essential nutrition for infants. • If the product is easier to access online, there is a risk that more caregivers will purchase it outside of a physical store, where there will be no contact with a healthcare professional. • Increases to costs will potentially increase risk to infants. Caregivers will pay a premium if forced to purchase from	DCANZ, A2M, AFGC, FCG	

Issue	Comment	Submitter(s)	FSANZ response
	pharmacies and may not be able to obtain product due to limited shelf space. • Caregivers need reasonable access to SMPPi outside of regular trading hours.		
	5. Inequity These submitters did not support the draft variation at the 2nd CFS because of equity concerns. The following reasons and supporting evidence was provided. • Potential to be inequitable due to limited access to pharmacies in rural and remote communities. (Woolworths Group stores are within a 10 km radius of 90% of the Australian population). • Restrictions may raise safety issues related to inequity where a caregiver may purchase an adult product at the supermarket and administer to their infant. • Those that rely on emergency relief assistance and depend on supermarket vouchers will be impacted.	NZFGC, AFGC, WW	For the reasons stated in section 4.3 of this report, FSANZ does not agree that a change to what was presented in the draft variation at the 2nd CFS is required.
	6. Supply chain issues These submitters did not support the draft variation at the 2nd CFS because of supply chain concerns. The following reasons and supporting evidence was provided. • Slower replenishment of stock in pharmacies compared to grocery retailers due to two-step supply via wholesalers. • Limited storage capacity in most pharmacies, compounded with increased number of caregivers sourcing products. • Limited financial resources in some pharmacies, especially in rural and regional communities, impacting ability to stock all product types.	NZFGC, DAN, INC, SML, DCANZ, A2M, AFGC, FCG	For the reasons stated in section 4.3 of this report, FSANZ does not agree that a change to what was presented in the draft variation at the 2nd CFS is required.

Issue	Comment	Submitter(s)	FSANZ response
	• Reduced opening hours in some pharmacies. • Larger retailers can check in-store availability in real time, giving caregivers the means to find products. • Calls to industry support lines may increase with further sale restrictions due to limited availability and risk of stockpiling. • Products will have limited availability within pharmacies both on geographical basis and time limits on access.		
	7. Connection with healthcare professionals This submitter did not support the draft variation at the 2nd CFS because of concerns about linkages with healthcare professionals. The submitter stated that a caregiver's decision to use products designed for a gastrointestinal condition or cow's milk protein allergy is tied to advice from a healthcare professional. The restriction on sale may break the point of contact between the healthcare professional and the consumer if the consumer feels that they only need to speak to someone in the pharmacy, rather than get a clinical diagnosis from their healthcare professional.	DAN	For the reasons stated in section 4.3 of this report, FSANZ does not agree that a change to what was presented in the draft variation at the 2nd CFS is required.
	8. Further assessment requested These submitters did not support the draft variation at the 2nd CFS. They recommended that FSANZ conduct a risk analysis on the restriction on sale of SMPPi, including the suitability of the pharmacy sector to ensure there is capacity for this change to occur without unintended, undesired or adverse consequences that will impact the infant and/or caregiver. These submitters also encouraged more consultation with remote and regional communities and charitable organisations to understand impacts of sale restriction on vulnerable populations.	DAN, WW	As outlined in the 1st and 2nd CFS, FSANZ did undertake a comprehensive assessment of restriction on sale of SMPPi. In addition to the six rounds of informal consultation, two rounds of legislated consultation and accompanying targeted consultation, since the 2nd CFS, FSANZ has undertaken additional targeted consultation with stakeholders including remote and regional communities, charitable organisations and pharmacy stakeholders. Further details are provided in section 4.3.

Issue	Comment	Submitter(s)	FSANZ response
Other comments related to restricted sale of SMPPi	If restriction on sale for SMPPi proceeds, this submitter suggested that change is communicated by FSANZ during implementation and over the period of transition, covering changes to availability and labels and emphasising that the change is regulatory and not due to health and safety concerns to previous products.	DAN	FSANZ agrees with this recommendation and will work with jurisdictions and relevant experts to develop appropriate educational resources to inform relevant stakeholders about changes to the Code relating to infant formula. See section 8.38 for further detail.
	This submitter recommended a communication plan to educate consumers about the change, so grocery store teams do not have the pressure of answering customer enquiries about the sale restriction.	WW	FSANZ agrees with this recommendation and will work with jurisdictions and relevant experts to develop appropriate educational resources to inform relevant stakeholders about changes to the Code relating to infant formula. This will include in relation to restriction on sale. See section 8.38 for further detail.
	This submitter suggested that if infant formula is categorised as SMPPi, the manufacturer should be required to notify FSANZ of shortages or recalls in order to alert the public. TGA legislation mandates pharmaceutical companies to communicate shortages of medications to the TGA.	A&AA	FSANZ does not agree with the suggestion. Mechanisms are already in place to alert the public to recalls of infant formula product. In addition, FSANZ was advised during consultation with the pharmacy sector that pharmacists are skilled at rationing products and ensuring those who need the products receive it. This was demonstrated on numerous occasions during the COVID pandemic where potential shortages of prescription and over-the-counter medication and general healthcare products were identified and managed early. The unique pharmacy supply chain as well as greater understanding of the needs of the communities they serve, ensures consumers who need these products are prioritised.

Section 4: Nutrient composition

Issue	Submitter(s)	FSANZ response
General composition		
Interpretation of compositional requirements		
This submitter did not support the proposed draft variation for subsection 2.9.1—4(2) and instead recommend amending the heading for section (2) to: *Calculation of energy, **~~and~~** protein **and vitamin A.***	NZFS	FSANZ agrees that the proposed amendments to the heading of section 2.9.1—4(2) better reflect the section's purpose. This change has been made to the draft variation.
Clarification requested on A1265 (FSANZ 2023j)		
This submitter sought clarity on if the draft Standard 2.9.1 would incorporate the variations introduced in Attachment A of A1265, specifically repealing subsection 2.9.1—7(2). A1265 Call for Submissions proposed to remove the current prohibition in Standard 2.9.1 on the use of ITF and/or GOS with LNnT.	DSM	A1265 has been approved and amendments to Standard 2.9.1 have been gazetted. This includes the removal of the prohibition in Standard 2.9.1 on the use of ITF and/or GOS with LNnT. This and other variations introduced from A1265 will be carried over into the P1028 draft variation.
Composition of transient gastrointestinal formulas		
FSANZ states that 'the presence of these representations [descriptions as colic or anti-reflux] can therefore influence consumer choice when purchasing formula and these products are typically sold at a higher price point despite not being that different compositionally.' (p21 SD4). The submitters strongly disputed the products are not that different compositionally. Extensive research and development has been applied to these products before they are ever released onto the market. FSANZ's off-handed statement is neither true nor helpful to the issues under discussion.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	This statement has been deduced from research (Bronsky et al. 2019; Vandenplas et al. 2019; Dipasquale et al. 2020; Hegar et al. 2021) that notes formulas for transient gastrointestinal conditions (such as fussing, colic, constipation and anti-reflux) differ from infant formula due to the following compositional requirements: • Partially hydrolysed protein • Reduced lactose content • Change in lipid content • Addition of thickening agents (in some cases).

Issue	Submitter(s)	FSANZ response
		All three of the above compositional modifications can be achieved under the current infant formula compositional requirements. Because of this, FSANZ reiterates that these formulas do not differ significantly from infant formula composition. Further, evidence to substantiate the view of these submitters was not provided to FSANZ via the 2nd CFS.
Optional ingredients		
The submitter did not support optional ingredients such as LC-PUFAs not being reviewed and does also not support maintaining indefinite optional status of nucleotides, taurine and lutein. The submitter requested FSANZ consider a mechanism to review the evidence after a specific timeframe (e.g. five years after gazettal) to ensure any future optional ingredients are either added to all infant formula or revoked.	TAS DoH	FSANZ notes that the inconsistency is with the EU regulations, not with international regulations more broadly. If there is a substantial evidence base, FSANZ would look to revise optional ingredients to mandatory. This would require evidence that demonstrates that they are essential nutrients and population level nutrient reference values would need to be identified. Examples of this include inositol, L-carnitine and choline.
This submitter requests special consideration beyond 'general practice' is needed for infant formula product regulation and optional ingredients should be assessed and converted to mandatory additions if the best available scientific evidence shows essentiality of these ingredients for the normal growth and development of infants.	NSWFA	FSANZ agrees that where the evidence shows an essential need for these ingredients, they should be mandated and no longer optional.
Level of evidence		
This submitter stated that there were several proposed changes ushered in by FSANZ throughout the 2nd CFS and SDs of P1028 with the rationale for change being based on 'no new evidence has been provided within the 1st CFS'. In these instances, it would have been prudent for FSANZ to conduct a review of all the existing evidence and/or await new evidence before making changes. Sheep milk as a protein source was cited as an example.	WA DoH	FSANZ undertook a full assessment of nutrient composition in 2016 (FSANZ 2016d) and this was supplemented by further assessment in the 2021 CP (FSANZ 2021g). There is no argument to support waiting for new evidence particularly when the change relates to aligning with international requirements and no safety issues have been identified. See section 4.7 on protein source for specific responses related to sheep milk protein.

Issue	Submitter(s)	FSANZ response
SMPPi nutrient composition		
This submitter disagreed with nutrient composition *to support normal growth and development* and suggests the wording is changed to ***'expected growth and development'*** to accommodate infants where SMPPi make up 20–100% of their nutritional requirements.	QIdH	FSANZ notes that the terminology *to support normal growth and development* is reflected in the Ministerial Policy Guideline and the NHMRC Infant Feeding Guidelines. In addition, SMPPi composition is required to deviate from infant formula composition. The terminology is used in the 2nd CFS and did not warrant any change to the drafting.
Establishment of expert panels for regulatory controls on composition of SMPPi		
The submitters noted that the regulatory controls in place in source countries for SMPPi, are excellent for low volume, high risk, specialist products within the SMPPi category, to deliver the life-saving nutritional requirements of infants requiring them. Even if an expert panel was established to assess every SMPPi imported, it could have a dire public health impact if there was any hold up or delay to imports.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	This issue was considered in the 2nd CFS (FSANZ 2023a). After consideration of submissions received, FSANZ's position remains the same. It does not intend to establish an expert panel to assess SMPPi imported into Australia and New Zealand.
Guidance Upper Levels *At the 2nd CFS the draft variation prescribed:* • *Current Division 6 Guideline Requirements would be replaced by Guidance Upper Limits (GULs) described in Schedule 29 and Standard 2.9.1, with accompanying Notes explaining that GULs are not mandatory or binding and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge.*		
This submitter supported the draft variation but is concerned that enforcement agencies may not understand the difference between a GUL and a maximum limit. Information provided in confidence where use of a GUL is justified.	DAN	FSANZ acknowledges that some naturally occurring nutrients in the base composition of milk have seasonal fluctuations. The GULs prescribed have accounted for this. FSANZ has provided further information on the difference between GULs and maximum limits in the AR and the ES.

Issue	Submitter(s)	FSANZ response
These submitters supported the continued use of GULs for the composition of infant formula and follow-on formula and the accompanying notes which provide an explanation.	INC, SML, DAN, NZFS, DCANZ, FCG, A2M, AFGC	Noted.
These submitters noted discrepancy in the GUL note compared to the equivalent statement in the relevant Codex standards. Two submitters requested that the word “usually” be included in alignment with the Codex wording, for example *‘these Guidance Upper Levels should **usually** not be exceeded’.* One submitter noted that Codex CXS 72-1981 highlights that GULs are set when there is insufficient evidence for a science-based risk assessment and are derived based on meeting nutrient requirements and an established history of safe use. This submitter noted that in some instances FSANZ is proposing values lower than found in products currently on the market and for which there is an apparent history of safe use and insufficient scientific evidence to inform a maximum or GUL. Two notable examples of the proposed GUL lower than used in current practice and for which there are no significant risks based on current scientific knowledge, are docosahexaenoic acid (DHA) and L-carnitine. NZFS requests that FSANZ reconsiders the proposed GULs for DHA and L carnitine.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFS	FSANZ acknowledges the discrepancy between the text in the draft variation at the 2nd CFS and the relevant note in Codex CXS 72-1981 (Codex 1981). FSANZ has amended the GUL to increase alignment with Codex CXS 72-1981 and address submitter concerns, where appropriate (changes are highlighted below in bolded text). *A Guidance Upper Level … is a recommended upper level for nutrients which pose no significant risks on the basis of current scientific knowledge. **These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use.** These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons.* The word 'usually' has not been added to the text of GUL. To do so would render the GUL unclear. FSANZ has addressed concerns regarding specific nutrients in their respective sections.
This submitter did not support GULs being exceeded due to high or variable contents in nutrients of infant formula and/or follow-on formula. This submission also noted the inclusion of unnecessary amounts of components may put a burden on metabolic and other physiological functions of the infant and will reduce the margin of safety. These maximum values should be based on available scientific data on infants' requirements and the absence of adverse effects.	WA DoH	FSANZ notes that GULs act as guidance levels for manufacturers. They are derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. In addition, GULs should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons.

Issue		Submitter(s)	FSANZ response
Nutrient composition in infant formula and follow-on formula			
Carbohydrate source *At the 2nd CFS the draft variation (2.9.1—5) prescribed:* *(2) Subject to subsection (3), infant formula and follow-on formula must not contain added fructose and/or added sucrose.* *(3) Infant formula manufactured from partially hydrolysed protein may contain added fructose and/or added sucrose, provided that:* *(a) the fructose and/or sucrose is added to the formula to provide a source of carbohydrate; and* *(b) the sum of the added fructose and/or sucrose in the formula does not exceed 20% of available carbohydrates in the formula.*			
Yes, the draft variation is supported.	This submitter supported the approach to carbohydrate source and the additional clarification that sucrose and fructose can only be added to partially hydrolysed infant formula.	TAS DoH	Noted.
	These submitters supported the intent of the proposed draft variation, however requested clarification regarding incidental presence of sucrose and fructose where residual fructose at small levels may be 'added' as part of the inulin-type fructans. As the prohibition in 2.9.1—5(2) is more restrictive than guidance provided in Codex it may create issues for infant formula products that contain ingredients such as FOS which may have small amounts of sucrose carried over. In addition, sucrose is a common carrier used in minor amounts in vitamins, for example, used in infant formula. Its use in this context is as a processing aid. These sugars may be present in low levels in other ingredients, for example fructo-oligosaccharides contains fructose. These submitters suggested amending the clause to read (added text highlighted in bolded text below) *'…infant formula and follow-on formula must not contain **directly** added fructose and/or added sucrose **as a carbohydrate source**'.*	DAN, INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ acknowledges that clarity is needed regarding the presence of sucrose and fructose where residual levels may be 'added' as part of the inulin-type fructans or as processing aids. FSANZ has amended the draft variation to clarify that the restriction on added fructose and/or sucrose does not apply to added fructose and/or sucrose that is present in infant formula and follow-on formula as a result of the addition of inulin-type fructans in accordance with the Standard and/or the use of a substance as a processing aid in accordance with the Code. This amendment is at subsection 2.9.1—5(4) of the primary variation. FSANZ has also provided further rationale in SD1 to note that residual levels from inulin-type fructans or processing aids may still be present in infant formula and follow-on formula.
	The submitter recommended that paragraph 2.9.1—5(3)(a) be re-drafted to remove the words 'source of' as this term is typically	NSWFA	FSANZ does not consider the words 'source of' need to be removed. Paragraph 2.9.1—5(3)(a) sets compositional

Issue		Submitter(s)	FSANZ response
	seen as a nutrition content claim. Given nutrition content claims are prohibited for infant formula products the use of the term here is potentially confusing.		parameters, which can note the reason or purpose for addition. For example 'source of carbohydrate'. This paragraph does not permit or prescribe nutrient content claims (labelling requirements). In addition paragraph 1.2.7—4(b) states that nutrient content claims and health claims cannot be made on infant formula products. There is a difference between carbohydrate added as a source of carbohydrate (i.e. as a macronutrient) versus carbohydrate added as a nutritive substance (e.g. a human identical milk oligosaccharide). In addition, the words 'source of' are also used in Codex CXS 72-1981 (Codex 1981).
No, the draft variation is not supported.	The submitter did not support the draft variation, as it did not prescribe a specification for the type of carbohydrate to be included in infant formula products. The submitter requested the introduction of specific carbohydrate source(s). This submitter also noted that both Codex and EFSA have strict recommendations for the types of carbohydrate provided in infant formula and follow-on formula. Setting a guideline for carbohydrate amount and type will minimise variations to the incorporation of free sugars, including glucose.	WA DoH	FSANZ notes the scientific literature provided has limited relevance to base regulatory limits for carbohydrate source. FSANZ does not agree for the reasons state in section 4.8 of this report.
Carbohydrate amount *At the 2nd CFS the draft variation:* • *did not prescribe a minimum or maximum amount for carbohydrate.*			
No, the draft variation is not supported.	These submitters did not support not prescribing a minimum or maximum amount for carbohydrate and requested the introduction of a specified carbohydrate amount.	WA DoH, QLDH	After consideration of submissions, FSANZ has retained its approach of not prescribing a minimum or maximum level for

Issue		Submitter(s)	FSANZ response
	This submitter noted that the regulations for carbohydrate limits are misleading and there is no appropriate longitudinal data providing long term safety.	PHI3	carbohydrate content in infant formula and follow-on formula for the reasons set out in section 4.8 of this report.
Lactose minimum *At the 2nd CFS the draft variation:* • *did not prescribe a minimum level for lactose.*			
No, the draft variation is not supported.	This submitter suggested a minimum standard lactose concentrations in infant formula must be included (reference limit, lactose >53.6 g/L) (Boss, Gardiner et al. 2018).	WA DoH	Regulation EU 2016/127 (European Commission 2016a) sets minimum lactose content of 1.1 g/100 kJ which does not apply to soy-based products or 'lactose free' products. There is no nutritional requirement for lactose (no NRV) and therefore nothing on which to define a minimum amount. FSANZ notes that the minimum lactose set by the EU appears to be based on the following statement EFSA (2014): *The Panel notes that the minimum lactose content has its origin in the traditional practice of diluting cow's milk to make it more suitable for infant feeding with respect to protein.* In addition, the protein source prescribed in the primary variation (cow, sheep, goat), which constitute base ingredients of infant formula products, have similar lactose content. This further ensures that lactose is the primary carbohydrate.
	This submitter did not support the proposed option and instead recommended a minimum level for lactose of 53.6 g/L is required in infant formula.	PHI1	
	This submitter noted that it is assumed that lactose would be the main carbohydrate component, as sucrose or fructose should not be added, however this needs to be clarified.	QLDH	
Fat requirements *At the 2nd CFS the draft variation (2.9.1—7(1)) prescribed clauses (a)–(f) for fat composition.*			
No, the draft variation is not supported.	This submitter did not support the draft variation and instead suggested the following amendments: • Amend paragraph 2.9.1—7(1)(c) for consistency to:	NZFS	FSANZ agrees with the simple corrections this submitter has proposed and has amended the primary variation at subsection 2.9.1—7.

Issue		Submitter(s)	FSANZ response
	*(c) have an arachidonic acid (20:4 **n-6**) content of equal to or more than docosahexaenoic acid (22:6 n-3) content; and* • Amend paragraph 2.9.2—7(1)(f) - first sentence of the note to: *"It is recommended that infant formula and follow-on formula contain a fatty acid listed in Column 1 of the table **in section S29—4** in an amount".*		
Long chain fatty acids *At the 2nd CFS the draft variation for S29—4 retained the current limits for long chain fatty acids present in infant formula and follow-on formula:* • *Long chain omega 6 series fatty acids (C> = 20) - Not more than 2% of the total fatty acids* • *Long chain omega 3 series fatty acids (C> = 20) - Not more than 1% of the total fatty acids.*			
No, the draft variation is not supported.	These submitters queried the inclusion of these limits given the consideration from 2016 and the consolidation of this view in SD1, Table 4.4 of the 2016 CP. The submitters had understood that this view had not changed in subsequent consultations. Submitters considered their inclusion as unnecessary regulation (and inconsistent with the Codex standard).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ acknowledges that the limits for n-6 and n-3 LC-PUFA were not discussed in the 2nd CFS. FSANZ position on this issue was and is as stated in the 2016 CP (FSANZ 2016b). After consideration of submissions, FSANZ's position on this issue remains unchanged. The. The consequential variation will replace the minimum ratio and limits for n-6 and n-3 LC-PUFA with the Codex minimum ratio of AA:DHA to avoid metabolic imbalance between n-3 LC-PUFAs and n-6 LC-PUFAs.
Docosahexaenoic Acid (DHA) *At the 2nd CFS the draft variation for S29—4 prescribed:* • *a GUL of 7 mg/100 kJ for DHA.*			
No, the draft variation is not supported.	These submitters did not support the GUL of 7 mg/100 kJ and recommend a higher level be prescribed. Three submitters recommended the level be increased to 12 mg/100 kJ which is within the range currently permitted, is	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFS,	FSANZ acknowledges that a maximum of 12 mg/100 kJ is consistent with the level reported in human milk, aligns with EU 2016/127 (European Commission 2016a) and is reflective of levels currently found in products on the Australia and New Zealand market. In addition, the draft variation also applies other mechanisms to ensure suitability of product formulations in

Issue		Submitter(s)	FSANZ response
	consistent with the level reported in human milk and aligns with the EU maximum level. One submitter also noted that there are currently products on the market that exceed this value. One submitter suggested a level of 9.6 mg/kJ in alignment with the recently updated Chinese infant formula regulations (GB10765-2021 and GB10766-2021) be adopted.	CCI Submission	relation to DHA levels through the specified ratios for arachidonic acid, eicosapentaenoic acid and other LC-PUFA. The consequential variation now prescribes a DHA maximum of 12 mg/100 kJ.
DHA requirements in infant formula products *At the 2nd CFS the draft variation prescribed:* • *DHA as an optional ingredient with a GUL of 7 mg/100 kJ in infant formula and follow-on formula.*			
No, the draft variation is not supported.	These submitters recommended a DHA minimum of 4.8 mg/100 kJ should be reached in follow-on formula, in line with the levels prescribed in CCNFSDU43 and Codex CXS 156-1987.	GOED, CCI submission	The views of this submitter have previously been explored and consulted on. FSANZ encourages this submitter to refer to the discussion in section 2.1.2 of SD2 to the 1st CFS (FSANZ 2022d). FSANZ reiterates the findings of FSANZ 2016 Nutrition Assessment (FSANZ 2016d) which stated 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. After consideration of submissions received to date, FSANZ 's position has not changed
	The submitter proposed that formula for infants (0–12 months) should contain, when added, a minimum level of 4.8 mg/100 kJ DHA, with ARA:DHA at a ratio of 1:1–2:1. Further details of the evidence provided in this submission can be found on the P1028 webpage [16].	DSM	As noted above, FSANZ has considered the divergent views on DHA in previous consultations (specifically SD2 to the 1st CFS (FSANZ 2022d) and SD2 to the 2nd CFS(FSANZ 2023c)). In these papers, FSANZ concluded mandatory inclusion of a minimum amount of DHA was based on mixed and inconclusive studies on infant development and therefore not needed.

[16] P1028 – Infant Formula (foodstandards.gov.au)

Issue		Submitter(s)	FSANZ response
			The current scientific evidence supporting the beneficial effects of DHA on normal growth and development of infants is vast and continues to be equivocal. For this reason, setting a mandatory requirement for DHA addition to infant formula products within this proposal would be inappropriate. FSANZ notes that anyone can apply to amend the Code at any time. Those seeking to set a DHA compositional requirement may apply for such an amendment and in doing so provide a dossier of evidence justifying mandating DHA in infant formula and follow-on formula.
	These submitters noted that infants receiving infant formula must receive adequate amounts of DHA to cover their nutritional requirements. The most recent guidelines EU (2016/27 Annex I&II) revision by the European Food Safety Authority (EFSA) (2016) recommend that infant formula and follow-on formula must contain a minimum (and maximum) level of DHA and it would be timely for FSANZ to consider a review of evidence on whether DHA is an essential or partially essential nutrient and as such, whether these ingredients should be mandatory.	WA DoH, TAS	This issue has previously been explored and consulted on. See in this regard, section 2.1.2 of SD2 to the 1st CFS (FSANZ 2022d) and section 4.5 of SD2 to the 2nd CFS (FSANZ 2023c). After consideration of submissions received, FSANZ is not aware of any evidence to warrant a change in its position on this issue.
Linoleic acid *At the 2nd CFS the draft variation prescribed that infant formula and follow-on formula must have:* • *no less than 90 mg/100 kJ of linoleic acid; and* • *not more than 335 mg/100 kJ of linoleic acid.*			
No, the draft variation is not supported.	This submitter did not support the proposed minimum or maximum for linoleic acid. The submitter noted that the July 2021 SD1 and April 2022 SD2 did not include a recent review of available evidence on the effects of linoleic acid in an infant diet on infant health outcomes in relation to the recently adapted regulatory changes for the addition of linoleic acid to infant formula (Carlson, Schipper et al., 2021). The review provides an overview of the outcomes of crossing recognised lower or upper	WA DoH	Section 5.3 of the 2021 CP2 (FSANZ 2021f) and section 2.1.2 of SD2 of the 1st CFS (FSANZ 2022d) discussed this issue extensively. After considering submissions, FSANZ stands by the response provided position stated in the 1st CFS. FSANZ acknowledges the review provided by this submitter, however notes the high degree of complexity in the bioconversion of essential fatty acids to LC-PUFAs (DHA and

Issue		Submitter(s)	FSANZ response
	levels of LA in infant formula which could increase the risk of negative short and long term consequences. In light of the review and the complexity of determining required levels of fatty acids in infant formula it would be prudent for FSANZ to reconsider the proposed minimum and maximum LA levels.		ARA) and lack of consensus amongst the scientific community related to dietary intakes of LA and ALA and LC-PUFAs (e.g. DHA). FSANZ also notes the review provided indicates that requirements may vary among individual infants and complicates the formulation of infant nutritional guidelines. It concludes that there is an evidence gap on potential impacts of LA and ALA and suggests a need for clinical intervention trials to create clarity about safe levels of LA. Based on the assessment, FSANZ considers the proposed values to still be appropriate.
Lecithin/phospholipids *At the 2nd CFS the draft variation prescribed:* • *a maximum limit of 5 g/L, subject to compliance with the maximum limit of total phospholipids of 72 mg/100 kJ (I.e. 2 g/L).*			
No, the draft variation is not supported.	This submitter supported the proposed limit of total phospholipids of 72 mg/100 kJ but recommends that the maximum is presented as a GUL on the basis of aligning with the principles for selection of GULs for vitamins and minerals and the absence of specific safety concerns or evidence of adverse effects of phospholipid intake in infants 0–12 months.	FCG	This issue has previously been explored and consulted on. See the discussion in section 4.5 of SD2 to the 2nd CFS (FSANZ 2023c). After consideration of submissions received, FSANZ is not aware of any evidence to warrant a change in its position on this issue. FSANZ reiterates that the phospholipid maximum is a restriction and should not be confused as a permission for addition of a nutritive substance. Therefore, adapting the phospholipid maximum to a GUL is not appropriate. The EU 2016/127 and Codex CXS 72-1981 (Codex 1981) do not express the phospholipid maximum as a GUL either.
	This submitter did not support the proposed option and instead recommended reducing the level to 1 g/L in line with the EU and breastmilk concentrations.	NSWFA	FSANZ has discussed this issue in section 6 of this Appendix.

Issue		Submitter(s)	FSANZ response
Nitrogen Conversion Factor (NCF) *In the 2nd CFS, the draft variation (S29—2A) prescribed:* • *protein content of an infant formula product must be calculated by multiplying the nitrogen content of the product by a nitrogen-to-protein conversion factor of 6.25.*			
No, the draft variation is not supported.	This submitter did not agree with the approach to adopt a single NCF for all protein sources and consider 6.38 to be more appropriate for dairy. The submitter considers that the full footnote for Codex CXS 72-1981 should be included.	FCG	FSANZ notes no new evidence was provided for consideration and therefore retains its position of adopting 6.25 as the NCF for all protein sources. This approach aligns with the most recent international regulations; EU 2016/127 and Codex CXS 156-1987. It is also considered to be a scientifically valid NCF for whey-based infant formula (which represents the majority of the market). It is also valid to apply this NCF for soy-based protein as long as the minimum protein amount is increased to 0.54 g/100 kJ (which is present within the consequential variation). Notes within the Code are not enforceable and therefore FSANZ does not consider adopting the footnote from Codex CXS 72-1981 is necessary or appropriate from a legal standpoint.
Protein source *At the 2nd CFS the draft variation prescribed:* • *an explicit list of protein sources that could be used in infant formula and follow-on formula, which includes* ○ *cow milk protein, goat milk protein, sheep milk protein, soy protein isolate and partially hydrolysed protein of one or more of these specified proteins.*			
Supported the draft variation to prescribe an explicit list of protein sources.	These submitters supported the proposal for prescribing the protein sources that have undergone pre-market assessment to be permitted in infant formula products.	QLDH, WA DoH, TAS DoH	Noted.

Issue		Submitter(s)	FSANZ response
No, the draft variation is not supported and/or recommend alternative.	This submitter supported the proposed option but maintained their previous position that a positive list of protein sources for use in infant and follow-on formula should not be needed.	FCG	This issue has previously been explored and consulted on. See section 4.4.4 of SD2 to the 2nd CFS (FSANZ 2023c). After consideration of submissions received, FSANZ is not aware of any evidence to warrant a change in its position on this issue.
	The submitter did not support restricting protein sources to cow milk protein, goat milk protein, soy protein isolate and partially hydrolysed protein derived from these specified proteins as it is not aligned with the Ministerial Policy Guideline and Codex. The submitter notes that only 'basic milk protein' and 'soy protein' has undergone pre-market assessment in Australia. Combining rice and pea protein offers a scientifically justified approach to obtain a complete amino acid profile. Sprout Organic Infant Formula which incorporates a combination of rice and pea protein has been available in Australia and New Zealand for over two years, with no reported health and safety concerns. The FSANZ proposal to remove plant-based options from the Australian market inhibits the transition to more sustainable diets.	SO	After consideration of submissions, FSANZ decided to maintain the approach of specifying an explicit list of protein sources permitted in infant formula and follow-on formula. This is to mitigate potential safety risks associated with new proteins being used in these products that have not been approved through the pre-market assessment process. While FSANZ acknowledges the significant investment of the submitter in developing its infant formula products, FSANZ has not been provided with sufficient evidence to allow for the safety of these products to be assessed. FSANZ notes the submitter can apply for permission to add additional protein sources to infant formula products through the pre-market assessment processes. Further discussion on protein sources is detailed in section 4.7 of this report.
Did not support sheep milk as a permitted protein source.	These submitters did not support the introduction of sheep milk as a permitted protein source without further regulatory investigation, including details of the long term studies on infants fed sheep milk. Sheep milk has not undergone a pre-market assessment and therefore potentially undermines the Ministerial Policy Guideline. Consideration of an application may be warranted. Allowing sheep milk without a pre-market assessment opens the gate for other products such as rice and pea protein infant formula that are already on the market.	TAS DoH, WA DoH	This issue has previously been explored and consulted on. See the discussion in section 4.4.4 of SD2 to the 2nd CFS (FSANZ 2023c). After consideration of submissions received, FSANZ is not aware of any evidence to warrant a change in its position on this issue. As discussed in section 4.70 of this report, rice and pea protein (or other plant-based proteins) are not permitted as protein sources in infant formula products and would require pre-market assessment to be used in infant formula products. However it may be used as protein source in SMPPi (if meets the requirements for that category).

Issue		Submitter(s)	FSANZ response
Protein requirements for soy-based formula.	The submitter supported the proposed approach to establish separate minimum protein requirements for milk-based and soy-based infant formula products as per subsection 2.9.1—6(2). However, since the definition of soy-based formula has been removed from the drafting, there is ambiguity as to whether a product that contains a mixture of soy protein isolate and milk proteins is considered 'milk-based' or 'other'.	NZFS	FSANZ agrees that the removal of the definition for soy-based formula from the primary variation is not prescriptive enough when noting protein requirements for soy-based formulas. FSANZ has amended the draft variation to replace 'for all other infant formula' and 'for all other follow-on formula' with 'soy protein isolate, alone or in a mixture with cow, goat or sheep milk'. This approach aligns with the EU 2016/127.
Ultra processed foods.	Recommends that any current and future applications for protein sources as ingredients in infant formula products should be extended to consider the manufacture and treatment of ingredients, to minimise Ultra Processed Foods content as much as practicable.	QLDH	The primary variation specifically defines permitted protein sources. Any new protein source would need to be approved through pre-market assessment in accordance with the requirements of the FSANZ Act and subject to the data and other requirements set out in the FSANZ Application Handbook.
Protein range *At the 2nd CFS the draft variation prescribed the following ranges for protein content:* *Infant formula must have a protein content of:* *(a) for a milk-based infant formula—no less than 0.43 g/100 kJ and no more than 0.72 g/100 kJ; and* *(b) for all other infant formula—no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.* *Follow-on formula must have a protein content of:* *(a) for a milk-based follow-on formula—no less than 0.38 g/100 kJ and no more than 0.72 g/100 kJ; and* *(b) for all other follow-on formula—no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.*			
Yes, the draft variation is supported.	This submitter supported the proposed ranges for milk-based infant formula and follow-on formula.	FCG	Noted.
No, the draft variation is not supported.	This submitter did not support the proposed maximum protein content for both infant formula and follow-on formula, as the maximum level is associated with evidence of higher risk of obesity. FSANZ has not addressed concerns raised previously	NSWFA	FSANZ has previously addressed the maximum protein content in Table 4 of SD2 to the 2nd CFS (FSANZ 2023c), section 2.1.1 of SD2 to the 1st CFS (FSANZ 2022d) and section 4.2 of CP2 (FSANZ 2021f). The protein range was based on the conclusions of the 2016 Nutrition Assessment which considered

Issue		Submitter(s)	FSANZ response
	that a level of 0.7 g protein/100 kJ has been associated with significantly higher risk of obesity in childhood. This submitter recommends reducing the maximum protein level to the EU levels of 0.6 g/100 kJ.		evidence identified by this submitter and noted an absence of evidence demonstrating harm to infant health at the maximum level of 0.72 g/100 kJ. The results of the study provided show protein content of infant formula to be associated with early growth in children. However, it did not provide evidence that reducing protein concentrations in infant formula has an effect on long term outcomes related to decreased risk of obesity. It also noted that there is insufficient direct evidence to evaluate this and FSANZ considers more studies are required to substantiate this position. FSANZ notes that the other evidence identified by the submitter is a policy framework that does not specifically address protein content in infant formula. FSANZ also notes that the proposed maximum aligns with the current requirement in the Code for infant formula. Further to this, the maximum is aligned with Codex CXS 72-1981 and Codex STAN 156-1987. Due to the lack of evidence to substantiate the views from this submitter, FSANZ does not consider that a change the maximum protein level is warranted.
Methionine to cysteine ratio *At the 2nd CFS the draft variation prescribed:* • *a ratio of methionine to cysteine of no more than 3 to 1.*			

Issue		Submitter(s)	FSANZ response
No, the draft variation is not supported.	This submitter did not support the proposed drafting and suggested the draft variation should more closely reflect the Codex and EU regulations. This will better protect infant safety by ensuring that infants receive appropriate levels of cysteine. The following amendment to subsection 2.9.1—6(5) of the draft variation is suggested: *'Infant formula **should aim to have a ratio of methionine to cysteine that is less than 2 to 1** and must have a ratio of methionine to cy~~sc~~teine of no more than 3 to 1.'*	NSWFA	FSANZ agrees with the suggestion made by this submitter and has amended the draft variation to better reflect and achieve alignment with Codex and EU regulations. See paragraph 2.9.1—6(5) – (7) of the primary variation.
Minimum amounts for amino acids *At the 2nd CFS, the draft variation (in the table to section S29—3) prescribed the following minimum amounts:* • *cysteine 9 mg/100 kJ* • *histidine 10 mg/100 kJ* • *methionine 6 mg/100 kJ* • *tryptophan 9 mg/100 kJ.*			
No, the draft variation is not supported.	These submitters did not support the conversion from kcal to kJ using 4.18 and applying conventional rounding and recommended adopting the values 9.1, 9.8, 5.7 and 7.9 mg/100 kJ for cysteine, histidine, methionine and tryptophan respectively.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ disagrees with the recommendations of these submitters and notes that the approach taken in the draft consequential variation aligns with Codex and ensures protein quality.
Combinations of sulphur and aromatic amino acids *At the 2nd CFS the draft variation in subsection 2.9.1—6(4) stated that the L-amino acids listed in the table to section S29—3 must be present in infant formula and follow-on formula at a level no less than the corresponding minimum level specified in the table.*			

Issue		Submitter(s)	FSANZ response
No, the draft variation is not supported.	These submitters did not support the draft variation and request the ability to combine the aromatic amino acids (AAA) and the sulphur amino acids (SAA) to achieve minimum amino acid requirements and avoid unnecessary addition of L-amino acids. The following example was provided using the draft amino acid minimums for SAA: *The L-amino acids listed in the table to section S29—3 must be present in infant formula and follow-on formula at a level* ***equal to*** *the corresponding minimum level specified in the table.* ***For calculation purposes concentrations of 'tyrosine and phenylalanine' and 'methionine and cysteine' may be added together****."*	NZFGC, INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NES	FSANZ notes that the intent of the draft variation at the 2nd CFS was to align with Codex CXS 72-1981 (Codex 1981). FSANZ has amended the primary variation at subsection 2.9.1—6(6) to allow the combination of cysteine and methionine and that the ratio of methionine to cysteine in the infant formula and follow-on formula is less than 2 to 1. FSANZ has amended the primary variation at subsection 2.9.1—6(7) to allow combination of phenylalanine and tyrosine and that the ratio of phenylalanine and tyrosine in the infant formula and follow-on formula is less than 2.
Vitamin A maximum *At the 2nd CFS the draft variation prescribed:* • *a vitamin A range of 14–43 µg RE/100 kJ in infant formula and follow-on formula.*			
No, the draft variation is not supported.	These submitters did not support vitamin A maximum and instead recommend adopting the lower EU maximum level of 27.2 µg RE/100 kJ. This is based on the proposed maximum exceeding the UL set by NHMRC by more than 15%.	NSWFA, WA DoH	This issue has previously been explored and consulted on. See the discussion in section 5.1 of SD2 to the 2nd CFS (FSANZ 2023c). After consideration of submissions received, FSANZ is not aware of any evidence to warrant a change in its position on this issue.
Vitamin B_{12} *At the 2nd CFS the draft variation prescribed:* • *a vitamin B_{12} range of 0.02–0.36 (GUL) µg/10 kJ in infant formula and follow-on formula.*			
No, the draft variation is not supported.	This submitter did not support the proposed vitamin B_{12} GUL in infant formula products as it does not reflect the gold standard of levels found in breastmilk and introduces unnecessary levels of substances into the infant's system.	WA DoH	This issue has previously been explored and consulted on. See the discussion in section 5.2 of SD2 to the 2nd CFS (FSANZ 2023c). After consideration of submissions received, FSANZ is not aware of any evidence to warrant a change in its position on this issue.

Issue		Submitter(s)	FSANZ response
Vitamin C *At the 2nd CFS the draft variation prescribed:* • *a vitamin C range of 1.7–17 mg/100 kJ in infant formula and follow-on formula.*			
No, the draft variation is not supported.	This submitter did not support the proposed vitamin C range in infant formula products, as the minimum is lower than potential infant needs and the proposed maximum questions the principle of avoiding unnecessary excesses of substances in infant formula.	WA DoH	This issue has previously been explored and consulted on. See the discussion in Table 5 of SD2 to the 2nd CFS (FSANZ 2023c). After consideration of submissions received, FSANZ is not aware of any evidence to warrant a change in its position on this issue.
Iodine *At the 2nd CFS the draft variation prescribed:* • *an iodine range of 2.4–14 (GUL) µg/100 kJ in infant formula and follow-on formula.*			
No, the draft variation is not supported.	This submitter did not support the proposed the maximum level as it exceeds the EU UL and also does not support this level being a GUL that legally allows even higher iodine content. This submitter also did not support the proposed the minimum level with the concern that the total iodine intake from formula and water may not sufficiently achieve the NHMRC AI of 90 µg/day (a mean daily intake for infants will be 59–91µg/day, depending on water content).	NSWFA	This issue has previously been explored and consulted on. See the discussion in section 5.8 of SD2 to the 2nd CFS (FSANZ 2023c). After consideration of submissions received, FSANZ is not aware of any evidence to warrant a change in its position on this issue.
Niacin *At the 2nd CFS the draft variation prescribed:* • *a niacin range of 70–(GUL) 359 ug/100 kJ (GUL) in infant formula and follow-on formula.*			
No, the draft variation is not supported.	This submitter noted that the minimum value for niacin in both infant formula and follow-on formula needed to be corrected to 72 µg/100 kJ as correctly converted from kcal in the Codex CXS 156-1987.	NZFS	FSANZ has made the relevant correction in the draft variation.

Issue		Submitter(s)	FSANZ response
	This submitter did not support the proposed range for niacin in infant formula and follow-on formula.	WA DoH	This issue has previously been explored and consulted on. See the discussion in section 5.4 of SD2 to the 2nd CFS (FSANZ 2023c). After consideration of submissions received, FSANZ is not aware of any evidence to warrant a change in its position on this issue.
L-carnitine *At the 2nd CFS the draft variation (S29—5) prescribed:* • *a mandatory minimum of 0.30 mg/100 kJ and a GUL of 0.8 mg/100 kJ for infant formula. ("NS" prescribed for follow-on formula).*			
Yes, the draft variation is supported.	This submitter supported the mandatory minimum for L-carnitine, however noted the value should be corrected to 0.29 mg/100 kJ (or 1.2 mg/100 kcal).	FCG	FSANZ does not agree that the level requires correction. All levels within the consequential variation have been set in line with the International Standard Unit conversion factors and conventional rounding. This includes the L-carnitine minimum. The minimum amount of 0.3 mg/100 kJ is aligned with EU 2016/127, in which the EU recalculated their values per 100 kJ.
No, the draft variation is not supported.	These submitters did not support a maximum or GUL imposed for L-carnitine in infant formula on the basis that this upper limit is not consistent internationally.	INC, SML, DAN, FCG, DCANZ, A2M, AFGC	This issue has previously been explored and consulted on. See the discussion in Table 7 of SD2 to the 2nd CFS (FSANZ 2023c). After consideration of submissions received, FSANZ is not aware of any evidence to warrant a change in its position on this issue.

Issue		Submitter(s)	FSANZ response
	This submitter noted that neither the EU or relevant Codex standards specify a maximum or GUL. If a GUL is to be established for infant formula, the submitter would like the value to reflect current product formulations and the apparent history of safe use in the absence of evidence to inform a science-based risk assessment. The submitter stated that information submissions highlight that dairy-based formulations will typically contain higher levels of L-carnitine than the proposed GUL.	NZFS	FSANZ notes that the previous maximum amount prescribed in Standard 2.9.1 was increased from the LSRO recommendation (0.48 mg/100 kJ) to accommodate the natural amount of carnitine that is typically found in cow's milk infant formulas (ANZFA 1999a). The LSRO recommended level aligns with breastmilk concentrations. FSANZ has previously assessed and considered this issue. FSANZ has also acknowledged the seasonal variations and higher levels in cow and goat milk. To account for this FSANZ, has again, proposed amending the L-carnitine requirements. This time from a maximum level to a GUL to provide further flexibility. FSANZ does not consider it required or is appropriate to increase the level further as a GUL is not a legally binding level. FSANZ has not been provided history of safe use data within the Australia and New Zealand population at a higher level than 0.8 mg/100 kJ and does not assume this data is available as this the maximum currently set in the Code. In addition, both the FSANZ 2016 NA and FSANZ 2021 NA concluded that on the basis of a lack of suitable information to assess the safety of high L-carnitine concentrations, it cannot be ruled out that the lack of a specification for a maximum amount of L-carnitine in infant formula (as is the case for Codex CXS 72-1981 and EU 2016/127) may pose a risk to infant health. Based on the above, FSANZ concludes the consequential variation will specify L-carnitine as a mandatory substance in infant formula with a range of 0.3–0.8 (GUL) mg/100 kJ.
Fluoride *At the 2nd CFS the draft variation prescribed:* • *infant formula and follow-on formula must not exceed a fluoride content of 17 µg/100kJ.*			

Issue		Submitter(s)	FSANZ response
No, the draft variation is not supported.	This submitter noted that subsection 2.9.1—4(1) should not apply to the fluoride limit (subsection 2.9.1—5(4)), however interpretation of the current drafting is that it does. Instead, limits for fluoride should apply to infant formula and follow-on formula 'as sold' (not as reconstituted). The submitter also stated that the original proposal was to establish a maximum level of 24 µg/100 kJ for all types of formula as prepared, including ready-to-drink. The submitter questioned whether the maximum for ready-to-drink products should be 24 µg/100 kJ as was the original intent since they don't require additional water.	NZFS	The primary variation has been amended at subsection 2.9.1—5(5) and 2.9.1—5(6) to require fluoride levels (17 µg/100 kJ) in powdered or concentrated infant formula and/or follow-on formula are as sold. This limit is different to Codex and EU (24 µg/100 kJ) limits due to the requirements applying to the product as sold (not as reconstituted) and accounts for the fluoride content in Australian and New Zealand water supplies. In addition, a subsection has been included to capture fluoride levels (24 µg/100 kJ) for ready-to-drink infant formula or follow-on formula as sold. Ready-to-drink infant formula and follow-on formula were not originally included in the draft variation at the 2nd CFS because FSANZ was not aware of their presence in the Australian and New Zealand markets. However, FSANZ recognises the importance of their inclusion in the Code as they may be available or may be made available in the future.
Iron *At the 2nd CFS the draft variation prescribed:* • *a minimum of 0.14 mg/100 kJ and a maximum of 0.48 mg/100 kJ for infant formula* • *a minimum of 0.24 mg/100 kJ and a maximum of 0.48 mg/100 kJ for follow-on formula.*			
No, the draft variation is not supported.	This submitter did not support the proposed iron range in infant formula products and questioned why FSANZ did not incorporate evidence from the NHRMC NRVs. The submitter has concerns regarding the potential for excess iron intakes.	WA DoH	FSANZ reconsidered iron requirements in section 5.7 of SD2 to the 2nd CFS (FSANZ 2023c). There it was noted FSANZ's decision to establish a range between 0.14–0.48 mg/100 kJ for infant formula and between 0.24–0.48 mg/100kJ for follow-on formula. This decision was based on a desire to meet the NHMRC NRVs, a consideration of infant iron absorption from formula, the desire to improve alignment with international regulations and recommendations of EFSA and the EC SCF. FSANZ also notes that the infant formula standard does not extend to health advice and/or guidance. Concerns relating to

Issue		Submitter(s)	FSANZ response
			older infants not meeting their iron requirements can be mitigated through caregivers selecting follow-on formula that has a higher minimum iron level, introduction of solid foods and referring to infant feeding guidance.
Taurine *At the 2nd CFS the draft variation prescribed:* • *a maximum of 2.9 mg/100 kJ for infant formula and follow-on formula as an optional permission.*			
No, the draft variation is not supported.	The submitter did not support the retention of the voluntary permission for taurine in infant formula products. A recent review purported a possible relationship between limited taurine levels during infant development and increased risk of chronic diseases during adulthood. It also noted the addition of taurine to infant formula was carried out in an absence of scientific evidence and that further research would help elucidate the benefits of taurine in infant development and supports its considered addition to infant formula (Tochitani, 2022).	WA DoH	Section 7.1 of SD2 to the 2nd CFS (FSANZ 2023c) outlines that prescribing taurine as an optional ingredient in infant formula and follow-on formula is based on alignment with Codex and EU, with no evidence of adverse effects and a history of safe use. Prescribing taurine as mandatory would not be consistent with international regulations. FSANZ notes that the study provided by the submitter is a review paper, rather than new primary evidence regarding taurine addition (Tochitani 2022). The paper indicates that 'further clinical studies are necessary for the evaluation of the beneficial effects of taurine in infant formulas. The paper also cites a recent systematic review with conflicting conclusions on the health benefits of taurine in infant formula (Almeida et al. 2021). FSANZ notes that the voluntary permission of taurine is long-standing and no safety risks have been identified and the scope of P1028 is not to remove permissions unless a safety risk is identified.
Nucleotides *At the 2nd CFS the draft variation:* • *retained the voluntary permission for all nucleotides in follow-on formula* • *prescribed a maximum total limit of nucleotides to account for total free nucleotides.*			

Issue		Submitter(s)	FSANZ response
No, the draft variation is not supported.	The submitter did not support the retention of the voluntary permission for nucleotides in infant formula products. The submitter stated that a review by Hodgkinson, Wall et al. (2022) identifies the addition of monomeric nucleotides to infant formula, which supplements the already present levels of total potentially available nucleotides in infant formula, may contribute to biological activities including immune function, lipid metabolism, intestinal function and iron absorption.	WA DoH	Table 10 of SD2 of the 2nd CFS (FSANZ 2023c) outlines that prescribing nucleotides as optional substances in follow-on formula is based on alignment with Codex and EU and has no evidence of safety concern. Nucleotides have held a voluntary permission in Schedule 29 for the past 20 years. As noted above, FSANZ does not consider it appropriate to remove permissions unless there is substantiated evidence to support the removal. Given the lack of evidence to suggest the voluntary addition is burdening infant systems and that nucleotides are present in human milk, they are not considered unnecessary ingredients. FSANZ acknowledges the review identified by the submitter however unless a safety risk is identified, FSANZ will not remove permissions.
	The submitter recommended that 2.9.1—13(b) be amended to incorporate the term 'free' (as per intent in Table 7 of SD1): (b) more than 3.8 mg/100 kJ of (free) nucleotide-5'-monophosphates.	NZFS	The exclusion of the word 'free' was an oversight by FSANZ and the primary variation has been amended.
Lutein *At the 2nd CFS the draft variation:* • *retained the voluntary permission for lutein in follow-on formula* • *prescribed a range of 1.5 µg/100 kJ in follow-on formula.*			
No, the draft variation is not supported.	The submitter did not support the retention of the voluntary permission for lutein in infant formula products. A systematic review by Zaidi, Stroh et al. (2022) concluded the presence of lutein as a carotenoid present in breastmilk. The submitter stated that it is timely that lutein is included and adopted more widely as the NHMRC undertakes a phased review of the NRVs.	WA DoH	FSANZ acknowledges the systematic review provided by the submitter. However, as noted in SD2 of the 2nd CFS (FSANZ 2023c), the lutein levels prescribed in Schedule 29 were assessed through Application A594 – Lutein as a nutritive substance in infant formula. As these requirements have already been assessed and consulted through a statutory process,

Issue		Submitter(s)	FSANZ response
			FSANZ will retain the minimum and maximum of 1.5–5 µg/100 kJ currently prescribed in Schedule 29 for lutein. Regarding the NHMRC review of NRVs, while a phased review is underway, at this stage a review of lutein is not scheduled.
Required nutritive substances *At the 2nd CFS the draft variation prescribed:* *Infant formula must contain each substance listed in Column 1 of the table to section S29—5 in an amount that is:* • *no less than the minimum amount specified in Column 2 of the table; and* • *no more than the maximum amount (if any) specified in Column 3 of the table.* *Follow-on formula must contain each substance listed in Column 1 of the table to section S29—6 in an amount that is:* • *no less than the minimum amount specified in Column 2 of the table; and* • *no more than the maximum amount (if any) specified in Column 3 of the table.*			
No, the draft variation is not supported.	The submitter recommended that in section 2.9.1—8 FSANZ insert the revised ratio of calcium to phosphorus, which appears to be missing from the drafting. The intent is that the ratio of calcium to phosphorus in infant formula and follow-on formula must be no less than 1 to 1 and no more than 2 to 1.	NZFS	FSANZ has made this amendment at subsection 2.9.1—8(3) of the primary variation.
	The submitter recommended that paragraph 2.9.1—8(1)(a) be amended (for consistency with section 2.9.1—9) to include the words "(including any naturally occurring amount)": *'Infant formula must contain each substance listed in Column 1 of the table to section S29—5 in an amount* ***(including any naturally occurring amount)*** *that is:…'.*	NZFS	FSANZ has made this amendment in section 2.9.1—8 and 2.9.1—9 of the primary variation.

Issue		Submitter(s)	FSANZ response
Restriction on levels of other substances *At the 2nd CFS the draft variation prescribed infant formula and follow-on formula must not contain:* • *detectable gluten; or* • *more than 3.8 mg/100 kJ of nucleotide-5´-monophosphates.*			
No, the draft variation is not supported	The submitter recommended that the note at section 2.9.1—13 is amended to reflect that there are other MLs for contaminants than lead in Schedule S19 that will apply to infant formula products.	NZFS	FSANZ has made the change in section 2.9.1—13 of the primary variation.
Vitamin D maximum for follow-on formula *At the 2nd CFS the draft variation* (S29—6) *prescribed:* • *a range 0.24–0.63 µg/100 kJ for all infant formula products.*			
No, the draft variation is not supported.	These submitters recommended that the maximum should be aligned with the Codex and EU follow-on formula maximum of 0.72 µg/100 kJ. Some submitters noted that the NHMRC data for the current AI is outdated and does not reflect the most recent science and therefore the level does not align internationally. The government submitter noted that SD2 of the 2nd CFS states that the proposed maximum of 0.63 µg/100 kJ is in alignment with international regulations, but it is not in alignment. One industry submitter noted that the lower maximum level limits the opportunity for recipe harmonisation with international jurisdictions as complying with EU limits and the Code would result in a narrow range of 0.48–0.63 µg/100 kJ that doesn't allow for raw material, analytical and processing variability.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFS, NES	FSANZ has amended section S29—6 of the consequential variation to increase the maximum to 0.72 µg/100 kJ. This issue is discussed further in section 4.9.
Inositol *At the 2nd CFS the draft variation prescribed:* • *a GUL of 9.5 mg/100 kJ.*			

Issue		Submitter(s)	FSANZ response
Note error in the draft variation.	The submitter states that the GUL for inositol for follow-on formula needs to be corrected to 10 mg/100 kJ to align with infant formula and the Codex Draft Standard FuFOI (CXS 156-1987).	NZFS	FSANZ has made the change in the consequential variation at section S29—8.
S29—6 Vitamins, minerals and electrolytes required in follow-on formula *At the 2nd CFS the draft variation stated in column 1:* • *Folic acid (not including naturally occurring folate).*			
Note error in the draft variation.	Section S29—6 should be amended for consistency with section S29—5: *Folic acid* ***~~(not including naturally occurring folate)~~***	NZFS	FSANZ has made the change in the consequential variation at sections S29—5 and S29—6.
S29—9 Infant formula products – substances permitted for use as nutritive substances *At the 2nd CFS the draft variation prescribed permitted forms of nutritive substances in infant formula and follow-on formula.*			
Note error in the draft variation.	These submitters noted the drafting of the table to section S29—9 has a subheading of 'Infant formula products – substances permitted for use as nutritive substances' which is inconsistent with the heading and is not stipulated in section 2.9.1—32.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NES	FSANZ has corrected this inconsistency.
S29—23 Permitted forms *At the 2nd CFS the draft variation prescribed permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants, formulated meal replacements (vitamin K) and food for special medical purposes.*			
Note error in the draft variation.	These submitters noted an error in the drafting: They commented the proposed draft variation does not prescribe a permitted form requirement for substances used as a nutritive substance in SMPPi however there is an error in the drafting of section S29—23 which refers to '*infant formula products*.'	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NES	FSANZ notes the table to S29—23 states 'infant formula products' in the title. This is correct as the table applied to all infant formula products, including SMPPi. Permitted forms are now included in the composition parameters for SMPPi in Division 4 of the standard.

Issue		Submitter(s)	FSANZ response
	Recommend the new permitted forms of vitamins, minerals and electrolytes are integrated alphabetically into the lists in section S29—23, for consistency and ease of use.	NZFS	FSANZ has made the change in section S29—23 of the consequential variation.
	The submitter requested FSANZ review the permitted form of folic acid to include calcium methylfolate. The submitter provided the rationale for the inclusion in their submission.	DSM	As it is unclear in the submission, FSANZ is assuming this permission request is specific to SMPPi. FSANZ makes this assumption because calcium methylfolate is not permitted in infant formula or follow-up formula under Codex CXS 72-1981 or Codex CXS 156-1987. The composition of SMPPi can deviate from infant formula where medically required. Therefore, a specific permission for calcium methylfolate is not required in the Code for SMPPi. FSANZ also notes that the bioconversion of calcium methylfolate to folic acid is not equivalent.

Section 5: Novel foods

Issue	Comment	Submitter(s)	FSANZ response
Amendments to Standard 1.5.1 Novel foods *At the 2nd CFS, the draft variation retained the current pre-market assessment requirements for novel foods used in infant formula products and clarified when an infant formula product may consist of, or have as an ingredient, a novel food by setting the following criteria in subsection 1.5.1—3(2):* • *The novel food is listed in the table to section S25—2.* • *The table to section S25—2 expressly permits the presence of that novel food in that infant formula product (i.e., the table contains an express permission).* • *Any conditions of use specified for that novel food in the table to section S25—2 are complied with.* • *Conditions do not apply to formulated supplementary foods for young children.*			
Yes, the draft variation is supported.	These submitters supported the proposed drafting to section 1.5.1—3 and Schedule 25 to improve regulatory clarity by prohibiting the use of novel foods for infant formula products unless explicitly permitted.	IFF, NSWFA, NZFGC, TAS DoH, NZFS, AFGC, INC, FCG, SML, DAN, DCANZ, A2M	Noted.
	Typo in subsection 1.5.1—3(2) identified as follows: *An infant formula product ~~**food**~~ for retail sale…*	FCG	FSANZ has amended this error in the consequential variation at subsection 1.5.1—3(2).
No, the draft variation is not supported and/or recommend alternative.	This submitter recommended a clause be added to Standard 2.9.1 to clarify that a substance must not be added to infant formula products unless expressly permitted.	VIC DoH & DEECA	FSANZ notes that subsection 1.1.1—10(5) and (6) of the Code notes that unless expressly permitted a food for retail sale (e.g. infant formula product) must not be a novel food.

Issue	Comment	Submitter(s)	FSANZ response
Pre-market assessment requirements for novel foods and nutritive substances *At the 2nd CFS, the draft variation did not include any changes to pre-market assessment requirements for novel foods and nutritive substances in infant formula products.*			
No, the draft variation is not supported and/or recommends alternative.	This submitter recommended amending the draft variation to clearly articulate that any new substance added to infant formula or follow-on formula is required to undergo pre-market assessment. This submitter suggested the following addition is made to subsection 2.9.1—5 the 2nd CFS draft variation: *(4) Pre-market assessment is required for any substance proposed to be used in infant formula and follow-on formula that:* *(i) does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or* *(ii) has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology'.*	NSWFA	As above. FSANZ considers any addition to this in the Code to be unnecessary duplication.
Amendments to Schedule 25 permissions *At the 2nd CFS, the draft variation prescribed permissions in Schedule 25 to reflect the new subsection 1.5.1—3(2) that prohibits the addition of novel foods to infant formula products unless expressly permitted. Amendments to S25—2 were intended to insert express permissions for micro-algal sources of DHA and trehalose.*			
Yes, the draft variation is supported.	These submitters supported the Schedule 25 amendments to improve regulatory clarity by prohibiting the use of novel foods for infant formula products unless explicitly permitted.	IFF, NSWFA, NZFGC, TAS DoH, NZFS, INC, NES, FCG, SML, DAN, DCANZ, A2M, AFGC	FSANZ notes that the proposed amendments at the 2nd CFS (see section 4.2.3; FSANZ 2023a) and the draft variation did not correctly capture the novel foods that were intended to have express permission to be added to infant formula products. Schedule 25 should only be amended to restrict use of α-cyclodextrin, γ-cyclodextrin, diacylglycerol oil (DAG oil), isomaltulose and D-tagatose from being used in infant formula products. In line with the 1st CFS, there was no intent to include restrictions on use of micro-algal sources of DHA, which are currently

Issue	Comment	Submitter(s)	FSANZ response
			permitted in infant formula products. FSANZ has amended this in the consequential variation, further clarification on this can be found in SD1.
No, the draft variation is not supported and/or recommend alternative.	While acknowledging it was out of scope, the submitter stated that amending Schedule 25 without the addition of infant foods and formulated supplementary foods for young children exacerbates the current regulatory ambiguity and inefficiencies with the food regulatory system and poses a level of risk to infants.	TAS DoH	FSANZ agrees that amending Schedule 25 is limited to infant formula products and this recommendation is out of scope.
Conditions of use for trehalose as a novel food *At the 2nd CFS, the draft variation in Schedule 25 states that for the purposes of 1.5.1—3(2) the condition of use for trehalose is:* • *may only be added to infant formula products as a cryo-preservative for L(+) lactic acid producing microorganisms.*			
Yes, the draft variation is supported.	These submitters supported FSANZ's condition statement that trehalose use be restricted to a cryo-preservative purpose (and not as a carbohydrate source) if trehalose is to be approved in infant formula.	TAS DoH, INC, NZFS, SML, DAN, DCANZ, A2M, AFGC, FCG	Noted.
Lactic Acid Producing Microorganisms (LAM) *At the 2nd CFS, the draft variation retained the current permission to add LAM to infant formula products**. This did not include the addition of specific strains as probiotics, which would represent the addition of a substance used for a nutritive purpose.** *The current permission to be retained includes restrictions on labelling and claims such that any indication of this purpose is not permitted unless approved for that purpose (i.e. used as a nutritive substance) which would be done via the FSANZ application process.*			
Yes, the draft variation is supported.	These submitters supported the proposed approach on the basis that it: • provided sufficient clarity on the permission to add LAM to infant formula products • is similar to the approach taken in the EU	IFF, NZFGC, NZFS, AFGC, NES, FCG, INC, SML, DAN, DCANZ, A2M	Noted.

Issue	Comment	Submitter(s)	FSANZ response
	• reflected a risk-based approach and • acknowledged the current level of due diligence while aligning with international regulations.		
	These submitters supported the view that novel LAM would require pre-market approval, as they are captured by horizontal standards in the regulation (e.g. Standard 1.5.1 Novel foods and Standard 1.5.2 Foods produced using gene technology etc).	INC, FCG, SML, DCANZ, A2M, AFGC, DAN	FSANZ has provided a more comprehensive discussion on this issue in section 4.11 of this report.
No, the draft variation is not supported and/or recommend alternative.	This submitter considered that enforcement agencies may have difficulty in determining the purpose of addition if the Code was to limit addition to acidification purposes only, or to require specific conditions to be met for other purposes. The submitter noted the rationale to not include a list of permitted LAM was based on the FSANZ view that assessment of novel foods was not part of P1028. The submitter acknowledged that Standard 1.5.1 included microorganisms as a potential novel food and notes the ACNF record of views lists several LAM that are deemed to be either traditional or not novel, with the rationale in some instances being that it is found in human milk. The submitter was open to exploring potential options which could provide regulatory certainty while retaining the general permission for addition of L(+) LAM to infant formula products.	NZFS	FSANZ considers the existing permission and labelling restrictions to be appropriate. Through FSANZ's risk assessment, the addition of LAM has already been determined to be safe and suitable for addition to infant formula products. In addition, a manufacturer would need to seek pre-market approval to use and label their specific strain as a nutritive substance. As such, there is little impetus to add LAM beyond acidification purposes.
	Submitters that did not support the retention of the open permission for LAM instead supported clarification in the Code that LAM may be added as an ingredient for acidification purposes and LAM added for these purposes may not be listed in the NIS.	NSWFA, VIC DoH & DEECA	As above, FSANZ reiterates that its risk assessment has already found the addition of LAM to infant formula products for acidification purposes

Issue	Comment	Submitter(s)	FSANZ response
	Submitters also did not support on the basis that it is inconsistent with the Ministerial Policy Guideline (all substances added to infant formula should undergo pre-market assessment and should demonstrate a beneficial effect). Without specifying the intended purpose for the LAM permission, new LAM strains will be permitted in the absence of a pre-market assessment in opposition to the intent of the guideline.		to be safe and suitable and has a history of safe use, consistent with the Ministerial Policy Guideline[17]. Based on this rationale, the draft variation maintains the existing permission. Reasoning for this was outlined in section 5 of the 2nd CFS (FSANZ 2023a) and is unchanged for this report and after consideration of submissions. Further, if the intended purpose is that of a nutritive substance for any strain of LAM, a manufacturer would need to seek pre-market approval (demonstrating a nutritive purpose in addition to alignment with policy guidance) to use and label their specific strain as a nutritive substance.
Other comments.	Regarding the labelling of LAM as nutritive substance, the submitter stated that LAM are not being declared as a nutritive substance on Stage 1 and 2 product labels, but it is commonplace for the Stage 3 product of the same product line to label the exact same LAM strain in the NIS and on the front of the package as a probiotic. The submitter also identified products where LAM are not represented as being used for a nutritional purpose on the label but are promoted as containing probiotics in product information targeted at healthcare professionals. Thus, it appears LAM are being added for a probiotic purpose but are intentionally not being represented as such in infant formula labels to avoid pre-market assessment requirements.	VIC DoH & DEECA	FSANZ notes that Stage 3 products and their labelling is out of scope for P1028. Regarding the promotion of products containing probiotics, section 9.4 of SD3 to the 2nd CFS (FSANZ 2023d) explains the scope of food regulatory measures in the Code for promotion and advertising, which remain unchanged under P1028. Whether the type of information that is targeted at healthcare professionals (i.e., non-label information) is considered to be promotional information would be a matter of interpretation and outside of FSANZ's remit.

[17] FSANZ refers to specific policy principle (i) of the Ministerial Policy Guideline on the Regulation of Infant Formula Products which states:

*Pre-market assessment, relative to principles (d) and (e), should be required for any substance **proposed to be used** in infant formula and follow-on formula that:*

i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or

ii. has a history of safe use in these products in Australia and New Zealand, but which, having regard to source[17], has a different form/structure, or is produced using a substantially different technique or technology.

Issue	Comment	Submitter(s)	FSANZ response
Other comments.	The submitter disagreed that permitting LAM for acidification only would cause a large reformulation cost to industry or loss of products from the market, on the basis that if added for probiotic purpose it is added in small amounts and do not perform technological functions. Removal should be technically possible within the transition time.	VIC DoH & DEECA	As FSANZ is retaining the status quo for this permission, it was not included within the Costs and Benefit analysis hence the absence of data available in the CFS. Through the P1028 consultation process, however, there have been several industry submitters that have provided evidence indicating the significant costs of reformulation if the permission was to change. There has been no public health or safety issue identified with the current permission and it is aligned with international regulations. FSANZ considers the cost of reformulation outweighs any benefit that might arise from removal of the permission.
Other comments.	This submitter stated that if the proposed five-year transition period is considered insufficient to assess LAM being used as probiotics, other options to avoid an open permission in infant formula products include applying a longer transition period for LAM, or a rapid review by FSANZ of overseas regulators' assessments that have considered specific strains (e.g. US and China). FSANZ has already conducted rapid review of some substances (e.g. trehalose) for use in infant formula products under P1028. This will ensure the safety and functional purpose of LAM is clarified in infant formula products and allow listing of appropriate strains in the NIS, aligned with their nutritive purpose.	NSWFA	FSANZ notes that if a safety issue was identified for the LAM permission, it would justify the extension of a transition period so that further assessment could be undertaken. A safety issue has not however been identified. The FSANZ Act sets specific requirements for amending the Code to include or set new permissions. Specific strains are considered a new permission and thus require FSANZ to conduct a full safety assessment. As such, in the case of new strains, FSANZ does not have the mandate to undertake a 'rapid review' of overseas regulators' assessments and incorporate these as a permission in the Code. In addition, as outlined in section 5.3 of the 2nd CFS (FSANZ 2023a), the scope of P1028 does not include assessing new permissions for substances or nutrients to be added to infant formula products, or assessing existing permitted substances intended to be used for a new purpose. Such permissions should be sought through the application process. The assessment that FSANZ undertook for trehalose was not a rapid review and instead related to an existing permission being used for the same purpose. In this case, under P1028, FSANZ asked the specific question of whether the existing permission in Schedule25 was used by manufacturers and if not, the permission would be removed. A stakeholder responded that the substance was currently in use and provided data demonstrating its safety.

Issue	Comment	Submitter(s)	FSANZ response
No, the draft variation is not supported and/or recommend alternative.	This submitter suggested drafting amendments are made to subsection *2.9.1—11* that provide clarification that LAM added to infant formula, follow-on formula or SMPPi for nutritional purposes is a nutritive substance and needs to be included in the table to Schedule 29-7 or Schedule 29-8.	NSWFA	FSANZ considers specific strains to be new permissions which should be sought through the application process. See above response for further explanation.
Other comments.	The current and proposed requirements do not appear to prevent the addition of microorganisms for a probiotic purpose. This submitter noted a loophole that if the probiotic has a tradition of use, e.g. in the general population, then the current drafting of the novel food requirements would be difficult to apply.	QLDH	Similar to the existing permission, the primary variation does not include the addition of LAM for a novel or nutritive purpose. Restrictions on labelling and claims preclude any indication of probiotic function unless sought through the application process. In addition, as the primary variation has amended the definition of a novel food and a non-traditional food to clarify that use of a novel food in or as a FSMP and/or SMPPi does not constitute a 'history of safe consumption', meaning the food may still be defined as a novel food and require pre-market assessment for the general population.
Other comments.	The submitter suggested FSANZ consider that in addition to permitting the strain, permitting the number of colony forming units (cfu) in the ingredients list or NIS would allow consumers to make informed decisions about products.	DAN	The prescribed formatting on the NIS in the draft variation (section S29—10) is restricted to only those substances that have been approved as a nutritive substance. Individual strains of LAM and their cfu are not permitted to be declared as a nutritive substance in infant formula products because they have not undergone pre-market assessment to meet current Code requirements. See section 4.11 for further discussion.
Other comments.	These submitters requested FSANZ clarify the risk assessment process used to justify retention of the current existing unrestricted permission to add LAM to infant formula products. In 2021 CP1 (SD2), FSANZ identified case reports of sepsis and bloodstream infections in infants with underlying clinical complications (including pre-term, low birth weight and immunocompromised infants) associated	NSWFA, TAS DoH	FSANZ understands the submitter concerns relate to pre-term neonates who are at risk of mortality, septicaemia and gastrointestinal morbidities, such as necrotising enterocolitis and that the submitters are concerned that an unqualified permission could lead to infant health and safety concerns. In response to the submitter question about the risk assessment, the assessment process for LAM was based on questions that examined public health and safety relating to the addition of L- and/or DL-lactic acid producing bacteria to infant formula products. For details, see SD2

Issue	Comment	Submitter(s)	FSANZ response
	with dietary supplementation with non-pathogenic L- and DL-lactic acid producing bacteria. The proposed broad permission for addition of any LAM is not consistent with FSANZ's own assessment based on best available scientific evidence if not qualified with appropriate criterion to address the previously identified risk. One submitter was concerned that an unqualified permission could lead to infant health and safety concerns. One submitter suggested consideration of a bulk application process of existing LAM currently permitted during the transition period may reduce the market impact.		to CP1 (FSANZ 2021c): Microbiology risk assessment: L-lactic acid producing microorganisms. Section 3.2.2 of that paper concluded: *….in pre-term, low birth weight and immunocompromised infants, predisposing clinical complications can increase the likelihood that infant formula supplemented with non-pathogenic L- and DL-lactic acid producing bacteria can cause opportunistic sepsis or bloodstream infections. However, due to a lack of sufficient data on infectivity and exposure, FSANZ is unable to assess the level of the risk in these circumstances.* FSANZ notes that the infants identified in the above risk assessment would not be consuming infant formula formulated for the general population but instead be consuming SMPPi, which are used in clinical settings and under medical supervision. Furthermore, FSANZ understands that these infants may be treated with therapies that include the use of probiotics, including LAM, under medical supervision and notes two recent papers on the issue (Kulkarni et al. 2022; Van den Akker et al. 2020). These papers provide results from a meta-analysis that identify probiotic strains with greatest efficacy regarding relevant clinical outcomes for pre-term neonates and recommendations from this study for clinicians. FSANZ however does not have a mandate to identify and specify strains to be used for pre-term infants and infants at risk of these conditions as this requires medical expertise. This is a reason why these products would be categorised as SMPPi.
No, the draft variation is not supported and/or recommend alternative.	Submitters suggested FSANZ consider permitting labelling of strains and count (cfu) on the labels of products containing microorganisms as this reflects best practice labelling guidance such as that issued jointly by the Council for Responsible Nutrition and the International Probiotics Association (2019).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	As stated above, labelling requirements for specific strains would be considered by FSANZ once approval is sought via the application process for LAM to be added for an intended purpose such as a probiotic.

Issue	Comment	Submitter(s)	FSANZ response
Other comment	Section 114 of the FSANZ Act is acknowledged however the provision of 'confidential information given to FSANZ provided an exposure estimate for trehalose when present in infant formula products as a cryo-preservative for LAM' (2nd CFS, p27) exhibits a lack of transparency and does not instil confidence in the decision-making processes surrounding the protection of vulnerable infants.	WA DoH	FSANZ acknowledges the need for transparency in its decision making and so with agreement from the submitter, FSANZ reproduced the safety information that was provided. This included toxicological information, most of which is publicly available. The exposure calculation was not published as it represented information that was of commercial value to the submitter. Given the very large margins that were calculated (see section 4.3.4 of the 2nd CFS; FSANZ 2023a), FSANZ was satisfied that this did not detract from the conclusion that trehalose as a cryo-preservative in infant formula products does not pose a safety risk for infants.
Pre-market safety assessment requirements for novel foods in SMPPi *At the 2nd CFS the draft variation retained:* • *subsection 1.5.1—2(2) with no amendments which notes 'The presence of a food in a food for special medical purposes or the use of a food as a food for special medical purposes does not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of this section'.*			
No, the draft variation is not supported.	This submitter did not support the proposed option and instead recommended that SMPPi should be added to subsection 1.5.1—2(2) so that use as a food represented as SMPPi does not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of this section.	NSWFA	FSANZ agrees that inclusion of SMPPi into the subsection adds clarity to the standard given the category of SMPPi is intended to align with FSMP. FSANZ has amended subsection 1.5.1—2(2) in the consequential variation to reflect the regulatory intent that the presence of or use of a novel food in a FSMP or SMPPi does not constitute a history of human consumption in Australia or New Zealand.
	The submitter did not support the total exemption from novel food restrictions for SMPPi and suggested placing some restrictions on the exemption that requires novel substances to have been approved by an equivalent government or scientific authority.	VIC DoH & DEECA	FSANZ notes the following restrictions (see section 4.3 for more detail) currently on substances that can be added to SMPPi: • substances must replicate compositional requirements for infant formula products and • substances that deviate from the compositional requirements must be for the intended medical purpose. FSANZ also notes that for an exemption to apply to novel substances that have been approved by an 'equivalent government or scientific authority', it would require FSANZ to determine who or what that

Issue	Comment	Submitter(s)	FSANZ response
			authority is. FSANZ also lacks the legislative authority to do this. See responses on this issue elsewhere in this report.
Novel technologies *Standard 2.9.1—30(a) proposes that paragraph 1.1.1—10(6)(f) relating to novel foods will not apply to SMPPi.*			
Yes, the draft variation is supported.	The submitters noted that the draft variation aligns with Standard 2.9.5 and that many SMPPi will be regulated under special medical purpose foods in international standards. This flexibility is important for SMPPi.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	Noted.
No, the draft variation is not supported.	The submitter requested that FSANZ consider restricting the application of paragraph 2.9.1—30(a) for ingredients and components produced by novel technologies. The submitter supported the intent of the provision, but was concerned that as it is drafted would allow ingredients and components produced by cell culture or precision fermentation to be added to SMPPi without pre-market assessment by FSANZ. In 2022, the Food Ministers' Meeting affirmed FSANZ's view that these foods will be captured within existing standards in the Code and require pre-market assessment. The submitter considers this must also apply to SMPPi.	NZFS	FSANZ considers it unlikely that products derived from cell culture or precision fermentation would proliferate in this category unless there was an evidenced, medical need. SMPPi must be based on the compositional requirements for infant formula and any deviation from that composition must be supported by scientific evidence. Furthermore, a further restriction to their proliferation will exist as these products will only be available for retail sale through pharmacies. FSANZ also notes that substances produced by precision fermentation are already permitted in infant formula products, for example, human identical milk oligosaccharides. These have been assessed as safe and approved via the pre-market assessment process. Components produced by cell culture are subject to the same pre-market assessment.
P1024 *At the 2nd CFS, FSANZ maintained the position to consider the broader role of nutritive substances and novel foods as part of Proposal 1024 - Revision of the Regulation of Nutritive Substances and Novel Food.*			
Other comments.	Submitters noted concerns regarding the difference in interpretation of nutritive substance and novel foods. Submitters considered the Code was ambiguous in its approach to new ingredients for use in infant formula products. One submitter considered the classification of	NZFGC, DAN, INC, SML, DCANZ, A2M, AFGC, FCG	FSANZ's intent is that many of the regulatory parameters implemented through P1028 will provide further clarity on the Code's approach to new ingredients for infant formula products. FSANZ also offers the following points to assist with further understanding the use of novel foods and nutritive substances:

Issue	Comment	Submitter(s)	FSANZ response
	nutritive substances and novel foods to be open to interpretation and difficult to enforce. The example used by two industry submitters was that the Code was ambiguous in the definition of a nutritive substance, as seen with the bovine lactoferrin (bLf) decision. They questioned why bLf was not assessed as a novel food.		• Subsection 1.1.1—10(5) and (6) notes that unless expressly permitted a food for retail sale (e.g. infant formula product) must not be a novel food. Any new substance not permitted in infant formula or follow-on formula under Standard 2.9.1, Schedule 29 or related standards must be approved through pre-market assessment. Any new novel food not SMPPi under Standard 2.9.1, Schedule 29 or related standards must be approved through pre-market assessment. For clarity, a protein source in infant formula and follow-on formula is now defined in section 2.9.1—6. New protein sources require pre-market assessment. • For clarity, fat sources (see section 2.9.1—7) are restricted in that they need to meet the prescription around fatty acid profiles. • Carbohydrate amount in infant formula products is self-limiting. Carbohydrate type is determined by the protein source and there are compositional restrictions on sugars. • The definition for 'used as a nutritive substance' (see section 1.1.2—12) means that a substance derived (i.e., concentrated, refined or synthesised, to achieve a nutritional purpose) from a macronutrient source will require pre-market assessment. Application A1253 Bovine lactoferrin in infant formula products (FSANZ 2023i) is a good example of alignment with the definition and interpretation of a nutritive substance in infant formula products. It was a permission for a nutritive substance that involved a concentrated, refined or synthesised product in a specific and limited category of special purpose foods (that is, infant formula products) to achieve a specific type of purpose. FSANZ remains satisfied that the use of bLf in that specific context constitutes use as a nutritive substance for Code purposes—see section 1.3.1.1 of the A1253 Bovine Lactoferrin approval report (FSANZ 2023i).
Other comments.	The submitter was concerned that the existing and proposed requirements for novel foods and nutritive substances were insufficient to require the pre-market	QLDH	See above. FSANZ considers that the current framework and regulatory requirements for infant formula products prohibits new substances from being added without pre-market assessment.

Issue	Comment	Submitter(s)	FSANZ response
	assessment of all substances added to infant formula, noting: • no distinction was made about the population group, that is, a substance may be traditional in the general population but not for infants • history of consumption does not mean it has a history of safe consumption. The submitter considered it appropriate for the above to be considered as part of P1028 regarding infant formula products and not as FSANZ previously argued to be addressed in P1024.		
Other comments.	Submitters supported the approach to exclude substantial consideration of novel foods and nutritive substances for use in infant formula products from P1028 and supports that these are considered as part or P1024 so that requirements for infant formula products are considered in parallel with other food categories.	NZFS, AFGC, FCG	Noted.
No, the draft variation is not supported.	The submitter did not support the proposed approach to not consider novel foods and nutritive substances under P1028. Submitter said it was unclear if bioactive components such as probiotics and postbiotics were currently captured under the definition of nutritive substance because they don't achieve a nutritional purpose but a health effect.	TAS DoH	Probiotics and postbiotics in infant formula products are required to seek pre-market assessment under subsections 1.1.1—10(5) and (6), which note that unless expressly permitted a food for retail sale (e.g. infant formula product) must not be a novel food. With regard to the assessment of these substances, FSANZ must have regard to the Ministerial Policy Guideline in any pre-market assessment of a new substance (noting that Guideline principles have already been incorporated into the FSANZ Application Handbook guidelines) and in particular, specific policy principle (j). In other words, for the purposes of the assessment, there is no distinction between a substance that has a nutritional purpose versus a health effect and it is the definition of an infant formula product which indicates the nutritional purpose of the product. FSANZ refers to the discussion in section 4.10 for more information.

Issue	Comment	Submitter(s)	FSANZ response
Other comments.	The submitter noted in the 2nd CFS the scope to consider the application of the Policy Guideline on the Regulation of Infant Formula Products. The submitter referred to the 4 April 2023 Food Ministers' Meeting and the consensus for the convening of a FRSC working group to examine the evidence required to substantiate whether an infant formula product has a beneficial role in the normal growth and development of infants, including considering the cumulative effects.	WA DoH	FSANZ is aware that on 4 April 2023, the Food Ministers' Meeting recommended that FRSC should examine and, if necessary, clarify the evidence required to substantiate whether an infant formula product has a beneficial role in the normal growth and development of infants including considering the cumulative effects.[18] However, FSANZ understands that work is yet to progress.

[18] Communiqué of outcomes from the Food Ministers' Meeting held on 4 April 2023.

Section 6: Food technology

A number of submitters provided general support of FSANZ's approach to food additives and contaminants. These comments have not been included in the below table unless there was a specific reference to the substance.

Issue	Comment	Submitter(s)	FSANZ response
General comments			
Technological justification			
The submitter requests further assessment be conducted	This submitter stated that it is important that food additives are not permitted in infant formula if their presence is not technologically justified. For new permissions for food additives in infant formula a completed CCNFSDU framework to evaluate the technological justification for use of food additives in infant formula products presented in the P1028 assessment report would demonstrate the justification and reasoning as well as provide further trust in the decision-making process.	SAH	This issue has previously been explored and consulted on. See the discussion in section 3.1 of SD1 to the 2nd CFS (FSANZ 2023c). After consideration of submissions received, FSANZ is not aware of any evidence to warrant a change in its position on this issue. Explanation and links to the use of the CCNFSDU framework for the technological justification for different food additives are also provided within that section of the report. FSANZ also notes that at its 43rd CCNFSDU meeting in March 2023 and following the release of the 2nd CFS, CCNFSDU completed its assessment of the technological justification framework for both sodium and potassium phosphates (Codex 2023b).
The submitter supports the approach taken	This submitter supported the technological justification provided for the proposed food additives for use in infant formula products.	NZFS	Noted.
General comments related to food additive use in nutritive preparations			
The submitter requests reconsiderati	This submitter requested FSANZ reconsider the manner by which regulatory permissions are expressed. If sodium ascorbate (INS 301) and silicon dioxide (INS 551) are stated in its use as part of a nutrient preparation, for consistency gum arabic (INS 414), mannitol (INS 441) and	DSM	Several industry members also requested explicit permissions be added where the technological purpose of the substance has a food additive function, such as an antioxidant (sodium ascorbate) and anticaking agent (silicon dioxide).

Issue	Comment	Submitter(s)	FSANZ response
on of approach	starch sodium octenyl succinate (INS 1450) should also similarly be stated. This relates to the Codex Guideline CXG 10-1979, Part D. If the latter three are not explicitly stated, the former two additives should also be excluded to minimise ambiguity. There was also discussion in relation to how the permissions for the food additives should be written into the Code to be consistent with Codex permissions for addition to nutrient preparations added to infant formula products.		A discussion on each of the food additives mentioned, including how permissions are entered into the Code, is considered below in separate entries. See the relevant section within section 4.13 in the main body of the report for more detail.
The submitter requests reconsiderati on of approach	Under EU Commission Regulation No. 1130/2011 (European Commission 2011a): Starch sodium octenyl succinate (E1450) is permitted in EU regulations for use within polyunsaturated fatty acid preparations where a maximum 1000 mg/kg carry over is permitted into foods for infants and young children. Alpha-tocopherol (E307a) (stated to include E307c under the [EU specifications] definition) is permitted for use within all nutrient preparations for use in foods for infants and young children [10 mg/L]. Sodium ascorbate (E301) is permitted for use within [coatings of nutrient preparations containing] polyunsaturated fatty acids where a maximum 75 mg/L carry over is permitted into foods for infants and young children. Slight amendments to what was written in the submission has been made using [ ] to ensure clarity of what the EU regulations state.	CCI submission	A detailed response is provided for each of the food additives within section 4.13 in the main body of the report.
Removal of carry-over			

Issue	Comment	Submitter(s)	FSANZ response
Yes, the draft variation is supported.	These submitters supported the proposed approach. Submitters continued to support the approach that carry-over of food additives should not be permitted in infant formula products unless specific permissions exist in the Code for that food additive to be used in the final infant formula product. The intent is to ensure that food additive use is minimised in products for infants and achieves consistency with Codex and EU regulations.	NZFS, WA DoH	Noted.
	These submitters supported the proposed approach to 'align as best as possible with relevant international regulations, especially Codex standards and EU regulations'. They noted that it was important to ensure that the removal of carry-over does not impact on the supply of infant formula products, so it is important that FSANZ aligns with international regulations. FSANZ may wish to consider the provision of sufficient resources prior to and within the transition period (for approvals) for unintended consequences due to the removal of carry-over provisions.	AFGC, CCI submission	Noted.
No, the draft variation is not supported.	The submitter proposed the option to retain the current permitted carry-over of food additives to infant formula products. However, if the carry-over principle is removed, the submitter requested a number of currently used food additive permissions be added* and that permissions be consistent across infant and follow-on formula, as raw materials are shared across these categories. **See entries below for INS 301, 304, 307b, 307c, 341, 414, 526, 551*	SML	The reasons for removal of carry-over are stated in the 2nd CFS (see section 3.2 of SD1 for the 2nd CFS (FSANZ 2023b)). After careful consideration of submissions received, FSANZ maintained its position on this issue. See section 4.13 of this report. Separate entries below address each individual food additive listed in the submission.
Food additives			

Issue	Comment	Submitter(s)	FSANZ response
Sodium ascorbate (301) *At the 2nd CFS the draft variation proposed:* • *50 mg/L for follow-on formula.*			
Yes, the draft variation is supported.	Supported the proposed approach.	NZFS	Noted.
No, the draft variation is not supported.	Submitters requested permission for use as an antioxidant in coating of nutrient preparations containing polyunsaturated fatty acids (PUFA) in infant formula and follow-on formula (75 mg/L) to align with EU regulations, Codex CXG 10-1979 and draft revised Codex CXS 192-1995. It was noted that FSANZ had proposed a permission for follow-on formula [at 50 mg/L, which was to be amended to 75 mg/L] as well as for use in nutrient preparations added to infant formula products with a MPL of 75 mg/L. This will cause problems for industry to identify which use has which MPL.	SML, INC, NZFGC, NES, FCG, DSM, CCI submission	As noted, sodium ascorbate does not have a technological function as a carrier but is more appropriately considered to function as an antioxidant food additive. FSANZ has revised the drafting to be consistent with CXG 10-1979 (Codex 1979), Part D and EU regulations for food additive use in nutrient preparations added to infant formula products. This required a new entry under food class/food category 13.1 for sodium ascorbate with the MPL of 75 mg/L with the condition for use only in nutrient preparations. The separate comment around having different MPLs for different uses of the food additive is noted and addressed by correcting the follow-on formula MPL as noted above. This is consistent with Codex. For further discussion see section 4.13 in the main body of the report.
Ascorbyl palmitate (304) *At the 2nd CFS the draft variation proposed:* • *10 mg/L for infant formula* • *50 mg/L for follow-on formula.*			
Yes, the draft variation is supported.	Supported the proposed approach.	SML, NZFS	Noted.

Issue	Comment	Submitter(s)	FSANZ response
Tocopherols concentrate, mixed (307b) *At the 2nd CFS the draft variation proposed:* • *10 mg/L for infant formula* • *30 mg/L for follow-on formula.*			
Yes, the draft variation is supported.	Supported the proposed approach.	SML, NZFS	Noted.
dl-alpha-tocopherol (307c) *At the 2nd CFS the draft variation proposed:* • *Not permitted.*			
Yes, the draft variation is supported.	Supported the proposed approach.	NZFS	Noted.
No, the draft variation is not supported.	Submitters disagreed with the statement in SD1 of the 2nd CFS that 307c is not permitted in the Code for any food classes. FSANZ had used this to argue that therefore 307c would require specific permission for use in infant formula products. Requested permission for use as an antioxidant in infant formula products (10 mg/L) to align with EU regulations (including SMPPi).	SML, INC, NZFGC, DAN, NES, CCI submission	FSANZ has reviewed its proposal at the 2nd CFS for dl-alpha-tocopherol (307c). FSANZ has conducted a risk assessment on dl-alpha-tocopherol (307c). The assessment concluded that the food additive is safe for the proposed purpose. For further discussion refer to section 4.13.1 in the main body of the report.
	The submitter requested FSANZ review its position in relation to tocopherol, d-alpha, concentrate (INS 307) and tocopherol, dl-alpha (INS 307c) in permitting its use as an antioxidant in infant formula products in alignment with CXS 156-1987 and the EU regulations.	DSM	See above response.

Issue	Comment	Submitter(s)	FSANZ response
	The submitter disagreed with section 3.3.2 in SD1 to the 2nd CFS which states neither tocopherols (307a and 307c) are permitted in the Code for any food classes. Schedule 15—5 category 0 (preparations of food additives) and category 2 (Edible oils and oil emulsions) permit INS 307 at MPL of GMP.		
	Alpha-tocopherol (E307) including dl-alpha-tocopherol (E307c) is listed within EU regulations for use within all nutrients intended for use within foods for infants and young children. The EU specifications for food additives, Commission Regulation (EU) No 231/2012 (European Commission 2012) contains a specification for E307 as alpha-tocopherol with a synonym of dl-alpha-tocopherol.	CCI submission	See above response.
Lecithin (322) *At the 2nd CFS the draft variation was:* • *13.1 Unchanged at 5,000 mg/L.*			
No, the draft variation is not supported.	The submitter did not support retaining the permission at 5000 mg/L due to EFSA's recent re-evaluation which concluded that intake of 1000 mg/L does not raise safety concerns (EFSA 2020a). The submission noted pages 34–35 of SD2 to the 2nd CFS in relation to a maximum limit for phospholipids of 2 g/L but this does not provide safety assurance as the use of lecithin is above the level present in human milk and inconsistent with the Ministerial Policy Guideline (MPG 2011) [on Infant Formula Products] Principle h) [*The composition of breastmilk should be used as a primary reference for determining the composition of infant formula and follow-on formula*].	NSWFA	FSANZ notes that the permission for lecithin as a food additive in EU Regulations (EC) 1333/2008 (European Commission 2008) was set at 1,000 mg/L when the regulations were first established in 2008 and has not changed since it was established. Whereas the Codex provisions for lecithin is 5,000 mg/L in both CXS 72-1981 and the GSFA. FSANZ does not consider there is any safety issue with maintaining the MPL of 5,000 mg/L. Therefore, FSANZ has not changed the permission for use of lecithin as a food additive in infant formula products. Further discussion is provided in SD2 of the 2nd CFS (FSANZ 2023c) and FSANZ has addressed the phospholipid aspect of this issue in the section called lecithin/phospholipids in section 4 of this Appendix.

Issue	Comment	Submitter(s)	FSANZ response
Calcium citrates (333) *At the 2nd CFS the draft variation proposed:* • *13.1 not permitted* • *13.1.1 – calcium citrate at GMP.*			
Yes, the draft variation is supported.	Supported the proposed approach	NZFS	Noted.
No, the draft variation is not supported.	The submitters requested permission for 0.1 mg/L total carry-over expressed as calcium to align with EU regulations (including SMPPi) for use as a food additive in nutrient preparations added to infant formula products. Proposed GMP for calcium citrates for SMPPi to align with EU regulations (SMPPi).	INC, NZFGC, DAN, NES	The food additive is technologically justified for use in nutrient preparations, with the functional class of acidity regulator or stabiliser and not as a carrier. To be consistent with EU regulations, specifically for the food additives added to nutrient preparations added to infant formula products, it will include the permission in new and modified entries to the consequential variation. For further discussion refer to section 4.13.2 in the main body of the report.
Phosphoric acid (338) *At the 2nd CFS the draft variation proposed:* • *13.1 450 mg/L, not for follow-on formula* • *13.1.1 450 mg/L, for pH adjustment only.*			
Yes, the draft variation is supported.	Supported the proposed approach.	NZFS	Noted.
No, the draft variation is	The submitters requested permission for 450 mg/L (as phosphorus) for all infant formula products—including	INC, NZFGC, NES	FSANZ acknowledges this misalignment error. FSANZ has amended its position relating to permissions for phosphates (phosphoric acid (338), sodium phosphates (339) and potassium phosphates (340)) in follow-on

Issue	Comment	Submitter(s)	FSANZ response
not supported.	follow-on formula—to align with EU regulations (including SMPPi). It is believed to be a drafting error as it is inconsistent with section 3.3 of SD1 to the 2nd CFS. The technological justification for its use as an acidity regulator applies equally in follow-on formula as it does for infant formula, so the restriction is not appropriate.		formula. For further details please refer to section 4.13.6 in the main body of the report.
Sodium phosphates (339) *At the 2nd CFS the draft variation proposed:* • *13.1 450 mg/L, not for follow-on formula* • *13.1.1 450 mg/L.*			
Yes, the draft variation is supported.	Supported the proposed approach.	NZFS	Noted.
No, the draft variation is not supported.	The submitters proposed 450 mg/L also be permitted for follow-on formula to align with EU regulations (including SMPPi). Submitters asked FSANZ to consider if provisions for INS 339 and 340 need to be listed in 13.1.1 for use in SMPPi given these permissions at the same dosage are listed under 13.1 for infant formula products (which includes SMPPi).	INC, NZFGC, NES, NZFS	See the above explanation for phosphoric acid.
Potassium phosphates (340) *At the 2nd CFS the draft variation proposed:* • *13.1 450 mg/L, not for follow-on formula* • *13.1.1 450 mg/L.*			

Issue	Comment	Submitter(s)	FSANZ response
Yes, the draft variation is supported.	Supported the proposed approach.	NZFS	Noted.
No, the draft variation is not supported.	The submitters requested 450 mg/L also be permitted for follow-on formula to align with EU regulations (including SMPPi).	INC, NES, NZFGC, DAN, CCI submission	See the above explanation for phosphoric acid.
Calcium phosphates (341) *At the 2nd CFS the draft variation proposed:* • *13.1 Not permitted* • *13.1.1 450 mg/L.*			
Yes, the draft variation is supported.	Supported the proposed approach	NZFS	Noted.
No, the draft variation is not supported.	The submitters requested permission for use in infant formula and follow-on formula (450 mg/L) to align with Codex.	SML, INC, NZFGC, NEC	Please refer to the above discussion on phosphoric acid (INS 338) and sodium and potassium phosphates (INS 339 and 340 respectively). In addition, there is no permission in EU regulations for this food additive in food class 13.1.1 (infant formula products), nor in any Codex standards. For further discussion refer to section 4.13.6 in the main body of the report.
Locust bean (carob bean) gum (410) *At the 2nd CFS the draft variation proposed:* • *13.1 1,000 mg/L (unchanged, current permission in the Code)* • *13.1.1 5,000 mg/L, only in a product specifically formulated for reduction of gastro-oesophageal reflux.*			

Issue	Comment	Submitter(s)	FSANZ response
Yes, the draft variation is supported.	Supported the proposed approach.	NZFS	Noted.
No, the draft variation is not supported.	The submitters recommended consideration of draft regulation to be issued by EU Commission in 2023. As locust bean (carob bean) gum is used in SMPPi, levels should be aligned with the EU regulations.	INC, NZFGC, DAN	FSANZ notes that no information has been provided by the submitter on what is being drafted or the possible timeframe. FSANZ's search did not locate any changes to EU Regulations due to the late 2022 EFSA re-evaluation of this food additive (as at end April 2024). On that basis FSANZ cannot consider amending the consequential variation on this basis. FSANZ notes that if any relevant reports are released prior to finalising the approval report they will be considered. If there is a change in the EU regulations after P1028 has been finalised and gazetted, an application can be made to FSANZ requesting an amendment to the Code. FSANZ's assessment of locust bean (carob bean) gum is provided within section 3.3.7 of SD1 of the 2nd CFS (FSANZ 2023b).
Guar gum (412) *At the 2nd CFS the draft variation proposed:* • *13.1 1,000 mg/L, only in a liquid product that contains hydrolysed protein* • *13.1.1 10,000 mg/L, only used in a product that contains one or more of the following: hydrolysed proteins, peptides; amino acids.*			
Yes, the draft variation is supported.	Supported the proposed approach.	NZFS	Noted.
No, the draft variation is not supported.	This submitter recommended EFSA's re-evaluation regarding the safety of guar gum for infants below 16 weeks of age should be considered if available before producing the approval report for P1028.	NSWFA	FSANZ's assessment of guar gum is provided within section 3.3.7 of SD1 of the 2nd CFS (FSANZ 2023b).

Issue	Comment	Submitter(s)	FSANZ response
Gum arabic (acacia) (414) *At the 2nd CFS the draft variation proposed:* • *Not to permit.*			
Yes, the draft variation is supported.	Supported the proposed approach	NZFS	Noted.
No, the draft variation is not supported.	The submitters requested permission for use as a stabiliser in vitamin preparations in infant formula and follow-on formula (150,000 mg/kg in nutrient preparation and 10 mg/kg as carry over in final product) to align with EU regulations (including SMPPi).	SML, INC, NES, CCI submission	Industry submissions noted that acacia gum (gum arabic) is permitted in EU Regulations 1333/2008 Annex III, part 5, section B. This is for all nutrients including those added to infant formula products with an MPL of 10 mg/L in the final product. FSANZ noted that both Codex CXG 36-1989 and Codex CXS 192-1979 (General Standard for Food Additives, GSFA) includes 'carrier' as well as 'emulsifier' and 'stabiliser' within the functional class and technological purpose of the food additive. The industry request sought permission for use as a stabiliser and not a carrier so FSANZ considers it appropriate to provide a food additive permission. The consequential variation now permits gum arabic (acacia) INS 414 in food class 13.1 with a MPL of 10 mg/L with the condition that it is only to be used in a nutrient preparation. This MPL is very low due to its use only in nutrient preparations to be added to infant formula products. It is also a GMP food additive within section S16—2 with a JECFA ADI of 'not specified' so quite a safe food additive.
Xanthan gum (415) *At the 2nd CFS the draft variation proposed:* • *13.1.1 1,000 mg/L, only in a powdered hydrolysed protein and/or amino acid based product* • *13.1.1 1,200 mg/L, only in a product that is: based on amino acids or peptides; and formulated for infants with gastrointestinal tract problems, protein malabsorption or inborn errors of metabolism.*			

Issue	Comment	Submitter(s)	FSANZ response
Yes, the draft variation is supported.	Supported the proposed approach.	NZFS	Noted.
No, the draft variation is not supported.	The submitter noted the latest EFSA's re-evaluation that concluded the use of xanthan gum for infants below 16 weeks of age up to a concentration of 1200 mg/L does not raise concerns. The submitter suggested that applying both Codex and EU MPLs for xanthan gum in SMPPi creates possible regulatory uncertainty. The proposed conditions for the two MPLs may be confusing as extensively hydrolysed protein can be used for gastrointestinal and protein malabsorption issues.	NSWFA	Noting EFSA's very recent re-evaluation of the food additive as safe for infants below 16 weeks at 1200 mg/L, FSANZ agrees that this is appropriate as the MPL. That re-evaluation (EFSA 2023b) was released on 4 May 2023, after FSANZ finalised the 2nd CFS and SD1. The consequential variation for the food additive in food class 13.1.1 (SMPPi) is now a single entry with a MPL of 1200 mg/L and condition being 'Only in a product that is based on hydrolysed protein, amino acids or peptides'. The earlier entry with the MPL of 1000 mg/L is now removed. For further discussion refer to section 4.13.3 in the main body of the report.
	The submitters requested amending to 1200 mg/L only in a powder-based hydrolysed protein and/or amino acids or peptides to align with EU regulations (for SMPPi).	INC, NZFGC, DAN, NES	As above.
Pectins (440) *At the 2nd CFS the draft variation proposed:* • *13.1 10,000 mg/L for follow-on formula only* • *13.1.1 2000 mg/L, only in a liquid product that contains hydrolysed protein* *5000 mg/L, only in a product formulated for infants with gastro-intestinal disorders.*			
No, the draft variation is not supported.	One submitter did not support the proposed MPL for pectins of 10,000 mg/L for follow-on formula and notes SD1 of the 2nd CFS (page 19) does not provide scientific evidence to support safety for the MPL, inconsistency between previous FSANZ assessments and misalignment with EU, JECFA and EFSA conclusions.	NSWFA, NZFS	FSANZ had proposed adding a permission for pectins for follow-on formula at 10,000 mg/L (incorrectly stated as 1000 mg/L on page 19 of SD1 of the 2nd CFS; FSANZ 2023b) to be consistent with Codex CXS 156-1987 as stated within that section. This change was made to ensure consistency with the Codex standard, which as noted in above sections, had been considered by both

Issue	Comment	Submitter(s)	FSANZ response
	Another submitter recommended deleting the permission of the use of pectins for follow-on formula, unless new evidence is provided to overturn the above-mentioned previous risk assessments.		CCNFSDU and CCFA in March 2023 meetings. As also outlined in earlier reports, FSANZ has ensured consistency with Codex standards to align with the Ministerial Policy Guideline (MPG 2011). The relevant section of the Policy Guideline is (underlined for emphasis): *Relevant international agreements* The regulation of infant formula products in Australia and New Zealand should be consistent to the greatest extent possible with: • relevant World Health Organization agreements; and • relevant World Trade Organization agreements, Codex standards and guidelines. FSANZ's assessment of pectin is provided within section 3.3.9 of SD1 of the 2nd CFS (FSANZ 2023b) and there has been no change to the consequential variation after consideration of submissions.
Mannitol (INS 441) *At the 2nd CFS the draft variation:* • *Did not propose any permissions.*			
No, proposed an alternative draft variation.	The submitter requested FSANZ reconsider the manner by which regulatory permissions are expressed. If sodium ascorbate (INS 301) and silicon dioxide (INS 551) are stated in its use as part of a nutrient preparation, for consistency, mannitol (INS 441) should also similarly be stated.	DSM	FSANZ did not agree to add a permission for this food additive since within Regulation (EC) No 1333/2008, Annex III, part 5, section 2 it is noted for use as a carrier for vitamin B_{12}. Carrier is a technological function of a processing aid and as such it does not require a specific food additive permission to be given in the Code. Mannitol is an additive permitted at GMP in Schedule 16—2 and so it is also a generally permitted processing aid as per paragraph 1.3.3—4(2).
Diacyltartaric and fatty acid esters of glycerol (INS 472e) *At the 2nd CFS the draft variation proposed to:* • *Remove the permission for this additive.*			

Issue	Comment	Submitter(s)	FSANZ response
Yes, the draft variation is supported.	Supported the proposed approach.	NZFS	Noted.
No, the draft variation is not supported.	These submitters did not support the proposed option and instead recommended continued permission for this food additive for use as an emulsifier and for it to be listed in S15—5 for SMPPi in alignment with both JECFA and EFSA reviews. That is, they propose permission for the food additive with a MPL of 2500 mg/L for SMPPi. The justification for the request is that the food additive is both safe and technologically justified as an emulsifier in infant formula, based on amino acids to ensure homogeneity. One submitter referenced JECFA 2003 and EFSA 2020a assessments as well as their own unpublished 3-week neonatal piglet study to assess the safety of the food additive in infant formula products.	AA, INC, NZFGC	FSANZ notes that there are no permissions for use of this food additive in any infant formula products in Codex standards or EU regulations. FSANZ notes that an industry stakeholder has now provided information on use diacyltartaric and fatty acid esters of glycerol (INS 472e) in their SMPPi in response to the 2nd CFS. The submission did not contain information that would allow FSANZ to conduct a risk assessment at 2500 mg/L and consider risk management options. The approved consequential variation will therefore maintain the current permission in the Code, i.e. for food class 13.1.1 (SMPPi) at the MPL of 400 mg/L. For further discussion refer to section 4.13.4 in the main body of the report.
Sucrose esters of fatty acids (473) *At the 2nd CFS the draft variation proposed:* • *13.1.1 120 mg/L, only in products that contain hydrolysed proteins, peptides and amino acids.*			
Yes, the draft variation is supported.	Submitters supported the proposed approach as a general all-encompassing note, without making any specific comment on this proposed permission.	INC, NZFGC, NES	Noted.
No, the draft variation is not supported.	These submitters noted that EFSA's (April 2023) re-evaluation (EFSA 2023a) identified that sucrose esters of fatty acids are not being used in infant formula products including SMPPi in Europe. Since FSANZ proposed permission for use of sucrose esters of fatty acids in SMPPi is solely to align with the EU, these submitters propose removing the permission.	NSWFA, NZFS	As the submitters noted, FSANZ used the justification of EU permissions for use of the food additive in SMPPi (i.e. food class 13.1.5.1) in EU regulations as the main justification for adding permissions into the Code. This was to allow the importation of such products from the EU for the small number of infants with specific medical conditions that depend on such products.

Issue	Comment	Submitter(s)	FSANZ response
			Due to the information provided in the recent EFSA re-evaluation which found that there is no use of the food additive in infant formula products in Europe, FSANZ has concluded that it is appropriate to remove permission for sucrose esters of fatty acids (INS 473) in food class 13.1.1. FSANZ has also consulted with the infant formula product industry and it agreed with FSANZ's to remove the permission from the consequential variation. For further discussion refer to section 4.13.5 in the main body of the report.
	The submitter stated that FSANZ did not undertake further safety assessment between the 1st and 2nd CFS to determine whether there is a history of safe use at the proposed level and for infants aged less than 12 weeks. The submitter requested FSANZ reconsider the need to permit INS 473 in SMPPi.	NZFS	See above response.
Calcium hydroxide (526) *At the 2nd CFS the draft variation proposed:* • *13.1 2,000 mg/L in infant formula and follow-on formula.*			
Yes, the draft variation is supported.	Supported the proposed approach.	SML, NZFS	Noted.
Silicon dioxide (amorphous) (551) *At the 2nd CFS the draft variation proposed:* • *13.1 10 mg/L in infant formula products. May only be added as part of a nutrient preparation.*			
Yes, the draft variation is supported.	Supported the proposed approach	SML, NZFS	Noted.

Issue	Comment	Submitter(s)	FSANZ response
Starch sodium octenyl succinate (1450) *At the 2nd CFS the draft variation proposed:* • *13.1.1 20,000 mg/L. May only be used in a product that contains hydrolysed proteins, amino acids or both.*			
No, proposed an alternative draft variation.	The submitter requested FSANZ reconsider the manner by which regulatory permissions are expressed for food additives used in nutritive preparations. If sodium ascorbate (INS 301) and silicon dioxide (INS 551) are stated in its use as part of a nutrient preparation, for consistency, starch sodium octenyl succinate (INS 1450) should also similarly be permitted. The submitter requested that permission be added for this food additive to be permitted for use in polyunsaturated fatty preparations added to infant formula products with an MPL of 1,000 mg/L, to also be consistent with EU regulations.	DSM, CCI submission	Codex Guideline CXG 10-1979 (Codex 1979), part D lists this food additive as a nutrient carrier with the MPL of 100 mg/kg in the final food. This is consistent with its use as a food additive in nutrient preparations within Regulation (EC) No 1333/2008, Annex III, part 5, section 2, for vitamin preparations with an MPL of 100 mg/kg. EU regulations also permit its addition to polyunsaturated fatty acid (PUFA) preparations added to infant formula products, with a MPL of 1,000 mg/L in the final food. A CCI submission and information was received requesting permission consistent with EU regulations, to ensure products are compliant. This is particularly relevant for PUFA preparations, i.e. DHA/ARA. The technological purpose (and functional class) of the food additive listed in the Codex guideline CXG 36-1989 is not as a carrier but as a stabiliser as part of the encapsulating process to ensure stability of the PUFA nutrient preparation. It was therefore considered appropriate to add two new specific permissions in food class 13.1 for this food additive for use in nutrient preparations to be added to infant formula products. The first to be consistent with Codex is an MPL of 100 mg/L, with the condition that it is only for use in a nutrient preparation. The second is to be consistent with EU regulations, with the condition that it is only for use in PUFA preparations. For further discussion refer to section 4.13 in the main body of the report.
Contaminants			

Issue	Comment	Submitter(s)	FSANZ response
General comment			
Yes, the draft variation is supported.	The submitter supported the proposed approach for all contaminants except for aluminium and tin and inorganic tin compounds.	NZFS	The comment is noted, with responses to the contaminants listed addressed separately below.
Yes, the draft variation is supported.	The submitter supported the approach to apply maximum levels for infant formula to an 'as consumed' form in mg/kg.	NZFS	FSANZ notes that the way contaminant MLs are provided within section S19—4 is already on an 'as consumed' basis due to subsection 1.4.1—2(1).
Aluminium *At the 2nd CFS the draft variation proposed:* • *Reducing the maximum level for soy from 1 mg/kg to 0.5 mg/kg (noting this would mean one level is used for both milk-based and soy-based products).*			
Yes, the draft variation is supported.	The submitter supported the draft variation but continued to consider an ML for aluminium in dairy [based] formula to be unnecessary and not internationally aligned with Codex, the EU and the US. However, it is able to comply with the requirement.	FCG	Noted.
No, the draft variation is not supported.	The submitters noted that the reduced ML may not always be met due to varying natural levels in soy ingredients. It is important that soy-based infant formula products can continue to be sold as an option for the management of dairy intolerance and allergy, or for caregivers who wish to use a plant-based product.	NZFGC, INC, DAN, AFGC, NZFS, CCI submission	FSANZ has reconsidered its proposal to reduce the ML for aluminium in soy-based infant formula products. For further discussion refer to section 4.14.2 in the main body of the report.
	The submitter considered if the first entry for aluminium that states 'infant formula and follow-on formula' should be extended to include SMPPi that are not formulated for pre-term infants. Currently, it is not clear which ML applies for these products but it is assumed the intent is for the ML of 0.5 mg/kg to apply.	NZFS	FSANZ confirms that is the intent. The contaminant ML for aluminium in SMPPi (excluding those specifically formulated for pre-term infants) is 0.5 mg/kg. For further discussion refer to section 4.14.2 in the main body of the report.

Issue	Comment	Submitter(s)	FSANZ response
Tin and inorganic tin compounds *At the 2nd CFS:* • *no change was proposed to the ML of 250 mg/kg.*			
No, the draft variation is not supported.	The submitter supported retaining the ML of 250 mg/kg as proposed however does not agree with the drafting. Currently the section S19—4 entry for tin lists 'all canned food', which does not capture all infant formula products (e.g. ready-to-drink products in a tetra pack). The submitter recommended S19—4 entry for Tin lists both *'all canned food'* and *'infant formula products'* for maximum clarity. The submitter also questioned whether the contaminant in section S19—4 should refer to *'Tin'* or *'Tin & inorganic tin'*.	NZFS	The need for a ML for tin is to address the contamination that can occur from storage of foods in cans. This is appropriate for canned infant formula products. This is not relevant for ready-to-drink infant formula products in a tetra pack. The comment to consider altering 'Tin' to 'Tin and inorganic tin' for all canned foods is noted. However, this impacts more than just infant formula products so it was not considered appropriate to make the change during this proposal.
Processing aids			
Processing aids • *No changes to the Code related to processing aids.*			
Yes, the draft variation is supported.	These submitters supported retaining the current standards for processing aids and that no changes are required.	NZFS, INC, FCG	Noted.

Section 7: Labelling

A number of submitters expressed support for specific labelling sections in the draft variations at 2nd CFS. FSANZ has only included these supportive comments in the table below when opposing comments were made about the specific section.

Issue	Comment	Submitter(s)	FSANZ response
2.9.1—15 Representations about food as infant formula or a follow-on formula *At the 2nd CFS the draft variation stated:* *(1) a food may only be represented as infant formula or follow-on formula if it complies with this standard.* *(2) a food represented as infant formula or follow-on formula must not be also represented as another food.* ***Example*** A food represented as infant formula must not be also represented as, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children.			
Yes, the draft variation is supported.	These submitters supported the proposed subsection 2.9.1—15(2). One public health submitter also supported subsection 2.9.1—15(1).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NES, ADG	FSANZ notes these comments, however after consideration of submissions, FSANZ has decided to amend the draft variation at 2nd CFS for the reasons stated in the response below.
No, the draft variation is not supported.	These submitters did not support subsection 2.9.1—15(2). Submitters stated the subsection is unclear regarding: • what would constitute IF or FoF being represented as another food and • which labelling aspects this section relates to beyond the use of prescribed names. Submitters stated that 'not represented as another food' would be unenforceable. Submitters recommended subsection 2.9.1—15(2) is more consistent with EU regulations, which states: *A food represented as infant formula or follow-on formula must be designed in such a way that it avoids any risk of confusion between*	NSWFA, NZFS, NZ MoH, VIC DoH & DEECA	After consideration of submissions, FSANZ amended the draft variations at 2nd CFS to clarify and strengthen the purpose of the provision (product differentiation) and how to achieve it (through text, pictures and/or colours). See section 2.9.1—15 of the primary variation.

Issue	Comment	Submitter(s)	FSANZ response
	infant formula and follow-on formula and enables consumers to make a clear distinction between them, in particular as to the text, images and colours used. One submitter suggested drafting adapted from the EU regulations as follows: *(2) A food represented as infant formula or follow-on formula shall be differentiated from one another and other foods through the text, images and colours used.* *Example: A food represented as infant formula must be distinguishable from, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children.* *Note: The purpose of differentiation is to avoid any risk of confusion between infant formula, follow-on formula and other foods, particularly formulated supplementary food for young children.* This submitter stated the Note is intended to provide context however alternatively the concept could be included in the Explanatory Statement to assist with interpretation of the standard.		
2.9.1—20 Statement of protein source *At the 2nd CFS the draft variation stated:* *(1) For the labelling provisions, the specific animal or plant source or sources of protein in infant formula and follow-on formula must be included in the statement of the name of the food required by section 2.9.1—19.*			
Yes, the draft variation is supported.	These submitters supported the requirement to include the specific animal or plant source(s) of protein in the statement of the name of the food.	A&AA, ADG, NAC, NZFS, TAS DoH	Noted.
No, the draft variation is not supported.	***1. Location of protein source statement*** These submitters did not support the protein source statement to be part of the name of the food.	DAN, SML, NSWFA, QLDH	After consideration of submissions, FSANZ has decided to maintain the approach at 2nd CFS for the reasons stated at section 4.15 of this report.

Issue	Comment	Submitter(s)	FSANZ response
	Industry submitters stated there should be no restriction on where it can be located on the label for the following reasons: • it provides information to assist caregivers to make informed choices. • it limits information to caregivers whose infants tolerate formula free from A1 beta casein protein. • the statement is not promotional in nature • restriction is inconsistent with international standards. Government submitters stated that partially hydrolysed proteins should only be referenced in the statement of ingredients. One government submitter stated there is no clear scope and scientific justification for this labelling provision that will assist caregivers to make informed choices. Further, the role and functional purpose of the partially hydrolysed protein in IF and FoF has not been defined and partially hydrolysed protein ingredients are compliant with baseline composition.		
	2. Limits protein source information These submitters did not support the draft variation because it is limited to *'the specific animal or plant source or sources of protein'*. They considered it is necessary to include information about the type of cow milk proteins (e.g. A2 beta casein protein) in order to communicate about how the product differs from others within the range.	A2M, DAN	After consideration of submissions, FSANZ has decided to maintain the approach at 2nd CFS for the reasons stated at section 4.15 of this report A Note has been added to subsection 2.9.1—20(1) of the primary variation as a signpost to the list of permitted protein sources in section 2.9.1—6.

Issue	Comment	Submitter(s)	FSANZ response
2.9.1—20 Statement of protein source *At the 2nd CFS the draft variation stated:* *(2) If a label of infant formula represents that the formula is partially hydrolysed, the words 'partially hydrolysed' must be used immediately adjacent to the statement of protein source required by subsection (1).* ***Example*** *'Partially hydrolysed Infant Formula based on cows' milk'.*			
Yes, the draft variation is supported.	These submitters supported the requirement to use the words 'partially hydrolysed' as described, if the label of IF represents the formula is partially hydrolysed.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, TAS DoH	After consideration of submissions, FSANZ has amended the draft variations at 2nd CFS to require that, if partially hydrolysed protein is used as a permitted protein source in IF and FoF, the words 'partially hydrolysed' must be used in association with the specific animal or plant source or sources of protein that it is derived from. That is, the requirement is based on its use rather than whether the product is represented as being partially hydrolysed. See section 4.15 of the report and the primary variation at subsection 2.9.1—20(2).
No, the draft variation is not supported.	***1. Prohibition of 'partially hydrolysed' on follow-on formula*** These submitters did not support the prohibition for the words 'partially hydrolysed' on FoF labels and requested the requirement in 2.9.1—20(2) be extended for the following reasons: • Such formula products are not necessarily formulated for specific health conditions. • Some partially hydrolysed formula currently in the market are standard formulas. • Absence of 'partially hydrolysed' could suggest FoF is an intact protein product. • Labelling 'partially hydrolysed' on FoF would assist caregivers to distinguish between products.	INC, SML, DAN, DCAN, A2M, AFGC, FCG, NES	FSANZ has extended the requirement for the words 'partially hydrolysed' to be declared in the protein source statement to FoF. See section 4.15 of the report and the primary variation at subsection 2.9.1—20(2).

Issue	Comment	Submitter(s)	FSANZ response
	2. Does not provide informed choice These submitters did not support subsection 2.9.1—20(2) and proposed it be removed for the following reasons: • Terms such as 'partially hydrolysed' require detailed nutritional knowledge to understand. Therefore, such terms have little use in aiding informed choice. • Emphasising this [partially hydrolysed] aspect would elevate this point of difference inferring it is important and of benefit to infants. • Information about partially hydrolysed protein should not be on the NIS without a clear definition of what 'partial hydrolysis' means.	NSWFA, QLDH, PHI2	After consideration of submissions, and for the reasons stated at section 4.15 of this report, FSANZ has decided to maintain the requirement to declare the words 'partially hydrolysed', however the requirement is now based on its use as a protein source.
	3. Permit 'partially hydrolysed' words within protein source statement This submitter noted the draft variation specified the words 'partially hydrolysed' be used immediately adjacent to the protein source statement e.g. *'Partially hydrolysed infant formula based on cow's milk'.* The submitter suggested allowing for the words 'partially hydrolysed' within the protein source statement e.g. *'Infant formula from partially hydrolysed cow's milk'.* This would more accurately describe the nature of the modification.	NES	FSANZ has amended the example to subsection 2.9.1—20(2) of the draft variations at 2nd CFS to indicate the words 'partially hydrolysed' may be used within the protein source statement. The words must be linked with the other permitted proteins where relevant, for the purpose of describing the nature of the modification more accurately. See section 4.15 of the report and subsection 2.9.1—20(2) in the primary variation.
	4. 'partially hydrolysed' is a claim These submitters commented there should be no claims permitted that imply there is an associated physiological or health effect, such as one relating to digestion. The words 'partially hydrolysed' may be an implied claim and are therefore inconsistent with the Ministerial Policy Guideline on the *Regulation of Infant Formula Products*.	NSWFA, QLDH	FSANZ has amended the declaration requirements to be based on use, rather than when a product is represented as 'partially hydrolysed'. Partially hydrolysed protein is a permitted protein source and 'partially hydrolysed' refers to an attribute of the protein source and not a health effect. Similar to other protein sources, FSANZ considers there should be a reference on the label to its presence in a formula. See section 4.15 of the report.

Issue	Comment	Submitter(s)	FSANZ response
Other	***5. Advisory statement*** These submitters recommended mandating an advisory statement on partially hydrolysed products with the words 'not suitable for infants with cow's milk allergy'. Submitters stated there is no clinical indication for partially hydrolysed protein in the prevention or treatment of cow's milk protein allergy.	ASCIA, PHI2, NSWFA	FSANZ does not agree that a mandatory advisory statement such as 'not suitable for infants with cow's milk protein allergy' is required. Partially hydrolysed protein is considered a safe protein source. Consistent with international regulations, its use is currently permitted in the Code and was explicitly listed as a permitted protein source in the draft variations at 2nd CFS at subsection 2.9.1—6(1).After consideration of submissions and for the reasons stated in this report, FSANZ has not changed this approach. Partially hydrolysed protein is commonly used in the formulation of IF and FoF for reasons other than for manufacturing products intended for transient gastrointestinal conditions. FSANZ acknowledges that health professional and caregiver education may be warranted regarding the fact that it must be declared because it is a permitted protein source and will consider when developing educational resources (see section 8.3 of the report). Further, as these infant formula products would not be able to refer to a medical condition or make a health claim, there would be no indication on the label that the product is for use in the case of cow's milk protein allergy. Formulas intended for the dietary management of a medically diagnosed disease, disorder or condition of an infant (including for cow's milk protein allergy) are categorised as SMPPi and must be specifically labelled to indicate the medical purpose of the food; that the food must be used under medical supervision; and a statement indicating, if applicable, any precautions and contraindications associated with the consumption of the food.
	6. Reference to health conditions on infant formula and follow-on formula labels This submitter recommended extending the approach to mandate specific words on other transient gastrointestinal conditions (such as anti-reflux, colic), noting that a requirement to use these words means they are not considered to be health claims.	AFGC	After consideration of submissions, FSANZ does not agree specific words on transient gastrointestinal conditions, such as 'anti-reflux' and 'colic', should be permitted on the labels of IF for the reasons stated in the 2nd CFS (section 8; FSANZ 2023d).

Issue	Comment	Submitter(s)	FSANZ response
	7. 'Partially' versus 'extensively' hydrolysed This submitter commented that the absence of a definition of 'partial hydrolysis' for IF products versus 'extensive hydrolysis' for SMPPi leaves the point of sale as the point of segregation. The submitter noted enforcement complications may arise where jurisdictions are examining labelling to make determinations between IF and SMPPi.	NSWFA	FSANZ does not agree with the suggestion that a definition of 'partially hydrolysed' is required. Differences in labelling requirements for IF and FoF in Division 3 and those for SMPPi in Division 4 will enable products to be identified and differentiated. For example, SMPPi must have a statement to the effect that the food must be used under medical supervision (paragraph 2.9.1—50(a) of the primary variation). Comments relating to a definition for 'extensively hydrolysed protein' have been addressed in section 3 of this Appendix.
2.9.1—21 Labelling requirements for food represented as lactose free and low lactose formulas *At the 2nd CFS the draft variation stated:* *(1) For the labelling provisions, if a label represents that an infant formula is lactose free or low lactose:* *(a) for a formula represented as lactose free—the words 'lactose free' must be included in the statement of the name of the food required by section 2.9.1—19; and* ***Example*** *'Lactose free infant formula from cows milk'.* *(b) For a formula represented as low lactose—the words 'low lactose' must be included in the statement of the name of the food required by section 2.9.1—19; and* ***Example*** *'Low lactose infant formula from cows milk'* *(c) The average quantity of lactose and galactose, expressed in grams, must be included in the statement required by section 2.9.1—25 and in the same format as specified in the table to section S29—10 for those substances.* ***Note*** *The labelling provisions are set out in Standard 1.2.1.* *(2) A labelling requirement of this standard, other than a requirement imposed by subsection (1), applies to an infant formula that is represented as lactose free or low lactose formula.*			
Yes, the draft variation is supported.	These submitters supported elements of the draft variation. Industry submitters supported the words 'lactose free' and 'low lactose' to be included with the name of the food on the front of the package, as in paragraphs 2.9.1—21(1)(a) and (b) and one of these	INC, SML, DAN, DCANZ, A2M, AFGC, FCG,	FSANZ notes these comments. However, for the reasons stated in this report, FSANZ has amended the draft variations at 2nd CFS to remove lactose modified products from Division 3.

Issue	Comment	Submitter(s)	FSANZ response
	submitters commented that these words provide clear information to the caregiver. A submitter from government and another from public health supported the removal of the permission for FoF to be represented as lactose free or low lactose. These submitters also commented on other aspects of the regulatory approach for lactose modified products they did not support (see below).	NSWFA, NAC	Lactose modified products will be regulated as SMPPi in Division 4. See section 4.4 of the report.
No, the draft variation is not supported.	***1. Categorise lactose modified products as SMPPi*** One government and one public health submitter did not support the categorisation of lactose modified products as infant formula and indicated they should be categorised as SMPPi for the following reasons: • The current labelling regulatory approach (inclusion of the specified words in the statement of the name of the food) was viewed as information typically deemed as nutrition content claims, which is inconsistent with the Ministerial Policy Guideline on the *Regulation of Infant Formula Products*. • There is confusion within the community between lactose intolerance and cow's milk protein allergy. The public health submitter suggested lactose free formula is consistent with the proposed definition of SMPPi and restricted sale would facilitate better care of the infant and may prevent caregivers mistakenly using lactose free products in cases of cow's milk protein allergy. In contrast, industry submitters did not support classification of products represented for use with lactose intolerance as SMPPi. They recommended dairy-based IF with modified lactose content have either extended labelling provisions (e.g. the statement 'for babies with lactose intolerance'), or the product is classified as SMPPi, but is exempt from the restriction on sale.	NSWFA, NAC, INC, SML, DAN, DCANZ, A2M, AFGC, FCG	As noted in the previous response, FSANZ is requiring lactose modified products to be regulated as SMPPi. See section 4.44.4 of the report.

Issue	Comment	Submitter(s)	FSANZ response
	2. Mandate 'lactose intolerance' as a permitted term for lactose modified infant formula and follow-on formula These submitters suggested the term 'lactose intolerance' is mandated similarly to the words 'lactose free' and 'low lactose' so it does not constitute a prohibited claim. One submitter also raised the following reasons to support the suggestion to mandate 'lactose intolerance' on the label. They stated that in the absence of 'lactose free' formula (which cannot be produced because of domestic requirements that 'free' means 'no presence of'), there was a potential safety issue arising from the sale of 'low lactose' formula. They commented that: • labelling requirements are not effective in presenting clear information to caregivers to ensure appropriate use of these products. • 'low lactose' products containing up to 0.3g lactose/100 mL may present a potential safety issue if caregivers are advised to purchase them for lactose intolerant infants.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NES	Given that lactose modified products will now be regulated as SMPPi, FSANZ has not considered mandating the term 'lactose intolerance' on the label of IF or FoF. See section 4.4 of the report.
	3. Restriction of the phrases 'lactose free' and 'low lactose' to the front of the package These submitters did not support the restriction of the phrases 'lactose free' and 'low lactose' to the front of the package for the following reasons: • They are prescribed terms and not nutrition content claims. • The statements provide information to caregivers to make informed decisions. • Duplication elsewhere on the package label increases caregiver awareness. • They are not promotional in nature. • Restriction is not consistent with international standards.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, DAN, NZFGC	Lactose modified products will now be regulated as SMPPi and therefore the restriction on the words 'lactose free' and 'low lactose' to the front of the package of infant formula is no longer relevant. See section 4.4 of the report.

Issue	Comment	Submitter(s)	FSANZ response
Other	These health professional and government submitters recommended lactose free and low lactose formulas be subject to a labelling statement 'not suitable for infants with cow's milk protein allergy' (or similar wording). The reasons provided for this statement were: • There is caregiver confusion around lactose intolerance and milk allergy and so this statement would ensure safe use. • There are anaphylaxis cases from caregivers providing lactose free products on the assumption they are suitable for milk allergies. • Lactose free and low lactose cow milk-based IF are suitable for infants with lactose intolerance but not suitable for infants with cow's milk protein allergy. This distinction needs to be clear on product labelling. A government submitter also stated it will need to be clear that low lactose and lactose free formulas included in the SMPPi category are not indicated for lactose intolerance. This submitter commented that some overarching advisory [statement] indicating that low lactose and lactose free formula are rarely required for an extended period will need to be considered.	A&AA, ADG, ASCIA, PHI2, PHI3, NAC, QLDH, WA DoH	Lactose modified formulas have been re-categorised as SMPPi. Mandatory statements for SMPPi and the restriction on their sale negate the need for the proposed labelling statement. See section 4.4 of the report.

2.9.1—22 Warning statements

At the 2nd CFS the draft variation stated:

Warning statements

*(1) For the labelling provisions, the following *warning statements are required for infant formula and follow-on formula:*

(a) 'Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill.'; and

*(b) a heading that states 'Important Notice' (or words to that effect), with under it the *warning statement—'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.'.*

***Note** The labelling provisions are set out in Standard 1.2.1.*

Issue	Comment	Submitter(s)	FSANZ response
No, the draft variation is not supported.	***1. Reference to 'breast milk' in paragraph 2.9.1—22(1)(b)*** This submitter supported retaining the statement breast milk is best for babies, however it requested the words 'breast milk' be changed to the word 'breastmilk' to reflect best practice taxonomy of using the word. For example: *'Breastmilk is best for babies.'*	WA DoH	FSANZ has decided to maintain the approach at the 2nd CFS. The spelling of 'breast milk' in the current standard has been amended in the variation to remove the hyphen, so there is consistency in the spelling between the definitions that refer to it and in the warning statement. FSANZ notes there is no consistency in the spelling of this term elsewhere. For example: • The Ministerial Policy Guideline on the *Regulation of Infant Formula Products* refers to 'breastmilk' (MPG 2011) • Codex CXS 72-1981 and the WHO Code of Marketing refer to 'breast-milk' (Codex 1981; WHO 1981) • the MAIF Agreement refers to 'breast milk' (Department of Health and Ageing 2022). Currently the Code sets out prescribed wording for the 'Breast milk is best' warning statement. To change this to one word would require a label change to all IF and FoF products at a cost to industry. This does not appear to be warranted given the lack of consistency elsewhere.
	2. Wording in paragraph 2.9.1—22(1)(b) does not adequately support breastfeeding This submitter commented that the 'breast milk is best' warning statement can be counterproductive in protecting breastfeeding. Research (Berry et al 2009) suggests that the 'breast is best' message idealises breastfeeding as optimal rather than the 'normal' way to feed infants. The submitter suggested FSANZ consider undertaking additional research on more appropriate language to convey this message.	TAS DoH	FSANZ has decided to maintain the current prescribed wording for the following reasons. The evidence cited by the submitter (Berry et al. 2010 [not 2009]) does not demonstrate that breastfeeding is idealised and thus is not the 'normal' way to feed infants. Rather, the study suggests that messaging similar to 'breast milk is best', alongside marketing of toddler milks, may be used by companies to guide caregivers to compare toddler milks favourably with breastfeeding in specific circumstances. It is not clear whether the specific language 'breast milk is best' was used in any of the advertisements considered in the study and the marketing that

Issue	Comment	Submitter(s)	FSANZ response
			was used in the study (nutrition content and health claims) is prohibited on IF and FoF. A study by Berry and Gribble (Berry and Gribble 2008) did raise concerns about the positive framing of the 'breast is best' statement not adequately conveying the health risks associated with formula feeding. The paper drew on three empirical studies from the US, to make this argument: • Hannan et al. (2005) found that while 55.3–75.1% participants agreed with the statement "breastfeeding is healthier for babies", 61.9–86.3% of participants did not agree with the statement "feeding a baby formula instead of breastmilk increases the chances the baby will get sick", which they suggest is a similar statement with a negative framing. • Li et al. (2007) found that a quarter (25.7%) of Americans believed IF was as good as breastmilk. • The US National Women's Health Information Centre (2004) found that women did not believe there were disadvantages associated with not breastfeeding and rather viewed it as like supplementing a standard diet with vitamins. This study is no longer available online to verify the findings. In contrast to the evidence from Berry and Gribble (2008), in 21 focus groups with Australian and New Zealand caregivers of formula-fed infants, Malek (2016a) found that the 'breast is best' statement was the most emotive labelling element. It was considered unnecessary, pointless and/or offensive by many caregivers especially those who struggled to breastfeed. Caregivers highlighted that breast is not always best, rather a 'fed' baby is best; and noted that the strong perceived social pressure to breastfeed can be compounded by the 'breast is best' statement. FSANZ considers moving to a negative framing of the 'breast milk is best' statement would likely exacerbate these concerns.

Issue	Comment	Submitter(s)	FSANZ response
			FSANZ previously undertook a review of the consumer evidence relating to the existing wording of the warning statement. The evidence indicated that, for the majority of women, the decision about whether to breastfeed or formula feed is made either before they conceive or during pregnancy. The review also examined whether a loss-framed 'breast milk is best' warning statement (e.g. emphasising the risks of formula feeding) and gain-framed messages (e.g. emphasising the benefits of breastfeeding) would have an impact on caregivers' breastfeeding intentions or outcomes. There was insufficient information available to determine whether either message type would have an impact (refer to Appendix A2.2 of SD2 of the FSANZ 2016 CP (FSANZ 2016f). FSANZ also noted in the FSANZ 2016 CP that the current warning statement aligns with the WHO Code principles and the corresponding Australian and New Zealand agreements, Codex CXS 72-1981 and public health messages about the superiority of breastfeeding compared to formula feeding (FSANZ 2016a; WHO 1981; Department of Health and Ageing 2022; Infant Nutrition Council 2018; Codex 1981).
Other	This submitter considered that, based on evidence for toddler milks and growing up milks, a warning statement on IF and FoF should be included in the statement of ingredients regarding sugar content or use of palatable sweeteners. The submitter also recommended a risk panel for other warning statements that would include the following new warning statement: *'Children who are not breastfed are at an increased risk of illness. The risks associated with the use of this product include: sudden infant death syndrome (SIDS), respiratory and gastrointestinal infections, acute ear infection, asthma, type 1 and 2 diabetes, overweight and obesity, leukaemia.'*	BAA	FSANZ considers that a warning statement about sugar content is unnecessary for IF and FoF for the following reasons: • Added fructose and/or added sucrose are prohibited unless the IF is manufactured from partially hydrolysed protein and then the amount of added fructose and/or added sucrose is controlled. • Sweeteners are not permitted to be added to IF or FoF. • The evidence cited refers to other categories of food, which are out of scope of Proposal P1028 and the evidence is not appropriate to consider in the context of IF and FoF. FSANZ does not agree that the proposed warning statement should be mandated. The requirements in Standard 2.9.1 and

Issue	Comment	Submitter(s)	FSANZ response
			Schedule 29 are intended to ensure that IFP are safe and suitable for consumption by an infant under the age of 12 months. This includes when products are consumed as a sole source of nutrition by an infant aged up to four to six months and as part of a progressively diversified diet, from six to 12 months. Further, FSANZ considered a similar suggestion to amend the existing 'breast milk is best' warning statement to become a risk-based statement, however this was not adopted for the reasons summarised in issue 2 above and set out in section 5.5.3 of FSANZ 2021 CP1 (FSANZ 2021a) and section 5.6 of FSANZ 2016 CP (FSANZ 2016f).
2.9.1—22 Required statements on use *At the 2nd CFS the draft variation stated:* *(2) For the labelling provisions, the required statements for infant formula and follow--on formula are ones indicating that:* *(a) for infant formula—the infant formula may be used from birth.*			
Yes, the draft variation is supported.	These submitters supported the proposed option. The industry submitter supported not prescribing the wording of the age statement and that manufacturers retain flexibility.	AFGC, NZFS	Noted.
No, the draft variation is not supported.	These submitters did not support the proposed option for the following reasons: • The age range 0–6 months sometimes used by manufacturers is misleading as it suggests that the product is not suitable after 6 months. It was suggested the use of the words 'birth to 12 months' or 'from birth' as the only two suitable statements on IF. • Current practice for 'stage 1' age labelling varies between products, with some labelling 'from birth' and others 'from birth to 6 months'. The following amendment was suggested:	NSWFA, TAS DoH, VIC DoH & DEECA	For the reasons stated in this report, FSANZ has decided to maintain the current age statement for IF. The wording of the statement is intended to be flexible rather than prescribed to account for the range of IF that are suitable for infants up to the age of six months or 12 months. The approach for the IF age statement is also consistent with Codex and EU regulations. See section 4.16 of the report on required statements, section 4.20 relating to stage labelling and SD1 for the regulatory intent relating to how this statement may appear on the label.

Issue	Comment	Submitter(s)	FSANZ response
	*(a) for infant formula—the infant formula may be used from birth **to the age of 12 months**; and* One submitter commented that this change would address concerns about stage labelling and reflect the accurate age range.		
2.9.1—22 Required statements on use *At the 2nd CFS the draft variation stated:* *(2) For the labelling provisions, the required statements for infant formula and follow--on formula are ones indicating that:* *(b) for follow-on formula—the follow-on formula should not be used for infants aged under the age of 6 months.*			
Yes, the draft variation is supported.	One government submitter supported the proposed option. One industry submitter supported not prescribing the wording of the age statement but made other comments about the interpretation of the statement (refer below).	TAS DoH, AFGC	Noted.
No, the draft variation is not supported.	***1. Specifying age range and reframing as a positive statement*** Industry submitters did not support the wording of the requirement in paragraph 2.9.1—22(2)(b) and suggested the drafting is clarified to: • confirm positive statements with the same intent are permitted e.g. *'from 6 months'* or *'6–12 months'* and • include examples of compliant statements in a Note.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NES	FSANZ considers label statements such as 'from 6 months' and '6–12 months' meet the intent of the required statement for FoF, noting the wording of the statement is not prescribed. FSANZ does not agree a Note is required. FSANZ has provided information in SD1 to indicate the regulatory intent of this provision and considers there is no need for a Note in the primary variation as recommended by some submitters. See section 4.16 of the report.
	2. Amend the existing requirement to become two required statements Government submitters recommended introducing a requirement for a new statement in addition to existing paragraph 2.9.1—22(2)(b), to clearly communicate the appropriate age of use of FoF (e.g. 'the follow-on formula may be used from the age of six months to the age of 12 months'). They recommended this would need to be co-located with the stage number (if used) on the front of the	NZFS, NZ MoH, NSWFA	FSANZ does not agree that an additional statement to that proposed in the draft variations at 2nd CFS is required. FSANZ considers the recommended new statement 'the follow-on formula may be used from the age of six months to the age of 12 months' is not as clear as the existing statement which accurately conveys the intent. See section 4.16 of the report.

Issue	Comment	Submitter(s)	FSANZ response
	package. They noted this new requirement would address concerns about stage labelling and ensure the accurate age range is highlighted on the front of the package, e.g. '*for follow-on formula—the follow-on formula may be used from the age of 6 months to the age of 12 months*'. These submitters suggested retaining paragraph 2.9.1—22(2)(b) as currently worded in the draft variation as a separate required statement that would not need to appear on the front of the package. One submitter considered the statement about 'follow-on formula should not be used for infants aged under the age of 6 months' is an important safety message and recommended it be required elsewhere on the label (i.e. not on the front of the package) and could be co-located with the required warning statements.		
2.9.1—22 Required statements on use *At the 2nd CFS the draft variation stated:* *(2) For the labelling provisions, the required statements for infant formula and follow--on formula are ones indicating that:* *(c) for infant formula and follow-on formula—it is recommended that infants from the age of 6 months should be offered foods in addition to the infant formula or follow-on formula.*			
Yes, the draft variation is supported.	These submitters supported the proposed option.	ADG, NZFS, TAS DoH	Noted.
No, the draft variation is not supported.	These submitters preferred the term 'around' to align with NHMRC Infant Feeding Guidelines, Healthy Eating Guidelines for New Zealand Babies and Toddlers (0–2 years old) and the ASCIA Guidelines: Infant Feeding and Allergy Prevention (ASCIA, 2020). This change would support the specific policy principle (b) in the Ministerial Policy Guideline on the *Regulation of Infant Formula Products* that the regulation of IFP should not be inconsistent with national nutrition guidelines. One submitter also did not agree with FSANZ's statement that the term 'around', 'could likely result in uncertainty and consequently,	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ's decision is to maintain the approach at the 2nd CFS (see Table 4 in SD3 (FSANZ 2023d)). FSANZ considers the current wording is appropriate to support infant feeding guidance, noting the wording of the statement is not prescribed (section 8.12.3 of SD1 to the 1st CFS; FSANZ 2022b). See section 4.16 of the report.

Issue	Comment	Submitter(s)	FSANZ response
	be open to interpretation' as there is no evidence that this is the case.		
2.9.1—22 Requirement for warning statements and directions *At the 2nd CFS the draft variation stated a heading for subsections 2.9.1—22(3) and (4):* *Location of warning statements and required statements*			
No, the draft variation is not supported.	This submitter noted that subsections 2.9.1—22(3) and (4) of 2.9.1—22 refer only to the required statements on use in subsection (2) and not the warning statements in subsection (1). NZFS recommends removing the reference to warning statements in the subheading to subsections 2.9.1—22(3) and (4) as follows: *'Location of* ***~~warning statements and~~*** *required statements'*	NZFS	FSANZ agrees the subheading wrongly implies there are location requirements for warning statements and that the words indicated should be removed. FSANZ has amended the draft variations at 2nd CFS to clarify the subheading relates only to the location of relevant, required statements. See the subheading to subsection 2.9.1—21(3) of the primary variation.
2.9.1—22 Requirement for warning statements and directions *At the 2nd CFS the draft variation stated:* (3) *The statements required by paragraphs (2)(a) and (b) must appear on the front of the package of the product.*			
Yes, the draft variation is supported.	These submitters supported the proposed option, as this aligns with current approaches by industry in provision of information to caregivers.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	Noted.
No, the draft variation is not supported.	***1. Drafting to specify prominent position*** This submitter recommended the draft variation mandate age statements to be in a <u>prominent</u> position on the front of the package, i.e.	NSWFA	FSANZ does not agree a change to the draft variation is required. Specifying what 'prominent position' means for implementation and enforcement purposes could be problematic. FSANZ noted previously that a requirement to locate the information 'prominently' (now explicitly on the front of the package) is not inconsistent with Codex. Mandating the location (front of the package) is consistent with current industry

Issue	Comment	Submitter(s)	FSANZ response
	*'The statements required by paragraphs (2)(a) and (b) must appear **in a prominent position** on the front of the package of the product.'*		practice, provides regulatory certainty for manufacturers and ensures the information is accessible for caregivers. See section 4.16 of the report.
	2. Require age statements elsewhere on the label This submitter recommended modifying the requirement so the statement in (b), (FoF should not be used for infants aged under the age of six months), would be required to be placed elsewhere on the label (i.e. not on the front of the package). They considered the statement would be well suited to be co-located with required warning statements.	NZFS	FSANZ considers it is unnecessary to require the age statement to appear elsewhere on the label, rather than on the front of the package. Mandating that it be co-located with required warning statements as suggested would be more onerous than international regulations. Further, subsection 2.9.1—21(4) of the primary variation indicates the age statement may appear more than once on the label. See section 4.16 of the report.
2.9.1—22 Directions on preparation and use *At the 2nd CFS the draft variation stated:* *(5) For the labelling provisions, directions on preparation and use are required for infant formula and follow-on formula which instruct (in words and pictures) that:* *(a) each bottle must be prepared individually; and* *(b) if a bottle of prepared formula is to be stored prior to use, it must be refrigerated and used within 24 hours; and* *(c) previously boiled and cooled potable water must be used; and* *(d) if a package contains a measuring scoop—only the enclosed scoop must be used; and* *(e) for powdered or concentrated formula—do not change proportions of the powder or concentrate or add other food except on medical advice; and* *(f) for ready-to-drink formula—do not dilute or add other food except on medical advice; and* *(g) formula left in the bottle after a feed must be discarded within 2 hours.* ***Note** The labelling provisions are set out in Standard 1.2.1.*			
Yes, the draft variation is supported.	These submitters supported the proposed option. This includes the use of the term 'must' (in place of 'should') in the statements relating to directions for preparation and use.	ADG, NZFS, TAS DoH	Noted.

Issue	Comment	Submitter(s)	FSANZ response
No, the draft variation is not supported.	***1. Changing the time to discard formula*** (paragraph 2.9.1—22(5)(g)) A public health submitter recommended applying the NHMRC Infant Feeding Guideline recommendations for the time to discard made-up formula, which is one hour. A government submitter requested changing this paragraph to: *'formula left in the bottle must be discarded within 2 hours of preparing the formula'.* This submitter also considered the current drafting may be incorrectly interpreted to mean within 2 hours of the infant stopping feeding.	DA, QLDH	Paragraph 18(2)(a) of the FSANZ Act requires FSANZ, in developing or reviewing food standards and variations of standards, to have regard to the need for standards to be based on risk analysis using the best available scientific evidence (among other things). The proposed direction to discard unfinished formula within 2 hours after a feed is supported by FSANZ's risk assessment using the best available scientific evidence (see section 8.2 of SD1 to the 1st CFS; FSANZ 2022b). FSANZ also notes the proposed direction is consistent with the recently updated New Zealand Infant Feeding guidance which says to *throw out any formula that the baby has not drunk after two hours* (Ministry of Health, 2021). Consumer evidence indicates a majority of caregivers want to know how long they can keep unfinished formula before they have to dispose of it (see SD4 to the FSANZ 2021 CP1 (FSANZ 2021e)). Providing a time limit of 2 hours would give assurance to caregivers that prepared formula remains safe for a longer feeding period. Further, manufacturers may choose to refer to one hour as wording of the direction is not prescribed and a shorter duration does not represent a risk to infants. Omitting the words 'after a feed' would mean the instruction for discarding formula could be inconsistent with the instruction for using formula within 24 hours that has been prepared and stored prior to use in the refrigerator (paragraph 2.9.1—21(5)(b) of the primary variation).
	2. Retaining 'should' instead of 'must' in paragraph 2.9.1—22(5)(a) This submitter recommended retaining the current word 'should', noting the proposed word 'must' contradicts (b).	QLDH	The intent of paragraph 2.9.1—22(5)(a) of the draft variations at 2nd CFS is that caregivers prepare bottles individually to ensure the correct powder to water ratio is used as opposed to preparing a larger quantity of formula that is subsequently dispensed into feeding bottles. The NHMRC infant feeding guidelines state 'ideally prepare only one bottle of formula at a

Issue	Comment	Submitter(s)	FSANZ response
			time, just before feeding' and also restate preparing one bottle at a time when preparing feeds in advance (NHMRC 2012). FSANZ does not consider 'must' in paragraph 2.9.1—22(5)(a) contradicts the intent of paragraph 2.9.1—22(5)(b) as together these directions would require a bottle to be prepared individually and if stored prior to use, refrigerated and used within 24 hours.
	3. Use simpler directions This submitter suggested keeping wording as simple as possible to meet the average literacy level in the community (about year 7 at school). For example, the direction at paragraph 2.9.1—22(5)(e) may be too complex.	QLDH	The wording of the directions for use is not prescribed. Manufacturers therefore have some flexibility in how to apply the directions for use on their product labels. The intent is that the manufacturer can refer to the specific product type (powder or concentrate), thereby shortening an instruction.
	4. Include 'dietitian advice' The submitter suggested adding *'or on the advice of a dietitian'* after medical advice in paragraphs 2.9.1—22(5)(e) and (f) as such advice is more commonly provided by dietitians than medical doctors.	QLDH	The phrase 'medical advice' is used in the existing warning statement requirements. Whether caregivers consider the term to mean advice can only be obtained from a medical doctor has not been specifically investigated and no evidence has been provided by the submitter on this matter. We note the NHMRC infant feeding guidelines refer to 'health workers' (NHMRC 2012) and the New Zealand Eating for Healthy Babies and Toddlers (Ministry of Health, 2021) refers to 'Well Child provider, or family doctor or nurse', indicating there is no consistency in terminology. The wording of the directions of use is also not prescribed, so manufacturers could choose to add the suggested wording. FSANZ's decision is to therefore maintain the current wording of the direction.
	5. Align directions with WHO Code This submitter recommended the following changes: (a) Update mandatory labelling on safe handling and preparation to align with WHO standards.	BAA	FSANZ has extensively reviewed the directions for preparation and use over the course of Proposal P1028 and does not agree the recommended changes are warranted. The assessment of whether existing food safety labelling requirements are appropriate for managing the risks associated with the preparation and handling of IF has been based on:

Issue	Comment	Submitter(s)	FSANZ response
	(b) A warning on all tins and packaging for powdered IF of the presence of inherent bacteria, which can only be destroyed by preparing to WHO standards as per recommendation 1. The submitter provided the following reasons for their recommendation: • Data from developed countries show that a substantial percentage of caregivers do not use basic hygiene and the recommended procedures within their country for safely preparing and feeding IF. • There has been difficulty in accessing clean water and electricity required for preparation during natural disasters (e.g. Australian 2019 bushfires and 2022 floods). • The current requirement to follow manufacturers' directions is dangerous because the lower temperatures they recommend are for the purpose of preserving certain ingredients e.g. probiotics and DHA.		• Stakeholder views and the information provided in submissions to FSANZ's 2016 and 2021 CP (FSANZ 2016f FSANZ 2021a) and the 1st CFS (FSANZ 2022b). • Consumer evidence on Australian and New Zealand caregiver practices and understanding (section 5.1.2 of the FSANZ 2021 CP1 (FSANZ 2021a)). This evidence indicated a range of reasons why Australian and New Zealand caregivers do not follow directions, including being unaware of particular instructions, noticing them less as they became more familiar with a product, not understanding them, or deliberately deviating from them. FSANZ has revised the wording of certain directions to assist consumer understanding and is developing additional communication messaging relating to the importance of following the directions for use and storage. Refer to section 8.3 of the report. • The findings from two microbiological safety risk assessments that used the Food and Agriculture Organization/World Health Organization (FAO/WHO) Risk assessment model for *Cronobacter sakazakki* (FSANZ 2021d; FSANZ 2022c). The most recent risk assessment found it was safe to use boiled water that had been cooled to lukewarm (20–42ºC) to reconstitute powdered IF that is then held at ambient temperatures (up to 32ºC) for immediate feeding over a period of one or two hours. The finding is consistent with updated domestic infant feeding guidelines (section 8.2 of SD1 to the 1st CFS; FSANZ 2022b). • Current international and domestic infant feeding guidelines, Codex and overseas regulations. Based on this assessment, FSANZ considers the directions for preparation and use (which includes a direction instructing that

Issue	Comment	Submitter(s)	FSANZ response
			previously boiled and cooled potable water must be used) are appropriate for Australia and New Zealand caregivers, noting all the directions are intended to be read together to ensure the safety of the prepared formula. A warning statement about the product not being sterile or the presence of inherent bacteria is not warranted and is not consistent with international regulations.
2.9.1—24 Optional format for the statement of ingredients – added vitamins and minerals *At the 2nd CFS the draft variation stated:* (1) *Despite section 1.2.4—5, where a vitamin or mineral is added to infant formula or follow-on formula in accordance with section 2.9.1—8, the statement of ingredients not need list the added vitamin and mineral in descending order of ingoing weight, provided that the statement of ingredients also:* *(a) lists all added vitamins together under the subheading 'Vitamins'; and* *(b) lists all added minerals together under the subheading 'Minerals'.*			
Yes, the draft variation is supported.	These submitters supported the draft variation.	ADG, NES	Noted.
No, the draft variation is not supported.	***1. Not consistent with requirements for general foods*** This submitter did not support the optional format that does not require ingredients in a statement of ingredients to be listed in descending order of ingoing weight. This does not align with section 1.2.4—5 of the Code and makes it difficult for caregivers to compare products.	WA DoH	FSANZ's decision is to maintain the approach at the 2nd CFS that vitamins and minerals in the statement of ingredients need not be listed in descending order of ingoing weight for the reasons previously provided. This included that grouping of vitamins and minerals in the ingredient list is a common industry practice and it assists caregiver understanding (see section 2.1 of SD3 to the 1st CFS (FSANZ 2022e). Given vitamins and minerals are subject to compositional limits (minimum and maximum amounts or recommended maximum amounts), the order in which they are declared is of less value to caregivers. FSANZ also notes the approach is consistent with Codex specifications.

Issue	Comment	Submitter(s)	FSANZ response
	2. Format of statement of ingredients This submitter recommended the addition of wording in section 2.9.1—24 to the effect that the format chosen for the statement of ingredients should be consistent for all ingredients, with the exception of headings. This submitter noted that currently there is nothing preventing the overemphasis of one ingredient over another with many infant formula products bolding certain nutrients. It would also reduce confusion with the required bolding of allergens in the statement of ingredients.	TAS DoH	FSANZ's decision is to maintain the approach at the 2nd CFS. FSANZ considers any further standardisation of the statement of ingredients beyond the current requirements would reduce labelling flexibility and be a barrier to trade, noting international regulations contain no such provisions.

2.9.1—25 Declaration of nutrition information

At the 2nd CFS the draft variation stated:

(1) For the labelling provisions, a statement of the following nutrition information is required for infant formula and follow-on formula:

*(a) the *unit quantity of the food expressed in per 100 mL; and*

*(b) the *average energy content expressed in kilojoules; and*

*(c) the *average quantity of protein, fat and *carbohydrate expressed in grams as 'protein', 'fat' and 'carbohydrate', respectively; and*

(d) the average quantity of each vitamin or mineral expressed in micrograms or milligrams (including any naturally-occurring amount); and

(e) for infant formula—the average quantity of choline, inositol and L-carnitine expressed in milligrams (including any naturally occurring amount);

(f) if added, the average quantity of the following, expressed in micrograms or milligrams:

*(i) any substance *used as a nutritive substance (including any naturally occurring amount); or*

(ii) inulin-type fructans; or

(iii) galacto-oligosaccharides; or

*(iv) a combination of *inulin-type fructans and galacto-oligosaccharides.*

***Note** The labelling provisions are set out in Standard 1.2.1.*

Issue	Comment	Submitter(s)	FSANZ response
Yes, the draft variation is supported.	These submitters supported the proposed option relating to paragraph 2.9.1—25(1)(a). INC also supported the use of 'average quantity' for this paragraph.	ADG, INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFS, TAS DOH	Reference to 'average quantity' of nutrients and substances has been retained. However, FSANZ has decided to clarify in the primary variation that nutrition information must be expressed in per 100 mL of formula (as reconstituted if applicable). The use of per 100 mL of the formula as sold (if sold in a concentrated form) or per 100 g of the formula as sold (if sold in a powdered form) is now optional in the NIS. Additionally, the primary variation no longer refers to '*unit quantity' for the base unit of expression. See section 4.17 of the report and section 2.9.1—24 of the primary variation.
2.9.1—25 Declaration of nutrition information *At the 2nd CFS the draft variation stated:* (2) *If one of the following substances is present in the infant formula or follow-on formula, the statement required by subsection (1) may include the average quantity of that substance (including any naturally-occurring amount), expressed in milligrams or grams:* *(a) docosahexaenoic acid; and* *(b) eicosapentaenoic acid; and* *(c) arachidonic acid; and* *(d) whey; and* *(e) casein.* *(3) If the infant formula and follow-on formula is in a powdered or concentrated form, the information mentioned in subsections (1) and (2) must be expressed in terms of the product as reconstituted according to the directions on the package.* *(4) Unless expressly provided elsewhere in this Code, the statement required by this section must not contain any other information.*			
Yes, the draft variation is supported.	This submitter supported the draft variation.	ADG	FSANZ has decided to separate the fatty acid declaration requirements from the declaration requirements for whey and casein. This amendment is required for the purposes of permitting the voluntary use of fatty acid acronyms in the NIS.

Issue	Comment	Submitter(s)	FSANZ response
			See section 4.18 of the report and paragraph 2.9.1—25(6) of the primary variation.
Does not support draft variation:	***1. Remove permission to declare casein and whey*** This submitter did not support including the casein and whey (ratio) in the NIS. Health professionals have access to this information directly from manufacturers and most caregivers are unlikely to understand the information which may lead to unnecessary purchasing decisions. It may also encourage manufacturers to develop new products with varying casein to whey ratios but with limited substantiation of the health effects.	TAS DoH	FSANZ's approach for permitting voluntary declaration of casein and whey in the NIS was based on submitter feedback that this information would be useful for health professionals, assist with informing caregivers' choices, align in part with international labelling regulations and provide some flexibility for industry (see section 3.4 of SD3 to the 1st CFS; FSANZ 2022e). This approach will also enable manufacturers to continue to provide information about casein and whey content given the new requirements for the statement on protein source do not permit declaration of protein fractions (see section 8.13 of SD1 to the 1st CFS; FSANZ 2022b). It is unclear how the permission to voluntarily declare casein and whey in the NIS would result in undesirable product innovation especially when nutrition content and health claims are prohibited.
	2. Minor drafting edit It was suggested an asterisk be inserted with 'average quantity' (i.e. *average quantity), for consistency across the Code as average quantity is a defined term.	NZFS	FSANZ agrees. The term 'average quantity' is defined in subsection 1.1.2—2(3) and the insertion of an asterisk would provide consistency with other defined terms in accordance with drafting convention. FSANZ has inserted asterisks in the relevant provisions in sections 2.9.1—24 and 25 of the primary variation.
	3. Prohibition of other information in the NIS These submitters did not support a restriction to the five nutrients listed in subsection 2.9.1—25(2) and opposed a prescribed list of voluntarily added nutrients that can be declared in the NIS. One submitter preferred the approach used for EU labelling, which allows more generally for the voluntary declaration of macronutrient components.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	After consideration of submissions, FSANZ has decided to maintain the current approach. These issues were addressed in Table 5 in SD3 to the 2nd CFS (FSANZ 2023d) and in sections 3.4 and 6.3 in SD3 to the 1st CFS (FSANZ 2022e). While Codex and the EU allow for voluntary declarations of optional components and macronutrient components in nutrition information, the regulatory approach for declaring nutrition information in Standard 2.9.1 is intentionally more prescriptive.

Issue	Comment	Submitter(s)	FSANZ response
	Another submitter commented that Codex permits optional components to be declared in the NIS voluntarily (CXS 72-1981 9.3(b)), which provides manufacturers with the ability to declare nutrients of interest to caregivers (e.g. A2 beta casein). Another submitter also opposed the subsection as it does not permit any of the sub-types of casein protein such as A1 type β-casein protein and A2 type β-casein protein to be mentioned. The submitter stated the proposed change: • restricts informed consumer choice • conflicts with fair trading laws • is inconsistent with policy guidelines • is inconsistent with international food standards which reduces efficiency and international competitiveness of Australian and New Zealand food industries.		This is due to the domestic policy environment that prohibits nutrition content and health claims and the requirement for nutritive substances to undergo a pre-market assessment before they are permitted to be used and therefore declared.
Other	Several industry submitters commented on declaring the strain and count (cfu) of LAM on the label. Three submitters recommended FSANZ consider permitting labelling of the strain and count (cfu) of LAM in the NIS. Two of these submitters also proposed declarations of cfu in the statement of ingredients in addition to the NIS. An industry submitter supported cfu declarations because they: • align with best practice labelling guidance, e.g. by the Council for Responsible Nutrition and the International Probiotics Association • allow manufacturers to add a meaningful amount of cfu and deters only adding nominal amounts • provide information to assist caregivers to make informed product choices.	INC, DAN, DCANZ, A2M, AFGC, FCG, NSWFA	FSANZ reiterates its position at 2nd CFS that LAM are not approved for use as a nutritive substance. As such, information about LAM is not permitted in the NIS. LAM are permitted to be used as an ingredient and, if added, must be listed in the statement of ingredients. See section 4.11 of the report.

Issue	Comment	Submitter(s)	FSANZ response
	In contrast, a government submitter proposed that LAM should not be declared in the NIS if they are added for acidification purposes. However they can be listed in the NIS if permitted to be added for a nutritive purpose.		
2.9.1—26 Required form for the declaration of nutrition information *At the 2nd CFS the draft variation stated:* *(2) The statement required by section 2.9.1—25 must:* *(d) have the following subheadings printed in a size of type that is the same or larger than the nutrient names in the statement:* *(i) for infant formula and follow-on formula—'Vitamins', 'Minerals' and 'Additional'; and* *(ii) for infant formula only—'Other nutrients'* *(e) state nutrients and subgroup nutrients using the names and units of measurement specified in that table for that nutrient and subgroup; and*			
Yes, the draft variation is supported.	Industry submitters supported most elements of the proposed option. One government submitter commented it supported use of the 'Other nutrients' subheading as the term 'nutrients' infers essentiality, which is appropriate for these substances. The consumer research also found a high level of understanding of the term 'additional'. Another government submitter commented it supported prescribing the names and units of measurement for mandatory ingredients in the NIS, as this will better assist caregivers to compare products.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NSWFA, NZFS, ADG	FSANZ has maintained the subheadings as drafted and the nutrient and subgroup units of measurement. However, after consideration of submissions (including those summarised below), FSANZ has amended the 2nd CFS draft variation to permit the voluntary declaration of fatty acid abbreviations and clarify names for four B vitamins. See further discussion below and section 4.18 of this report.
No, the draft variation is not supported.	***1. Fatty acid names in the NIS*** These submitters advocated the removal of restrictions on use of common terms, acronyms/abbreviations and additional information. Specifically, prohibiting the use of acronyms for long chain polyunsaturated fatty acids was not supported.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NES, NZFGC	For the reasons stated in this report, FSANZ has decided that, if the permitted fatty acids are declared in the NIS voluntarily, the acronyms DHA, EPA and ARA may be included. If declared, they must be added in brackets immediately after the mandatory full name. If the manufacturer chooses to declare these fatty acids, all three must be included in the NIS.

Issue	Comment	Submitter(s)	FSANZ response
	These submitters commented that the typical caregiver is not familiar with scientific names (SD3 to 1st CFS – Attachment 1) and therefore providing additional information can provide more context. An industry submitter noted that the research FSANZ cited (Malek et al. 2019) was about consumer lack of understanding of nutrition content claims when stated as either a full name or acronym and did not compare understanding of nutrients when labelled with the full name compared to acronyms. They also noted that the use of plain English language can help consumer understanding, citing the change to allergen declarations using simple, plain English, that resulted from P1044. They commented that caregivers are more likely to be familiar with acronyms such as DHA over the full name as they are easier to remember and commonly used in other products. They suggested that permitted acronyms could be specified within S29—10 and their use could be optional, in addition to the full name. These submitters generally supported the voluntary permission to list the nutrients in subsection 2.9.1—25(2), however they also requested acronyms be permitted in addition to the scientific name. This request extended to linolenic acid and α-linoleic acid. A submitter requested these fatty acids be permitted in the NIS because they are currently declared on product labels and it would provide continuity of labelling.		FSANZ has retained its position that linoleic acid and α-linolenic acid are not permitted to be declared in the NIS. See section 4.18 of the report.
	2. Restriction on vitamin full names Two submitters supported number notations for vitamins to be voluntarily permitted in addition to scientific names (e.g. Niacin (B_3)). One submitter commented it is important to provide the notation (numbers) for vitamins as these are helpful to caregivers generally and non-English speaking caregivers, in particular: • Niacin (B_3) • Pantothenic acid (B_5)	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ has decided to require the use of notations as part of the name declared for niacin, pantothenic acid, riboflavin and thiamine. The notation for each of these vitamins must be provided in brackets immediately following the name and the number must appear in subscript form. See section 4.18 of the report.

Issue	Comment	Submitter(s)	FSANZ response
	• Riboflavin (B_2) • Thiamin (B_1).		
	3. Folate versus folic acid in the NIS These industry submitters did not agree with declaring 'folate' in the NIS rather than 'folic acid', as this risks misrepresenting the ingredient being added. They stated there is no evidence of folate being more commonly recognised than folic acid. One submitter noted folic acid is used in the Ministry of Health pregnancy guidelines and on general food nutrition information panels (NIPs). Another submitter commented that the more familiar term prevailing over a technical term contradicts the restriction placed on common terms, acronyms and abbreviations for other nutrients.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC	After considering submissions, FSANZ has decided to maintain the current approach. The primary purpose of declarations in the NIS is to provide nutrition information to caregivers to enable product comparisons and inform choice. The declaration in the NIS should include both naturally occurring folate and added folic acid, hence using the term 'folic acid' may not relate to the amount declared. The term 'folic acid' is used in New Zealand guidance in the context of recommendations to take supplements which contain folic acid (and not folate) (Ministry of Health 2023). Whether folate or folic acid is used in the NIP for general foods may depend on the specific nutrition content or health claim made. FSANZ also notes that in the draft variation the acronyms DHA, EPA and ARA may be used.
	4. Location of mandatory versus voluntary nutrients and substances These submitters stated that the NIS needs a clearer separation of mandatory and voluntary substances. One submitter proposed that docosahexaenoic acid should be listed under the 'Additional' subheading for consistency with its voluntary permission, instead of under the 'Long chain polyunsaturated fatty acids' subheading. This submitter suggested adding 'novel food' in paragraph 2.9.1—25(1)(f): *(insert any other substance used as a nutritive substance;; or inulin-type fructans and / or galacto-oligosaccharides **or novel food** ….., to be declared).* Another recommended all voluntary substances should be listed under the heading 'Additional', including novel foods and nutritive substances to ensure regulatory clarity. The submitter considered	VIC DoH & DEECA, TAS DoH	FSANZ does not agree with the suggested amendment to require listed fatty acids and novel foods to be declared under the 'Additional' subheading. The primary variation requires that: • If a permitted nutritive substance, an inulin-type fructan or galacto-oligosaccharide is added to IFP, it must be included in the NIS under the subheading 'Additional'. • If DHA, EPA, ARA are present in the IFP they may be declared voluntarily in the NIS. If declared they must be listed together under the 'long chain polyunsaturated fatty acids' heading. The distinction between the labelling approaches is based on the way the substances are regulated. Nutritive substances, inulin-type fructans and galacto-oligosaccharides are optional and are required to be declared

Issue	Comment	Submitter(s)	FSANZ response
	including voluntary ingredients in different sections of the NIS is confusing and potentially misleading.		under 'additional' if used, however DHA, EPA and ARA are required to be present in the formula but not necessarily declared on the label. FSANZ notes nutritive substances have to be declared in the NIS as they have a nutritive purpose, whereas novel foods need only be declared in the statement of ingredients (for more on the differences between declaring nutritive substances and novel foods, see section 4.11 Lactic acid producing microorganisms). In the case of DHA, section S25—2 contains permitted forms of DHA for use as novel food ingredients. However, there are no specific labelling conditions of use associated with these permissions and so ingredient and nutrition declaration requirements for DHA in standards 1.2.4 and 2.9.1 will apply to IF and FoF. In other words, the permitted forms of DHA have no bearing on how DHA is declared on an IFP label. Substances such as lactoferrin are permitted for use as a nutritive substance and (if used) would need to be listed under the 'Additional' subheading. FSANZ maintains it is appropriate for whey and casein to be indented under 'Protein' and DHA, EPA and ARA under 'Long chain polyunsaturated fatty acids', which is indented under 'Fat'. When declared, the location of these subgroup nutrients will provide context to caregivers regarding the type of substance.
2.9.1—26 Required form for the declaration of nutrition information *At the 2nd CFS the draft variation stated:* *(2) The statement required by section 2.9.1—25 must:* *(f) not include a *unit quantity other than per 100 mL.*			
Yes, the draft variation is supported.	These submitters supported the draft variation.	ADG, TAS DOH	FSANZ has amended this requirement as discussed in the response below.

Issue	Comment	Submitter(s)	FSANZ response
No, the draft variation is not supported.	These submitters did not support the restriction of base units to per 100 mL for the following reasons: • Prohibiting base units of expression other than per 100 mL does not align with Codex CXS 72-1981, which allows per 100 g or 100 mL [concentrate] as sold, as well as per 100 mL as consumed. Overseas regulators such as the US and EU mandate one base unit of expression and permit another. • There are domestic products sold to smaller markets that follow Codex requirements (e.g. some Pacific Island nations). The inability to harmonise labels with these countries could result in a public health issue if existing products are withdrawn from sale. • Most labels already display nutrition information per 100 mL only. Most manufacturers only declare nutrition information using additional unit quantities where necessary, for example, for harmonisation with other markets. Australian and New Zealand consumers of general foods are familiar with two base units presented in two columns in the NIP (e.g. per serving and per 100 g/100 mL). One submitter suggested a second table be added to Schedule 29 that prescribes the format of the NIS when the per 100 g unit of expression is voluntarily included in the NIS (see comments for section 2.9.1—26). This is similar to the approach taken for general NIPs in Standard 1.2.8.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NES, NZFS	FSANZ has decided to permit the voluntary use of per 100 g (as sold), or per 100 mL (as sold) in an additional column, as well as the requirement for per 100 mL of the food as prepared, to enable products to align with provisions in Codex CXS 72-1981 (Codex 1981). See section 4.17 of the report, subsections 2.9.1—24(6) and (7) of the primary variation and section S29—10 of the consequential variation.

Issue	Comment	Submitter(s)	FSANZ response
2.9.1—26 Required form for the declaration of nutrition information *At the 2nd CFS the draft variation stated:* *(3) If the statement includes the average quantity of a permitted nutritive substance, an inulin-type fructan or a galacto-oligosaccharide, that average quantity must be included in the statement:* *(a) under the subheading 'Additional'; and* *(b) in the same format as specified in the table for that substance.*			
No, the draft variation is not supported.	This submitter did not support the requirement in subsection 2.9.1—26(3) because the names and units of measurement for optional ingredients (e.g. human identical milk oligosaccharides) permitted to be declared in the NIS under the subheading 'Additional' are not prescribed. This submitter recommended further prescription for nutritive substances to improve product comparison and informed purchase decisions. Additional paragraphs were suggested: *(a) under the subheading 'Additional'; and* ***(b) using the names as listed in S29—7 (for infant formula) or S29—8 (for follow-on formula); and*** ***(c) expressed in micrograms or milligrams; and*** (d) *in the same format as specified in the table for that substance.*	NSWFA	FSANZ does not agree that additional requirements for NIS declarations of optional ingredients are warranted. The current regulatory approach is to not prescribe the name for nutritive substances. This approach applies to all special purpose foods and not just IF and FoF. Further, subparagraph 2.9.1—24(3)(e)(i) of the primary variation requires the average quantity of any added substance used as a nutritive substance (including any naturally-occurring amount), to be expressed in micrograms, milligrams or grams.

Issue	Comment	Submitter(s)	FSANZ response
2.9.1—28 Requirements for use of stage numbers *At the 2nd CFS the draft variation stated:* *(1) The following numbers may be used on the label on a package of infant formula or follow-on formula to identify for consumers that product is infant formula or follow-on formula:* *(a) if the product is infant formula—the number '1'; and* *(b) if the product is follow-on formula—the number '2'.*			
Yes, the draft variation is supported.	These submitters supported the draft variation. Two industry submitters also pointed to the consumer research in the 2nd CFS stating that caregivers generally understand that each formula stage has a specific nutrient composition.	INC, SML, DAN, FCG, DCANZ, A2M, AFGC, NZFGC, NES, VIC DoH & DEECA, NZFS	Noted.
No, the draft variation is not supported.	These submitters did not support stage numbers for the following reasons: • They indicate a progressive feeding regime, creating the impression that there are nutritional benefits in moving from Stage 1 to Stage 2 and beyond. Using stages may be seen as promoting continued use and entrench this marketing practice, particularly to Stages 2 and 3 where the evidence to support this extension is limited. This is inconsistent with New Zealand's infant feeding guidelines. • Health professionals support labelling that clearly indicates there is no need to transition to Stage 2 FoF at age six months and similarly no need to progress to Stage 3 and 4 formulas, noting young children aged one year old do not usually require a nutritional supplement and consumption of such products could promote overweight and obesity.	DA, NZ MoH, NSWFA, WA DoH, BAA	After consideration of submissions, FSANZ has decided to permit stage numbers on the labels of IF or FoF and, if used, require the number to appear on the front of the package immediately adjacent to the age statement for that product. See the rationale, including consumer evidence, in section 9.5 of SD3 to the 2nd CFS (FSANZ 2023d) and section 4.20 of this report.

Issue	Comment	Submitter(s)	FSANZ response
	• This regulatory approach will encourage line marketing practices e.g. use of nutrition content claims or health claims on Stages 3 and 4 products (noting they contain similar ingredients to Stages 1 and 2 products). A government submitter referred to published literature that demonstrates the use of line marketing practices to circumvent prohibition of advertisements and claims on IFP. They considered this is inconsistent with the specific policy principle n)ii in the Ministerial Policy Guideline on the *Regulation of Infant Formula Products*. To protect breastfeeding rates, IFP should not be advertised or have health claims either directly or indirectly. • Consumer evidence in Attachment 1 to SD3 (pg 62) of the 2nd CFS shows caregivers are confused by stage labelling and there is misinterpretation of the function of stage labelling. • Recent reviews have identified negative impacts of stage labelling, including the unnecessary use of products and the use of the older stages as ways to circumvent marketing and claims restrictions on IFP. • Both IF and FoF have virtually the same ingredients. This is outlined in the proposed nutrient composition table of the draft standard of the Code (See Table 7, 2nd CFS p35). • Removing stage numbering helps minimise caregiver confusion and aligns more closely with the WHO Code for the Marketing of Breastmilk (World Health Organization 1981). • Stage labelling is a violation of the WHO Marketing Code and age statements are sufficient to avoid incorrect product choice.		
Other	One government submitter considered stage labelling and product differentiation need to be considered together to address concerns that stage labelling may promote a progressive feeding regime. This could be achieved by strengthening product differentiation requirements or by restricting the use of stage numbers to IF and FoF, thereby prohibiting their use on formulated supplementary	NZFS, NZ MoH, NSWFA	FSANZ has strengthened product differentiation requirements in the primary variation. See section 4.20 of the report. Consideration of the suggestion to prohibit stage 3 and 4 numbers is out of scope of Proposal P1028, as is a review of Standard 2.9.3.

Issue	Comment	Submitter(s)	FSANZ response
	foods for young children (1–3 years) or 'growing up' milks for older children. Another submitter also suggested prohibiting the use of stage 3 and 4 numbers on toddler milks and products for older children to address the use of stage numbers to promote the entire range. One submitter encouraged FSANZ to review Standard 2.9.3 to close the loop on proxy marketing of IF and FoF on toddler milks (stage 3) and pre-schooler milk (stage 4).		
2.9.1—28 Requirements for use of stage numbers *At the 2nd CFS the draft variation stated:* *(2) A number used in accordance with subsection (1) must appear:* *(a) on the front of the package of the product; and* *(b) immediately adjacent to:* *(i) for infant formula—the statement required by paragraph 2.9.1—22(2)(a); and* *(ii) for follow-on formula—the statement required by paragraph 2.9.1—22(2)(b).*			
Yes, the draft variation is supported.	This submitter strongly supported the co-location of stage and age information to prevent any misunderstanding regarding stage labelling.	VIC DoH & DEECA	Noted.
No, the draft variation is not supported.	Should stage labelling not be prohibited, a government submitter proposed mandating the size of age labelling to be no more than the size of the stage labelling. One submitter noted the FSANZ Rapid Systematic Evidence Summary reported that stage labelling may encourage continuation of formula feeding beyond infancy and early childhood. The submitter therefore recommended the stage labelling font be reduced to a small font to minimise marketing impact and the age labelling font be enlarged, ensuring age labelling is more prominent to guide selection of age-appropriate products.	NSWFA, QLDH	FSANZ considers co-locating the stage and age information label elements on the front of the package and permitting the use of the number elsewhere on the label, is sufficient to ensure caregivers can identify the appropriate product for their infant. Other labelling provisions support product differentiation. See section 4.20 of the report.

Issue	Comment	Submitter(s)	FSANZ response
2.9.1—29 Prohibited representations *At the 2nd CFS the draft variation stated:* *(1) The label on a package of infant formula or follow-on formula must not contain:* *(c) information relating to another product*			
Yes, the draft variation is supported.	These submitters supported the proposed variation at 2nd CFS.	ADG, FCG, NSWFA, NZFGC, SML, NES	FSANZ has amended this requirement as discussed in the response below.
No, the draft variation is not supported.	This submitter suggested the following wording change to paragraph 2.9.1—29(1)(c) to clearly capture formulated supplementary food and other foods: *(c) information relating to another* ***food*** ~~***product***~~	NZFS	FSANZ agrees that the intent to capture foods such as IF, FoF, formulated supplementary foods or formulated supplementary food for young children (including those for women who are pregnant) and special medical purpose product for infants may not be clear if the term 'product' is used. FSANZ has therefore amended the 2nd CFS draft variation to refer explicitly to these other foods. See paragraph 2.9.1—28(1)(c) of the primary variation.
2.9.1—29 Prohibited representations *At the 2nd CFS the draft variation stated:* *(1) The label on a package of infant formula or follow-on formula must not contain:* *(j) information relating to ingredients, except for a reference in:* *(i) a statement of ingredients; or* *(ii) a declaration or statement expressly permitted or required by this Code; or*			
Yes, the draft variation is supported.	This submitter supported the draft variation.	ADG	FSANZ has amended this requirement as discussed in the response below.

Issue	Comment	Submitter(s)	FSANZ response
No, the draft variation is not supported.	***1. Prohibition of the word 'milk'*** Three submitters commented that the draft variation would prohibit statements such as 'made with New Zealand **milk**', 'made with A2 **milk** (protein)' because they would constitute ingredient claims. One submitter considered there is no justifiable reason for prohibiting such statements elsewhere on pack. Two submitters considered provenance-related statements do not imply nutrition or health benefits to consumers and they have been inadvertently captured by the draft variation. The proposed restriction on provenance statements will impact caregivers' ability to make informed choices and will be extremely detrimental for the competitiveness of the Australian and New Zealand infant formula industry in export markets. One submitter challenged if capturing 'milk' was the intent of the proposal given original concerns outlined in the FSANZ 2016 CP appeared more focussed on addressing implied nutrition content and health claims.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC, NES	FSANZ has decided to include a provision permitting the word 'milk' to appear outside the statement of ingredients and elsewhere on the product label. See section 4.19 of the report and subparagraph 2.9.1—28(1)(j)(i) of the primary variation.
	2. Prohibition of information about ingredients These submitters did not support the prohibition of information about ingredients (except in the statement of ingredients and, where relevant in the NIS) for the following reasons: • The approach is not internationally aligned with Codex, the WHO code, the EU or the US. Codex Standard CXS 72-1981 only prohibits nutrition and health claims except where specifically provided for in relevant codex standards or national legislation. Likewise the WHO Code WHA58.32 only prohibits nutrition and health claims except where national/regional legislation allows. EU regulation 2016/127 restricts nutrition and health claims on IF but allows them on FoF. • One submitter commented it has a responsibility to accurately describe the ingredients and their performance characteristics	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC, NES	This issue was discussed in section 6.3 of SD3 to the 1st CFS (FSANZ 2022e) and Table 5 in SD3 to the 2nd CFS (FSANZ 2023d). After consideration of submissions, FSANZ has decided to retain the approach at 2nd CFS. See section 4.19 of the report.

Issue	Comment	Submitter(s)	FSANZ response
	to caregivers. Attributes such as the quality and performance characteristics of ingredients, the infant for whom the product was created or those who should not consume the product and general suitability and the intended purpose of the product, are all key. Omitting this relevant information, or omitting highlighting key ingredients or purposes of the product, is considered misleading. • One submitter expressed concern that the drafting may be interpreted to apply to a broader range of statements than the specific ingredient claims (e.g. 'fish oil) included in the consumer evidence reviewed by FSANZ. For example, general information about ingredients outside the statement of ingredients is required for some products to provide caregivers with a truthful and accurate representation of the product (e.g. products made with organic ingredients). They also noted that consumer understanding of ingredient claims and its impact on caregivers' perceptions of IF and FoF was based on consumer studies (1st CFS) that only included claims on specific ingredients (e.g. fish oil), not a broader reference to the term 'ingredients'. • FSANZ will not define 'ingredient' in the Code, which means that that there will be no legislative certainty as to whether and the extent to which, 'information relating to ingredients' differs from a 'nutrition content claim' or 'health claim', creating uncertainty about the scope of the prohibition. • FSANZ has proposed a note to 2.9.1—29 which further clarifies the requirements within the standard. Considers such a note would address FSANZ's concern around implied nutrition and health claims, without the need for a prohibition on ingredient statements. • Two submitters understand that 2.9.1—29(1)(j) does not preclude a general statement about ingredients, for example "high quality ingredients" or "sustainably sourced ingredients". This is not clear from the drafting and could raise interpretation		

Issue	Comment	Submitter(s)	FSANZ response
	issues between different jurisdictions. Suggested a comment is made in the approval report to clarify the intent of this requirement.		
2.9.1—29 Prohibited representations *At the 2nd CFS the draft variation stated:* *(1) The label on a package of infant formula or follow-on formula must not contain:* *(k) information relating to the animal or plant source or sources of protein in the infant formula or follow-on formula, except:* *(i) in a statement of ingredients; or* *(ii) where required by subsection 2.9.1—20(1);*			
Yes, the draft variation is supported.	This submitter supported the draft variation.	ADG	Noted.
No, the draft variation is not supported.	These submitters did not support the draft variation for the following reasons: • Restricting declaration of protein source limits important product information and is counter intuitive to the provision of information for informed choice. • Statements which ensure adequate information about protein sources and protein fractions on the product label such as "made with A2 milk (protein)", A2 beta-casein protein fraction (or absence of the A1 beta-casein fraction) provide useful and necessary information to enable caregivers to make informed choices. One submitter stated there are no justifiable reasons for preventing information about protein sources and protein fractions elsewhere on the label. • One submitter considered the restriction overreaches in terms of FSANZ objectives as it does not materially add to food safety outcomes, restricts consumer information and at the same time results in significant commercial costs and barriers to	DCANZ, FCG, SML	Information about the animal or plant source or sources of protein in IF or FoF is only permitted to be co-located with the statement of the name of the food on the front of the package and in the statement of ingredients to prevent nutrition content claims from being made (see section 4 of SD3 to the 2nd CFS; FSANZ 2023d). FSANZ notes information about protein subgroup nutrients such as beta-casein protein on a label would not constitute protein source information but rather a nutrition content claim about a protein subgroup. A1 beta casein is permitted as an ingredient and not permitted as a nutritive substance in infant formula, hence, the potential to inform caregivers of gastrointestinal discomfort is not relevant for infant formula which are intended for healthy infants. FSANZ considers requiring a protein source statement on the front of the package and in the statement of ingredients (therefore in two fields of view) provides for informed choice. Additionally, FSANZ has amended the draft variation to permit the term 'milk' elsewhere on the label (see section 4.19 of the

Issue	Comment	Submitter(s)	FSANZ response
	competitive trade in export markets for the New Zealand dairy industry. • One submitter commented that prohibiting such information would mean caregivers of infants who tolerate formula free from A1 beta-casein would be unable to choose a formula suitable for gastrointestinal comfort. • One submitter commented that the restriction to the front of the package only is not internationally aligned with Codex, the WHO Code, the EU or the US. Generally, international standards do not prohibit ingredient statements elsewhere on a label. The approach is inconsistent with FSANZ's stated objective of assisting international trade by harmonising with international standards.		report for discussion on this issue and subparagraph 2.9.1—28(1)(j)(i) of the primary variation). In preparing a food regulatory measure FSANZ has to consider not only the FSANZ objectives but also have regard to a range of other matters such as whether the costs arising from the proposed measure would outweigh the direct or indirect benefits, the best available evidence, the promotion of consistency between domestic and international food standards, the desirability of an efficient and internationally competitive food industry and any policy guidelines formulated by ministers. See section 4.19 of the report for discussion on international alignment. See response about trademarks under 'Other' below.
2.9.1—29 Prohibited representations *At the 2nd CFS the draft variation stated:* *(1) The label on a package of infant formula or follow-on formula must not contain:* *(l) the words 'partially hydrolysed' or any word or words having the same or similar effect, except:* *(i) in a statement of ingredients; or* *(ii) where required by subsection 2.9.1—20(2);*			
Yes, the draft variation is supported.	These submitters supported the draft variation. One submitter commented that the restriction on 'partially hydrolysed' in the name of the food and the statement of ingredients goes some way to ensure appropriate presentation of these formulas.	ADG, VIC DoH & DEECA	Noted.
No, the draft variation is not supported.	These submitters did not support a prohibition on the use of 'partially hydrolysed' outside of the ingredient list (and the protein source statement) for the following reasons:	INC, SML, DAN, DCANZ, A2M, AFGC,	FSANZ has amended the declaration requirements for partially hydrolysed protein to be based on use rather than when a product has been represented as 'partially hydrolysed' (see section 4.15 of the report). Given 'partially hydrolysed' is

Issue	Comment	Submitter(s)	FSANZ response
	• One submitter commented that the words 'partially hydrolysed' are prescribed words and do not constitute a nutrition content or health claim. • Another submitter considered a prohibition on the back of the package when the words are permitted on the front as making no sense. It is unclear how such terms suddenly become claims by moving 15 cm to the back of pack. If a term is prescribed or permitted on the front of the package, then its use on the back is confirmatory and raises awareness for the caregiver selecting the product.	FCG, NZFGC	required in conjunction with the protein source statement on the front of the package, FSANZ considers there is no need for 'partially hydrolysed' to be provided elsewhere on the package, other than as part of an ingredient name in the statement of ingredients. This approach allows for the information to be in two fields of view on the package to provide adequate information for consumers.
Other	These submitters recommended the statement of ingredients include 'partially hydrolysed protein'. These submitters considered this name is required because it is useful for clinicians to be able to differentiate between tolerance of intact cow's milk protein and partially hydrolysed proteins in the diagnosis of cow's milk protein allergy.	ASCIA, PHI2	FSANZ does not agree the words 'partially hydrolysed protein' should be mandated in the statement of ingredients of infant formula for the reasons previously stated in section 8.3.2 of SD3 to the 2nd CFS. The words 'partially hydrolysed' may be included as part of the name of the relevant protein ingredient. However, an IFP that is formulated for a medical condition such as cow's milk protein allergy will be a SMPPi and will be subject to different labelling requirements as set out in Division 4 of the primary variation.
2.9.1—29 Prohibited representations *At the 2nd CFS the draft variation stated:* *(1) The label on a package of infant formula or follow-on formula must not contain:* *(m) the words 'lactose free' or 'low lactose', except for a declaration or statement required by section 2.9.1—21*			
No, the draft variation is not supported.	These industry submitters did not support the explicit prohibition of the words elsewhere on the product label. One submitter commented they are prescribed terms and not nutrition content or health claims (see comments on the Note to subsection 2.9.1—29(1)).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC	As outlined above regarding section 2.9.1—21, FSANZ has amended the 2nd CFS draft variation to remove lactose modified products from Division 3. These products are now regulated as SMPPi in Division 4 and will be subject to SMPPi labelling requirements. See section 4.4 of the report.

Issue	Comment	Submitter(s)	FSANZ response
	Another submitter commented that it fails to see how such terms suddenly become claims when included on the back of the pack. It considered duplicating these words is confirmatory and raises awareness for the caregiver.		
2.9.1—29 Prohibited representations *At the 2nd CFS the draft variation stated:* *(1) The label on a package of infant formula or follow-on formula must not contain:* *(n) a number used to identify for consumers that the product is infant formula or follow-on formula, except where required by section 2.9.1—28.*			
Yes, the draft variation is supported.	This submitter supported the draft variation.	VIC DoH & DEECA	Noted.
No, the draft variation is not supported.	***1. Prohibit stage numbers*** This submitter did not support the use of stage numbers and recommends amending paragraph 2.9.1—29(1)(n) to become an explicit prohibition: *'**Sequential stage numbers or letters** used to identify for consumers that the product is infant formula or follow-on formula. **For the avoidance of doubt, aged-related descriptors (0–12 months, 6–12 months) are not prohibited representations**.'*	NSWFA	After consideration of submissions, FSANZ has decided to maintain the approach at the 2nd CFS. The rationale for permitting stage numbers on IF and FoF remains as described in section 9.5 of SD3 in the 2nd CFS (FSANZ 2023d). See section 4.20 of the report for further discussion on stage labelling.
	2. Location of stage numbers These submitters did not support restricting stage numbers to the front of the package for the following reasons: • Where companies are unable to declare the number on the back of the package, caregivers may be unintentionally misled about the true nature of the product and suitability for their infant.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC, NES	For the reasons stated in this report, FSANZ has decided to permit the voluntary use of a stage number elsewhere on the label. See section 4.20 of the report and subparagraph 2.9.1—27(3) of the primary variation.

Issue	Comment	Submitter(s)	FSANZ response
	• Use of stage numbers on other parts of the label including on back of pack promotes product differentiation and assists caregivers to make informed choices. • Caregivers do not make purchasing decisions solely on information provided on the front of the package. • Duplication can be an important driver for consumer awareness as well recognised through the plain English allergen labelling assessment e.g. allergens required to be declared multiple times in the statement of ingredients in addition to the summary statement. • Some companies may have numbers included within their brand trademarks and some brands have the same product name across both stage 1 and 2 with the stage number being the main differentiator. • The numbers '1' and '2' are often used by manufacturers elsewhere on the label as a simple and easy mechanism to refer to the product, compared to the terms 'infant formula' and 'follow-on formula'. • Prescribing the location of stage labelling is not consistent with international standards.		
2.9.1—29(1)(Note) Prohibited representations *At the 2nd CFS the draft variation stated:* *Note: Standard 1.2.7 prescribes requirements for making health claims and nutrition content claims, including in relation to infant formula products. Section 1.2.7—4 provides that a nutrition content claim or *health claim must not be made about an infant formula product. Section 1.2.7—8 provides that a claim – including a claim about an infant formula product - must not be therapeutic in nature.*			
Yes, the draft variation is supported.	These submitters supported the prohibition for nutrition content, health and therapeutic claims on labels.	ADG, DA	The Note has been amended. However, it still clearly states and refers to the prohibition of claims on infant formula products imposed by Standard 1.2.7. The Note has also been moved to the beginning of Division 3 of the (revised) Standard 2.9.1.

Issue	Comment	Submitter(s)	FSANZ response
No, the draft variation is not supported.	This submitter supported the regulatory approach to prohibit claims on IF and FoF. However, this submitter reiterated the need to ensure the prohibition of nutrition content, health claims, therapeutic and prophylactic claims is clear and effective in accordance with specific policy principle n) in the Ministerial Policy Guideline on the *Regulation of Infant Formula Products.* This includes claims being made via trademarks or by means of abbreviations (e.g. HA or 'hypoallergenic'; AR for 'anti-reflux'), as well as by way of line marketing. This submitter proposed adding the following paragraph to the section 2.9.1—29: *(o) any abbreviation having the same or similar effect of nutrition content claims or health claims*	NSWFA	FSANZ considers the proposed amendment is not required for the following reasons. References to 'HA' or 'hypoallergenic' would relate to a SMPPi and are therefore not relevant to IF or FoF. Given the condition 'anti-reflux' will be prohibited for IF and FoF, FSANZ considers the abbreviation 'AR' is unlikely to be understood by caregivers. Further, it is unlikely that IFP manufacturers will use the abbreviation in isolation on IF and FoF represented as 'partially hydrolysed', as they have indicated they will position them as SMPPi. FSANZ has not prohibited trademarks for the reasons discussed below.
2.9.1—29 Prohibited representations *At the 2nd CFS the draft variation stated:* *(2) For the purposes of subsection (1), 'information' includes a reference by means of a name, a number, a picture, an image, a word or words.*			
Yes, the draft variation is supported.	These submitters supported the draft variation.	ADG, NSWFA	FSANZ has amended this requirement as discussed in the response below.
No, the draft variation is not supported.	These submitters commented that the drafting reference to subsection (1) is too broad and would capture any reference to information in that subsection. They recommended revising the subsection so that it applies to paragraph 2.9.1—29(1)(c) only. Two submitters stated that numbers, pictures and images are important to enable easy identification of products. These are used to support other statements made on the label and enable caregivers to make an informed choice. Imagery in particular can be an important tool in communicating this information, particularly where caregivers have low literacy and/or English is not their first language. Two other submitters commented that a prohibition for	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	The intent was to align with the provision in the revised Codex Standard for Follow-up Formula (now renamed Standard for Follow-up Formula for Older Infants and Product for Young Children and adopted by the Codex Alimentarius Committee at the CAC46 meeting; Codex 2023) in relation to proxy advertising (see section 9.7 of SD3 to the 2nd CFS; FSANZ 2023d). However, as noted further above, FSANZ has decided to prohibit any information relating to the different product types (for example, for IF - information relating to FoF, a special medical purpose product for infants or a formulated supplementary food

Issue	Comment	Submitter(s)	FSANZ response
	images and pictures of information relating to milk sources (cows, goats, sheep) would be unnecessarily restrictive.		for young children will be prohibited). See paragraph 2.9.1—28(1)(c) of the primary variation. FSANZ considers it is more important to specify the product type that the information relates to (e.g. formulated supplementary foods for young children) rather than how the information may be provided on a label (e.g. as a name, a number, a picture, an image, a word or words). Subsection 2.9.1—29(2) of the 2nd CFS draft variation has therefore been removed as it is now redundant.
2.9.1—29(3) Prohibited representations *At the 2nd CFS the draft variation stated:* (3) *For the purposes of paragraph (1)(i), the following substances are listed:* *(a) an inulin-type fructan; and* *(b) a galacto-oligosaccharide; and* *(c) a nutrient; and* *(d) a substance *used as a nutritive substance'.*			
No, the draft variation is not supported.	***1. 'Nutrient' versus 'nutritive substance'*** The submitter noted the use of the term 'nutrient' in subsection 2.9.1—26 may imply that this term refers to mandatory ingredients in the NIS as opposed to voluntary ingredients. Mandatory ingredients include nutritive substances such as vitamins, minerals and other essential substances required in S29—5 and S29—6. The use of the term 'nutrient' in the proposed draft subsection 2.9.1—29(3), together with 'a nutritive substance' does not provide clarity as to the difference between the two terms. The submitter recommends defining the term or avoiding the use of this term in section 2.9.1—29. Subsection 2.9.1—29(3) (and paragraph 2.9.1—29(1)(i)) could refer to the NIS requirement in sections 2.9.1—25 and 2.9.1—26 as an alternative.	NSWFA	FSANZ does not agree that a definition of the term 'nutrient' is required, or that the term should not be used. Section 2 of this Appendix outlines why defining the term 'nutrient' is not feasible and notes the term is not defined in the Code for any other purpose. The intent of the term 'nutrient' is to capture all the other substances referred to in section 2.9.1—24 of the primary variation that are not an inulin-type fructan, a galacto-oligosaccharide or 'a substance used as a nutritive substance' (a defined term). The Note to subsection 2.9.1—29(3) (now subsection 2.9.1—28(2) of the primary variation) cross references section 2.9.1—24, which specifies what must or may be declared in the NIS.

Issue	Comment	Submitter(s)	FSANZ response
No, the draft variation is not supported.	***2. Prohibition to refer to conditions*** These submitters considered that the situation where IF cannot reference conditions such as anti-reflux, colic, or lactose intolerance because they would constitute a prohibited health claim is only true if the terms are not prescribed as they are now (e.g. clause 2.9.1—14(2)(d)). A submitter pointed out that the claim of lactose free can be made under the proposed drafting because it is a prescribed term.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ does not agree that references to certain health conditions should be permitted on IF or FoF labels, because they would constitute a health claim (see section 8.3 in SD3 of the 2nd CFS (FSANZ 2023d). Further, lactose modified products will be regulated as SMPPi, meaning infant formula will no longer be able to refer to 'lactose free' or 'low lactose' on the product label. See sections 4.4 and 4.15 of the report.
S29—10 Required format for a NIS			
No, the draft variation is not supported.	***1. Format of headings*** This submitter did not support the proposed option. To prevent the overemphasis of one heading over another, requests that the format chosen in the NIS (e.g. lines, bolding, shading, font or text size) for one heading is the same as all other headings to ensure all nutrients are equally identified.	TAS DoH	FSANZ considers there is no need for further format prescription of NIS subheadings beyond the size of type required in paragraph 2.9.1—25(2)(d) in the primary variation, for the reasons set out in section 6 of SD3 to the 2nd CFS (FSANZ 2023d). Further, there is no evidence from the market survey that manufacturers currently using NIS subheadings are emphasising one heading over another.
	2. Indenting line entries This submitter recommended that substances under the subheadings 'vitamins', 'minerals', 'other nutrients' and 'additional' are indented in the required format for the NIS, as done for the subcategories of macronutrients. The current industry practice to emphasise subheadings from surrounding text using lines, bolding or shading will be restricted, so the format required under S29—10 needs to resolve this issue.	NZFS	FSANZ's decision is to require the subheadings 'Vitamins', 'Minerals' and 'Additional' in the NIS for IF and FoF and 'Other nutrients' for IF. The subheadings must be printed in a size of type that is the same or larger than the nutrient names. Consistent with the approach taken for the format of the nutrition information panel for general foods, the draft variation does not prevent manufacturers from using bolding, lines or a different typeface in the NIS, as is common current practice (see section 6.3 of SD3 to 2nd CFS; FSANZ 2023d). It is not appropriate to require indenting of substances under subheadings such as 'Vitamins' given each vitamin is not a component nutrient of the group 'Vitamins' (in contrast to macronutrients e.g. 'Protein' with 'whey' indented).

Issue	Comment	Submitter(s)	FSANZ response
	3. Units of measurement – Vitamins A and E These submitters did not support the units proposed for the declaration of Vitamins A and E in the NIS. Those shown in section S29—6 should reflect Table 7 of the 2nd CFS report (Vitamin E as mg α-TE and Vitamin A as µg RE). In contrast, one submitter suggested amending the unit for Vitamin E to mg.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC, NZFS	FSANZ's decision is to maintain the approach for the units of measurement for Vitamin A and Vitamin E for the reasons summarised in SD3 of the 2nd CFS (pages 29–30; FSANZ 2023d). FSANZ is requiring Vitamin E to be expressed in milligrams in the NIS. See section 4.18 of the report.
	4. Units of measurement – Niacin This submitter suggested amending the unit for niacin to µg.	NZFS	FSANZ agrees and is requiring niacin to be expressed in micrograms in the NIS. See section 4.18 of the report.
2.9.1—33 Representations about food as a special medical purpose product for infants *At the 2nd CFS the draft variation stated:* *A food may only be presented as a special medical purpose product for infants if it complies with this Division.*			
No, the draft variation is not supported.	***1. Prescribed name*** This submitter suggested adding a prescribed name for SMPPi to section 2.9.1—33, with flexibility in elements to allow continuous import of necessary clinical products, in line with Codex, for example: *'Special medical purpose product for infants' is the *prescribed name for special medical purpose product for infants. Where this requirement would prevent the sale of an imported product, an alternative name indicating the nature as a special medical purpose product for infants is permitted.*	NSWFA	FSANZ does not agree that SMPPi should have a prescribed name for the reasons provided in Table 7 in SD3 to the 2nd CFS (FSANZ 2023d). As part of these reasons, FSANZ referred to section 9.1.2 (Part B) of Codex CXS 72-1981, which specifies '*the name of the product shall be 'Formula for Special Medical Purposes Intended for Infants' or any appropriate designation indicating the true nature of the product, in accordance with national usage'* (Codex 1981). The Codex provision allows for deviation by way of appropriate designations mandated by Member countries. It does not constitute binding legislation and does not suggest both options for naming of these products are adopted in national legislation. FSANZ considers it is inappropriate to prescribe a name under the Code and then permit deviations from it. The rationale for the

Issue	Comment	Submitter(s)	FSANZ response
			Code's prescribed name regime is that a name is prescribed, it must be used in all instances.
	2. Clarify text for product differentiation The submitter suggested additional text to ensure that an appropriate product differentiation requirement applies to SMPPi, for example: *'A food represented as a special medical purpose product for infants must be designed in such a way that it avoids any risk of confusion between infant formula and SMPPi and enables consumers to make a clear distinction between them, in particular as to the text, images and colours used'.*	NSWFA	FSANZ agrees that SMPPi should be appropriately differentiated from IF, FoF, formulated supplementary foods and formulated supplementary foods for young children. Although there are specific SMPPi labelling requirements that differ from IF and FoF, there are no requirements that specify SMPPi must be differentiated from one another and from other foods by way of text and pictures and/or colours used. FSANZ has included a specific provision requiring SMPPi to be differentiated from IF, FoF, formulated supplementary foods for young children and formulated supplementary foods for young children to assist caregivers to make appropriate product choices. This requirement is consistent with: • Part B section 9.6.5 of Codex CXS 72-1981 for formula for special medical purposes intended for infants (Codex 1981) and • Article 8(3) of European Regulations for food for special medical purposes (European Commission 2016b). See section 2.9.1—44 of the primary variation.

2.9.1—35 Prohibited representations

At the 2nd CFS the draft variation stated:

The label on a package of a special medical purpose product for infants must not contain:

(a) *a picture of an infant;*

(b) *the word 'humanised' or 'maternalised' or any word or words having the same or similar effect; or*

(c) *the words 'human milk oligosaccharide', 'human identical milk oligosaccharide' or any word or words having the same or similar effect; or*

(d) *the abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect'; or*

Issue	Comment	Submitter(s)	FSANZ response
(e) *information relating to another food.* ***Note*** *S*tandard 1.2.7 prescribes requirements for making health claims and nutrition content claims, including in relation to infant formula products, including a special medical purpose product for infants. Section 1.2.7—4 provides that a nutrition content claim or *health claim must not be made about an infant formula product. Section 1.2.7—8 provides that a claim – including a claim about a special medical purpose product for infants - must not be therapeutic in nature.			
Yes, the draft variation is supported.	This submitter supported the prohibition for nutrition content, health and therapeutic claims on SMPPi labels.	WA DoH	For regulatory clarity, noting provisions in Part 1.2 of the Code do not apply to SMPPi unless the contrary intention appears and Notes are not legally binding, FSANZ has decided to include an explicit prohibition for nutrition content, health and therapeutic claims in the primary variation. See response to issue 4.
	1. Overseas and international alignment These submitters did not support the prohibited representations, because they are not aligned with international regulations. As a large number of SMPPi are imported from the EU, the draft variation should align with Article 8 of EU Regulation 2016/128. It is critical that SMPPi retain flexibility in permissions on labelling, to prevent any potential trade barriers. In relation to paragraphs 2.9.1—35(a) and (b), these submitters supported restrictions on any pictures or text which may idealise the use of the product, but considered they must not prevent a SMPPi from providing information on the properties and characteristics for the condition for which it is suitable. Paragraphs 2.9.1—35 (c) and (d) referring to human milk oligosaccharides (HMOs) and human identical milk oligosaccharides (HiMOs) should be deleted.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC	After consideration of submissions, FSANZ has decided to remove the prohibited representation relating to the word 'humanised' or 'maternalised' or similar word(s) on SMPPi labels and replace it with the prohibited representation about 'a picture or text that idealises the use of the product'. FSANZ has also decided to maintain the prohibitions relating to HMOs and HiMOs. See section 4.21 of the report and section 2.9.1—45 of the primary variation.

Issue	Comment	Submitter(s)	FSANZ response
No, the draft variation is not supported.	***2. Same prohibited representations for infant formula should apply to SMPPi*** This submitter considered some of the prohibited representations for IF and FoF that were omitted in the draft variation should also apply to SMPPI because: • these prohibitions would ensure the WHO Marketing Code is applied to SMPPi, noting certain products such as colic/reflux formulas are marketed to manage normal infant behaviours • caregivers from culturally- and linguistically-diverse backgrounds or with low literacy levels need to identify the appropriate formula for their infant. This submitter proposed amending the drafting to include: *(f) a picture that idealises the use of infant formula product* *(g) words claiming that the formula is suitable for all infants* *(h) information relating to the nutritional content of human milk.*	NSWFA	As noted in the previous response, FSANZ is including the prohibited representation about 'a picture or text that idealises the use of the product'. For the reasons stated in this report, FSANZ has decided not to adopt the other proposed amendments. See section 4.21 of the report.
	3. Paragraph 2.9.1—35(e) Information relating to another food These submitters commented that FSANZ needs to consider the reasoning behind this prohibition. Many infants who use SMPPi are on restricted diets and the label may include information on other products and/or nutrients which are suitable for their condition (INC). There can sometimes be a need to mention other products in some instances e.g. the product should only be taken in combination with a hypoallergenic product or human milk to ensure adequate nutrition. One submitter recommended deleting this paragraph.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	After consideration of submissions, FSANZ has decided to remove this prohibited representation. See section 4.21 of the report.
	4. Explicit prohibition for claims needed This submitter noted Part 1.2 of Chapter 1 does not apply to SMPPi as indicated in subparagraph 2.9.1—30(b)(i), unless the contrary intention appears. Further, the Note to 2.9.1—35 remains	NSWFA	As noted above, FSANZ has decided to replace the Note with a new section to explicitly prohibit nutrition content and health claims and therapeutic claims being made about a SMPPi unless a claim is expressly permitted (section 2.9.1—46 of the

Issue	Comment	Submitter(s)	FSANZ response
	ambiguous and is not enforceable. They requested adding explicit prohibitions for nutrition content, health and therapeutic claims in section 2.9.1—35 consistent with specific policy principle n) in the Ministerial Policy Guideline on the *Regulation of Infant Formula Products*.		primary variation). Section 2.9.1—47 of the primary variation permits a claim that a SMPPi is lactose free if that SMPPi contains no detectable lactose. See section 4.21 of the report.
2.9.1—37 Mandatory labelling information *At the 2nd CFS the draft variation stated:* *(1) The label that is required for a special medical purpose product for infants must state the following information in accordance with the provision indicated:* *(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2);* *(b) lot identification (see section 1.2.2—3);* *(c) if the sale of the food for sale is one to which Division 2 or Division 3 of Standard 1.2.1 applies:* *(i) information relating to *foods produced using gene technology (see section 1.5.2—4); and* *(ii) information relating to irradiated food (see section 1.5.3—9);* *(d) any required advisory statements, *warning statements, other statements, and declarations (see section 2.9.1—38);* *(e) information relating to ingredients (see section 2.9.1—39);* *(f) date marking information (see section 2.9.1—40);* *(g) directions for the use and storage of the food, if the food is of such a nature to require such directions for health or safety reasons;* *(h) nutrition information (see section 2.9.1—41).* *(2) The label must comply with Division 6 of Standard 1.2.1.*			
No, the draft variation is not supported.	***1. Minor edit*** This government submitter requested changing paragraph 2.9.1—37(1)(g) to reflect the wording used under section 2.9.1—22(5): *(g) directions for the use **and preparation** or the storage of the food, if the food is of such a nature to require such directions for health or safety reasons;*	NZFS	FSANZ agrees the requirement should more accurately reflect information that must be stated on the label, including directions about the preparation of the food. FSANZ has decided to require the word 'preparation' to appear before 'use', noting this is consistent with subsection 2.9.1—21(5) of the primary variation and with Codex specifications and EU regulations. See paragraph 2.9.1—49(1)(g) of the primary variation.

Issue	Comment	Submitter(s)	FSANZ response
	2. Legibility requirements These submitters did not support 2.9.1—37(2) because the minimum size of type (at least 1.5 mm) in section 1.2.1—25 is not aligned with Article 13(2) of EU Regulation 1169/2011 (minimum text height 1.2 mm). This could impact access to SMPPi where it is not viable to have unique labels for Australia and New Zealand.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NES	FSANZ is only requiring the general legibility requirements in section 1.2.1—24 to apply to SMPPi. This requires that: • any words must be English. • any word, statement, expression or design must, wherever occurring be legible and be prominent so as to contrast distinctly with the background of the label. • if a language other than English is also used on the label, the information in that language must not negate or contradict the information in English. These requirements do not conflict with the EU requirements for minimum text height as indicated in Article 13 (European Commission 2011b). See subsection 2.9.1—49(2) of the primary variation.

2.9.1—38 Mandatory statements and declarations — SMPPi

At the 2nd CFS the draft variation stated:

(1) For paragraph 2.9.1—37(1)(d), the following statements are required:

(a) a statement to the effect that the food must be used under medical supervision;

(b) a statement indicating, if applicable, any precautions and contraindications associated with the consumption of the food;

(c) a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated;

(d) a statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated in paragraph (c);

(e) if the food has been formulated for a specific age group—a statement to the effect that the food is intended for persons within the specified age group;

(f) a statement indicating whether or not the food is suitable for use as a sole source of nutrition;

(g) if the food is represented as being suitable for use as a sole source of nutrition:

(i) a statement to the effect that the food is not for parenteral use; and

(ii) if the food has been modified to vary from the compositional requirements of section 2.9.1—32 such that the content of one or more nutrients falls short of the prescribed minimum, or exceeds the prescribed maximum (if applicable):

Issue	Comment	Submitter(s)	FSANZ response
	(A) a statement indicating the nutrient or nutrients which have been modified; and *(B) unless provided in other documentation about the food—a statement indicating whether each modified nutrient has been increased, decreased, or eliminated from the food, as appropriate.* *(2) For paragraph 2.9.1—37(1)(d), the required advisory statements and declarations are any that are required by:* *(a) items 1, 4, 6, 9 of the table to section S9—2; or* *(b) subsection 1.2.3—2(2); or* *(c) section 1.2.3—4* *(3) For paragraph 2.9.1—37(1)(d), the *warning statement referred to in section 1.2.3—3, if applicable, is required.*		
Yes, the draft variation is supported.	This submitter supported the draft variation.	SML	Noted.
No, the draft variation is not supported.	***1. Clarity sought between the statement indicating the medical purpose of the food required by paragraph 2.9.1—38(1)(c) and a health claim*** One government submitter sought clarity regarding the difference between a health claim (e.g. a reference to a condition) and the required labelling information on SMPPi labels in relation to the medical purpose including mention of a disease, disorder or medical condition. This submitter considered that the definitions for 'health claim', 'health effect' and 'high level health claim' imply that health claims are potentially indistinguishable from the required statement for SMPPi. The other submitter commented it will be of significant regulatory importance to ensure the mandatory statement meets the need for the provision of the correct formula for the dietary management of a medically diagnosed disease, disorder, or condition and that there is a conclusive evidence base to support this mandatory statement.	NSWFA, WA DoH	Products represented as SMPPi must meet the definition of SMPPi in section 2.9.1—3 and comply with all compositional and labelling requirements in Division 4 of Standard 2.9.1. The statement required by paragraph 2.9.1—50(c) of the primary variation is a singular statement required to indicate the medical purpose of the food which may be achieved by referring to a disease, disorder or medical condition. The information is intended to assist caregivers and health professionals to understand the particular purpose of a product, and to ensure caregivers can identify appropriate products. Therefore, references elsewhere on the label to other diseases, disorders or medical conditions would be non-compliant with the requirement. This approach is consistent with Codex and EU regulations. In regard to a SMPPi meeting a medical purpose need and conclusive evidence to support the mandatory statement indicating the medical purpose of the food, FSANZ notes the relevant food acts require all food products for sale in Australia and New Zealand to be safe and suitable. Enforcement agencies

Issue	Comment	Submitter(s)	FSANZ response
			can request information from food businesses if they have any concerns.
	2. Amendment to paragraph 2.9.1—38(1)(d) One government submitter stated that the proposed drafting is not prescriptive enough to prevent the statement from being presented as a health or therapeutic claim. A solution could be to reword the section to align with the approach in EU regulation 2016/128 on Foods for Special Medical Purposes, which is more specific and requires *'the statement 'For the dietary management of …' where the blank shall be filled in with the disease, disorder or medical condition for which the product is intended.* Another submitter commented that the Code does not provide clarity on the difference between nutrition content and health claims and the properties and characteristics for the stated medical purpose. Another submitter made the same comment to paragraph 2.9.1—38(1)(c) for this paragraph.	VIC DoH & DEECA, WA DoH, NSWFA	FSANZ disagrees that the wording of the statement should be amended to reflect the wording required by EU Regulation 2016/128 Article 5(2)(e) (European Commission 2016b), as that would constitute a prescribed statement (i.e. prescribed wording). A prescribed statement would pose a trade barrier for SMPPi that are imported from countries outside Europe. FSANZ has instead adopted a flexible approach that is consistent with the regulatory approach for FSMP in Standard 2.9.5. The requirement for a statement describing the properties or characteristics which make the food appropriate for the medical purpose is also a single statement, indicating multiple properties or characteristics must be presented together.
	3. Statements on nutrient modifications in 2.9.1—38(1)(g)(ii) These submitters did not support the provision in this subparagraph. Two submitters suggested the additional statements for SMPPi in this subparagraph may be provided off-label to health professionals upon request. One submitter therefore recommended flexibility in labelling for nutritional modifications of vitamins and minerals specifically. The following reasons were provided: • The information should only be provided to health professionals, who are best placed to share information about nutritional modification with caregivers.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NES, NZFGC	FSANZ has decided to permit the statement required by paragraph 2.9.1—50(g)(ii)(A) of the primary variation to be provided in other documentation. See section 4.22 of the report.

Issue	Comment	Submitter(s)	FSANZ response
	• There is a risk an imported product's label will not be compliant due to the breadth of SMPPi and misalignment of Standard 2.9.1 with international regulations. • The cost/benefit analysis outlined in SD4 states that SMPPi would not be required to be re-labelled. This would not be the case if paragraph 2.9.1—38(g)(ii) applies unchanged. These products would also be stopped at the border or not allowed entry. • Pre-term formulas have a significant number of nutrients which vary from the compositional requirements of section 2.9.1—32. • Some nutrients will vary from the composition criteria in Standard 2.9.1 and Schedule 29, however, this level is within the composition criteria of international regulations, specifically, the EU and Codex. So imported products will not specify a change to this nutrient.		
	4. Mandatory advisory statements required by paragraph 2.9.1—38(2)(a) These submitters commented it is unclear whether all of these required advisory statements and declarations are applicable to SMPPi. One submitter provided the following advisory statements in section S9—2 as examples: statements about bee pollen, aspartame (contains phenylalanine), guarana (contains caffeine), propolis, quinine, cola beverages, unpasteurised egg products and unpasteurised milk.	NSWFA, NZFS	FSANZ agrees and has removed the requirement for the advisory statements in items 1, 4, 6 or 9 of the table to section S9—2. See section 4.22 of the report.
	5. Mandatory advisory statement required by paragraph 2.9.1—38(2)(b) This submitter did not support the inclusion of this paragraph as there are differences in what must be included in mandatory	DAN	FSANZ agrees and has removed the requirement for the advisory statement required by subsection 1.2.3—2(2) relating to listed polyols and polydextrose. See section 4.22 of the report.

Issue	Comment	Submitter(s)	FSANZ response
	declarations between FSANZ and other major international regulatory requirements.		
2.9.1—41 Nutrition information — SMPPi *At the 2nd CFS the draft variation stated:* *(1) For paragraph 2.9.1—37(1)(h), the nutrition information required for a special medical purpose product for infants is the following, expressed per given amount of the food:* *(a) the minimum or *average energy content; and* *(b) the minimum amount or *average quantity of:* *(i) protein, fat and carbohydrate; and* *(ii) any vitamin, mineral or electrolyte that has been *used as a nutritive substance in the food; and* *(c) any other substance:* *(i) *used as a nutritive substance in that product; and* *(ii) added to that product to achieve that product's intended medical purpose as described in the statement required by paragraph 2.9.1—38(1)(c).*			
No, the draft variation is not supported.	***Does not align with international nutrition information requirements*** These submitters did not support subsection 2.9.1—41(1) relating to SMPPi nutrition information requirements for the following reasons: • the following requirements for the NIS do not align with overseas regulations: – the amounts of essential and non-essential amino acids and/or essential fatty acids – no permission to include osmolality or osmolarity and/or on acid-base balance as per Codex CXS 72-1981	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NES	FSANZ has decided to permit additional information on SMPPi labels in accordance with Codex and EU regulations. See paragraph 2.9.1—53(1)(d) of the primary variation. A new subsection has also been added to clarify that a reference to the intended medical purpose is to the intended medical purpose as described in the statement required by paragraph 2.9.1—50(c) of the primary variation. See section 4.23 of the report.

Issue	Comment	Submitter(s)	FSANZ response
	– the components and/or modification of proteins, fats or carbohydrates or other nutrients whereby its presence is appropriate for product's intended medical purpose. • they prevent the use of shared international labels • consideration should be given to the nutrition information requirements of Codex CXS 72-1981 and the U.S. Code of Federal Regulations for Exempt Infant Formula (NES). A submitter recommended changes to paragraph 2.9.1—41(1)(c) as follows: *(c) any other substance:* *(i) *used as a nutritive substance in that product; **~~and~~*** *(ii) Added **~~to~~** **or removed from** that product to achieve that product's intended medical purpose as described in the statement required by paragraph 2.9.1—38(1)(c).* Removal of the word 'and' allows for all nutritive substances to be included in the NIS, including those that may not be present to achieve the product's intended medical purpose e.g. taurine.		

Issue	Comment	Submitter(s)	FSANZ response
2.9.1—43 Labelling requirement — a special medical purpose product for infants in transportation outer *At the 2nd CFS the draft variation stated:* (1) *If packages of a special medical purpose product for infants are contained in a transportation outer, the information specified in subsection (2) must be:* *(a) contained in a label on the transportation outer; or* *(b) contained in a label on a package of the food for sale, and clearly discernible through the transportation outer.* (2) *For subsection (1), the information is:* *(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2); and* *(b) lot identification (see section 1.2.2—3); and* *(c) unless it is provided in accompanying documentation—the name and address of the *supplier (see section 1.2.2—4).*			
No, the draft variation is not supported.	These submitters did not support that SMPPi are exempt from the general labelling requirement for the name and address of the supplier (section 1.2.2—4) and made the following comments. • One submitter noted section 2.9.1—43 requires this information for the transportation outer, but considered this is ineffective in the case of a recall. This submitter stated the information is also important for investigating complaints, foodborne illness cases and for enforcement purposes. • The submitter suggested including the words 'name and address of the supplier' in 2.9.1—37. • Another submitter noted information on outer packaging will likely be discarded and therefore the information would not usually be available for caregivers. • Another submitter did not consider the cost of over stickering supplier information outweighs the potential risks to infants posed by a delayed recall, particularly given product volumes are likely to be modest due to their specialised nature.	NSWFA, QLDH, VIC DoH & DEECA	FSANZ has decided to maintain the approach at 2nd CFS for the name and address of the supplier to be in a label on the transportation outer, or in a label of the food for sale if it is clearly discernible through the transportation outer, or provided in accompanying documentation. This approach is consistent with the regulatory approach for adult FSMP. See section 4.24 of the report.

Issue	Comment	Submitter(s)	FSANZ response
Other – Certain provisions for infant formula should apply to SMPPi			
No, the draft variation is not supported.	***1. 'Breast milk is best' warning statement*** This submitter commented its own experts have provided divergent comments on section 2.9.1—37. Queensland Children's Hospital clinical dietitians agree the warning statement 'breast milk is best' should not apply to the SMPPi category, in particular to products requiring prescription by a medical professional. Public health nutritionists from the Prevention Strategy Branch of Queensland Health do not support exempting SMPPi from this warning statement, because Australia's application of the WHO Marketing Code is already extremely weak.	QLDH	FSANZ noted previously in section 3.3.2 of SD4 to the 1st CFS (FSANZ 2022g) and in Table 7 of SD3 to the 2nd CFS (FSANZ 2023d) that it considers it is inappropriate to apply this warning statement to SMPPi. An infant is fed a SMPPi because a medical condition necessitates a partial or whole replacement of breast milk with a product specially formulated for their condition. The majority of SMPPi are imported from the EU, where the 'breast milk is best' labelling statement is not required. Mandating this statement for SMPPi in the domestic market would pose a trade barrier and potentially interrupt supply. Further, these products are intended for use under medical supervision and their sale would be restricted. FSANZ considers health professionals to be best placed to advise when to breastfeed an infant with medical conditions, rather than relying on SMPPi labels for this information. For these reasons, after consideration of submissions, FSANZ has maintained the approach presented in the 2nd CFS draft variation.
	2. Certain requirements for infant formula should also apply to SMPPi This submitter commented that information [requirements for IF] such as 'directions for preparation and use', 'follow instructions exactly' and 'age related statements' are still relevant and required on the labelling of SMPPi. Directions are utilised daily by paediatric clinical dietitians as a starting or reference point, to guide caregivers to vary how they make their formula to their child's specific requirements.	QLDH	Under section 2.9.1—37(1)(g) of the primary variation, directions for preparation, use and storage are mandatory for SMPPi however the prescriptive nature of the directions for IF and FoF set out in Division 3 are inappropriate for SMPPi. In the first instance, FSANZ considered in section 3.2 of SD4 to the 1st CFS (FSANZ 2022g) that the directions for preparation and use for FSMP should apply to SMPPi as part of the overall approach to adopt FSMP labelling. However, more specific instructions would not be prohibited by the Code if they are included voluntarily on the label. Secondly, regarding the use of statements to follow instructions exactly, in section 3.3.2 of SD4 of the 1st CFS (FSANZ 2022g),

Issue	Comment	Submitter(s)	FSANZ response
			FSANZ considered this warning statement should not apply to SMPPi because it is not required by either EU regulations or specified by Codex and prescribed wording would present a trade barrier. FSANZ also noted that SMPPi are intended for use under medical supervision, so the risks that this statement manages are addressed. Division 4, paragraph 2.9.1—50(e) of the primary variation requires an age statement only if the food has been formulated for a specific age group. For SMPPi, which may be highly specialised and intended for a broader age group, it may not be appropriate to require an age statement. As outlined above and in section 3.2 of SD4 of the 1st CFS (FSANZ 2022g), FSANZ considers that FSMP statements in Standard 2.9.5 should apply to SMPPi.
Other – Trade marks and claims			
No, the draft variation is not supported.	***1. Trade marks*** A government submitter commented that if FSANZ cannot address the issue of IFP labels making health claims through the use of trade marks on IF in this proposal, then it is important that this issue be addressed in the future. FSANZ could include a specific regulation in the IF standard that would make it illegal to use a health claim trade mark on IF by providing grounds for rejection under the Trade Mark Regulations 42(b) (the trade mark is contrary to law). Another government submitter remains concerned the intentions of the Code in ensuring appropriate presentation of these products will be undermined if the suggestive labelling is trademarked. An industry submitter considered existing trade marks for similar terms held by other companies would create unfair competition to	SAH, VIC DoH & DEECA, DAN	Noted. These issues relating to trade marks were considered in previous consultation papers and call for submissions and FSANZ is not aware of any evidence to warrant a change in its position as stated in the latter. As explained, these issues are not ones that FSANZ can address and are outside FSANZ's remit. Trade marks are regulated through the Australian Trade Marks Act 1995 and the New Zealand Trade Marks Act 2002. IP Australia and the Intellectual Property Office of New Zealand (IPONZ) are responsible for the administration and application of these laws. FSANZ understands that, in Australia, the Commonwealth trade mark legislation and the Code as applied by State and Territory food laws are intended for different purposes and concern different rights and obligations. A provision in the Code that

Issue	Comment	Submitter(s)	FSANZ response
	companies that do not have the ability to use the trademarked information.		specifically prohibited a trade mark on IF and FoF labels may not be appropriate and would be invalid and unenforceable. As stated in the 2nd CFS, FSANZ will inform IP Australia and IPONZ of the relevant changes to Standard 2.9.1, once gazetted (see Table 5 in SD3 to the 2nd CFS; FSANZ 2023d).
	2. Vegan claims Plant protein formulas should not be able to use the term 'vegan' on can/in marketing because a vegan claim is very different to a 'free from' claim. This is problematic and unsafe as many people in the community expect vegan products to be completely free from milk, egg and fish.	A&AA	The Code does not regulate 'vegan' claims on food labels. This type of representation (claim) is subject to consumer protection legislation which prohibits misleading or deceptive conduct and false or misleading representations about food offered for sale. IFP labels are required to comply with allergen declaration requirements in the Code. As for general foods, caregivers can check the presence of allergens by looking at the statement of ingredients and summary statement.
	3. Various claims and representations This submitter recommended the following prohibitions be mandated for IF and FoF to protect infants from potentially consuming growing up milks by mistake and to ensure the label information is clear and free of marketing tactics: • claim or suggestion of superiority (e.g. 'premium', 'patented formula') • text that is harmful to breastfeeding or creates idealisation of formula use (e.g. 'trusted', 'backed by', 'helps to ease') • vitamin and mineral descriptors or claims (e.g. 'X number of vitamins and minerals', 'essential nutrients') • imagery (e.g. characters, animals, colours and shapes such as stars, ticks, flags) • nutritional or scientific claims or jargon (e.g. 'organic', 'immune boosting', 'nutritionally complete')	BAA	Prohibited representations in section 2.9.1—28 of the primary variation support the Australian and New Zealand governments' international commitments to the WHO Marketing Code (WHO 1981) and are consistent with the Ministerial Policy Guidelines on the *Regulation of Infant Formula Products* and *Nutrition, Health and Related Claims*. These prohibited representations include, amongst other things, a picture of an infant, a picture that idealises the use of IF and FoF and nutrition content, health and therapeutic claims. The draft variation has also been clarified to prohibit references to conditions (e.g. constipation) on IF and FoF labels. Further, the draft variation includes a new provision to require products within a product range to be differentiated using text, pictures and colours, to enable caregivers to make a clear distinction between them (see section 2.9.1—15 of the primary variation). The new provision is consistent with the Codex draft Standard for Follow-up Formula for Older Infants. Stage numbers are permitted because consumer evidence indicates caregivers use them together with age statements to

Issue	Comment	Submitter(s)	FSANZ response
	• age suitability (e.g. stages (1, 2, etc), inconsistent with legal requirements (0–12 month range), suitable for newborn) • 'Made in' symbol – country of origin should be stated but not used as a selling tactic (e.g. 'made with the goodness of NZ milk') • awards (e.g. any suggestion of being an award winner 'Australia's best') • sponsorships/endorsements (mention of other brands, endorsements of other companies, organisations) • specialised formulation (e.g. day and night, anti-colic, easy to digest, constipation, digestive discomfort) • environmental and/or sustainability claims (e.g. waste reduction and recycling initiatives, sustainable agriculture, animal welfare, reduced carbon footprint).		make appropriate product choices for their infants (see section 2.9.1—27 of the primary variation). FSANZ has not changed requirements for age statements (see section 4.16 of the report for discussion on this issue). Many of the suggested prohibitions are not regulated by the Code. Issues mentioned, such as country of origin labelling, organic, environmental and/or sustainability claims, fall under consumer protection legislation in Australia and New Zealand. As noted further above, Australian and New Zealand governments have implemented the relevant principles of the WHO Marketing Code into voluntary codes of practice. FSANZ notes the MAIF Agreement is currently under review.
Other – Marketing of infant formula			
No, the draft variation is not supported.	***1. Mandate labelling information consistent with WHO Marketing Code*** FSANZ should fulfil Australia's requirements as a WHO Marketing Code member by: • mandating information about the recommended age for introduction of the product, importance of continuing breastfeeding for 2+ years; and importance of no complementary foods < 6 months. • prohibiting image/text suggesting use [of IF] at <6 months; images/text that undermines or discourages breastfeeding or compares to breastmilk; messages that recommend or promote bottle feeding; and professional endorsements.	BAA	See response to issue 3 above. Further, some of the points raised in these comments are not captured by the Code (e.g. professional endorsements).

Issue	Comment	Submitter(s)	FSANZ response
	2. Wait for review of MAIF Agreement These government submitters commented that Proposal P1028 needs to consider the outcomes of the current review of the MAIF agreement. One submitter suggested FSANZ wait until a clear conclusion is reached, while the other submitter stated that the MAIF review and outcomes should be considered in parallel with P1028 to enable a robust update of marketing policy and further tightening and restriction of IF product marketing practices.	NSWFA, QLDH	FSANZ acknowledges the views about considering outcomes from the review of the MAIF Agreement within Proposal P1028, however the timelines for Proposal P1028 and the MAIF review do not align. FSANZ has discussed the matter of alignment with the MAIF review with the Australian Government Department of Health.
Other – Terminology and format of labelling information			
No, the draft variation is not supported.	***1. Clarify labelling terms for nutritive substances and novel foods*** These submitters suggested consideration be given to the labelling of novel foods and nutritive substances on IF and FoF given the restrictions that have been recently applied to terminology, which do not use 'consumer friendly' terms. As applications are very costly, it was requested clarity be provided prior to submitting an application on permitted labelling to determine the value an application may bring. It was noted the Application Handbook does not sufficiently address this issue.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	Labelling terminology is considered on a case-by-case basis during pre-market assessment of applications seeking permission to use nutritive substances or novel foods. There are no naming restrictions for the majority of nutritive substances and novel foods already permitted in the Code. This is the general labelling approach which applies to all special purpose foods, hence there is no specific requirement in the Application Handbook. Note item B7 of Guideline 3.3.3 (Substances used for a nutritive purpose) of the Handbook specifies information on the proposed food label must be provided, including details of the proposed labelling statements relating to the presence of the nutritive substance in the food. FSANZ notes a restriction was applied to labelling of human milk oligosaccharides in Application A1155 (2′-FL and LNnT in infant formula and other products; FSANZ 2019) as there was a conflict with an existing provision in the Code (see section 2.3.4 of the A1155 approval report).
	2. Plain packaging This submitter suggested all brand imagery should be removed from IF and FoF labels and there should be a mandated size, font and location for the brand name, health warnings and other	BAA	FSANZ has assessed evidence and relevant information in considering product differentiation and proxy advertising of IF and FoF (see sections 9.6 and 9.7 in SD3 of the 2nd CFS; FSANZ 2023d).

Issue	Comment	Submitter(s)	FSANZ response
	required information. Unappealing colours such as dark brown for IF and mustard for growing up milks would allow for easy product differentiation, less opportunity for cross promotion and less room for caregivers to choose an inappropriate product. The size and shape of the package should also be regulated.		To minimise the risk of caregivers being confused and purchasing an inappropriate product, a food represented as IF or FoF must be differentiated from one another and other foods through the use of text, pictures and/or colours (section 2.9.1—15 of the primary variation). Paragraph 2.9.1—28(1)(c) of the primary variation prohibits information relating to another product type from being on IF or FoF. The format of the NIS is mandated (see section 2.9.1—25 of the primary variation) and the location of certain labelling information is prescribed (e.g. protein source statement, name of the food, age statements, voluntary stage numbers). The size of type is mandated for warning statements (see section 2.9.1—22 of the primary variation).
Other – Meeting FSANZ Act requirements and having regard to policy guidance			
No, the draft variation is not supported.	***(1) FSANZ Act Requirements*** The submitter expressed concerns about proposed labelling changes in relation to FSANZ's obligations under the FSANZ Act. The submitter commented that labelling requirements: • will impair public health and safety if industry stops innovating due to lack of return on investment because it is unable to communicate its innovations (section 18(1)(a) protection of public health and safety). • will impair the provision of adequate information to enable caregivers to make informed choices e.g. not able to use acronyms such as DHA, probiotic, a2 Milk and provenance representations about milk (section 3(c) and section 18(1)(b) provision of adequate information). • may lead to misleading or deceptive conduct and/or a decrease in the promotion of fair trading in food e.g. a2 Milk, use of	DAN	FSANZ has assessed the proposal and developed and approved the draft variations in accordance with the FSANZ Act, including section 18 and 59 of that Act . See section 6 of this report, FSANZ's assessment against the objectives in subsections 18(1) and 18(2) of the FSANZ Act at approval is outlined in section 6.5 and 6.6. of this report. The specific labelling concerns identified by the submitter have been addressed above in the relevant sections of this table, noting that FSANZ's position has changed on some of these issues following consultation.

Issue	Comment	Submitter(s)	FSANZ response
	scientific nomenclature to describe LAM (section 18(1)(c) prevention of misleading or deceptive conduct; and section 18(3)(d) promotion of fair trading in food). • will further increase technical barriers for export and negatively impact the ability to compete in global markets e.g. differences in existing labelling requirements compared with export countries (section 9(1)(b)(i-ii) and section 18(2)(d) promotion of fair trading in food). • may mean that the latest science is not available if there is no opportunity for a return on investment from research and innovations and could lead to manufacturers deciding to exit the domestic market. • are inconsistent with claim restrictions, particularly ingredient statement restrictions, that apply in other international standards. • negatively impact the ability to have an efficient and internationally competitive infant formula product industry, ultimately resulting in depriving consumers the ability access products which benefit from innovation that will continue to be available outside Australia and New Zealand.		
	(2) Ministerial Policy Guideline on the Regulation of Infant Formula Products This submitter considered Proposal P1028 limits the objective of the High Order Policy Principle 1(b) to provide adequate information relating to food to enable consumers to make informed choices. They considered it is vital that labelling requirements for all IFP including IF, FoF and SMPPi allow for sufficient provision of information to ensure informed choice. The proposal limits consistency between domestic and international food standards by further restricting the ability of products	DAN	Three Ministerial Policy Guidelines apply to Proposal P1028: • Regulation of Infant Formula Products (MPG 2011) • Intent of Part 2.9 – Special Purpose Foods (MPG 2009) • Nutrition, Health and Related Claims (MPG 2003) At each stage of this Proposal, FSANZ had due regard to each Ministerial Policy Guideline, including when approving the draft variations – see section 6.6 of this report. In particular, appropriate regard was had to the objective relating to enabling consumers to make informed choice – see, for example, section 6.5.2 of this report and 10.2.2 of the 2nd CFS (FSANZ 2023a).

Issue	Comment	Submitter(s)	FSANZ response
	manufactured in Australia and New Zealand to provide information to consumers.		See also the responses on informed choice throughout this report. More broadly, FSANZ considers these Ministerial Policy Guidelines have been addressed in its assessment for the reasons summarised in this report (after consideration of submissions), the 2nd CFS and the SDs. SD6 to the 1st CFS (FSANZ 2022i) included detail on FSANZ's assessment against the Ministerial Policy Guidelines.

Section 8: Costs and benefits and transition period

The following comments relate to the costs and benefits and the transitional arrangements proposed by FSANZ.

Summary of comment	Submitter(s)	FSANZ response to comment
General comments on the cost and benefit analysis		
This submitter stated that a DRIS must be prepared and highlight the unintended consequences of this proposal (including reduced innovation and less availability, less choice, less access and higher prices for SMPPi).	DAN	A DRIS was prepared and can be found at SD2. After consideration of submissions, FSANZ's view remains that, relative to the status quo, there is unlikely to be a reduction in innovation, or access to/availability of products. Potential impacts on consumer choice and prices are discussed in the DRIS.
This submitter requested to see a more detailed break-even analysis as it becomes available in order to support informed ministerial decision-making.	VIC DoH & DEECA	The break-even analysis was updated for the DRIS, using the best available evidence.
These submitters stated that the problems (as defined by FSANZ) with the standard are not small, but they are numerous.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	Noted, FSANZ has removed this sentence.
These submitters supported the assessment that the Code is out of date with current scientific knowledge for some issues, not harmonised with international regulations and difficult to interpret in some areas.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	Noted.
This submitter did not agree with the heading 'Population health benefits from promoting breast milk, rather than substitutes.' Breast milk and infant formula products are needed to serve the needs of different categories of infants. The heading implies that no population health benefits will result from substitutes. This is not correct and inconsistent with FSANZ's own stated view.	DAN	FSANZ notes that the intended meaning of the heading was that population health benefits from the promotion of breast milk. It was not the intention to say that there are no health benefits to infant formula, as noted this is not FSANZ's view. This section is not used in the DRIS.

Summary of comment	Submitter(s)	FSANZ response to comment
This submitter stated that formula-fed infants require extra protection from any possible long-term health impacts of unnecessary consumption of infant formula products.	QLDH	The DRIS notes that because infant formula may be the only source of nutrition for some infants, there is a greater level of risk to be managed compared to other population groups.
These submitters did not agree with the statement in this section that labelling a product for 'colic' or 'anti-reflux' is a prohibited health claim.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	This issue has previously been explored and consulted on. FSANZ disagrees noting the reasons provided previously in the discussions within section 5.2.2 in SD3 to the 1st CFS (FSANZ 2022e) and repeated in section 8.3.1 in SD3 to the 2nd CFS (FSANZ 2023d). After consideration of submissions received, FSANZ is not aware of any evidence to warrant a change in its position on this issue. However, if these products are positioned as SMPPi, other labelling requirements will apply including the requirement for a mandatory statement indicating the medical purpose of the food.
Conclusion of the cost and benefit analysis		
This submitter supported the conclusion that the benefits will outweigh costs.	AFGC	Noted.
These submitters stated that benefits in the long run (10 years) could be marginally higher than costs (noting the below caveat on restricted sale and provenance statements).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	Noted.
These submitters stated that if restricted sale and restrictions on provenance statements remain as part of the proposal, it is unlikely benefits will outweigh costs.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ has amended the primary variation to remove the restriction on provenance statements.
This submitter stated that benefits will only outweigh costs in the long run (10 years) if the restriction on provenance related labelling statements are removed.	NZFGC	See above comment.

Summary of comment	Submitter(s)	FSANZ response to comment
Transitional arrangements		
These submitters did not support the five-year transitional period because it is too long.	WA DoH, QLDH	FSANZ's assessment is that the transition period strikes an appropriate balance between the impact on industry arising from needing to make numerous changes to numerous products and delaying some of the benefits. For further detail on FSANZ's rationale for this transition period, refer to section 7 of this report and the DRIS.
This submitter recommended that a combined stock-in-trade and implementation period is no longer than three to four years. This time frame is provided with the consideration that most products have a two-year expiry date and time will be required for manufacturers to reformulate infant formula products.	QLDH	See above comment.
These submitters stated that a five year transition will create an unnecessarily extended period of regulatory crossover and may cause confusion or uncertainty among caregivers, medical professionals and regulators.	VIC DoH & DEECA, QLDH	See above comment.
This submitter stated that certain non-dairy infant formula would continue to be able to be sold for up to five years. This period appears contradictory to the potential public health and safety risks (identified for this group of products) discussed in the 2nd CFS.	QLDH	After consideration of submissions, FSANZ decided not include rice or other plant-based proteins in the prescribed protein source due to the lack of evidence available to assess comprehensively rice protein for use in infant formula and follow-on formula (FSANZ 2023a). If a potential public health or safety risk with a non-dairy infant formula on the Australia and New Zealand market has been identified, FSANZ encourages jurisdictions to investigate or take further compliance action, as the Food Acts in each state and territory require food to be safe and suitable, irrespective of the prescribed requirements in the Code.

Summary of comment	Submitter(s)	FSANZ response to comment
These submitters stated that by the time a five-year transition period takes full effect there may be significant advancements in infant formula products over this time where the revised standard is no longer fit for purpose.	VIC DoH & DEECA	Regarding the length of the transition period, see above comment. Any application can be made or a proposal prepared at any time during the transition period to amend the Standard if and when required to take account of future scientific developments.
These submitters suggested a shorter transition period of three years in conjunction with stock-in-trade provisions would effectively provide the same five-year transition period (noting shelf life of infant formula may be up to 24 months) but with opportunity for earlier transition where sales volumes are higher and products are sold through sooner.	VIC DoH & DEECA	See comment above in relation to the transition period.
These submitters suggested there should be a five-year transition period plus two years stock-in-trade.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC	See comment above in relation to the transition period.
This submitter stated that they would agree to a compromised transition period in which infant formula products can be sold either compliant the Code as it currently stands, or the Code as amended by the draft variations.	AFGC	Noted.
This submitter stated that transitional arrangements should be extended further. Relevant authorities will need to consider how to communicate these regulatory changes to health professionals, pharmacies and consumers during this five year transition period.	NZ MoH	See comment above in relation to the proposed transition period. To complement the gazettal of the regulatory changes, FSANZ – in cooperation with jurisdictions - will undertake extensive targeted communication activities with key stakeholders and provide information for the broader community. FSANZ will ensure comprehensive information for consumers and industry about the changes in advance of them coming into effect.
These submitters recommended a communication plan be developed and implemented by FSANZ and the jurisdictions to proactively inform consumers and heath care professionals.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ notes that a comprehensive communication plan has been developed to compliment the approval report package. See section 8.27 for more detail.

Summary of comment	Submitter(s)	FSANZ response to comment
These submitters stated that a risk for industry is that consumers believe that individual businesses have chosen to make wholesale changes when that is not the case. The changes are due to regulatory requirements. Consumers are not always accepting of change in this product category.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	See above comment.
The benefit of improved infant health		
This submitter agreed that clearer preparation instructions benefits consumers.	DAN	Noted.
These submitters stated that the proposal lowers overall health of infants relative to other markets, because the proposal reduces the incentive to innovate by restricting composition and labelling, resulting in lesser quality formula relative to what is available in other markets.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ does not agree that the proposal reduces the incentive to innovate any more than the status quo. The 'restrictiveness' of the standards relative to other markets has not changed.
This submitter stated that the labelling requirements will result in market participants (with proprietary rights) withdrawing improved products based on the latest science to the Australian and New Zealand market due to a lack of return on investment.	DAN	The changes to the labelling requirements are designed to clarify the existing intent of the Code. While the potential impact is noted, any potentially withdrawn products do not meet the intent of the existing Code due to their label. The Office of Impact Analysis guidance does not consider clarifying the intent of existing regulations as having a regulatory impact because the impact of the regulation would have been considered at the time the regulation was created.
Potential for lower cost infant formula products		
This submitter stated the price of infant formula may be lower in the short term only, because industry will be unable to differentiate products, then infant formula will become a commodity leading to price competition.	DAN	FSANZ considers infant formula products are unlikely to become a commodity. There are many existing ways that products are currently differentiated, including through branding (both existing company- or product-specific branding) or product attributes like optional ingredients (which can be listed on the NIS). Differentiation of attributes is therefore likely continue to result in differently-priced products in the market.

Summary of comment	Submitter(s)	FSANZ response to comment
This submitter stated that prices may increase in the longer term. As observed in other commoditised products, companies adjust to the pricing strategies of others in the industry, potentially leading to cartels or price gouging.	DAN	See above comment.
This submitter did not agree with the assessment that costs will be lower. Refer to IQVIA research (*submitted to FSANZ in response to the 2nd CFS by INC*) which suggests higher costs at pharmacies.	NZFGC	After consideration of submissions, FSANZ's assessment remained that overall prices of infant formula products will be lower, primarily due to manufacturing cost savings. The size of this effect is unclear. Some caregivers may also stop purchasing SMPPi for their infant (substituting infant formula) potentially resulting in savings for this set of consumers as general formula is typically lower priced than SMPPi. This is discussed in the DRIS. FSANZ considered the IQVIA research before making its decision. In FSANZ's view the research does not conclusively demonstrate that prices will be higher for the average consumer who purchases SMPPi at pharmacies. This is for a number of reasons: • The data was collected under the status quo, but increasing demand (as a result of restricting sale to pharmacies) may result in lower SMPPi prices at pharmacies under the proposal. • Supermarkets sell a limited range of the most in-demand SMPPi. Pharmacists can sell any infant formula products requested by carers. Therefore, the pharmacy sales data may include lower-demand products that are not subject to the same level of price competition which may have increased the average price paid per consumer. • Consumers are expected to (in most cases), purchase SMPPi at large pharmacies. Data collected by FSANZ indicates that large pharmacies and large supermarkets (where a significant majority of SMPPi is sold) sell SMPPi for the same price. This point is discussed in the DRIS in more detail (SD2 of this report).

Summary of comment	Submitter(s)	FSANZ response to comment
Improved comparability of infant formula products		
These submitters challenged the assertion that all proposed labelling changes provide the benefit of comparability between products.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ notes the potential for some aspects of the changes to reduce comparability. This is noted in section 6.3 of the DRIS. However, FSANZ concluded that comparability will be enhanced overall.
These submitters stated that the benefit of comparability identified in SD4 of the 2nd CFS will be offset by removing commonly understood terms from labels.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, CCI submission	This impact was noted in section 6.3 of the DRIS (SD2 of this report). FSANZ concluded that comparability will be enhanced overall.
These submitters stated that there is no evidence acronyms pose any different level of confusion when compared to full biochemical terms.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	The evidence cited by an industry submitter was a qualitative study in which caregivers were asked to rank how useful various labelling elements were to their infant formula purchasing decisions. They reported finding both abbreviations and the full names of ingredients difficult to understand (see section 4.18.3 in this report). There is no specific evidence relating to caregivers' understanding of acronyms compared to the full name. However, FSANZ has changed its approach to permit the optional addition of acronyms in the NIS for the specified fatty acids. This is discussed in section 4.18 of this report.
This submitter stated that comparability will be reduced by removing signifiers of quality (like provenance statements).	DAN	Provenance statements (or country of origin labels) are not regulated under the Code. However, the primary variation will permit the word 'milk' to be used on the label outside of the statement of ingredients. This will allow consumers to compare the origin of ingredients (for example New Zealand milk) where this information is provided (or not provided) by manufacturers.
This submitter stated comparability will be reduced for SMPPi where pharmacies have limited shelf space and do not stock all products to enable comparison.	DAN	Advice to FSANZ is that caregivers will be able to discuss and compare products with their pharmacist, even where that pharmacist does not have the product in stock.

Summary of comment	Submitter(s)	FSANZ response to comment
Health benefits from restricting sale of special purpose products to healthcare settings		
This submitter stated that in bigger pharmacy chains consumers have little engagement with healthcare professionals and are unlikely to speak to retail or floor staff, resulting in no benefit in this circumstance.	DAN	This potential limitation of the changes to the standards was noted in the DRIS (SD2). However, this limitation exists for all pharmacist only products that are not kept behind the counter. However, consumers can still relatively easily get questions they may have answered in this setting by approaching staff.
These submitters provided an IQVIA survey on the most important source of influence for respondents with a child under two years old. Results showed 82% of respondents ranked general practitioners within the top three most influential, while only 30% ranked pharmacists within the top three. This shows pharmacists may not currently play a significant advisory role in SMPPi for caregivers, limiting the effectiveness of removing products from grocery stores.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ notes the survey data. However, ranking of sources of advice in terms of influence is not a measure of the value of advice received. The survey data is also reflective of current practice, where medica formulas are sold in grocery retailers where no medical professionals have the opportunity to provide advice. See the above response and section 4.3 of this report.
This submitter stated that the benefit will be limited where products are no longer available to consumers in the grocery channel and they choose to buy products online. Disclaimers on websites will have a limited impact on this issue, as they are not necessarily read.	DAN	The DRIS (SD2) noted situations where the benefit of health advice may be limited, including when shopping online. However, there is a likelihood that these sales will only be for subsequent purchases after the consumer has sought advice on the appropriateness of a product for their child.
Other potential benefits for consumers		
This submitter stated that consumers may turn to online international sources of products they are no longer able to access in store, increasing convenience and accessibility for required products.	DAN	Consumers may purchase products online from international sources, however FSANZ expects that few consumers, if any, will do this. Trust and safety is especially important for infant formula products, making it unlikely that consumers will import non-compliant infant formula products. Therefore this benefit is not expected to occur.
Other potential costs for consumers		

Summary of comment	Submitter(s)	FSANZ response to comment
This submitter stated that industry may choose to reduce the range and number of infant formula market SKUs available for the domestic and export market, thereby reducing the choice available to the consumer.	DAN	FSANZ notes that the potential for products to be withdrawn was detailed and considered in the DRIS (SD2).
Impacts of restricting the sale of SMPPi		
These submitters stated that the impacts of restricted SMPPi sales have been severely understated/minimised by FSANZ.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC	After consideration of submissions, FSANZ's assessment remains that there will be minimal negative impacts on consumers resulting from restricting the sale of SMPPi, in addition to some positive impacts. For more details, refer to the DRIS (SD2).
These submitters stated that restricting sales of SMPPi (for issues like regurgitation, colic and constipation) will have negative health effects for infants (by limiting where and when the products can be accessed) and caregivers (through panic, confusion, mental anxiety).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, WW	After consideration of submissions, FSANZ's conclusion remains that caregivers will not have difficulty accessing SMPPi. Therefore there will not be negative health impacts. This is discussed in detail in the DRIS (SD2). In addition, advice from pharmacists on managing health concerns will resolve caregiver panic, confusion or anxiety.
These submitters stated that the impacts (outlined above) of restricted sales are more pronounced in New Zealand with the majority of SMPPi volume sales (76%) sold through grocery stores.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ presented statistics for both New Zealand and Australia in the DRIS (SD2), highlighting the differences between the two markets. As noted in the DRIS, other data provided in the IQVIA report provides further context for the relative difference in impact between Australia and New Zealand. SMPPi sales are a much smaller proportion of infant formula sales in New Zealand, meaning the proportion of caregivers impacted is lower in New Zealand. In addition, no 'milk allergy' products (as defined in the IQVIA report) are sold in New Zealand supermarkets, meaning this stakeholder group is not impacted (where Australian caregivers are).
These submitters stated that moving SMPPi from the grocery channel to the pharmacy channel will mean less availability (in terms of product range), less choice, likely higher prices and less access (due to store locations and opening hours).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC, NES, WW	FSANZ however does not agree with the conclusion that there will be less choice and higher prices for consumers. The reasons are discussed in the DRIS (SD2).

Summary of comment	Submitter(s)	FSANZ response to comment
This is due to pharmacies (relative to supermarkets) having less shelf space, less warehousing and logistics not designed for Fast Moving Consumer Goods (FMCGs).		In addition to the commentary in the DRIS, FSANZ notes that the features listed of the grocery channel are only true for large supermarkets. Small supermarkets have less shelf space, limiting range and choice. The smaller customer base they serve typically means that they have higher prices. Large pharmacy chains stock the same SMPPi range as large supermarkets and in some cases, given their role as specialist healthcare providers, may stock a greater range than some large supermarkets. Data collected by FSANZ from retailer websites for products sold at both supermarkets and large pharmacies shows (at the time of analysis) that the pharmacy price was commonly lower than the supermarket price. Choice will not be reduced at any pharmacy (small or large), as pharmacies are able to order in any infant formula product that they currently do not stock, as is the case under the status quo.
This submitter stated that customers need reasonable access to SMPPi outside of the regular trading hours available at other retail outlet options and provided data to show 34.6% of SMPPi are sold outside of 9 am to 5 pm trading hours and that the most common day to purchase SMPPi is Sunday.	WW	FSANZ directs submitters to data presented on this topic in the DRIS. FSANZ does not agree that consumers will lose reasonable access to SMPPi, for the following reasons: • some consumers will substitute with general formula (for example, after seeking advice) • some will already be visiting the pharmacy for other health needs • many pharmacies trade outside of 9 am to 5 pm as well as on weekends • consumers will be able to purchase the products online at any time of day.
This submitter stated that reducing accessibility for caregivers may also further add to the stress that often comes with caring for infants where they are unwell. It is of significant practical assistance and reassurance to many	WW	FSANZ notes in many cases a carer's 'local' supermarket may be too small to carry the specific SMPPi a carer needs and many pharmacies are open 'after-hours'. Where an infant is unwell, seeking the advice of a health professional may lead to better outcomes for the infant and carer.

Summary of comment	Submitter(s)	FSANZ response to comment
caregivers to know that convenient after-hours access is available at a local supermarket.		
These submitters stated that according to the submitted IQVIA report, removal of the grocery channel necessitates transition of approximately 70,000 cans of SMPPi into pharmacies in Australia and 77,000 in New Zealand.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	The quantity of SMPPi sold in supermarkets was noted in the DRIS.
These submitters stated that in Australia, grocery sales account for 63% of volume sales for reflux/regurgitation products, 55% for colic/constipation products and 61% for sensitivity/intolerance products. In New Zealand, grocery accounts for 93% volume sales of reflux/regurgitation, 88% of colic/constipation and 85% of sensitivity/intolerance (IQVIA report).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	The DRIS referenced the proportion of SMPPi sold at pharmacies, by product type, which is another way of representing this statistic.
These submitters stated that in Australia, 80% of SMPPi unit sales are in 807 pharmacy outlets, despite 3,807 outlets registering at least one can of SMPPi sale in the last year. In New Zealand, 80% of SMPPi unit sales are in 80 pharmacy outlets, while 346 outlets registered at least one can of SMPPi sale in the last year (IQVIA report).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	This statistic was used in the DRIS.
These submitters stated that caregivers living in Queensland, Tasmania and Northern Territory/South Australia will likely be most impacted by the proposed restriction on sale, where grocery accounts for 54%, 53% and 51% of total SMPPi volume sales, respectively (IQVIA report).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	The DRIS did not go into a state by state breakdown. The potential for difference between jurisdictions is noted.
These submitters stated that in New Zealand, the lower North Island and the South Island have the highest proportion of affected population, predominately living in urban areas (IQVIA report).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	As above, the DRIS did not break down the results on a regional basis, however the potential for difference between jurisdictions is noted.

Summary of comment	Submitter(s)	FSANZ response to comment
These submitters stated that the distance travelled by caregivers to access products may increase. 483 Australian grocery outlets lack a pharmacy within 1.5 km driving distance, affecting 398 postcodes with impeded access. For 24 of these grocery outlets, the nearest pharmacy is more than 10 km away. In New Zealand, 320 grocery outlets lack a pharmacy within 1.5 km driving distance, affecting 203 postcodes with impeded access. For 118 of these grocery outlets, the nearest pharmacy is more than 10 km away. (IQVIA report).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NES	FSANZ did not include this aspect of the IQVIA analysis in the DRIS. The reason the IQVIA analysis was not included is that it only considers the distance between Coles and Woolworths stores and the nearest pharmacy. It does not consider the home location of the caregiver. The caregiver may have a pharmacy on the way to/from the supermarket, or may already be visiting a pharmacist for other needs. Government polices (such as the Australian Pharmacy Location Rules) and commercial incentives mean that pharmacies are situated in locations the majority of the population can access within a reasonable distance.
These submitters stated that in New Zealand there is a 60 hour difference between pharmacy opening hours and grocery opening hours, where SMPPi will be unavailable (IQVIA report).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	This statistic is noted, however: • not all pharmacies have limited hours • many consumers may be visiting a pharmacy for other health needs during opening hours • products will be able to be ordered online.
These submitters stated that in Australia, SMPPi were priced approximately 6% higher in pharmacies compared to groceries, an additional cost of $94 for the first year of an infant's life. In New Zealand SMPPi cost an average of 3% more in pharmacies compared to groceries and this price difference increases to 7% in the South Island. This is an additional cost of $61 for the first year of an infant's life (IQVIA report).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ notes the current difference in price between SMPPi sold in supermarkets and pharmacies. FSANZ refers these submitters to the commentary above on why this price difference was not used in the cost analysis. It should also be noted that if consumers are appropriately directed to products that are suitable for their child this may result in savings.
This submitter stated that those who require emergency relief assistance and depend upon supermarket vouchers to be able to access essential foods and household items. These changes may impact on the ability of vulnerable populations to access at times of need.	WW	FSANZ notes this comment. However, the changes to the standard treat infant formula consistently with other food for special medical purposes. Therefore, the potential for this issue to occur already exists for other medical purpose foods. This issue already exists under the status quo, where infants are fed formula that is not sold at supermarkets (due to the sale of these products being commercially unviable). Note that small supermarkets (found in rural areas more likely to experience floods and bushfire) stock small ranges of products under

Summary of comment	Submitter(s)	FSANZ response to comment
		the status quo due to their small size, limiting the scope of this issue to cities.
These submitters stated that the restriction on sale will have impacts on rural and remote communities and is therefore inequitable. Some caregivers would not have access to some SMPPi in the pharmacy channel.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, WW	FSANZ however did not agree that restricting the sale of SMPPi is inequitable for consumers in rural and remote communities. This is because in these communities SMPPi are already difficult to access (relative to larger communities) under the status quo. Supply of SMPPi is limited in rural areas under the status quo as small supermarkets do not stock a complete range of SMPPi. Pharmacies will be able to order any SMPPi, if requested and products will be able to be ordered online. The impact on rural and remote communities is discussed further in the DRIS (SD2).
These submitters stated that restricted sales will result in some products exiting the market, limiting choice to consumers.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ notes that the potential for this impact was addressed in the DRIS.
This submitter stated that if SMPPi are not available some caregivers may substitute inappropriate products (for example, products designed for adults) for infant formula.	AFGC	FSANZ notes that SMPPi are to be used under medical supervision and typically infants that require these products would be seen by a medical professional on a regular and ongoing basis. Because of this, FSANZ considered this suggestion that caregivers may substitute SMPPi for adult products to be unrealistic. FSANZ also notes there was no evidence provided to substantiate or support this possibility.
This submitter stated that additional pressure will be placed on supermarket staff to explain why products are no longer available on supermarket shelves. Staff do not have expertise in answering these queries.	WW	This impact is noted. This has not been included in the impact analysis, as it is a relatively minor issue. Supermarkets and other retailers could instruct staff to advise caregivers to contact the manufacturer or direct caregivers to a pharmacy. It is not a typical expectation that supermarket staff would be providing advice on infant formula.
These submitters stated that FSANZ's online sales assumptions need correcting. Less than 5% of Australian consumers have switched to ordering most or all of their groceries on the internet.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC	This was corrected in the DRIS.

Summary of comment	Submitter(s)	FSANZ response to comment
Benefits to industry from greater alignment with international standards		
These submitters agreed that Proposal P1028 does achieve greater harmonisation with international standards, which will benefit manufacturers.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC, CCI submission	Noted.
This submitter stated that the proposal does not achieve harmonisation for all inputs to base powder, resulting in cost inefficiencies.	DAN	The analysis (at 2nd CFS) noted that full harmonisation will not occur and that the benefits are a result of improved harmonisation. This conclusion remains in the DRIS.
This submitter stated that in some international markets, HMOs are added to infant formula products where industry is able to communicate that its products contain these ingredients. Australia and New Zealand is out of step with this permission, decreasing cost efficiencies.	DAN	Infant formula products containing permitted HiMO are prohibited from using HMO terminology or related abbreviations. The prohibition was proposed under Application 1155 - 2-FL and LNnT in infant formula and other products, through an independent, statutory assessment. FSANZ notes the presence of these substances may be communicated using another name such as the scientific name.
A CCI submission argued that while FSANZ has extended additive permissions in the Code to alleviate the impact of the removal of the carry over principle, there remain some additives present as carry over additives that are not covered by the draft variation. As a result, the costs for industry will increase, with a risk to product supply.	CCI submission	FSANZ has adopted several EU/Codex food additive permissions, following the removal of the carry over principle. The adoption of these permissions allows use of important nutrient preparations in infant formula products and therefore avoids unnecessary reformulation with consequential added costs.
Impacts on soy based infant formula manufacturers		
These submitters stated that the cost of meeting the lower permitted aluminium levels in soy formula as not been sufficiently considered.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ has reconsidered this issue and there will be no change to the permitted aluminium levels for soy-based infant formula products (the status quo will continue). As submitters have stated (in the next comment) industry is either not able to meet the proposed aluminium contaminant level, or if it is able to meet the specification, it will be at greater cost.

Summary of comment	Submitter(s)	FSANZ response to comment
This submitter stated that due to natural variation in aluminium in soy ingredients industry is either not able to meet the proposed aluminium contaminant level, or if it is able to meet the specification, it will be at greater cost.	DAN	See above response.
Increased cost of goods due to reduced competition between manufacturers		
This submitter stated that if competition between manufacturers of finished goods decreases (due to the proposal), demand for base powder will decrease, reducing demand for ingredients to base powder. This may result in a higher cost of final goods and job losses.	DAN	FSANZ notes it is not clear from available information that this is a likely consequence.
Reformulation costs for manufacturers		
These submitters stated that the estimates for the quantifiable costs to industry are good estimates.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC	FSANZ notes that the estimated cost per SKU used in the 2nd CFS (referred to in the comment) was used in the DRIS.
A CCI submission noted that the cost estimated is lower than the submitter's costs, however supports the cost being used as a general indication.	CCI submission	See above.
A CCI submission stated that reformulation of infant formula products could most likely trigger reformulation of formulated supplementary foods for young children (FSFYC) for technical or commercial reasons. This also results in relabelling costs for impacted FSFYC products.	CCI submission	The DRIS noted the potential impact on FSFYC. FSANZ notes that the reformulation of FSFYC will only be considered a regulatory impact (and therefore a cost impact for the proposal) where there is a forced change to the manufacturing of FSFYC products. For example, if the products share a base powder which is no longer able to be used in infant formula products, forcing a change in the FSFYC base powder. FSANZ does not consider there to be a regulatory impact where an ingredient is removed from FSFYC after it is no longer able to be used in infant formula products. While there may be a cost change (reduced economies of scale for buying or using the ingredient), this cost change

Summary of comment	Submitter(s)	FSANZ response to comment
		is a secondary impact and it is not clear from available information that this is a likely consequence.
Re-label cost for manufacturers		
These submitters stated that the estimates for the quantifiable costs to industry are good estimates.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC	Noted.
A CCI submission supported $16,000 per SKU as a reasonable assumption. This cost would include resourcing and any write-off costs for existing packaging on hand at the time of the change.	CCI submission	Noted.
A CCI submission stated that relabel cost per SKU can range from $8000 to $20,000.	CCI submission	For the DRIS, FSANZ measured the relabelling costs as a range between $8400 and $16,000. The reasons why are explained in the DRIS (SD2).
A CCI submission confirmed that all infant formula products will need relabelling (as was stated in the analysis).	CCI submission	Noted.
A CCI submission noted that some products are packaged in both sachets and tins, which both require relabelling.	CCI submission	The updated relabelling costs in the DRIS took this into account. The cost estimate for these products included the cost of updating the tins, the sachets and the box the sachets are contained in.
This submitter stated that the cost benefit analysis should note multi-label change as a cost.	AFGC	FSANZ assumed that manufacturers will minimise relabel costs and make only one label change.
Cost of exporting products from New Zealand		

Summary of comment	Submitter(s)	FSANZ response to comment
These submitters stated that being issued with an exemption from the *Food Act 2014* (NZ) from the compositional requirements of the Code is costly and time consuming and would limit those products from being sold into the domestic market (where necessary). This impacts on New Zealand businesses disproportionately.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, NZFGC	This issue was considered in the DRIS.
A CCI submission noted there is no blanket exemption from the labelling requirements of the Code for infant formula products exported from New Zealand. Manufacturers must also comply with the Animal Products Act Notice for Infant Formula Labelling. The requirements currently mimic the FSANZ labelling requirements, as such, changes to the FSANZ Code could introduce further restrictions on export product labelling, limiting industry's ability to make ingredient statement on labels.	CCI submission	These requirements were noted in the DRIS. However, the Notice requirements are separate to the Code and changes to the Code do not automatically result in changes to the Notice requirements. Changes to the Notice requirements are a matter for the New Zealand government.
Cost of prohibited representation		
These submitters stated that the restriction on ingredient statements (e.g. made from New Zealand milk) is a significant potential cost, which was not considered by the cost benefit analysis.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	FSANZ provided the rationale for generally prohibiting a reference to ingredients in section 6.3.5 of SD3 to the 1st CFS (FSANZ 2022e). Such references are considered contrary to Ministerial Policy Guidelines. After consideration of submissions, FSANZ's conclusion at approval remains unchanged – with one exception. FSANZ is now permitting the word 'milk' to appear elsewhere on the label. This will enable manufacturers to continue to make provenance statements about milk.
This submitter stated that the prohibition on provenance statement disadvantages New Zealand manufacturers in overseas markets where such restrictions are not placed on our in-market competitors who manufacture in other jurisdictions.	NZFGC	Refer to previous response.
Impact on industry of restricting sale of special purpose infant formula		

Summary of comment	Submitter(s)	FSANZ response to comment
These submitters stated that sales lost by supermarkets (where consumers do not substitute with infant formula) will not be gained by pharmacies in all cases. Some products will not be stocked and some products will be withdrawn (not commercially viable).	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	The evidence available to FSANZ is that most large pharmacies will stock a complete range of products. Where a product is not stocked, a pharmacist can order the product on request. The potential for some products to be withdrawn was noted in the DRIS.
This submitter stated that the loss of SKUs on shelf may drive consumers to source products online from international retailers.	DAN	It is unclear whether this comment refers to the loss of SMPPi sales, or sales of non-IF products that consumers buy with infant formula. As noted in response to an earlier comment, FSANZ does not expect a significant number of consumers would source a product like infant formula from international sources. Loss of sales of other products is a secondary impact which is not typically analysed in cost benefit analysis. As indicated, it is not clear from available information that this will be a likely or possible consequence.
These submitters stated that restricted sales will result in some products exiting the market, resulting in a cost to industry. This could result in manufacturing being moved offshore, reducing employment in Australia and New Zealand.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	The potential for some products to exit the market was considered in the DRIS. Having regard to the DRIS, and after consideration of submissions, FSANZ does not expect the net demand for infant formula products to change as a result of this proposal, therefore there will be no net impact on manufacturing.
Costs for specialised retailers (including pharmacies)		
This submitter stated that other retailers (including pharmacy) will experience costs in order to sell SMPPi, for example logistics, warehousing, greater online presence.	DAN	FSANZ notes that this not a regulatory impact, it is a business investment made in expectation of a financial return. Extending this argument, supermarkets will now also save on these cost.
This submitter stated that where other retailers (including pharmacy) do not make the required investment to sell more SMPPi, they will lose revenue. Consumers may choose to purchase products from international retailers rather than local retailers.	DAN	See responses above.

Summary of comment	Submitter(s)	FSANZ response to comment
Transition costs for industry		
These submitters stated that finished product manufacturers will experience short term increases to calls to hotlines when products change composition, labelling and sales channels.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG	This was considered in the DRIS.
This submitter stated that there will be a cost associated with development and implementation of manufacturer communications to healthcare professionals.	AFGC	This was considered in the DRIS.
Impacts on market access and competition		
This submitter stated that the analysis of costs and benefits only focuses on the impact within the Australian and New Zealand market and does not consider the impact on the export trade.	DAN	The section of the cost and benefit analysis (at 2nd CFS) this comment refers to (market access and competition) was expanded in the DRIS to consider market access to (and competition within) external markets.
These submitters stated that labelling restrictions disadvantage New Zealand and Australian manufacturers in overseas markets (including via cross-border e-commerce in China, daigou) where such restrictions are not placed on competitors which manufacture in other jurisdictions. For example, restrictions on country of origin of ingredients claims and restricting information to the front of the package.	INC, SML, DAN, DCANZ, A2M, AFGC, FCG, DCANZ, NZFGC, A2M, CCI submission	FSANZ has decided to permit the word 'milk' to appear outside the statement of ingredients. This permission will enable manufacturers to continue to make provenance statements about milk. Limiting certain information to appearing on the front of the package enables it to be displayed without it constituting a prohibited claim. The standard is being clarified to better reflect existing claim prohibitions in the Code and the Ministerial Policy Guidelines on the *Regulation of Infant Formula Products* and *Nutrition, Health and Related Claims*. Locating required information (for example, the protein source) on the front of the package will assist consumers to make informed choices and select infant formula products that are appropriate for their infants. However, stage numbers will now be permitted elsewhere on the label.
A CCI submission stated that labelling restrictions disadvantage the Australian and New Zealand subsidiaries of global companies. Subsidiaries in other markets may be chosen by the head companies to manufacture products for export (that could have been made in Australia or New	CCI submission	As stated above, the standard is being updated to better reflect existing claim prohibitions in the Code and the Ministerial Policy Guidelines on the *Regulation of Infant Formula Products* and *Nutrition, Health and Related Claims*

Summary of comment	Submitter(s)	FSANZ response to comment
Zealand) due to their ability to make more claims on product labels. This impact is mitigated to an extent by exemptions for labelling requirements for export products (in markets other than China).		In addition, this issue exists under the status quo. The Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children also places a number of labelling restrictions on New Zealand exporters. The Notice remains a matter for the New Zealand Government.
This submitter stated that New Zealand imports 30–40% of infant formula inputs.	NZFGC	This statistic was taken into account by the DRIS.
This submitter stated infant formula exports from New Zealand are around 141,000 t or $1.93 billion.	NZFGC	This statistic was taken into account by the DRIS.
Potential increased compliance costs for industry		
This submitter stated the proposed prohibition would introduce considerable uncertainty about the scope of the amended food labelling regime and thereby increase the costs of compliance by industry, by not defining what is considered information when prohibiting 'information relating to ingredients'.	A2M	FSANZ noted previously that the ordinary meaning of 'ingredient' would apply and considers it unnecessary to define the term for this purpose (item B7 in Table 5 of SD3 in the 2nd CFS; FSANZ 2023d). The regulatory intent is to prohibit references to any ingredient, nutritive substance, nutrient or other substance outside the statement of ingredients or in the NIS, unless expressly permitted. This regulatory approach supports the prohibition of claims and the Ministerial Policy Guidelines on the *Regulation of Infant Formula Products* and *Nutrition, Health and Related Claims*
Healthcare savings for governments		
This submitter stated healthcare savings will not materialise because there are systemic issues in healthcare that affect access, availability and affordability.	DAN	FSANZ notes that these issues do not prevent a benefit being realised.

Summary of comment	Submitter(s)	FSANZ response to comment
This submitter stated that the proposed regulatory technical barriers create a reputation that local conditions for infant formula product research and development have ceased to exist. This will drive investment offshore because the conditions for trade and innovation are not optimised, let alone efficient.	DAN	FSANZ notes that aspects of the variation that restrict what can be put on labels are existing government policy; the variation re-confirms this existing policy.
Improved ability to enforce standards		
This submitter stated the ability to enforce standards will not be improved because there will still be diversity in enforcement regimes and approaches.	DAN	FSANZ expects that individual governments will have a greater ability to enforce the standard within their jurisdiction (and jointly within the food regulatory system) as a result of clearer drafting.
Cost impacts for governments		
This submitter stated that the public health implications of unnecessary consumption of infant formula products need to be placed more squarely at the forefront and considered as contributing to the overall cost to both community and government. Currently, annual global losses in unrealised health and human development benefits associated with inadequate breastfeeding protection, promotion and support are currently estimated at US$341.3 billion.	QLDH	FSANZ does not expect this proposal to significantly increase (or decrease) demand for infant formula products and therefore does not expect it to have a significant impact on breastfeeding rates. In FSANZ's view, the primary driver of demand of infant formula products in Australia and New Zealand are economic or lifestyle factors, rather than factors regulated within the standard. In addition, marketing restrictions prevent industry from increasing the level of demand by highlighting positive changes to products as a result of the proposal. Therefore there will be no change to any cost to governments that may arise from 'unnecessary consumption of infant formula products'.
This submitter stated that the proposal will cause the infant formula market to shrink, resulting in less goods and services tax and income tax revenue, less export revenue, delayed economic recovery post-COVID, job losses (in industry and across the supply chain) and a weaker research and development sector.	DAN	As explained above, FSANZ expects that demand for infant formula products overall will not change. Therefore the listed impacts will not occur.

Summary of comment	Submitter(s)	FSANZ response to comment
This submitter stated that it has been estimated that a one standard deviation fall in innovation by the Australian dairy industry equates to a reduction of AUD$27.5 million in dairy exports annually (approximately 1.4%). A similar decline in innovation would reduce NZ exports by NZD$234.6 million a year (Kollmann et al, 2021).	DAN	FSANZ does not agree that there is no incentive for manufacturers to innovate; this is discussed in relation to other comments above.
This submitter stated that the reduction in social and environmental programmes driven by industry disadvantages communities and the individuals in them as their access to socially beneficial programmes reduce/disappear and measures to improve the environment around them receive less funding and know-how.	DAN	As explained above, FSANZ expects that demand for infant formula overall will not change, therefore the listed impacts will not occur.

Section 9: WTO notification responses

Issue	Comment	Submitter	FSANZ response
Yes, the draft variation is supported.	The submitter supported efforts to ensure products are sold and prepared for their intended and appropriate use through the new SMPPi category.	US Government	Noted.
Facilitation of trade, availability and accessibility.	The submitter enquired whether regulatory approaches had been considered that would facilitate trade, availability and accessibility of SMPPi, noting that US regulation does not restrict sale.	US Government	FSANZ confirms the amendment of Division 4 and the SMPPi category considered trade, availability and accessibility. Division 4 has been constructed to allow for compositional variation and flexible labelling to aid harmonisation with both Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981) and EU regulations. The flexibility granted to facilitate trade and import has been balanced with appropriate risk management strategies such as the restriction on sale. This proposed restriction is aligned with the sale requirements of Standard 2.9.5.As SMPPi are a special medical purpose product for a very vulnerable population, FSANZ considers a restriction on sale important and appropriate. FSANZ acknowledges that this restriction is not applied in the US and may be considered to be internationally inconsistent. However, retail channels operate substantially differently overseas, where pharmacies can be located inside supermarkets and grocery stores. FSANZ also notes the restriction on sale posed by the primary variation would not affect the import or export of these products. Further information is at 4.3 of this report.
	The submitter noted the prohibition on labels of words to the effect of 'human milk oligosaccharide' or 'HMO' and enquired whether FSANZ would consider labelling flexibility to ensure these products are more readily available for infants who need them. The submitter noted that additional labelling and packaging costs may discourage manufacturers from making these products available.	US Government	These prohibitions were included in the Code by A1155 which was assessed in accordance with the Act and notified in accordance with WTO requirements. The prohibitions can be amended at any time by means of an Application or Proposal. In this regard, evidence of an undue effect on trade may be provided to FSANZ at any time and will be considered.

Issue	Comment	Submitter	FSANZ response
	The submitter sought clarification as to whether the minimum amino acid requirements outlined in Division 2, section 2.9.1—6 allow for combined calculations of tyrosine and phenylalanine, as well as combined calculations of cysteine and methionine when appropriate, in accordance with the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981).	US Government	FSANZ confirms that the intention of the draft variation was to allow combined calculations of both of tyrosine and phenylalanine and cysteine and methionine in alignment with Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981; Codex 1981). FSANZ acknowledges that the draft variation to the 2nd CFS did not clearly articulate this. FSANZ is clarifying this aspect of the drafting to ensure alignment is achieved.
	The submitter enquired whether FSANZ would consider harmonising Division 3, section 2.9.1—26(2)(f), which states that the nutrition information required in section 2.9.1—25 must be expressed in a unit quantity 'per 100ml', with the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981) to allow the expression of nutrients per 100 grams as a trade facilitating step.	US Government	FSANZ has considered the expression of nutrients as per 100 grams, in addition to the per 100 mL as prescribed in Division 3, section 2.9.1—26(2)(f) of the primary variation. Please see section 4.17 of this report.

Attachments

A. Approved primary draft variation to the *Australia New Zealand Food Standards Code*
B. Approved consequential draft variation to the *Australia New Zealand Food Standards Code*
C. Explanatory Statement
D. Primary draft variations to the *Australia New Zealand Food Standards Code* (call for submissions)
E. Consequential draft variations to the *Australia New Zealand Food Standards Code* (call for submissions)

Attachment A - Approved primary draft variation to the Australia New Zealand Food Standards Code

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

Food Standards (Proposal P1028 – Infant Formula) Variation

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1 Name

This instrument is the *Food Standards (Proposal P1028 – Infant Formula) Variation*.

2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The instrument commences on gazettal.

4 Effect of the variations made by this instrument

(1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.

(2) During the transition period, a food product may be sold if the product complies with one of the following:

(a) the Code as in force without the variations made by the instruments; or

(b) the Code as amended by the variations made by the instruments.

(3) For the purposes of this clause:

(a) the **instruments** means:

(i) this instrument; and

(ii) the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*;

(b) the **transition period** means the period commencing on this instrument's date of commencement and ending 60 months after the date of commencement.

Schedule

Standard 2.9.1

[1] Sections 2.9.1—2 to 2.9.1—25

Repeal the sections, substitute:

2.9.1—2 Outline of Standard

(1) This Standard regulates various types of infant formula products.

(2) Division 1 deals with preliminary matters.

(3) Division 2 sets out compositional requirements for infant formula and follow-on formula.

(4) Division 3 sets out labelling and packaging requirements for infant formula and follow-on formula.

(5) Division 4 sets out compositional, labelling and restriction on sale requirements for a special medical purpose product for infants.

2.9.1—3 Definitions

Note In this Code (see sections 1.1.2—2 and 1.1.2—3):

follow-on formula means an infant formula product that is represented as:

(a) either a breast milk substitute or replacement for infant formula; and

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

infant formula means an infant formula product that is represented as:

(a) a breast milk substitute for infants; and

(b) satisfying by itself the nutritional requirements of infants under the age of 6 months.

infant formula product means a product based on milk or other edible food constituents of animal or plant origin which is represented as 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.

inner package, in relation to a special medical purpose product for infants, means an individual package of the food that is:

(a) contained and sold within another package that is labelled in accordance with Division 4 of Standard 2.9.1; and

(b) not designed for individual sale, other than a sale by a *responsible institution to a patient or resident of the responsible institution.

Example An example of an inner package is an individual sachet (or sachets) of a powdered food contained within a box that is fully labelled, being a box available for retail sale.

responsible institution means a hospital, hospice, aged care facility, disability facility, prison, boarding school or similar institution that is responsible for the welfare of its patients or residents and provides food to them.

special medical purpose product for infants means an infant formula product that is:

(a) represented as being:

(j) specially formulated for the dietary management of infants who have medically determined nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food); and

(iii) suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product; and

(iii) for the dietary management of a medically diagnosed disease, disorder or condition of an infant; and

(b) intended to be used under medical supervision; and

(c) not suitable for general use.

2.9.1—4 Interpretation

Interpretation of compositional requirements

(1) Unless otherwise expressly stated, compositional requirements in this Standard apply to:

(a) a powdered or concentrated form of infant formula product that has been reconstituted with water according to directions; and

(b) an infant formula product in ‘ready to drink’ form.

Calculation of energy, protein and vitamin A

(2) In this Standard:

(a) energy must be calculated in accordance with section S29—2; and

(b) protein content must be calculated in accordance with section S29—2A; and

(c) vitamin A content must be calculated in accordance with section S29—2B.

Division 2 Compositional requirements for infant formula and follow-on formula

Note Subsection 1.5.1—3(2) provides that an infant formula product for retail sale may consist of, or have as an ingredient or a component, a novel food only if each condition specified in that subsection is met.

2.9.1—5 General requirements

(1) Infant formula and follow-on formula must have an energy content of no less than 2510 kJ/L and no more than 2930 kJ/L.

(2) Subject to subsections (3) and (4), infant formula and follow-on formula must not contain added fructose and/or added sucrose.

(3) Infant formula and follow-on formula manufactured from partially hydrolysed protein may contain added fructose and/or added sucrose, provided that:

(a) the fructose and/or sucrose is added to the formula to provide a source of carbohydrate; and

(b) the sum of the fructose and/or sucrose in the formula does not exceed 20% of available carbohydrates in the formula.

(4) Subsection (2) does not apply to added fructose and/or added sucrose that is present in infant formula and follow-on formula as a result of:

(a) the addition of inulin-type fructans to the infant formula or follow-on formula in accordance with this Standard; and/or

(b) the use of a substance as a processing aid in accordance with this Code in the manufacture of the infant formula or follow-on formula.

(5) The fluoride content of infant formula and follow-on formula must not exceed:

(a) if in a powdered or concentrated form—17 µg/100 kJ; and

(b) if in a 'ready-to-drink' form—24 µg/100 kJ.

(6) The amounts in subsection (5) apply to the infant formula or follow-on formula as sold.

2.9.1—6 Protein requirements

(1) Infant formula and follow-on formula must be derived only from one or more of the following proteins:

(a) cow milk;

(b) goat milk;

(c) sheep milk;

(d) soy protein isolate;

(e) a partially hydrolysed protein of one or more of the above.

(2) Infant formula must have a protein content of:

(a) for milk-based infant formula—no less than 0.43 g/100 kJ and no more than 0.72 g/100 kJ; and

(b) for infant formula that is not milk-based infant formula—no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.

(3) Follow-on formula must have a protein content of:

(a) for milk-based follow-on formula—no less than 0.38 g/100 kJ and no more than 0.72 g/100 kJ; and

(b) for follow-on formula that is not milk-based follow-on formula—no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.

(4) For the purposes of subsections (2) and (3):

(a) ***milk-based infant formula*** means infant formula that is derived only from one or more of the following proteins: cow milk; goat milk; sheep milk; a partially hydrolysed protein of one or more of cow milk, goat milk and sheep milk; and

(b) ***milk-based follow-on formula*** means follow-on formula that is derived only from one or more of the following proteins: cow milk; goat milk; sheep milk; a partially hydrolysed protein of one or more of cow milk, goat milk and sheep milk.

(5) The L-amino acids listed in the table to section S29—3 must be present in infant formula and follow-on formula at a level not less than the corresponding minimum level specified in the table.

(6) The minimum levels specified in the table to section S29—3 for cysteine and for methionine do not apply if:

(a) the minimum amount of combined cysteine and methionine in the infant formula and follow-on formula is not less than 15 mg per 100 kJ; and

(b) the ratio of methionine to cysteine in the infant formula and follow-on formula is less than 2 to1.

(7) The minimum levels specified in the table to section S29—3 for phenylalanine and for tyrosine do not apply if:

(a) the minimum amount of combined phenylalanine and tyrosine in the infant formula and follow-on formula is not less than 37 mg per 100 kJ; and

(b) the ratio of tyrosine to phenylalanine in the infant formula and follow-on formula is less than 2 to 1.

(8) Despite subsections (5), (6) and (7), L-amino acids listed in the table to section S29—3 must only be added to infant formula or follow-on formula in an amount necessary to improve protein quality.

2.9.1—7 Fat requirements

(1) Infant formula and follow-on formula must:

(a) have a fat content of no less than 1.1 g/100 kJ and no more than 1.4 g/100 kJ; and

(b) have a ratio of linoleic acid to α-linolenic acid of no less than 5 to 1 and no more than 15 to 1; and

(c) contain no less than:

(i) 90 mg/100 kJ of linoleic acid; and

(ii) 12 mg/100 kJ of α-linolenic acid; and

Note. It is recommended that infant formula and follow-on formula contain not more than 335 mg/100 kJ of linoleic acid. This amount is a Guidance Upper Level and a recommended upper level for this nutrient which poses no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. This Guidance Upper Level should not be exceeded unless a higher nutrient level cannot be avoided due to high or variable contents in constituents of infant formulas and follow-on formula or due to technological reasons.

(d) have an arachidonic acid (20 to 4 n-6) content of equal to or more than docosahexaenoic acid (22 to 6 n-3) content; and

(e) contain no less than 0.5 mg of vitamin E per gram of polyunsaturated fatty acids; and

(f) for any long chain *polyunsaturated fatty acids that are present—have an eicosapentaenoic acid (20 to 5 n-3) content of no more than the docosahexaenoic acid (22 to 6 n-3) content; and

(g) for a fatty acid listed in Column 1 of the table to section S29—4 and present in the formula—contain not more than the maximum amount (if any) specified in Column 2 of the table for that fatty acid.

(2) Infant formula and follow-on formula may only contain medium chain triglycerides that:

(a) contain predominantly the saturated fatty acids designated by 8 to 0 and 10 to 0; and

(b) are one of the following:

(i) a natural constituent of a milk-based ingredient of that formula; or

(ii) for a fat soluble vitamin that is specified in a following table—a substance that was *used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the formula:

(A) for infant formula—the table to section S29—5; and

(B) for follow-on formula—the table to section S29—6.

(3) Infant formula and follow-on formula must not have a phospholipid content of more than 72 mg/100 kJ.

2.9.1—8 Required nutritive substances

(1) Infant formula must contain each substance listed in Column 1 of the table to section S29—5 in an amount (including any naturally-occurring amount) that is:

(a) no less than the minimum amount specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note It is recommended that infant formula contain a substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in Column 4 of that table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons.

(2) Follow-on formula must contain each substance listed in Column 1 of the table to section S29—6 in an amount (including any naturally-occurring amount) that is:

(a) no less than the minimum amount specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note It is recommended that follow-on formula contain a substance listed in Column 1 of the table to section S29—6 in an amount that is not more than the amount (if any) specified for that substance in Column 4 of that table. The amounts specified in Column 4 are Guidance Upper Levels, which are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. The Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formulas or due to technological reasons.

(3) The ratio of calcium to phosphorus in infant formula and follow-on formula must be no less than 1 to 1 and no more than 2 to 1.

2.9.1—9 Optional nutritive substances

(1) A substance listed in Column 1 of the table to section S29—7 may be *used as a nutritive substance in infant formula, provided that the amount of the substance in the formula (including any naturally-occurring amount) is:

(a) no less than the minimum amount (if any) specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

(2) A substance listed in Column 1 of the table to section S29—8 may be *used as a nutritive substance in follow-on formula, provided that is the amount of the substance in the formula (including any naturally-occurring amount) is:

(a) no less than the minimum amount (if any) specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note It is recommended that follow-on formula contain a substance listed in Column 1 of the table to section S29—8 in an amount that is not more than the amount (if any) specified for that substance in Column 4 of that table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formulas or due to technological reasons.

2.9.1—10 Required forms for nutritive substances

A substance used in infant formula or follow-on formula in accordance with section 2.9.1—8 or 2.9.1—9 must be added in a permitted form listed in:

(a) if a vitamin, mineral or electrolyte—the table to section S29—23; and

(b) in any other case— the table to section S29—9.

2.9.1—10A Infant formula products—conditions on use of permitted nutritive substances

(1) This section applies to a substance that is:

(a) used as a nutritive substance in an infant formula product; and

(b) listed in Column 1 of the table to section S29—9A; and

(c) in a permitted form listed in Column 2 of that table for that substance.

(2) The substance must comply with the conditions (if any) specified in Column 3 of the table to section S29—9A for that substance in that permitted form.

2.9.1—11 Addition of lactic acid producing microorganisms

L(+) lactic acid producing microorganisms may be added to infant formula and follow-on formula.

2.9.1—12 Restriction on addition of inulin-type fructans and galacto-oligosaccharides

If an *inulin-type fructan or a *galacto-oligosaccharide is added to infant formula or follow-on formula, the product must contain (taking into account both the naturally-occurring and added substances) no more than:

(a) if only inulin-type fructans are added—110 mg/100 kJ of inulin-type fructans; or

(b) if only galacto-oligosaccharides are added—290 mg/100 kJ of galacto-oligosaccharides; or

(c) if both inulin-type fructans and galacto-oligosaccharides are added:

(i) no more than 110 mg/100 kJ of inulin-type fructans; and

(ii) no more than 290 mg/100 kJ of combined inulin-type fructans and galacto-oligosaccharides.

2.9.1—13 Restriction on levels of other substances

Infant formula and follow-on formula must not contain any of the following:

(a) detectable gluten; or

(b) more than 3.8 mg/100 kJ of free nucleotide-5′-monophosphates.

Note 1 Section S19—4 contains the maximum levels (ML) of contaminants in infant formula products.

Note 2 Standard 1.3.1 and Schedule 15 permit the use of certain substances as food additives in infant formula products.

Division 3 Labelling and packaging requirements for infant formula and follow-on formula

Note Standard 1.2.7 provides that a nutrition content claim or *health claim must not be made about infant formula products. See paragraph 1.2.7—4(b). Paragraph 1.2.7—6(a) provides that this prohibition does not apply to claims that are expressly permitted by the Code, including by this Division.

2.9.1—14 Representations about food as infant formula or follow-on formula

A food may only be represented as infant formula or follow-on formula if the food complies with this Standard.

2.9.1—15 Product differentiation

The label on a package of infant formula or follow-on formula must differentiate that infant formula or follow-on formula from other foods by the use of text, pictures and/or colour.

Example The text, pictures and/or colours used on a label of infant formula must differentiate that product from, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children.

2.9.1—16 Prescribed names

(1) 'Infant formula' is the *prescribed name for infant formula.

(2) 'Follow-on formula' is the *prescribed name for follow-on formula.

Note Under the labelling provisions in Standard 1.2.1 and section 1.2.2—2, if a food has a prescribed name, that prescribed name must be used in the labelling of the food.

2.9.1—17 Requirement for measuring scoop

(1) A package of infant formula or follow-on formula in a powdered form must contain a scoop to enable the use of the formula in accordance with the directions contained in the label on the package.

(2) Subsection (1) does not apply to single serve sachets, or packages containing single serve sachets, of formula in a powdered form.

2.9.1—18 Storage instructions

For the labelling provisions, the storage instructions for infant formula and follow-on formula must cover the period after the package is opened.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—19 Requirement for the name of the food

For the labelling provisions, the name of the food must be stated on the front of a package of infant formula or follow-on formula.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—20 Statement of protein source

(1) For the labelling provisions, the specific animal or plant source or sources of protein in infant formula and follow-on formula must be included in the statement of the name of the food required by section 2.9.1—19.

Examples 'Infant formula based on cow milk'. 'Follow-on formula based on goat milk. 'Infant formula based on soy protein'.

Note 1 Section 2.9.1—6(1) lists the permitted sources of protein for infant formula and follow-on formula.

Note 2 The labelling provisions are set out in Standard 1.2.1.

(2) If infant formula and follow-on formula are derived solely or in part from a partially hydrolysed protein, the words 'partially hydrolysed' must be used immediately adjacent to the protein source required by subsection (1).

Example 'Infant formula based on partially hydrolysed cow milk'.

(3) The statement of protein source required by subsection (1) must not use the word 'milk' as the sole descriptor of the protein source.

Example 'Infant formula based on milk' or 'Infant formula sourced from milk' is not permitted.

Note See subparagraph 2.9.1—28(1)(j)(i) in relation to the use of the word 'milk' on the label separately and in addition to in a statement of protein source.

2.9.1—21 Requirement for warning statements and directions

Warning statements

(1) For the labelling provisions, the following *warning statements are required for infant formula and follow-on formula:

(a) 'Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill.'; and

(b) a heading that states 'Important Notice' (or words to that effect), with under it the *warning statement—'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.'.

Note The labelling provisions are set out in Standard 1.2.1.

Required statements on use

(2) For the labelling provisions, the required statements for infant formula and follow-on formula are ones indicating that:

(a) for infant formula—the infant formula may be used from birth; and

(b) for follow-on formula—the follow-on formula should not be used for infants aged under the age of 6 months; and

(c) for infant formula and follow-on formula—it is recommended that infants from the age of 6 months should be offered foods in addition to the infant formula or follow-on formula.

Note The labelling provisions are set out in Standard 1.2.1.

Location of required statements

(3) The statements required by paragraphs (2)(a) and (b) must appear on the front of the package of the product.

(4) Subsection (3) does not prevent a statement required by subsection (2) from appearing more than once on the label.

Directions on preparation and use

(5) For the labelling provisions, directions on preparation and use are required for infant formula and follow-on formula which instruct (in words and pictures) that:

(a) each bottle must be prepared individually; and

(b) if a bottle of prepared formula is to be stored prior to use, it must be refrigerated and used within 24 hours; and

(c) previously boiled and cooled potable water must be used; and

(d) if a package contains a measuring scoop—only the enclosed scoop must be used; and

(e) for powdered or concentrated formula—do not change proportions of the powder or concentrate or add other food except on medical advice; and

(f) for ready-to-drink formula—do not dilute or add other food except on medical advice; and

(g) formula left in the bottle after a feed must be discarded within 2 hours.

Note The labelling provisions are set out in Standard 1.2.1.

(6) Paragraphs (5)(a), (b) and (c) do not apply to ready-to-drink formula.

(7) Paragraph (5)(d) does not apply to concentrated formula and ready-to drink formula.

(8) For the labelling provisions, the following must be declared for infant formula and follow-on formula:

(a) for a product in powdered or concentrated form—the proportion of powder or concentrate required to reconstitute the formula according to directions; and

(b) for a product in powdered form—the weight of one scoop.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—22 Print size

The warning statements required by subsection 2.9.1—21(1) must be in a *size of type of at least:

(a) if the package of infant formula or follow-on formula has a net weight of more than 500 g—3 mm;

(b) if the package of infant formula or follow-on formula has a net weight of 500 g or less—1.5 mm.

2.9.1—23 Optional format for the statement of ingredients – added vitamins and minerals

(1) Despite section 1.2.4—5, where a vitamin or mineral is added to infant formula or follow-on formula in accordance with section 2.9.1—8, the statement of ingredients need not list the added vitamin and mineral in descending order of ingoing weight, provided that the statement of ingredients:

(a) lists all added vitamins together under the subheading 'Vitamins'; and

(b) lists all added minerals together under the subheading 'Minerals'.

Note See Standard 1.2.4 for other ingredient labelling requirements.

(2) Section 1.2.4—8 does not apply to a statement of ingredients referred to in subsection (1).

2.9.1—24 Declaration of nutrition information

(1) For the labelling provisions, a statement of nutrition information is required for infant formula and follow-on formula.

(2) A reference in this section to 'the statement' is the statement required by subsection (1).

(3) The statement must contain the following information:

(a) the *average energy content expressed in kilojoules per 100 mL of formula; and

(b) the *average quantity of protein, fat and *carbohydrate expressed in grams per 100 mL of formula and as 'protein', 'fat' and 'carbohydrate', respectively; and

(c) the *average quantity of each vitamin or mineral expressed in micrograms or milligrams per 100 mL of formula (including any naturally-occurring amount); and

(d) for infant formula—the *average quantity of choline, inositol and L-carnitine expressed in milligrams per 100 mL of formula (including any naturally-occurring amount); and

(e) if added, the *average quantity of the following, expressed in grams, micrograms or milligrams per 100 mL of formula:

(i) any substance *used as a nutritive substance (including any naturally-occurring amount); or

(ii) *inulin-type fructans; or

(iii) *galacto-oligosaccharides; or

(iv) a combination of inulin-type fructans and galacto-oligosaccharides.

Note The labelling provisions are set out in Standard 1.2.1.

(4) The statement may include the *average quantity of each of the following substances that is present in the infant formula or follow-on formula, expressed in grams per 100 mL of formula (including any naturally-occurring amount):

(a) whey; and

(b) casein.

(5) The statement may include the *average quantity of each of the following substances that is present in the infant formula or follow-on formula, expressed in milligrams per 100 mL of formula (including any naturally-occurring amount):

(a) docosahexaenoic acid; and

(b) eicosapentaenoic acid; and

(c) arachidonic acid.

(6) If the infant formula or follow-on formula is in a powdered or concentrated form, information included in the statement in accordance with subsection (3), (4) or (5) must be expressed in terms of per 100 mL of formula as reconstituted according to the directions on the package.

(7) In addition to being expressed in accordance with subsection (6), information included in the statement in accordance with subsection (3), (4) or (5) may also be expressed:

(a) if sold in a concentrated form —per 100 mL of the formula as sold; or

(b) if sold in a powdered form —per 100 g of formula as sold.

(8) Unless expressly provided elsewhere in this Code, the statement must not contain any other information.

2.9.1—25 Required form for the declaration of nutrition information

(1) A reference to 'the table' in this section is a reference to the table to section S29—10.

(2) Subject to this section, the statement required by section 2.9.1—24 must:

(a) be in the same format as specified in the table; and

(b) state the nutrition information in the order specified in the table; and

(c) be titled 'Nutrition Information' in bold font; and

(d) have the following subheadings printed in a size of type that is the same or larger than the nutrient names in the statement:

(i) for infant formula and follow-on formula—'Vitamins', 'Minerals' and 'Additional'; and

(ii) for infant formula only—'Other nutrients'; and

(e) state nutrients and subgroup nutrients using the names and units of measurement specified in the table for that nutrient and subgroup; and

(f) not express an amount or quantity other than in accordance with section 2.9.1—24.

(3) If the statement includes the *average quantity of a permitted nutritive substance, an *inulin-type fructan or a *galacto-oligosaccharide, that average quantity must be included in the statement:

(a) under the subheading 'Additional'; and

(b) in the same format as specified in the table for that substance.

(4) If the statement includes the *average quantity of choline, inositol or L-carnitine, that average quantity must be included in the statement:

(a) for infant formula—under the subheading 'Other nutrients'; and

(b) for follow-on formula—under the subheading 'Additional'; and

(c) in the same format as specified in the table for that substance.

(5) If the statement includes the *average quantity of a substance listed in subsection 2.9.1—24(4), that average quantity must be included in the statement in the same format as specified in the table for that substance.

(6) If the statement includes the *average quantity of the substances listed in subsection 2.9.1—24(5), the statement:

(a) must include the subheading ‘Long chain polyunsaturated fatty acids’ that is printed in a size of type that is the same or larger than the nutrient names in the statement; and

(b) must include that average quantity:

(i) under the subheading ‘Long chain polyunsaturated fatty acids’; and

(ii) in the same format as specified in the table for those substances; and

(c) must use the name for each substance specified in the table for that substance; and

(d) may use the acronym specified in the table for the following substances in addition to the name required for those substances by paragraph (c):

(i) docosahexaenoic acid; and

(ii) eicosapentaenoic acid; and

(iii) arachidonic acid.

Example The statement may use ‘Docosahexaenoic acid (DHA)’ or ‘Docosahexaenoic acid’, but not ‘DHA’.

(7) If the statement includes information expressed in accordance with subsection 2.9.1—24(7), that information must be in an additional column at the right hand side of the column shown in the table.

(8) Information included in the additional column required by subsection (7) must be in the form required by this section.

Note For an example nutrition information statement including information expressed in accordance with subsection 2.9.1—24(7), see section S29—10A.

2.9.1—26 How average quantity is to be calculated

Despite section 1.1.1—6, the method in paragraph 1.1.1—6(3)(c) must not be used to calculate the *average quantity of a substance in infant formula or follow-on formula.

2.9.1—27 Requirements for use of stage numbers

(1) The following numbers may be used on the label on a package of infant formula or follow-on formula to identify for consumers that the product is infant formula or follow-on formula:

(a) if the product is infant formula—the number ‘1’; and

(b) if the product is follow-on formula—the number ‘2’.

(2) A number used in accordance with subsection (1) must appear:

(a) on the front of the package of the product; and

(b) immediately adjacent to:

(i) for infant formula—the statement required by paragraph 2.9.1—21(2)(a); and

(ii) for follow-on formula—the statement required by paragraph 2.9.1—21(2)(b).

(3) Subsection (2) does not prevent a number used in accordance with subsection (1) from also appearing elsewhere on the label.

2.9.1—28 Prohibited representations

(1) The label on a package of infant formula or follow-on formula must not contain:

(a) a picture of an infant; or

(b) a picture that idealises the use of infant formula or follow-on formula; or

(c) information relating to:

(i) for infant formula—follow-on formula, a special medical purpose product for infants, a formulated supplementary food or a formulated supplementary food for young children; or

(ii) for follow-on formula—infant formula, a special medical purpose product for infants,a formulated supplementary food or a formulated supplementary food for young children.

(d) the word ‘humanised’ or ‘maternalised’ or any word or words having the same or similar effect; or

(e) the words ‘human milk oligosaccharide’, ‘human identical milk oligosaccharide’ or any word or words having the same or similar effect; or

(f) the abbreviations ‘HMO’ or HiMO’ or any abbreviation having the same or similar effect; or

(g) words claiming that the formula is suitable for all infants; or

(h) information relating to the nutritional content of human milk; or

(i) information relating to the presence of a substance listed in subsection (2), except for a reference in:

(i) a statement of ingredients; or

(ii) a declaration or statement expressly permitted or required by this Code; or

(j) information relating to ingredients, except for:

(i) use of the word ‘milk’; or

(ii) a reference in a statement of ingredients; or

(iii) a reference in a declaration or statement expressly permitted or required by this Code; or

(k) information relating to the animal or plant source or sources of protein except:

(i) in a statement of ingredients; or

(ii) where required by subsection 2.9.1—20(1); or

(l) the words ‘partially hydrolysed’ or any word or words having the same or similar effect, except:

(i) in a statement of ingredients; or

(ii) where required by subsection 2.9.1—20(2).

(2) For the purposes of paragraph (1)(i), the following substances are listed:

(a) an *inulin-type fructan; and

(b) a *galacto-oligosaccharide; and

(c) a nutrient; and

(d) a substance *used as a nutritive substance.

Note Section 2.9.1—24 expressly requires or permits these substances to be declared or stated in the nutrition information statement required by that section.

Division 4 Special medical purpose product for infants

2.9.1—30 Application of other Standards

Unless the contrary intention appears, the following provisions do not apply to a special medical purpose product for infants:

(a) Part 1.2 of Chapter 1 (labelling and other information requirements); and

(b) Division 3 of this Standard.

2.9.1—31 Restriction on the sale of special medical purpose products for infants

(1) A special medical purpose product for infants must not be sold to a consumer, other than from or by:

(a) a medical practitioner or dietitian; or

(b) a medical practice, pharmacy or *responsible institution; or

(c) a majority seller of that special medical purpose product for infants.

(2) In this section:

majority seller means, in relation to a special medical purpose product for infants, a person who:

(a) during any 24 month period, sold that special medical purpose product for infants to any of the following:

(i) a medical practitioner;

(ii) a dietitian;

(iii) a medical practice;

(iv) a pharmacy;

(v) a *responsible institution; and

(b) the sales mentioned in paragraph (a) represent more than one half of the total amount of that special medical purpose product for infants sold by the person during that 24 month period.

medical practitioner means a person registered or licensed as a medical practitioner under legislation in Australia or New Zealand, as the case requires, for the registration or licensing of medical practitioners.

2.9.1—32 General compositional requirements

(1) A special medical purpose product for infants must have an energy content of no less than 2510 kJ/L and no more than 2930 kJ/L.

(2) Subject to subsections (3) and (4), a special medical purpose product for infants must not contain added fructose and/or added sucrose.

(3) A special medical purpose product for infants manufactured from partially hydrolysed protein may contain added fructose and/or added sucrose, provided that:

(a) the fructose and/or sucrose is added to the product to provide a source of carbohydrate; and

(b) the sum of the fructose and/or sucrose in the product does not exceed 20% of available carbohydrates in the product.

(4) Subsection (2) does not apply to added fructose and/or added sucrose that is present in a special medical purpose product for infants as a result of:

(a) the addition of *inulin-type fructans to the product in accordance with this Standard; and/or

(b) the use of a substance as a processing aid in accordance with this Code in the manufacture of the product.

(5) The fluoride content of a special medical purpose product for infants must not exceed:

(a) if in a powdered or concentrated form—17 µg/100 kJ; and

(b) if in a 'ready-to-drink' form—24 µg/100 kJ.

(6) The amounts in subsection (5) apply to the special medical purpose product for infants as sold.

2.9.1—33 Protein requirements

(1) A special medical purpose product for infants must be only derived from one or more of the following proteins:

(a) cow milk;

(b) goat milk;

(c) sheep milk;

(d) soy protein isolate;

(e) a partially hydrolysed protein of one or more of the above.

(2) A special medical purpose product for infants must have a protein content of:

(a) for a milk-based product—no less than 0.43 g/100 kJ and no more than 0.72 g/100 kJ; and

(b) for a product that is not milk-based product—no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.

(3) For the purposes of subsection (2), ***milk-based product*** means a special medical purpose product for infants that is derived only from one or more of the following proteins: cow milk; goat milk; sheep milk; a partially hydrolysed protein of one or more of cow milk, goat milk and sheep milk.

(4) The L-amino acids listed in the table to section S29—3 must be present in a special medical purpose product for infants at a level not less than the corresponding minimum level specified in the table.

(5) The minimum levels specified in the table to section S29—3 for cysteine and for methionine do not apply if:

(a) the minimum amount of combined cysteine and methionine in the special medical purpose product for infants is not less than 15 mg per 100 kJ; and

(b) the ratio of methionine to cysteine in the special medical purpose product for infants is less than 2 to 1.

(6) The minimum levels specified in the table to section S29—3 for phenylalanine and for tyrosine do not apply if:

(a) the minimum amount of combined phenylalanine and tyrosine in the special medical purpose product for infants is not less than 37 mg per 100 kJ; and

(b) the ratio of tyrosine to phenylalanine in the special medical purpose product for infants is less than 2 to 1.

(7) Despite subsections (4), (5) and (6), L-amino acids listed in the table to section S29—3 must only be added to a special medical purpose product for infants in an amount necessary to improve protein quality.

2.9.1—34 Fat requirements

(1) A special medical purpose product for infants must:

(a) have a fat content of no less than 1.1 g/100 kJ and no more than 1.4 g/100 kJ; and

(b) have a ratio of linoleic acid to α-linolenic acid of no less than 5 to 1 and no more than 15 to 1; and

(c) contain no less than:

(i) 90 mg/100 kJ of linoleic acid; and

(ii) 12 mg/100 kJ of α-linolenic acid; and

Note. It is recommended that a special medical purpose product for infants contain not more than 335 mg/100 kJ of linoleic acid. This amount is a Guidance Upper Level and a recommended upper level for this nutrient which poses no significant risks on the basis

of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. This Guidance Upper Level should not be exceeded unless a higher nutrient level cannot be avoided due to high or variable contents in constituents of a special medical purpose product for infants or due to technological reasons.

(d) have an arachidonic acid (20 to 4 n-6) content of equal to or more than docosahexaenoic acid (22 to 6 n-3) content; and

(e) contain no less than 0.5 mg of vitamin E per gram of polyunsaturated fatty acids; and

(f) for any long chain *polyunsaturated fatty acids that are present in the product—have an eicosapentaenoic acid (20 to 5 n-3) content of no more than the docosahexaenoic acid (22 to 6 n-3) content; and

(g) for a fatty acid listed in Column 1 of the table to section S29—4 and present in the product—contain not more than the maximum amount (if any) specified in Column 2 of the table for that fatty acid.

(2) A special medical purpose product for infants may only contain medium chain triglycerides that are:

(a) a natural constituent of a milk-based ingredient of that product; or

(b) for a fat soluble vitamin that is specified in the table to section S29—5—a substance that was *used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the product.

(3) A special medical purpose product for infants must not have a phospholipid content of more than 72 mg/100 kJ.

2.9.1—35 Permitted novel foods

Despite any other provision in the Code, a special medical purpose product for infants for retail sale may have, as an ingredient or a *component, a novel food, provided that the presence of that novel food in the product is necessary to achieve that product's intended medical purpose.

2.9.1—36 Required nutritive substances

(1) A special medical purpose product for infants must contain each substance listed in Column 1 of the table to section S29—5 in an amount (including any naturally-occurring amount) that is:

(a) no less than the minimum amount specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note It is recommended that a special medical purpose product for infants contain a substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in Column 4 of that table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of a special medical purpose product for infants or due to technological reasons.

(2) The ratio of calcium to phosphorus in a special medical purpose product for infants must be no less than 1 to 1 and no more than 2 to 1.

2.9.1—37 Optional nutritive substances

A substance listed in Column 1 of the table to section S29—7 may be *used as a nutritive substance in a special medical purpose product for infants, provided that the amount of the substance in the product (including any naturally-occurring amount) is:

(a) no less than the minimum amount (if any) specified in Column 2 of the table; and

(b) no more than the maximum amount specified in Column 3 of the table.

2.9.1—38 Required forms for nutritive substances

A substance used in a special medical purpose product for infants in accordance with section 2.9.1—36 or 2.9.1—37 must be in a permitted form listed in:

(a) if a vitamin, mineral or electrolyte—the table to section S29—23; and

(b) in any other case— the table to section S29—9.

2.9.1—39 Addition of lactic acid producing microorganisms

L(+) lactic acid producing microorganisms may be added to a special medical purpose product for infants.

2.9.1—40 Restriction on addition of inulin-type fructans and galacto-oligosaccharides

If an *inulin-type fructan or a *galacto-oligosaccharide is added to a special medical purpose product for infants, the product must contain (taking into account both the naturally-occurring and added substances) no more than:

(a) if only inulin-type fructans are added—110 mg/100 kJ of inulin-type fructans; or

(b) if only galacto-oligosaccharides are added—290 mg/100 kJ of galacto-oligosaccharides; or

(c) if both inulin-type fructans and galacto-oligosaccharides are added:

(i) no more than 110 mg/100 kJ of inulin-type fructans; and

(ii) no more than 290 mg/100 kJ of combined inulin-type fructans and galacto-oligosaccharides.

2.9.1—41 Restriction on levels of other substances

A special medical purpose product for infants must not contain any of the following:

(a) detectable gluten; or

(b) more than 3.8 mg/100 kJ of free nucleotide-5′-monophosphates.

Note 1 Section S19—4 contains the maximum levels (ML) of contaminants in infant formula products.

Note 2 Standard 1.3.1 and Schedule 15 permit the use of certain substances as food additives in infant formula products including a special medical purpose product for infants.

2.9.1—42 Permitted variation from compositional requirements

(1) A special medical purpose product for infants need not comply with a compositional requirement to the extent that a variation from that requirement:

(a) is necessary to achieve the product's intended medical purpose; or

(b) would otherwise prevent the sale of the product.

(2) For the purposes of subsection (1), ***a compositional requirement*** means a requirement imposed in relation to a special medical purpose product for infants by any of the following:

(a) any of sections 2.9.1—32 to 2.9.1—41, but not section 2.9.1—35;

(b) paragraph 1.1.1—10(6)(a);

(c) paragraph 1.1.1—10(6)(b);

(d) paragraph 1.1.1—10(6)(c).

2.9.1—43 Representations about food as a special medical purpose product for infants

A food may only be represented as a special medical purpose product for infants if it complies with this Division.

2.9.1—44 Product differentiation

The label on a package of a special medical purpose product for infants must differentiate that product from other foods by the use of text, pictures and/or colour.

Example The text, pictures and/or colours used on a label of a special medical purpose product for infants must differentiate that product from, among other things, infant formula, follow-on formula or a formulated supplementary food for young children.

2.9.1—45 Prohibited representations

The label on a package of a special medical purpose product for infants must not contain:

(a) a picture of an infant; or

(b) a picture or text that idealises the use of special medical purpose product for infants; or

(c) the words 'human milk oligosaccharide', 'human identical milk oligosaccharide' or any word or words having the same or similar effect; or

(d) the abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect.

2.9.1—46 Prohibited claims

(1) A claim in relation to a special medical purpose product for infants must not:

(a) refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or

(b) compare the product with a good that is:

(i) represented in any way to be for therapeutic use; or

(ii) likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason.

(2) A nutrition content claim or *health claim must not be made about a special medical purpose product for infants.

(3) This section does not apply to:

(a) a claim that is expressly permitted by this Code; or

(b) a declaration that is required by an application Act.

2.9.1—47 Permitted lactose free claim

A claim that a special medical purpose product for infants is lactose free may be made if that special medical purpose product for infants contains no detectable lactose.

2.9.1—48 Labelling and related requirements

(1) This section applies to a food for sale that is a special medical purpose product for infants.

(2) If the food for sale is in a package, it is required to *bear a label that complies with section 2.9.1—49.

(3) If the food for sale is in an *inner package:

(a) the inner package is required to *bear a label that complies with section 2.9.1—54; and

(b) there is no labelling requirement under this Code for any other packaging associated with the food for sale.

(4) If the food for sale is in a *transportation outer:

(a) the transportation outer or package containing the food for sale is required to *bear a label that complies with section 2.9.1—55; and

(b) there is no labelling requirement under this Code for any other packaging associated with the food for sale.

2.9.1—49 Mandatory labelling information

(1) The label that is required for a special medical purpose product for infants must state the following information in accordance with the provision indicated:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2);

(b) lot identification (see section 1.2.2—3);

(c) if the sale of the product for sale is one to which Division 2 or Division 3 of Standard 1.2.1 applies:

(i) information relating to *foods produced using gene technology (see section 1.5.2—4); and

(ii) information relating to irradiated food (see section 1.5.3—9);

(d) any mandatory statements and declarations (see section 2.9.1—50);

(e) information relating to ingredients (see section 2.9.1—51);

(f) date marking information (see section 2.9.1—52);

(g) directions for the preparation, use or storage of the product, if the product is of such a nature to require such directions for health or safety reasons;

(h) nutrition information (see section 2.9.1—53).

(2) The label that is required for a special medical purpose product for infants must comply with section 1.2.1—24 of Standard 1.2.1.

2.9.1—50 Mandatory statements and declarations— special medical purpose product for infants

For paragraph 2.9.1—49(1)(d), the following statements are required:

(a) a statement to the effect that the product must be used under medical supervision;

(b) a statement indicating, if applicable, any precautions and contraindications associated with consumption of the product;

(c) a statement indicating the medical purpose of the product, which may include a disease, disorder or medical condition for which the product has been formulated;

(d) a statement describing the properties or characteristics which make the product appropriate for the medical purpose indicated in paragraph (c);

(e) if the product has been formulated for a specific age group—a statement to the effect that the product is intended for persons within the specified age group;

(f) a statement indicating whether or not the product is suitable for use as a sole source of nutrition;

(g) if the product is represented as being suitable for use as a sole source of nutrition:

(i) a statement to the effect that the product is not for parenteral use; and

(ii) if the product has been modified to vary from the compositional requirement of this Division such that the content of one or more nutrients falls short of the prescribed minimum, or exceeds the prescribed maximum (if applicable):

(A) unless provided in other documentation about the product—a statement indicating the nutrient or nutrients which have been modified; and

(B) unless provided in other documentation about the product—a statement indicating whether each modified nutrient has been

increased, decreased, or eliminated from the product, as appropriate; and

(h) the declarations required by section 1.2.3—4.

2.9.1—51 Information relating to ingredients—special medical purpose product for infants

For paragraph 2.9.1—49(1)(e), the information relating to ingredients is:

(a) a statement of ingredients; or

(b) information that complies with Articles 18, 19 and 20 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers; or

(c) information that complies with 21 CFR § 101.4.

2.9.1—52 Date marking information—special medical purpose product for infants

(1) For paragraph 2.9.1—49(1)(f), the required date marking information is date marking information in accordance with Standard 1.2.5.

(2) Despite subsection (1), for subparagraph 1.2.5—5(2)(a)(ii), the words 'Expiry Date', or similar words, may be used on the label.

2.9.1—53 Nutrition information—special medical purpose product for infants

(1) For paragraph 2.9.1—49(1)(h), the nutrition information required for a special medical purpose product for infants is the following, expressed per given amount of the product:

(a) the minimum or *average energy content; and

(b) the minimum amount or *average quantity of:

(i) protein, fat and carbohydrate; and

(ii) any vitamin, mineral or electrolyte that has been *used as a nutritive substance in the product; and

(c) any other substance:

(i) *used as a nutritive substance in that product; and

(ii) added to that product to achieve that product's intended medical purpose; and

(d) any of the following information if declaration of that information is necessary for use of the special medical purpose product for infants for its intended medical purpose:

(i) information on sub-group nutrients of protein, fat and/or carbohydrate;

(ii) osmolality and osmolarity;

(iii) acid-base balance.

(2) A reference in subsection (1) to the intended medical purpose is to the intended medical purpose as described in the statement required by paragraph 2.9.1—50(c).

(3) The label that is required for a special medical purpose product for infants may state information relating to the source or sources of protein in that product.

2.9.1—54 Labelling requirements—special medical purpose product for infants in inner package

(1) The label on an *inner package that contains a special medical purpose product for infants must state the following information in accordance with the provision indicated:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2);

(b) lot identification (see section 1.2.2—3);

(c) any declaration that is required by section 1.2.3—4;

(d) date marking information (see section 2.9.1—52).

(2) The label must comply with section 1.2.1—24 of Standard 1.2.1.

(3) To avoid doubt, this section continues to apply to the label on the *inner package if a *responsible institution subsequently supplies the inner package to a patient or resident of the responsible institution.

2.9.1—55 Labelling requirements—special medical purpose product for infants in transportation outer

(1) If packages of a special medical purpose product for infants are contained in a transportation outer, the information specified in subsection (2) must, in accordance with the provisions indicated, be:

(a) contained in a label on the transportation outer; or

(b) contained in a label on a package of the food for sale, and clearly discernible through the transportation outer.

(2) For subsection (1), the information is:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2); and

(b) lot identification (see section 1.2.2—3); and

(c) unless it is provided in accompanying documentation—the name and address of the *supplier (see section 1.2.2—4).

Attachment B - Approved consequential draft variation to the Australia New Zealand Food Standards Code

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

Food Standards (Proposal P1028 – Infant Formula Products – Consequential Amendments) Variation

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1 Name

This instrument is the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*.

2 Variation to standards in the *Australia New Zealand Food Standards Code*

(1) The Schedules to this instrument vary Standards in the *Australia New Zealand Food Standards Code*.

(2) Each Standard that is specified in a Schedule to this instrument is amended as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

3 Commencement

This instrument commences immediately after the commencement of the *Food Standards (Proposal P1028 – Infant Formula) Variation.*

4 Effect of the variations made by this instrument

(1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.

(2) During the transition period, a food product may be sold if the product complies with one of the following:

(a) the Code as in force without the variations made by the instruments; or

(b) the Code as amended by the variations made by the instruments.

(3) For the purposes of this clause:

(a) the **instruments** means:

(i) this instrument; and

(ii) the *Food Standards (Proposal P1028 – Infant Formula) Variation*;

(b) the **transition period** means the period commencing on the date of commencement of the *Food Standards (Proposal P1028 – Infant Formula) Variation* and ending 60 months after that date of commencement.

Schedule 1

Schedule 29—Special purpose foods

[1] Sections S29—2 to S29—10

Repeal the sections, substitute:

S29—2 Infant formula products—calculation of energy content

(1) For paragraph 2.9.1—4(2)(a), the energy content of infant formula product must be calculated using:

(a) the energy contributions of the following *components only:

(i) fat; and

(ii) protein; and

(iii) carbohydrate; and

(b) the relevant energy factors set out in section S11—2.

(2) The energy content of an infant formula product must be expressed in kilojoules.

S29—2A Infant formula products—calculation of protein content

For paragraph 2.9.1—4(2)(b), the protein content of infant formula product must be calculated by multiplying the nitrogen content of the product by a nitrogen-to-protein conversion factor of 6.25.

S29—2B Infant formula products—calculation of vitamin A content

For paragraph 2.9.1—4(2)(c), the vitamin A content of infant formula products must be calculated using only the retinol forms of vitamin A prescribed in Column 1 of Table S29—23.

S29—3 Infant formula products—L-amino acids that must be present

For subsection 2.9.1—6(5) and section 2.9.1—33, the table is:

L-amino acids that must be present in infant formula products

L-amino acid	***Minimum amount per 100 kJ***
Cysteine	9 mg
Histidine	10 mg
Isoleucine	22 mg
Leucine	40 mg
Lysine	27 mg
Methionine	6 mg
Phenylalanine	19 mg
Threonine	18 mg
Tryptophan	8 mg
Tyrosine	18 mg
Valine	22 mg

S29—4 Infant formula products—limits on fatty acids

For paragraphs 2.9.1—7(1)(g) and 2.9.1—34(1)(g), the table is:

Limits on fatty acids that may be present in infant formula products

Column 1	***Column 2***
Substance	*Maximum amount per 100 kJ*
Docosahexaenoic acid	12 mg
Total *trans* fatty acids	Not more than 4% of the total fatty acids

Erucic acid (22:1)	Not more than 1% of the total fatty acids

S29—5 Vitamins, minerals, electrolytes and other substances required in infant formula and special medical purpose product for infants

For sections 2.9.1—7(2)(b)(i), 2.9.1—8(1), 2.9.1—34(2)(b) and 2.9.1—36(1), the table is:

Vitamins, minerals, electrolytes and other nutritive substances required in infant formula and special medical purpose product for infants

Column 1	***Column 2***	***Column 3***	***Column 4***
Substance	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*	*Guidance upper level per 100 kJ (see Note)*
Vitamins			
Vitamin A	14 µg RE	43 µg RE	
Vitamin D	0.24 µg	0.63 µg	
Vitamin C	1.7 mg		17 mg
Thiamin	10 µg		72 µg
Riboflavin	14.3 µg		120 µg
Niacin	72 µg		359 µg
Vitamin B_6	8 µg		42 µg
Folic acid	2.4 µg		12 µg
Pantothenic acid	96 µg		478 µg
Vitamin B_{12}	0.02 µg		0.36 µg
Biotin	0.24 µg		2.4 µg
Vitamin E	0.14 mg α-TE		1.2 mg α-TE
Vitamin K	0.24 µg		6 µg
Minerals			
Calcium	12 mg		35 mg
Phosphorus	6 mg		24 mg
Magnesium	1.2 mg		3.6 mg
Iron	0.14 mg	0.48 mg	
Iodine	2.4 µg		14 µg
Copper	8 µg		29 µg
Zinc	0.12 mg		0.36 mg
Manganese	0.24 µg		24 µg
Selenium	0.48 µg		2.2 µg
Electrolytes			
Chloride	12 mg	38 mg	
Sodium	4.8 mg	14 mg	
Potassium	14 mg	43 mg	
Other essential substances			
Choline	1.7 mg		12 mg

L-carnitine	0.3 mg	0.8 mg
Inositol	1 mg	10 mg

Note It is recommended that infant formula and a special medical purpose product for infants contain a substance listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in Column 4 of the table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or special medical purpose product for infants; or due to technological reasons.

S29—6 Vitamins, minerals and electrolytes required in follow-on formula

For subparagraph 2.9.1—7(2)(b)(ii) and subsection 2.9.1—8(2), the table is:

Vitamins, minerals and electrolytes required in follow-on formula

Column 1	***Column 2***	***Column 3***	***Column 4***
Vitamin, mineral or electrolyte	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*	*Guidance upper level per 100 kJ (see Note)*
Vitamins			
Vitamin A	14 µg RE	43 µg RE	
Vitamin D	0.24 µg	0.72 µg	
Vitamin C	1.7 mg		17 mg
Thiamin	10 µg		72 µg
Riboflavin	14.3 µg		120 µg
Niacin	72 µg		359 µg
Vitamin B_6	8 µg		42 µg
Folic acid	2.4 µg		12 µg
Pantothenic acid	96 µg		478 µg
Vitamin B_{12}	0.02 µg		0.36 µg
Biotin	0.24 µg		2.4 µg
Vitamin E	0.14 mg α-TE		1.2 mg α-TE
Vitamin K	0.24 µg		6 µg
Minerals			
Calcium	12 mg		43 mg
Phosphorus	6 mg		24 mg
Magnesium	1.2 mg		3.6 mg
Iron	0.24 mg	0.48 mg	
Iodine	2.4 µg		14 µg
Copper	8 µg		29 µg
Zinc	0.12 mg		0.36 mg
Manganese	0.24 µg		24 µg
Selenium	0.48 µg		2.2 µg
Electrolytes			
Chloride	12 mg	38 mg	
Sodium	4.8 mg	14 mg	
Potassium	14 mg	43 mg	

Note It is recommended that follow-on formula contain a substance listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in column 4 of the table. The amounts specified are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. The Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formula or due to technological reasons.

S29—7 Optional nutritive substances in infant formula and special medical purpose product for infants

For subsection 2.9.1—9(1) and section 2.9.1—37, the table is set out below.

Optional nutritive substances in infant formula and special medical purpose product for infants

Column 1	***Column 2***	***Column 3***
Substance	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*
2′-fucosyllactose permitted for use by Standard 1.5.2		96 mg
3′-sialyllactose sodium salt permitted for use by Standard 1.5.2		8 mg
6′-sialyllactose sodium salt permitted for use by Standard 1.5.2		16 mg
A combination of 2′-fucosyllactose and difucosyllactose, permitted for use by Standard 1.5.2		96 mg
A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2		96 mg which contains not more than 24 mg of lacto-N-neotetraose
Adenosine-5′-monophosphate		0.36 mg
Cytidine-5′-monophosphate		0.6 mg
Guanosine-5′monophosphate		0.4 mg
Inosine-5′-monophosphate		0.24 mg
Lactoferrin		40 mg
lacto-N-tetraose permitted for use by Standard 1.5.2		32 mg
Lutein	1.5 µg	5 µg
Taurine		2.9 mg
Uridine-5′-monophosphate		0.42 mg

S29—8 Optional nutritive substances in follow-on formula

For subsection 2.9.1—9(2), the table is set out below.

Optional nutritive substances in follow-on formula

Column 1	***Column 2***	***Column 3***	***Column 4***

Substance	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*	*Guidance upper level per 100 kJ (see Note)*
2′-fucosyllactose permitted for use by Standard 1.5.2		96 mg	
3′-sialyllactose sodium salt permitted for use by Standard 1.5.2		8 mg	
6′-sialyllactose sodium salt permitted for use by Standard 1.5.2		16 mg	
A combination of 2′-fucosyllactose and difucosyllactose, permitted for use by Standard 1.5.2		96 mg	
A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2		96 mg which contains not more than 24 mg of lacto-N-neotetraose	
Adenosine-5′-monophosphate		0.36 mg	
L-carnitine	0.3 mg		
Choline			12 mg
Cytidine-5′-monophosphate		0.6 mg	
Guanosine-5′-monophosphate		0.4 mg	
Inosine-5′-monophosphate		0.24 mg	
Lactoferrin		40 mg	
lacto-N-tetraose permitted for use by Standard 1.5.2		32 mg	
Lutein	1.5 µg	5 µg	
Inositol			10 mg
Taurine		2.9 mg	
Uridine-5′-monophosphate		0.42 mg	

Note It is recommended that follow-on formula contain a substance listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in Column 4 of the table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. The Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formula or due to technological reasons.

S29—9 Permitted forms of nutritive substances in infant formula products

For paragraphs 2.9.1—10(b) and 2.9.1—38(b), the table is set out below.

Permitted forms for nutritive substances used in infant formula products

Substance	***Permitted forms***
2′-fucosyllactose permitted for use by Standard 1.5.2	2′-fucosyllactose
3′-sialyllactose sodium salt permitted for use by Standard 1.5.2	3′-sialyllactose sodium salt
6'-sialyllactose sodium salt permitted for use by Standard 1.5.2	6'-sialyllactose sodium salt
A combination of 2′-fucosyllactose and	2'-fucosyllactose and difucosyllactose

difucosyllactose, permitted for use by Standard 1.5.2	
A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2	2′-fucosyllactose and lacto-N-neotetraose
Adenosine-5′-monophosphate	Adenosine-5′- monophosphate
L-carnitine	L-carnitine L-carnitine hydrochloride L-carnitine tartrate
Choline	Choline chloride Choline bitartrate Choline Choline citrate Choline hydrogen tartrate
Cytidine-5′-monophosphate	Cytidine-5′-monophosphate
Guanosine-5′-monophosphate	Guanosine-5′-monophosphate Guanosine-5′-monophosphate sodium salt
Inosine-5′-monophosphate	Inosine-5′-monophosphate Inosine-5′-monophosphate sodium salt
Lactoferrin	Bovine lactoferrin
lacto-N-tetraose permitted for use by Standard 1.5.2	lacto-N-tetraose
Lutein	Lutein from *Tagetes erecta L.*
Inositol	Myo-inositol
Taurine	Taurine
Uridine-5′-monophosphate	Uridine-5′-monophosphate sodium salt

Note Section S29—23 lists the permitted forms of vitamins, minerals and electrolytes in infant formula products.

S29—9A Infant formula products—conditions on use of permitted nutritive substances

The table for this section is as follows:

Conditions of use for permitted nutritive substances

Column 1	*Column 2*	*Column 3*
Substance	***Permitted Form***	***Conditions of use***
Lactoferrin	Bovine lactoferrin	1. During the exclusive use period, may only be sold under the brand Synlait for *use as a nutritive substance in an infant formula product. 2. For the purposes of condition 1 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1253 – Bovine Lactoferrin in Infant Formula Products) Variation* and ending 15 months after that date.

S29—10 Required format for a nutrition information statement

The table to this section is:

NUTRITION INFORMATION	
	Average quantity per 100 mL prepared formula
Energy	kJ
Protein	g
— Whey*	g
— Casein*	g
Fat	g
— Long chain polyunsaturated fatty acids*	
— Docosahexaenoic acid (DHA)*	mg
— Eicosapentaenoic acid (EPA)*	mg
— Arachidonic acid (ARA)*	mg
Carbohydrate	g
Vitamins	
Vitamin A	µg
Vitamin B_6	µg
Vitamin B_{12}	µg
Vitamin C	mg
Vitamin D	µg
Vitamin E	mg
Vitamin K	µg

Biotin	µg
Niacin (B_3)	µg
Folate	µg
Pantothenic acid (B_5)	µg
Riboflavin (B_2)	µg
Thiamin (B_1)	µg
Minerals	
Calcium	mg
Copper	µg
Iodine	µg
Iron	mg
Magnesium	mg
Manganese	µg
Phosphorus	mg
Selenium	µg
Zinc	mg
Chloride	mg
Potassium	mg
Sodium	mg
Other nutrients*	
Choline*	mg
Inositol*	mg
L-carnitine*	mg
Additional	
(insert any other substance used as a nutritive substance; or inulin-type fructans and / or galacto-oligosaccharides, to be declared)	g, mg, µg

Note: *See the following.

Entries and amounts for the following need only be included when stated in accordance with subsection 2.9.1—24(4), 2.9.1—24(5) and paragraph 2.9.1—25(6)(d): whey; casein; docosahexaenoic acid; eicosapentaenoic acid; arachidonic acid.

The heading 'Other nutrients' need only be included when required by subparagraph 2.9.1—25(2)(d)(ii) and paragraph 2.9.1—25(4)(a).

The heading 'Long chain polyunsaturated fatty acids' need only be included when required by paragraph 2.9.1—25(6)(a).

Entries and amounts for choline, inositol, L-carnitine are included under the heading 'Other nutrients' when required by paragraph 2.9.1—25(4)(a) and under the heading 'Additional' when required by paragraph 2.9.1—25(4)(b).

S29—10A Example of a nutrition information statement including quantities expressed as sold

For subsection 2.9.1—25(7), an example nutrition information statement including information expressed in accordance with subsection 2.9.1—24(7) is:

NUTRITION INFORMATION

	Average quantity per 100 mL prepared formula	Quantity per 100 g powder (or 100 mL liquid concentrate)
Energy	kJ	kJ
Protein	g	g
— Whey	g	g
— Casein	g	g
Fat	g	g
— Long chain polyunsaturated fatty acids		
— Docosahexaenoic acid (DHA)	mg	mg
— Eicosapentaenoic acid (EPA)	mg	mg
— Arachidonic acid (ARA)	mg	mg
Carbohydrate	g	g
Vitamins		
Vitamin A	µg	µg
Vitamin B_6	µg	µg
Vitamin B_{12}	µg	µg
Vitamin C	mg	mg
Vitamin D	µg	µg
Vitamin E	mg	mg
Vitamin K	µg	µg
Biotin	µg	µg
Niacin (B_3)	µg	µg
Folate	µg	µg
Pantothenic acid (B_5)	µg	µg
Riboflavin (B_2)	µg	µg
Thiamin (B_1)	µg	µg
Minerals		
Calcium	mg	mg
Copper	µg	µg
Iodine	µg	µg
Iron	mg	mg
Magnesium	mg	mg
Manganese	µg	µg
Phosphorus	mg	mg
Selenium	µg	µg
Zinc	mg	mg
Chloride	mg	mg
Potassium	mg	mg
Sodium	mg	mg

Other nutrients		
Choline	mg	mg
Inositol	mg	mg
L-carnitine	mg	mg
Additional		
(insert any other substance used as a nutritive substance; or inulin-type fructans and / or galacto-oligosaccharides, to be declared)	g, mg, µg	g, mg, µg

[2] After section S29—22

Insert:

S29—23 Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants, formulated meal replacements (vitamin K) and food for special medical purposes

For sections 2.9.1—10(a), 2.9.1—38(a), 2.9.2—4, 2.9.2—5, 2.9.2—6, 2.9.3—3(2)(c)(iii) and 2.9.5—6, the table is:

Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants, formulated meal replacements (vitamin K) and food for special medical purposes

Vitamin, mineral or electrolyte	***Permitted forms***
Vitamin A	
Retinol forms	vitamin A (retinol)
	vitamin A acetate (retinyl acetate)
	vitamin A palmitate (retinyl palmitate)
	retinyl propionate
Provitamin A forms	beta-carotene
Vitamin C	L-ascorbic acid
	L-ascorbyl palmitate
	calcium ascorbate
	potassium ascorbate
	sodium ascorbate
Vitamin D	vitamin D_2 (ergocalciferol)
	vitamin D_3 (cholecalciferol)
	vitamin D (cholecalciferol-cholesterol)
Thiamin	thiamin hydrochloride
	thiamin mononitrate
Riboflavin	riboflavin
	riboflavin-5′-phosphate, sodium
Niacin	niacinamide (nicotinamide)
Vitamin B_6	pyridoxine hydrochloride
	pyridoxine-5′-phosphate

Folate	Folic acid
Pantothenic acid	calcium pantothenate
	dexpanthenol
	D-panthenol
	calcium D-pantothenate
	sodium D-pantothenate
Vitamin B_{12}	cyanocobalamin
	hydroxocobalamin
Biotin	d-biotin
Vitamin E	dl-α-tocopherol
	d-α-tocopherol concentrate
	tocopherols concentrate, mixed
	d-α-tocopheryl acetate
	dl-α-tocopheryl acetate
	d-α-tocopheryl acid succinate
	dl-α-tocopheryl succinate
Vitamin K	Vitamin K_1 as phylloquinone (phytonadione)
Calcium	calcium carbonate
	calcium chloride
	calcium citrate
	calcium gluconate
	calcium glycerophosphate
	calcium hydroxide
	calcium lactate
	calcium oxide
	calcium phosphate, dibasic
	calcium phosphate, monobasic
	calcium phosphate, tribasic
	calcium sulphate
Chloride	calcium chloride
	magnesium chloride
	potassium chloride
	sodium chloride
Chromium	chromium sulphate
Copper	copper gluconate
	cupric sulphate
	cupric citrate
	cupric carbonate
Iodine	potassium iodate
	potassium iodide
	sodium iodide
Iron	ferric ammonium citrate
	ferric citrate

	ferric pyrophosphate
	ferrous bisglycinate
	ferrous citrate
	ferrous fumarate
	ferrous gluconate
	ferrous lactate
	ferrous succinate
	ferrous sulphate
Magnesium	magnesium carbonate
	magnesium chloride
	magnesium gluconate
	magnesium oxide
	magnesium phosphate, dibasic
	magnesium phosphate, tribasic
	magnesium sulphate
	magnesium hydroxide carbonate
	magnesium hydroxide
	magnesium salts of citric acid
Manganese	manganese carbonate
	manganese chloride
	manganese citrate
	manganese gluconate
	manganese sulphate
Molybdenum	sodium molybdate VI
Phosphorus	calcium glycerophosphate
	calcium phosphate, dibasic
	calcium phosphate, monobasic
	calcium phosphate, tribasic
	magnesium phosphate, dibasic
	potassium phosphate, dibasic
	potassium phosphate, monobasic
	potassium phosphate, tribasic
	sodium phosphate, dibasic
	sodium phosphate, monobasic
	sodium phosphate, tribasic
Potassium	potassium bicarbonate
	potassium carbonate
	potassium chloride
	potassium citrate
	potassium glycerophosphate
	potassium gluconate
	potassium hydroxide
	potassium phosphate, dibasic

	potassium phosphate, monobasic
	potassium phosphate, tribasic
	potassium L-lactate
Selenium	seleno methionine
	sodium selenate
	sodium selenite
Sodium	sodium bicarbonate
	sodium carbonate
	sodium chloride
	sodium chloride iodised
	sodium citrate
	sodium gluconate
	sodium hydroxide
	sodium iodide
	sodium lactate
	sodium phosphate, dibasic
	sodium phosphate, monobasic
	sodium phosphate, tribasic
	sodium sulphate
	sodium tartrate
Zinc	zinc acetate
	zinc chloride
	zinc citrate (zinc citrate dihydrate or zinc citrate trihydrate)
	zinc gluconate
	zinc lactate
	zinc oxide
	zinc sulphate

Schedule 2

Standard 1.1.2—Definitions used throughout the Code

[1] Subsection 1.1.2—2(3)

Insert:

inner package, in relation to a special medical purpose product for infants, means an individual package of the food that is:

(a) contained and sold within another package that is labelled in accordance with Division 4 of Standard 2.9.1; and

(b) not designed for individual sale, other than a sale by a *responsible institution to a patient or resident of the responsible institution.

Example An example of an inner package is an individual sachet (or sachets) of a powdered food contained within a box that is fully labelled, being a box available for retail sale.

[2] Subsection 1.1.2—2(3) (definition of *medium chain triglycerides*)

Repeal the definition.

[2A] Subsection 1.1.2—2(3) (definition of *protein substitute*)

Repeal the definition.

[3] Subsection 1.1.2—2(3) (paragraph (c) of the definition of *warning statement*)

Repeal the paragraph, substitute:

(c) subsection 2.9.1—21(1) (warning statements for infant formula product);

[4] Subsection 1.1.2—3(2) (definitions—particular foods)

Insert:

special medical purpose product for infants means an infant formula product that is:

(d) represented as being:

(k) specially formulated for the dietary management of infants who have medically determined nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food); and

(iv) suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product; and

(iii) for the dietary management of a medically diagnosed disease, disorder or condition of an infant; and

(e) intended to be used under medical supervision; and

(f) not suitable for general use.

[5] Subsection 1.1.2—3(2) (definition of *follow-on formula*)

Repeal the definition, substitute:

follow-on formula means an infant formula product that is represented as:

(a) either a breast milk substitute or replacement for infant formula; and

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

[6] Subsection 1.1.2—3(2) (definition of *infant formula*)

Repeal the definition, substitute:

infant formula means an infant formula product that is represented as:

(a) a breast milk substitute for infants; and

(b) satisfying by itself the nutritional requirements of infants under the age of 6 months.

[7] Subsection 1.1.2—3(2) (definition of *infant formula product*)

Repeal the definition, substitute:

infant formula product means a product based on milk or other edible food constituents of animal or plant origin which is represented as 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.

[8] Subsection 1.1.2—3(2) (definition of *pre-term formula*)

Repeal the definition.

[8A] Subsection 1.1.2—8(2) (definition of *novel food*)

Repeal the subsection, substitute:

(2) Any of the following:

(a) the presence of a food in a food for special medical purposes;

(b) the presence of a food in a special medical purpose product for infants;

(c) the use of a food as a food for special medical purpose;

(d) the use of a food as a special medical purpose product for infants;

does not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of this section

Standard 1.2.3—Information requirements – warning statements, advisory statements and declarations

[9] Paragraph 1.2.3—6(4)(b)

Repeal the paragraph, substitute

(b) a special medical purpose product for infants.

[10] Note 2 to subsection 1.2.3—6(4)

Repeal the note, substitute:

Note 2 Division 4 of Standard 2.9.1 applies to a special medical purpose product for infants and sets out compositional and labelling requirements for such food**.**

Standard 1.3.1—Food Additives

[11] Subsection 1.3.1—3(2)

After ‘any food’, insert ‘(other than an infant formula product)’

[12] Paragraph 1.3.1—4(6)(k)

Repeal the paragraph, substitute:

(k) rosemary extract is calculated as the sum of carnosic acid and carnosol;

(l) phosphoric acid and phosphates are calculated as phosphorus.

Standard 1.5.1—Novel Foods

[13] Note to subsection 1.5.1—2(2) (Definition of novel food)

Repeal subsection (2) of the definition, substitute:

(2) Any of the following:

(a) the presence of a food in a food for special medical purposes;

(b) the presence of a food in a special medical purpose product for infants;

(c) the use of a food as a food for special medical purpose;

(d) the use of a food as a special medical purpose product for infants;

do not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of this section.

[13A] Section 1.5.1—3

Repeal the section, substitute:

1.5.1—3 Sale of novel foods

(1) Despite paragraphs 1.1.1—10(5)(b) and (6)(f), a food offered for retail sale (other than an infant formula product) may consist of, or have as an ingredient, a *novel food if:

(a) the novel food is listed in the table to section S25—2; and

(b) any conditions of use specified in the corresponding row of that table are complied with.

Note Novel foods are added to the table to section S25—2 by variations to the Code. When added for the first time, the conditions may include some that apply to the novel food only during the first 15 months after gazettal of the variation. Conditions may also deal with matters such as the following:

- the need for preparation or cooking instructions, warning statements or other advice;
- the need to meet specific requirements of composition or purity;
- the class of food within which the food must be sold;
- during the first 15 months after gazettal, the brand under which the food may be sold.

(2) Despite paragraphs 1.1.1—10(5)(b) and (6)(f), an infant formula product for retail sale may consist of, or have as an ingredient or a *component, a novel food only if:

(a) the novel food is listed in the table to section S25—2; and

(b) the presence of that novel food in the infant formula product is expressly permitted by that table; and

(c) any conditions of use specified in the corresponding row of that table are complied with.

Standard 2.9.2—Food for infants

[14] Section 2.9.2—4

Omit ‘section S29—7’ (wherever occurring), substitute ‘section S29—23’.

[15] Section 2.9.2—5

Omit ‘section S29—7’ (wherever occurring), substitute ‘section S29—23’.

[16] Subsection 2.9.2—6(3)

Omit ‘section S29—7’, substitute ‘section S29—23’.

Standard 2.9.3—Formulated meal replacements and formulated supplementary foods

[17] Subparagraph 2.9.3—3(2)(c)(iii)

Omit ‘section S29—7’, substitute ‘section S29—23’.

Standard 2.9.5—Food for special medical purposes

[18] Paragraph 2.9.5—6(1)(b)

Omit ‘section S29—7’, substitute ‘section S29—23’.

Schedule 8—Food additive names and code numbers (for statement of ingredients)

[19] The table to section S8—2 (food additive names—alphabetical listing)

Insert:

dl-Alpha-tocopherol	307c
Potassium hydroxide	525
Sodium hydroxide	524

[20] The table to section S8—2 (food additive names—numerical listing)

Insert in numerical order:

307c	dl-Alpha-tocopherol
524	Sodium hydroxide
525	Potassium hydroxide

Schedule 15—Substances that may be used as food additives

[21] The table to section S15—5 (food classes 13.1, 13.1.1, 13.1.2 and 13.1.3)

Repeal the food classes, substitute:

13.1	***Infant formula products***		
270	Lactic acid	GMP	
300	Ascorbic acid	50 mg/L	See Note 1, below.
301	Sodium ascorbate	50 mg/L	See Note 1, below.
		75 mg/L	May only be added to polyunsaturated fatty acid preparations
302	Calcium ascorbate	50 mg/L	See Note 1, below.
304	Ascorbyl palmitate	50 mg/L	See Note 1, below.
304	Ascorbyl palmitate	10 mg/L	
307b	Tocopherols concentrate, mixed	10 mg/L	
307b	Tocopherols concentrate, mixed	30 mg/L	See Note 1, below
307c	dl-Alpha-tocopherol	10 mg/L	
307c	dl-Alpha-tocopherol	30 mg/L	See Note 1, below
308	Gamma-tocopherol	10 mg/L	
309	Delta-tocopherol	10 mg/L	
322	Lecithin	5 000 mg/L	
330	Citric acid	GMP	
331	Sodium citrates	GMP	
332	Potassium citrates	GMP	
333	Calcium citrates	0.1 mg/L	As calcium, may only be added as part of a nutrient preparation
338	Phosphoric acid	450 mg/L	
339	Sodium phosphates	450 mg/L	
340	Potassium phosphates	450 mg/L	
407	Carrageenan	300 mg/L	Only in a liquid product
410	Locust bean (carob bean) gum	1 000 mg/L	
412	Guar gum	1 000 mg/L	Only in a liquid product that contains hydrolysed protein

414	Gum arabic (acacia)	10 mg/L	May only be added as part of a nutrient preparation
440	Pectins	10 000 mg/L	See Note 1, below
471	Mono- and diglycerides of fatty acids	4 000 mg/L	
472c	Citric and fatty acid esters of glycerol	7 500 mg/L	Only in a powdered product
		9 000 mg/L	Only in a liquid product
500	Sodium carbonates	2 000 mg/L	
501	Potassium carbonates	2 000 mg/L	
524	Sodium hydroxide	2 000 mg/L	
525	Potassium hydroxide	2 000 mg/L	
526	Calcium hydroxide	2 000 mg/L	
551	Silicon dioxide (amorphous)	10 mg/L	May only be added as part of a nutrient preparation
1412	Distarch phosphate	5 000 mg/L	See Note 2, below.
1413	Phosphated distarch phosphate	5 000 mg/L	See Note 3, below.
1414	Acetylated distarch phosphate	5 000 mg/L	See Note 4, below.
1422	Acetylated distarch adipate	5 000 mg/L	See Note 5, below.
1440	Hydroxypropyl starch	5 000 mg/L	See Note 6, below.
1450	Starch sodium octenylsuccinate	100 mg/L	May only be added as part of a nutrient preparation
		1 000 mg/L	May only be added to polyunsaturated fatty acid preparations

Note 1. For additives 300, 301, 302, 304, 307b, 307c, 440—the additive may only be used in follow-on formula products.

Note 2. Additive 1412 may only be used in:

(a) soy based infant formula product (other than follow-on formula) either singly or in combination with one or more of additives 1413, 1414 and 1440; and

(b) soy based follow-on formula either singly or in combination with one or more of additives 1413, 1414 and 1422.

Note 3. Additive 1413 may only be used in:

(a) soy based infant formula product (other than follow-on formula) either singly or in combination with one or more of additives 1412, 1414 and 1440; and

(b) soy based follow-on formula either singly or in combination with one or more of additives 1412, 1414 and 1422.

Note 4. Additive 1414 may only be used in:

(a) soy based infant formula product (other than follow-on formula) either singly or in combination with one or more of additives 1412, 1413, and 1440; and

(b) soy based follow-on formula either singly or in combination with one or more of additives 1412, 1413, and 1422.

Note 5. Additive 1422 may only be used in soy based follow-on formula, either singly or in combination with one or more of additives 1412, 1413 and 1414.

Note 6. Additive 1440 may only be used in soy based infant formula product (other than follow-on formula), either singly or in combination with one or more of additives 1412, 1413, and 1414.

13.1.1	**Special medical purpose product for infants**		
170	Calcium carbonates	GMP	
304	Ascorbyl palmitate	100 mg/L	
333	Calcium citrates	GMP	
338	Phosphoric acid	450 mg/L	For pH adjustment only
339	Sodium phosphates	450 mg/L	
340	Potassium phosphates	450 mg/L	
341	Calcium phosphates	450 mg/L	

401	Sodium alginate	1 000 mg/L	Only in a product specifically formulated for both the dietary management of metabolic disorders of infants aged 4 months and above and general tube-feeding of infants aged 4 months and above.
407	Carrageenan	1 000 mg/L	Only in a liquid product that contain hydrolysed proteins and/or amino acids
410	Locust bean (carob bean) gum	5 000 mg/L	Only in a product specifically formulated for reduction of gastro-oesophageal reflux
412	Guar gum	10 000 mg/L	See Note 1, below.
415	Xanthan gum	1 200 mg/L	Only in a product that is based on hydrolysed protein, amino acids or peptides
440	Pectins	2 000 mg/L	Only in a liquid product that contain hydrolysed protein
		5 000 mg/L	Only in a product formulated for infants with gastro-intestinal disorders
471	Mono- and diglycerides of fatty acids	5 000 mg/L	Only in product formulated for diets devoid of proteins
472e	Diacyltartaric and fatty acid esters of glycerol	400 mg/L	
1412	Distarch phosphate	25 000 mg/L	See Notes 2 and 7, below.
1413	Phosphated distarch phosphate	25 000 mg/L	See Notes 3 and 7, below.
1414	Acetylated distarch phosphate	25 000 mg/L	See Notes 4 and 7, below.
1422	Acetylated distarch adipate	25 000 mg/L	See Notes 5 and 7, below
1440	Hydroxypropyl starch	25 000 mg/L	Sees Note 6 and 7, below.
1450	Starch sodium octenylsuccinate	20 000 mg/L	See Note 7, below

Note 1. Additive 412 may only be used in a product that contains one or more of the following: hydrolysed proteins; peptides; amino acids.

Note 2. Additive 1412 may only be used in:

(a) a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1413, 1414 and 1440; and

(b) a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1413, 1414 and 1422.

Note 3. Additive 1413 may only be used in:

(a) a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1412, 1414 and 1440; and

(b) a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1412, 1414 and 1422.

Note 4. Additive 1414 may only be used in:

(a) a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1412, 1413 and 1440; and

(b) a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1412, 1413 and 1422.

Note 5. Additive 1422 may only be used in a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1412, 1413 and 1414.

Note 6. Additive 1440 may only be used in a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1412, 1413, and 1414.

Note 7. Additives 1412, 1413, 1414, 1422, 1440 and 1450 may only be used in a product that contains hydrolysed proteins, amino acids or both.

Schedule 19—Maximum levels of contaminants and natural toxicants

[22] The table to section S19—4 (Maximum levels of metal contaminants)

Insert:

Aluminium	Infant formula, follow-on formula and special medical purpose product for infants (other than special medical purpose product for infants formulated for pre-term infants)	0.5
	Soy-based infant formula products	1
	Special medical purpose product for infants formulated for pre-term infants	0.2

[23] The table to section S19—4 (table item dealing with "Lead", entry dealing with the food "infant formula products" and its associated maximum level)

Repeal the entry, substitute:

	Infant formula products	0.01

Schedule 25—Permitted novel foods

[24] Subsection S25—2

Repeal

Dried marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)	
Oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695)	1. May only be added to infant formula products in accordance with Standard 2.9.1.

Oil derived from marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)	
Oil derived from marine micro-algae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA)	

substitute:

Dried marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)	1. May be added to infant formula products in accordance with Standard 2.9.1.
Oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695)	1. Only permitted for use in infant formula products in accordance with Standard 2.9.1
Oil derived from marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)	1. May be added to infant formula products in accordance with Standard 2.9.1.
Oil derived from marine micro-algae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA)	1. May be added to infant formula products in accordance with Standard 2.9.1.

[25] Subsection S25—2 (table item dealing with "Isomalto-oligosaccharide")

Repeal the table item, substitute:

Isomalto-oligosaccharide	1. Must not be added to: (a) food for infants; and (b) formulated supplementary food for young children.

[26] Subsection S25—2 (table item dealing with "Rapeseed protein isolate", column headed "*Conditions of use*", condition 2)

Repeal the condition, substitute:

2. Must not be added to food for infants.

[27] Subsection S25—2 (table item dealing with "Trehalose")

Repeal the table item, substitute:

Trehalose	1. May be added to infant formula products only as a cryo-preservative for L(+) lactic acid producing microorganisms.

Attachment C - Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Proposal P1028 – Infant Formula) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1028 to revise and clarify standards relating to infant formula products. The Authority has considered the Proposal in accordance with Division 2 of Part 3 and has approved two draft variations – the *Food Standards (Proposal P1028 – Infant Formula) Variation* and the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*.

This Explanatory Statement relates to the *Food Standards (Proposal P1028 – Infant Formula) Variation* (the approved draft variation).

Following consideration by the Food Ministers Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by

the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority approved the *Food Standards (Proposal P1028 – Infant Formula) Variation* and the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*. The purpose of both instruments is to amend the Code to revise and clarify the Code's provisions relating to infant formula products, including those relating to category definitions, composition, labelling and representation of infant formula products.

4. Documents incorporated by reference

Section 14 of the *Legislation Act 2003* provides that a legislative instrument may:

- apply, adopt or incorporate provisions of a Commonwealth disallowable legislative instrument, with or without modification, as in force at a particular time or as in force from time to time; and
- incorporate any other document in writing which exists at the time the legislative instrument commences or a time before its commencement.

The Code currently contains provisions that incorporate other legislative instruments and other written documents by reference in accordance with the above section.

The approved draft variation contains one section that will incorporate a document by reference. New section 2.9.1—51 lists the information relating to ingredients that must be stated on the label of a special medical purpose product for infants. It provides that that information may be:

- information that complies with Articles 18, 19 and 20 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers; or
- information that complies with 21 CFR § 101.4. That is, section 101.4 of Title 21 of the United States Code of Federal Regulations.

A copy of the EU Regulation is freely and publicly available online at various websites. These include https://eur-lex.europa.eu/homepage.html and https://www.legislation.gov.uk/eur/2011/1169/contents

A copy of the United States Code of Federal Regulations is freely and publicly available online at https://www.govinfo.gov/app/collection/cfr

5. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1028 included two rounds of public comment following an assessment and the preparation of draft variations and associated assessment summaries. The first call for submissions was issued on 4 April 2022 for an 11 week consultation period. The second call for submissions (including draft variations) was issued on 26 April 2023 for a 10-week consultation period.

The Authority also released a number of consultation papers prior to the issue of the first call for submissions, with each consultation paper focused on a key aspect of infant formula regulation.

A decision Regulation Impact Statement was prepared by the Authority and has been approved by The Office of Best Practice Regulation (Reference - OBPR 25089)

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

In this section, references to 'the variation' are references to the approved draft variation.

Clause 1 provides that the name of the variation is the *Food Standards (Proposal P1028 – Infant Formula) Variation.*

Clause 2 provides that the Code is amended by the Schedule to the variation.

Clause 3 provides that the variation will commence on the date of gazettal of the instrument.

Clause 4 provides a transitional arrangement.

Subclause 4(1) provides that the stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 does not apply to any of the amendments made by the variation.

Instead, subclauses 4(2) and (3) provide a transitional arrangement where during a five year transition period commencing on the date of gazettal of the variation, an infant formula product may be sold if the product complies with either: the Code as in force without the amendments made by the variation and the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*; or the Code as amended by those two instruments.

Schedule of the Variation

The Schedule of the variation amends Standard 2.9.1 of the Code.

Item [1] of the Schedule repeals sections 2.9.1—2 to 2.9.1—25 and substitutes them with new provisions as follows.

Section 2.9.1—2: This provision provides an outline for the new Standard 2.9.1. The outline explains that the Standard regulates various types of infant formula products and then what each division of the new Standard 2.9.1 covers. Division 1 deals with preliminary matters. Division 2 sets out the compositional requirements for infant formula and follow-on formula, while Division 3 sets out their labelling and packaging requirements. Division 4 sets out sale, compositional and labelling requirements for special medical purpose product for infants.

Section 2.9.1—3: The Note to this provision sets out definitions for certain key words used in the Standard. These definitions are contained within sections 1.1.2—2 and 1.1.2—3 of the Code and are restated in Standard 2.9.1 for convenience. The Note includes a definition for S*pecial medical purpose product for infants,* which is a newly defined term in the Code. The definition of that term is inserted into Standard 1.1.2 by the *Food Standards (Proposal P1028 – Infant Formula Products – Consequential Amendments) Variation.*

Section 2.9.1—4: This provision provides that, unless expressly stated otherwise, the compositional requirements contained in the Standard apply to: a powdered or concentrated form of infant formula product that has been reconstituted with water in accordance with the relevant directions; and an infant formula product in 'ready to drink' form. The section also prescribes how energy, protein and vitamin A content must be calculated for the purposes of the Standard.

Division 2: Division 2 contains the compositional requirements for infant formula and follow-on formula. Division 2 comprises sections 2.9.1—5 to 2.9.1—13**.**

The Note to the heading for Division 2 alerts readers to subsection 1.5.1—3(2). That provision provides that an infant formula product for retail sale may consist of, or have as an ingredient or a component, a novel food only when and if each condition specified in that subsection is met. The terms 'component' of a food and 'novel food' are defined in subsection 1.1.2—2(3) and section 1.1.2—8 of the Code respectively.

Subsection 1.5.1—3(2) is a new provision inserted into Standard 1.5.1 by the *Food Standards (Proposal P1028 – Infant Formula Products – Consequential Amendments) Variation*.

Section 2.9.1—5: This section sets general compositional requirements for infant formula and follow-on formula.

Subsection 2.9.1—5(1) provides that infant formula and follow-on formula must have an energy content of no less than 2510 kJ/L and no more than 2930 kJ/L.

Subsection 2.9.1—5(2) provides that, subject to subsections 2.9.1—5(3) and (4), infant formula and follow-on formula must not contain added fructose and/or added sucrose.

Subsection 2.9.1—5(3) provides an exception to the prohibition imposed by subsection 2.9.1—5(2). This exception applies only to infant formula and follow on formula manufactured from partially hydrolysed protein. The subsection provides that these types of formula may contain added fructose and/or added sucrose provided that: that fructose and/or sucrose is added to the formula to provide a source of carbohydrate; and the sum of the added fructose and/or sucrose in the formula does not exceed 20% of available carbohydrates in that formula.

Subsection 2.9.1—5(4) also provides an exception to the prohibition imposed by subsection 2.9.1—5(2). Subsection (4) provides that the prohibition does not apply to added fructose and/or added sucrose that is present in infant formula or follow-on formula as a result of: the addition of inulin-type fructans to the infant formula or follow-on formula in accordance with Standard 2.9.1; and/or the use of a substance as a processing aid in accordance with the Code in the manufacture of the infant formula or follow-on formula. The phrase 'used as a processing aid' in relation to a food is defined in section 1.1.2—13 of the Code.

Subsection 2.9.1—5(5) provides that the fluoride content of infant formula and follow-on formula must not exceed 17 µg/100 kJ if in a powdered or concentrated form; and 24 µg/100 kJ if in a ready-to-drink form.

Subsection 2.9.1—5(6) provides that the limits set by subsection 2.9.1—5(5) apply to the infant formula and follow-on formula as sold.

Section 2.9.1—6: This section sets out the protein requirements for infant formula and follow-on formula.

Subsection 2.9.1—6(1) provides that infant formula and follow-on formula must be derived only from one or more of the proteins listed in that subsection.

Subsection 2.9.1—6(2) provides mandatory protein content requirements for infant formula. Milk-based infant formula must have a protein content of no less than 0.43 g/100 kJ and no more than 0.72 g/100 kJ. Infant formula that is not a milk-based infant formula must have a protein content of no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ. Subsection 2.9.1—6(4) defines what is a 'milk-based infant formula' for the purposes of subsection 2.9.1—6(2).

Subsection 2.9.1—6(3) provides mandatory protein content requirements for follow-on formula. Milk-based follow-on formula must have a protein content of no less than 0.38 g/100 kJ and no more than 0.72 g/100 kJ. Follow-on formula that is not a milk-based follow-on formula must have a protein content of no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ. Subsection 2.9.1—6(4) defines what is a 'milk-based follow-on formula' for the purposes of subsection 2.9.1—6(3).

Subsection 2.9.1—6(4) defines what is a milk-based infant formula and a milk-based follow-on formula for the purposes of subsections 2.9.1—6(2) and (3) respectively. Paragraph 2.9.1—6(4)(a) defines ***milk-based infant formula*** to mean infant formula that is derived only from one or more of the following proteins: cow milk; goat milk; sheep milk; a partially hydrolysed protein of one or more of cow milk, goat milk and sheep milk. Paragraph 2.9.1—6(4)(b) defines ***milk-based follow-on formula*** to mean follow-on formula that is derived only from one or more of the following proteins: cow milk; goat milk; sheep milk; a partially hydrolysed protein of one or more of cow milk, goat milk and sheep milk.

Subsection 2.9.1—6(5) requires that the L-amino acids listed in the table to section S29—3 must be present in infant formula and follow-on formula at or above the minimum levels specified in that table.

Subsection 2.9.1—6(6) provides an exception to the requirement imposed by subsection 2.9.1—6(5). This exception applies only to the minimum levels specified in the table to section S29—3 for cysteine and for methionine. Subsection 2.9.1—6(6) provides that these minimum levels do not apply to infant formula and follow-on formula when both the following conditions are met: the minimum amount of combined cysteine and methionine in the infant formula and follow-on formula is not less than 15 mg per 100 kJ; and the ratio of methionine to cysteine in the infant formula and follow-on formula is less than 2 to 1.

Subsection 2.9.1—6(7) provides another exception to the requirement imposed by subsection 2.9.1—6(5). This exception applies only to the minimum levels specified in the table to section S29—3 for phenylalanine and for tyrosine. Subsection 2.9.1—6(7) provides that these minimum levels do not apply to infant formula and follow-on formula when both the following conditions are met: the minimum amount of combined phenylalanine and tyrosine in the infant formula and follow-on formula is not less than 37 mg per 100 kJ; and the ratio of tyrosine to phenylalanine in the infant formula and follow-on formula is less than 2 to 1.

Subsection 2.9.1—6(8) provides that, despite the above-mentioned requirement that the L-amino acids listed in the table to section S29—3 must be present in infant formula and follow-on formula at levels in accordance with subsections (5), (6) and (7), these L-amino acids must only be added to infant formula and follow-on formula in an amount necessary to improve protein quality.

Section 2.9.1—7: This section sets out the fat requirements for infant formula and follow-on formula.

Paragraph 2.9.1—7(1)(a) requires that infant formula and follow-on formula must have a fat content of no less than 1.1 g/100 kJ and no more than 1.4 g/100 kJ.

Paragraph 2.9.1—7(1)(b) requires that infant formula and follow-on formula must have a ratio of linoleic acid to α-linolenic acid of no less than 5 to 1 and no more than 15 to 1.

Paragraph 2.9.1—7(1)(c) requires that infant formula and follow-on formula must contain no less than 90 mg/100 kJ of linoleic acid and no less than 12 mg/100 kJ of α-linolenic acid.

The Note to paragraph 2.9.1—7(1)(c) identifies and explains that it is recommended that infant formula and follow-on formula contain not more than 335 mg of linoleic acid. This is not a mandatory or binding maximum limit. This amount or Guidance Upper Level is provided as guidance only and a recommended upper level for this nutrient which poses no significant risks on the basis of current scientific knowledge. The level is a value derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the amount specified not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons.

Paragraph 2.9.1—7(1)(d) requires that infant formula and follow-on formula must have an arachidonic acid (20 to 4 n-6) content of equal to or more than docosahexaenoic acid (22 to 6 n-3) content.

Paragraph 2.9.1—7(1)(e) requires that infant formula and follow-on formula must contain no less than 0.5 mg of vitamin E per gram of polyunsaturated fatty acids.

Paragraph 2.9.1—7(1)(f) requires that any long chain polyunsaturated fatty acids that are present in infant formula or follow-on formula must have an eicosapentaenoic acid (20:5 n-3) content that is not more than the docosahexaenoic acid (22 to 6 n-3) content.

Paragraph 2.9.1—7(1)(g) lists requirements for certain fatty acids present in infant formula and follow-on formula. The paragraph provides that, if a fatty acid listed in Column 1 of the table to section S29—4 is present in infant formula or follow-on formula, that formula must contain not more than the maximum amount (if any) of that fatty acid that is specified in Column 2 of that table.

Subsection 2.9.1—7(2) provides that infant formula and follow-on formula may only contain medium chain triglycerides that contain predominantly the saturated fatty acids designated by 8 to 0 and 10 to 0 and are either: a natural constituent of a milk-based ingredient of that formula; or for a fat soluble vitamin that is specified in either section S29—5 (in the case of infant formula) or section S29—6 (in the case of follow-on formula), a substance that was used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the formula. The phrase ‘used as a processing aid’ in relation to a food is defined in section 1.1.2—13 of the Code.

Subsection 2.9.1—7(3) provides that infant formula and follow-on formula must not have a phospholipid content of more than 72 mg/100 kJ.

Section 2.9.1—8: This section provides that infant formula and follow-on formula must contain certain nutritive substances.

Subsection 2.9.1—8(1) provides that infant formula must contain each substance listed in Column 1 of the table to section S29—5 in an amount (including any naturally occurring

amount) complying with the corresponding minimum amount and any corresponding maximum amount specified in Columns 2 and 3 respectively of that table.

The Note to subsection 2.9.1—8(1) identifies and explains for readers the operation of Column 4 of the table to section S29—5. This Note explains that it is recommended that infant formula contain a substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in Column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the amounts specified in Column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

Subsection 2.9.1—8(2) provides that follow-on formula must contain each substance listed in the table to section S29—6 in an amount (including any naturally occurring amount) complying with the corresponding minimum amount and any corresponding maximum amount specified in Columns 2 and 3 respectively of that table.

The Note to subsection 2.9.1—8(2) identifies and explains for readers the operation of Column 4 of the table to section S29—6. This Note explains that it is recommended that follow-on formula contain a substance listed in Column 1 of the table to section S29—6 in an amount that is not more than the amount (if any) specified for that substance in Column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the amounts specified in Column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formulas or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

Subsection 2.9.1—8(3) provides that the ratio of calcium to phosphorus in infant formula and follow-on formula must be no less than 1 to 1 and no more than 2 to 1.

Section 2.9.1—9: This section provides that certain substances may be used as a nutritive substance in infant formula and in follow-on formula. The phrase ‘used as a nutritive substance’ in relation to a food is defined in section 1.1.2—12 of the Code.

Subsection 2.9.1—9(1) provides that a substance listed in Column 1 of the table to section S29—7 may be used as a nutritive substance in infant formula, provided that the amount of the substance in the formula (including any naturally-occurring amount) is: no less than the minimum amount (if any) specified in Column 2 of the table; and no more than the maximum amount (if any) specified in Column 3 of the table.

Subsection 2.9.1—9(2) provides that a substance listed in Column 1 of the table to section S29—8 may be used as a nutritive substance in follow-on formula, provided that the amount of the substance (including any naturally-occurring amount) is: no less than the minimum amount (if any) specified in Column 2 of the table; and no more than the maximum amount (if any) specified in Column 3 of the table.

The Note to subsection 2.9.1—9(2) identifies and explains for readers the operation of Column 4 of the table to section S29—8. This Note explains that it is recommended that

follow-on formula contain a substance listed in Column 1 of the table to section S29—8 in an amount that is not more than the amount (if any) specified for that substance in Column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the amounts specified in Column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formulas or due to technological reasons.

Section 2.9.1—10: This section requires that any substance used in either infant formula or follow-on formula in accordance with section 2.9.1—8 or 2.9.1—9 must be in the permitted form listed in the table to section S29—23 (for vitamin, mineral or electrolytes) or the table to section S29—9 (in all other cases).

Section 2.9.1—10A: This section sets conditions of use for certain substances used as a nutritive substance in an infant formula product.

The section refers to the table to subsection S29—9A(2) (the table) and provides that a substance that is:

- used as a nutritive substance in an infant formula product; and
- listed in Column 1 of the table; and
- in a permitted form listed in Column 2 of the table for that substance,

must comply with any corresponding conditions specified in Column 3 of the table for that substance in that permitted form.

At present -

- ‘Lactoferrin’ is the only substance listed in Column 1 of the table.
- ‘Bovine lactoferrin’ is listed in Column 2 of the table as the permitted form for that substance.
- Two conditions (providing a time limited exclusive use permission) are listed in Column 3 for that permitted form.

Section 2.9.1—11: This section permits the addition of L(+) lactic producing microorganisms to infant formula and follow-on formula.

Section 2.9.1—12: This section restricts the addition of inulin-type fructans and galacto-oligosaccharides in infant formula and follow-on formula. The terms ‘inulin-type fructans’ and ‘galacto-oligosaccharides’ are defined in subsection 1.1.2—2(3) of the Code.

Section 2.9.1—12 lists the requirements that must be met if an inulin-type fructan or a galacto-oligosaccharide is added to infant formula or follow-on formula. The requirements are that, following the addition of the latter, the product must contain (taking into account both the naturally-occurring and added substances) no more than:

(a) if only inulin-type fructans are added—110 mg/100 kJ of inulin-type fructans; or

(b) if only galacto-oligosaccharides are added—290 mg/100 kJ of galacto-oligosaccharides; or

(c) if both inulin-type fructans and galacto-oligosaccharides are added:
    (i) no more than 110 mg/100 kJ of inulin-type fructans; and
    (ii) no more than 290 mg/100 kJ of combined inulin-type fructans and galacto-oligosaccharides.

Section 2.9.1—13: This section provides that infant formula and follow-on formula must not contain: detectable gluten; and/or more than 3.8 mg/100 kJ of free nucleotide-5′-monophosphates.

Note 1 to section 2.9.1—13 refers the reader to section S19—4 which sets out the maximum levels of contaminants permitted in infant formula products.

Note 2 to section 2.9.1—13 refers the reader to Standard 1.3.1 and Schedule 15, which permit the use of certain substances as food additives in infant formula products. The phrase ‘used as a food additive’ in relation to a food is defined in section 1.1.2—11 of the Code.

Division 3: Division 3 contains the labelling and packaging requirements for infant and follow-on formula. Division 3 comprises sections 2.9.1—14 to 2.9.1—28.

The Note to Division 3 refers to Standard 1.2.7 and, in particular, paragraph 1.2.7—4(b), which provides that a nutrition content claim or health claim must not be made about infant formula products. The Note also explains that paragraph 1.2.7—6(a) provides that this prohibition does not apply to claims that are expressly permitted by the Code, including by Division 3 of Standard 2.9.1.

Section 2.9.1—14: This section provides that a food may only be represented as infant formula or follow-on formula if that food complies with Standard 2.9.1.

Section 2.9.1—15: This section provides that the label on a package of infant formula or follow-on formula must differentiate that infant formula or follow-on formula from other foods through the use of text, pictures and/or colour. The example provided explains that the text, pictures and/or colours used on a label of infant formula must differentiate that product from, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children.

Section 2.9.1—16: This section sets out the prescribed names for infant formula and follow on formula for the purposes of the Code. Subsection 2.9.1—16(1) provides that ‘Infant formula’ is the prescribed name for infant formula. Subsection 2.9.1—16(2) provides that ‘Follow-on formula’ is the prescribed name for follow-on formula.

The Note to section 2.9.1—16 explains to readers that, under the labelling provisions in Standard 1.2.1 and section 1.2.2—2 of the Code, if a food has a prescribed name, that prescribed name must be used in the labelling of the food, i.e. wherever the Code requires the name of that food to be stated or used.

Section 2.9.1—17: This section sets out the requirement for a measuring scoop in some packages of infant formula and follow-on formula in powdered form.

Subsection 2.9.1—17(1) requires that a package of infant formula or follow-on formula in a powdered form must contain a scoop to enable the use of the formula in accordance with the directions contained in the label on the package.

Subsection 2.9.1—17(2) provides that subsection 2.9.1—17(1) does not apply to single serve sachets, or packages containing single serve sachets, of formula in a powdered form.

Section 2.9.1—18: This section requires that, for the Code’s labelling provisions, the storage instructions for infant formula and follow-on formula must cover the period after the package is opened.

The Note to section 2.9.1—18 advises that the labelling provisions are set out in Standard 1.2.1.

Section 2.9.1—19: This section provides that, for the Code's labelling provisions, the name of the food must be stated on the front of a package of infant formula or follow-on formula. The effect of the section is that, while the name of the food may also appear elsewhere on the package, the name must appear on the front of the package at least once.

In accordance with section 2.9.1—16, the name of the food is the prescribed name (for example, 'Infant formula' or 'Follow-on formula').

The ordinary meaning of 'front of a package' will apply (for example, the surface that is displayed or visible to the purchaser under customary conditions of sale or use).

The Note to section 2.9.1—19 advises the reader that the labelling provisions are set out in Standard 1.2.1.

Section 2.9.1—20: This section sets out requirements related to the statement of the protein source or sources in infant formula and follow-on formula.

Subsection 2.9.1—20(1) provides that, for the Code's labelling provisions, the specific animal or plant source or sources of protein in the infant formula or follow-on formula must be included in the statement of the name of the food required by section 2.9.1—19 (see above). Three examples are provided to assist readers: 'Infant formula based on cow milk'; 'Follow-on formula based on goat milk'; and 'Infant formula based on 'soy protein'.

The effect of the subsection is that the specific protein source must be included in the statement of the name of the food (the prescribed name) required by section 2.9.1—19 and that both the statement of protein source and name of the food must appear on the front of the package of infant formula or follow-on formula.

The first Note to subsection 2.9.1—20(1) advises the reader that the permitted protein sources for infant formula and follow-on formula are listed in subsection 2.9.1—6(1).

The second Note to subsection 2.9.1—20(1) advises the reader that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—20(2) provides that, if infant formula and follow-on formula are derived solely or in part from a partially hydrolysed protein, the words 'partially hydrolysed' must be used immediately adjacent to the statement of protein source required by subsection 2.9.1—20(1). An example is provided to assist readers: 'Infant formula based on partially hydrolysed cow milk'.

The effect of subsection 2.9.1—20(2) is that the words 'partially hydrolysed' must appear together with the statement of protein source and the name of the food on the front of the package of infant formula or follow-on formula if the infant formula and follow-on formula are derived solely or in part from a partially hydrolysed protein.

Subsection 2.9.1—20(3) provides that the statement of protein source required by subsection 2.9.1—20(1) must not use the word 'milk' as the sole descriptor of the protein source.

The example to subsection 2.9.1—20(3) illustrates that protein source statements such as 'Infant formula based on milk' or 'Infant formula sourced from milk' are not permitted.

The Note to subsection 2.9.1—20(3) refers to sub-paragraph 2.9.1—28(1)(j)(i) (see below) in relation to the use of the word 'milk' on the label separately and in addition to in a statement of protein source.

Section 2.9.1—21: This section sets out requirements related to warning statements, statements on use, and directions for infant formula and follow-on formula.

Subsection 2.9.1—21(1) provides that, for the Code's labelling provisions, both of the following warning statements are required for infant formula and follow on formula:

- 'Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill.' (paragraph 2.9.1—21(1)(a)); and
- A heading that states 'Important Notice' (or words to that effect), with under it the warning statement—'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.' (paragraph 2.9.1—21(1)(b)).

The term 'warning statement', in relation to a food for sale, is defined in subsection 1.1.2—2(3) of the Code.

The Note to subsection 2.9.1—21(1) explains that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—21(2) provides that, for the Code's labelling provisions, the required statements on use for infant formula and follow-on formula are ones indicating that:

- for infant formula—the infant formula may be used from birth (paragraph 2.9.1—21(2)(a)); and
- for follow-on formula—the follow-on formula should not be used for infants aged under the age of 6 months (paragraph 2.9.1—21(2)(b)); and
- for infant formula and follow-on formula—it is recommended that infants from the age of 6 months should be offered foods in addition to the infant formula or follow-on formula (paragraph 2.9.1—21(2)(c)).

The Note to subsection 2.9.1—21(2) advises the reader that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—21(3) provides that the statements required by paragraphs 2.9.1—21(2)(a) and (b) must appear on the front of the package of the product.

Subsection 2.9.1—21(4) provides that, notwithstanding subsection 2.9.1—21(3), a statement required by subsection 2.9.1—21(2) may appear more than once on the label.

Subsection 2.9.1—21(5) sets out, for the Code's labelling provisions, requirements relating to the directions on preparation and use that are required for infant formula and follow-on formula.

The directions must instruct in words and pictures that:

- each bottle must be prepared individually (paragraph 2.9.1—21(5)(a)); and
- if a bottle of prepared formula is to be stored prior to use, it must be refrigerated and used within 24 hours (paragraph 2.9.1—21(5)(b)); and
- previously boiled and cooled potable water must be used (paragraph 2.9.1—21(5)(c)); and
- if a package contains a measuring scoop—only the enclosed scoop must be used

(paragraph 2.9.1—21(5)(d)); and

- for powdered or concentrated formula—do not change proportions of the powder or concentrate or add other food except on medical advice (paragraph 2.9.1—21(5)(e)); and
- for ready-to-drink formula—do not dilute or add other food except on medical advice (paragraph 2.9.1—21(5)(f)); and
- formula left in the bottle after a feed must be discarded within 2 hours (paragraph 2.9.1—21(5)(g)).

The Note to subsection 2.9.1—21(5) advises the reader that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—21(6) provides that paragraphs 2.9.1—21(5)(a), (b) and (c) do not apply to ready-to-drink formula.

Subsection 2.9.1—21(7) provides that paragraph 2.9.1—21(5)(d) does not apply to concentrated formula and to ready-to drink formula.

Subsection 2.9.1—21(8) provides that, for the Code's labelling provisions, both of the following must be declared for infant formula and follow-on formula:

- for a product in powdered or concentrated form—the proportion of powder or concentrate required to reconstitute the formula according to directions (paragraph 2.9.1—21(8)(a)); and
- for a product in powdered form—for a product in powdered form—the weight of one scoop (paragraph 2.9.1—21(8)(b)).

The Note to subsection 2.9.1—21(8) advises the reader that the labelling provisions are set out in Standard 1.2.1.

Section 2.9.1—22: This section prescribes the print size for the warning statements required by subsection 2.9.1—21(1).

If the package of infant formula or follow-on formula has a net weight of more than 500 g, paragraph 2.9.1—22(a) requires that the statements must be in a size of type of at least 3 mm. If the package of infant formula or follow-on formula has a net weight of 500 g or less, paragraph 2.9.1—22(b) requires that the statements must be in a size of type of at least 1.5 mm. The term 'size of type' is defined by subsection 1.1.2—2(3) of the Code.

Section 2.9.1—23: This section provides an optional format to declare added vitamins and minerals in the statement of ingredients for infant formula and follow-on formula.

Subsection 2.9.1—23(1) provides an exception to section 1.2.4—5 of the Code. Section 1.2.4—5 requires a statement of ingredients to list each ingredient in descending order of ingoing weight. Subsection 2.9.1—23(1) provides that, where a vitamin or mineral is added to infant formula or follow-on formula in accordance with section 2.9.1—8, the statement of ingredients need not list the added vitamin and mineral in descending order of ingoing weight, provided that that statement of ingredients lists all added vitamins together under the subheading 'Vitamins', and lists all added minerals together under the subheading 'Minerals'.

The Note to subsection 2.9.1—23(1) refers to Standard 1.2.4 for all other ingredient labelling requirements.

Subsection 2.9.1—23(2) provides that section 1.2.4—8 of the Code does not apply to a statement of ingredients referred in subsection 2.9.1—23(1). Section 1.2.4—8 permits a vitamin or mineral that has been added to a food to be declared in accordance with section 1.2.4—7 using the class name 'vitamin' or 'mineral'. Subsection 1.2.4—7(1) provides that a substance (including a vitamin or mineral) used as a food additive must be listed in a statement of ingredients by specifying:

- if the substance can be classified into a class of additives listed in Schedule 7 (whether prescribed or optional)—that class name, followed in brackets by the name or *code number of the substance as indicated in Schedule 8; or
- otherwise—the name of the substance as indicated in Schedule 8.

The phrase 'used as a food additive' in relation to a food is defined in section 1.1.2—11 of the Code.

Section 2.9.1—24: This section sets out requirements related to the declaration of nutrition information for infant formula and follow-on formula.

Subsection 2.9.1—24(1) provides that, for the Code's labelling provisions, a statement of nutrition information is required for infant formula and follow-on formula.

Subsection 2.9.1—24(2) provides that a reference in this section to 'the statement' is the statement required by subsection 2.9.1—24(1).

Subsection 2.9.1—24(3) provides that the statement must contain all of the following information:

- The average energy content expressed in kilojoules per 100 mL of formula (paragraph 2.9.1—24(3)(a)).
- The average quantity of protein, fat and carbohydrate expressed in grams per 100 mL of formula and as 'protein', 'fat' and 'carbohydrate', respectively (paragraph 2.9.1—24(3)(b)).
- The average quantity of each vitamin or mineral expressed in micrograms or milligrams per 100 mL of formula (including any naturally-occurring amount) (paragraph 2.9.1—24(3)(c)).
- For infant formula only—the average quantity of choline, inositol and L-carnitine expressed in milligrams per 100 mL of formula (including any naturally-occurring amount) (paragraph 2.9.1—24(3)(d)).
- The average quantity of the following if added: any substance used as a nutritive substance (including any naturally occurring amount); inulin-type fructans; galacto-oligosaccharides; or a combination of inulin-type fructans and galacto-oligosaccharides (paragraph 2.9.1—24(3)(e)). These amounts must be expressed in grams, micrograms or milligrams per 100 mL of formula.

The terms 'average quantity', 'carbohydrate', 'inulin-type fructans', and 'galacto-oligosaccharides' are defined in subsection 1.1.2—2(3) of the Code.

The phrase 'used as a nutritive substance' in relation to a food is defined in section 1.1.2—12 of the Code.

The Note to subsection 2.9.1—24(3) explains that the labelling provisions are set out in Standard 1.2.1.

Subsection 2.9.1—24(4) permits the statement to include the average quantity of each of the following substances that is present in the infant formula or follow-on formula, expressed in grams per 100 mL of formula (including any naturally occurring amount):

- whey (paragraph 2.9.1—24(4)(a)); and
- casein (paragraph 2.9.1—24(4)(b)).

The term 'average quantity' is defined in subsection 1.1.2—2(3) of the Code.

Subsection 2.9.1—24(5) permits the statement to include the average quantity of each of the following substances that is present in the infant formula or follow-on formula, expressed in milligrams per 100 mL of formula (including any naturally occurring amount):

- docosahexaenoic acid (paragraph 2.9.1—24(5)(a)); and
- eicosapentaenoic acid (paragraph 2.9.1—24(5)(b)); and
- arachidonic acid (paragraph 2.9.1—24(5)(c)).

Subsection 2.9.1—24(6) requires that, if the infant formula or follow-on formula is in a powdered or concentrated form, information included in the statement in accordance with subsection 2.9.1—24(3), (4) or (5) (see above) must be expressed in terms of per 100 mL of formula as reconstituted according to the directions on the package.

Subsection 2.9.1—24(7) permits information included in the statement in accordance with subsection (3), (4) or (5) to also be expressed:

- if sold in a concentrated form —per 100 mL of the formula as sold (paragraph 2.9.1—24(7)(a)); or
- if sold in a powdered form —per 100 g of formula as sold (paragraph 2.9.1—24(7)(b)).

That optional method of expressing the information included in the statement is *additional to* the mandatory method of expressing the information in accordance with subsection 2.9.1—24(6) (see above),

Subsection 2.9.1—24(8) requires that unless expressly provided elsewhere in this Code, the statement must not contain any other information.

Section 2.9.1—25: This section sets out the requirements for the form for the declaration of nutrition information required by section 2.9.1—24 (see above).

Subsection 2.9.1—25(1) provides that a reference to the table in subsections 2.9.1—25(2) to (6) is a reference to the table to section S29—10.

Subsection 2.9.1—25(2) sets out the following requirements for the nutrition information statement.

- The statement must be in the same format as specified in the table to section S29—10 (paragraph 2.9.1—25(2)(a)).
- The statement must state the nutrition information in the order specified in the table to section S29—10 (paragraph 2.9.1—25(2)(b)).
- The statement must be titled 'Nutrition Information' in bold font (paragraph 2.9.1—25(2)(c)).
- The statement must have the following subheadings - 'Vitamins', 'Minerals' and 'Additional'. Infant formula must also have the subheading 'Other nutrients'. Each subheading must be printed in a size of type that is the same or larger than the nutrient names stated in the statement (paragraph 2.9.1—25(2)(d)). The term 'size of type' is defined by subsection 1.1.2—2(3) of the Code.

- The statement must state nutrients and subgroup nutrients using the names and units of measurement that are specified in the table to section S29—10 for that nutrient and subgroup (paragraph 2.9.1—25(2)(e)).
- The statement must not express an amount or quantity other than in accordance with section 2.9.1—24 (paragraph 2.9.1—25(2)(f)).

The intent of subsection 2.9.1—25(2) is to ensure the format and grouping of nutrients and substances in the nutrition information statement is presented in a consistent manner.

Subsection 2.9.1—25(3) applies if the average quantity of a permitted nutritive substance, an inulin-type fructan or a galacto-oligosaccharide is included in the nutrition information statement. In this case, the subsection requires that that average quantity must be included in the nutrition information statement under the subheading 'Additional' and in the same format as specified in the table for that substance.

Subsection 2.9.1—25(4) applies if the average quantity of choline, inositol or L-carnitine is included in the nutrition information statement. Paragraph 2.9.1—25(4)(a) provides that, for infant formula, the average quantity must be included in the statement under the subheading 'Other Nutrients'. Paragraph 2.9.1—25(4)(b) provides that, for follow-on formula, the average quantity must be in the statement under the subheading 'Additional'. Paragraph 2.9.1—25(4)(c) requires that, in each case, the average quantity must be included in the nutrition information statement in the same format that is specified in the table for the relevant substance.

Subsection 2.9.1—25(5) applies if the nutrition information statement includes the average quantity of a substance listed in subsection 2.9.1—24(4). In that case, the subsection requires that the average quantity must be included in the nutrition information statement in the same format that is specified for that substance in the table to section S29—10.

Subsection 2.9.1—25(6) applies if the nutrition information statement includes the average quantity of a substance listed in subsection 2.9.1—24(5). In that case –

Paragraph 2.9.1—25(6)(a) provides that the nutrition information statement must include the subheading 'Long chain polyunsaturated fatty acids' and that subheading must be printed in a size of type that is the same or larger than the nutrient names in the statement. The term 'size of type' is defined by subsection 1.1.2—2(3) of the Code.

Paragraph 2.9.1—25(6)(b) provides that the nutrition information statement must include that average quantity under the subheading 'Long chain polyunsaturated fatty acids' and in the same format as specified for those substances by the table to section S29—10.

Paragraph 2.9.1—25(6)(c) provides that the nutrition information statement must use the name for each substance that is specified by the table to section S29—10 for that substance.

Paragraph 2.9.1—25(6)(d) provides that the nutrition information statement may use the acronym specified in the table to section S29—10 for the following substances in addition to the name required by paragraph 2.9.1—25(6)(c). These substances are: docosahexaenoic acid, eicosapentaenoic acid and arachidonic acid. An example is provided to assist readers: if the average quantity of docosahexaenoic acid is included in the nutrition information statement, the statement may state that average quantity using either 'Docosahexaenoic acid (DHA)' or 'Docosahexaenoic acid', but not 'DHA'.

Subsection 2.9.1—25(7) provides that if the nutrition information statement includes information expressed in accordance with subsection 2.9.1—24(7) (see above), that

information must be in an additional column at the right hand side of Column 2 shown in the table to section S29—10A.

Subsection 2.9.1—25(8) provides that information included in the additional column required by subsection 2.9.1—25(7) must be in the form required by this section.

The Note to subsection 2.9.1—25(8) refers the reader to section S29—10A for an example of a nutrition information statement including information expressed in accordance with subsection 2.9.1—24(7).

The term 'average quantity' is defined in subsection 1.1.2—2(3) of the Code.

Section 2.9.1—26: This section provides that the method listed in paragraph 1.1.1—6(3)(c) of the Code must not be used to calculate the average quantity of a substance in infant formula or follow-on formula. This is an exception to section 1.1.1—6 which lists the methods for how average quantity is to be calculated for Code purposes.

Section 2.9.1—27: This section sets out the requirements for the use of stage numbers on a package of infant formula or follow-on formula.

Paragraph 2.9.1—27(1)(a) provides that the number '1' may be used on the label on a package of infant formula in order to identify for consumers that that product is infant formula.

Paragraph 2.9.1—27(1)(b) provides that the number '2' may be used on the label on a package of follow-on formula in order to identify for consumers that that product is follow-on formula.

Subsection 2.9.1—27(2) sets out where a number used in accordance with subsection 2.9.1—27(1) must appear on the package of the product. For infant formula, the number must appear on the front of the package of the product, immediately adjacent to the statement required by paragraph 2.9.1—21(2)(a) (see above). For follow-on formula, the number must appear on the front of the package of the product, immediately adjacent to the statement required by paragraph 2.9.1—21(2)(b) (see above).

Subsection 2.9.1—27(3) provides that subsection (2) does not prevent a number used in accordance with subsection (1) from also appearing elsewhere on the label.

Section 2.9.1—28: This section sets out representations that the label on a package of infant formula or follow-on formula must not contain**.**

Subsection 2.9.1—28(1) provides that the label on a package of infant formula or follow-on formula must not contain any of the following:

- A picture of an infant (paragraph 2.9.1—28(1)(a)).
- A picture that idealises the use of infant formula or follow-on formula (paragraph 2.9.1—28(1)(b)).
- For infant formula—information relating to follow-on formula, a special medical purpose product for infants, a formulated supplementary food or a formulated supplementary food for young children (subparagraph 2.9.1—28(1)(c)(i))
- For follow-on formula— information relating to infant formula, a special medical purpose product for infants,a formulated supplementary food or a formulated supplementary food for young children (subparagraph 2.9.1—28(1)(c)(ii))
- The word 'humanised' or 'maternalised' or any word or words having the same or similar effect (paragraph 2.9.1—28(1)(d)).

- The words ‘human milk oligosaccharide’, ‘human identical milk oligosaccharide’ or any word or words having the same or similar effect (paragraph 2.9.1—28(1)(e)).
- The abbreviations ‘HMO’ or HiMO’ or any abbreviation having the same or similar effect (paragraph 2.9.1—28(1)(f)).
- Words claiming that the formula is suitable for all infants (paragraph 2.9.1—28(1)(g)).
- Information relating to the nutritional content of human milk (paragraph 2.9.1—28(1)(h)).
- Information relating to the presence of a substance listed in subsection 2.9.1—28(2) (paragraph 2.9.1—28(1)(i)). The paragraph provides that this prohibition does not apply to a reference in a statement of ingredients or in a declaration or statement expressly permitted or required by the Code.
- Information relating to ingredients (paragraph 2.9.1—28(1)(j)). The paragraph provides that this prohibition does not apply to: the use of the word ‘milk’; a reference in a statement of ingredients; or a reference in a declaration or statement expressly permitted or required by the Code.
- Information relating to the animal or plant source or sources of protein in the formula (paragraph 2.9.1—28(1)(k)). The paragraph provides that this prohibition does not apply to a reference in a statement of ingredients or where the information is required by subsection 2.9.1—20(1).
- The words ‘partially hydrolysed’ or any word or words having the same or similar effect (paragraph 2.9.1—28(1)(l)). The paragraph provides that this prohibition does not apply to the use of these words in a statement of ingredients or where required by subsection 2.9.1—20(2) of the Code.

Subsection 2.9.1—28(2) lists the substances to which the prohibition imposed by paragraph 2.9.1—28(1)(i) applies. The listed substances are: an inulin-type fructan; a galacto-oligosaccharide; a nutrient; and a substance used as a nutritive substance.

The terms ‘inulin-type fructans’ and ‘galacto-oligosaccharides’ are defined in subsection 1.1.2—2(3) of the Code. The phrase ‘used as a nutritive substance’ in relation to a food is defined in section 1.1.2—12 of the Code.

The Note to subsection 2.9.1—28(2) explains that section 2.9.1—24 expressly requires or permits these substances to be declared or stated in the nutrition information statement required by that section.

Division 4: Division 4 contains the sale, compositional, labelling and packaging requirements for special medical purpose products for infants. Division 4 comprises sections 2.9.1—30 to 2.9.1—55.

Section 2.9.1—30: This section provides that, unless the contrary intention appears, Part 1.2 of Chapter 1 of the Code and Division 3 of Standard 2.9.1 do not apply to special medical purpose products for infants. Part 1.2 of Chapter 1 deals with labelling and other information requirements. Division 3 of Standard 2.9.1 contains the labelling and packaging requirements for infant and follow-on formula (see above).

Section 2.9.1—31: This section imposes restrictions on the sale of special medical purpose products for infants.

Subsection 2.9.1—31(1) provides that a special medical purpose product for infants must not be sold to a consumer, other than from or by: a medical practitioner or dietitian; a medical practice, pharmacy or responsible institution; or a majority seller of that special medical purpose product for infants.

Subsection 2.9.1—31(2) defines who is a majority seller and a medical practitioner for the

purposes of section 2.9.1—31.

A majority seller of a special medical purpose product for infants is defined to mean a person who: during any 24 month period, sold that special medical purpose product for infants to any of the following: a medical practitioner; a dietitian; a medical practice; a pharmacy; a responsible institution, provided that these sales represented more than half of the total amount of that product sold by the person during that 24 month period.

A ***medical practitioner*** is defined to mean a person registered or licensed as a medical practitioner under legislation in Australia or New Zealand, as the case requires, for the registration or licensing of medical practitioners.

The term “responsible institution” is defined in subsection 1.1.2—2(3) of the Code.

Section 2.9.1—32 This section sets general compositional requirements for special medical purpose products for infants.

Subsection 2.9.1—32(1) provides that a special medical purpose product for infants must have an energy content of no less than 2510 kJ/L and no more than 2930 kJ/L.

Subsection 2.9.1—32(2) provides that, subject to subsections 2.9.1—32(3) and (4) (see below), a special medical purpose product for infants must not contain added fructose and/or added sucrose.

Subsection 2.9.1—32(3) provides an exception to the prohibition imposed by subsection 2.9.1—32(2). This exception applies only to special medical purpose products for infants manufactured from partially hydrolysed protein. The subsection provides that these types of special medical purpose product for infants may contain added fructose and/or added sucrose provided that the fructose and/or sucrose is added to the product to provide a source of carbohydrate; and the sum of the added fructose and/or sucrose to in the product does not exceed 20% of available carbohydrates in that product.

Paragraph 2.9.1—32(4) also provides an exception to the prohibition imposed by subsection 2.9.1—32(2). Section 2.9.1—32(4)provides that that prohibition does not apply to added fructose and/or added sucrose that is present in a special medical purpose product for infants as a result of: the addition of inulin-type fructans to the special medical purpose product for infants in accordance with Standard 2.9.1 (paragraph 2.9.1—32(4)(a)); and/or the use of a substance as a processing aid in accordance with the Code in the manufacture of the special medical purpose products for infants (paragraph 2.9.1—32(4)(b)).

The term ‘inulin-type fructans’ is defined in subsection 1.1.2—2(3) of the Code. The phrase ‘used as a processing aid’ in relation to a food is defined in section 1.1.2—13 of the Code.

Subsection 2.9.1—32(5) provides that the fluoride content of a special medical purpose product for infants must not exceed 17 µg/100 kJ if the product is in a powdered or concentrated form; and 24 µg/100 kJ if the product is in a ready-to-drink form.

Subsection 2.9.1—32(6) provides that the amounts set by subsection 2.9.1—32(5) apply to the special medical purpose product for infants as sold.

Section 2.9.1—33: This section sets out the protein requirements for special medical purpose products for infants.

Subsection 2.9.1—33(1) provides that special medical purpose product for infants must be only derived from one or more of the following proteins listed in that subsection:

- cow milk;
- goat milk;
- sheep milk;
- soy protein isolate;
- a partially hydrolysed protein of one or more of the above.

Subsection 2.9.1—33(2) provides mandatory protein content requirements for special medical purpose products for infants. A special medical purpose product for infants that is a milk-based product must have a protein content of no less than 0.43 g/100 kJ and no more than 0.72 g/100 kJ. A special medical purpose product for infants that is not a milk-based product must have a protein content of no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.

Subsection 2.9.1—33(3) defines what is a milk-based product for the purposes of subsection 2.9.1—33(2). A ***milk-based product*** is defined mean a special medical purpose product for infants that is derived only from one or more of the following proteins: cow milk; goat milk; sheep milk; a partially hydrolysed protein of one or more of cow milk, goat milk and sheep milk.

Subsection 2.9.1—33(4) requires that the L-amino acids listed in the table to section S29—3 must be present in a special medical purpose product for infants at or above the corresponding minimum level specified in that table.

Subsection 2.9.1—33(5) provides an exception to the requirement imposed by subsection 2.9.1—33(4). This exception applies only to the minimum levels specified in the table to section S29—3 for cysteine and for methionine. Subsection 2.9.1—33(5) provides that these minimum levels do not apply to a special medical purpose product for infants when both the following conditions are met: the minimum amount of combined cysteine and methionine in the special medical purpose product for infants is not less than 15 mg per 100 kJ; and the ratio of methionine to cysteine in the special medical purpose product for infants is less than 2 to 1.

Subsection 2.9.1—33(6) provides another exception to the requirement imposed by subsection 2.9.1—33(4). This exception applies only to the minimum levels specified in the table to section S29—3 for phenylalanine and for tyrosine. Subsection 2.9.1—33(6) provides that these minimum levels do not apply to a special medical purpose product for infants when both following conditions are met: the minimum amount of combined phenylalanine and tyrosine in the special medical purpose product for infants is not less than 37 mg per 100 kJ; and the ratio of tyrosine to phenylalanine in the special medical purpose product for infants is less than 2 to 1.

Subsection 2.9.1—33(7) provides that, despite the above-mentioned requirements in subsections 2.9.1—33(4), (5) and (6)), relating to the levels of L-amino acids listed in the table to section S29—3 in special medical purpose products for infants, those L-amino acids must only be added to special medical purpose product for infants in an amount necessary to improve protein quality.

Section 2.9.1—34: This section sets out the fat requirements for special medical purpose products for infants.

Paragraph 2.9.1—34(1)(a) requires that a special medical purpose product for infants must have a fat content of no less than 1.1 g/100 kJ and no more than 1.4 g/100 kJ.

Paragraph 2.9.1—34(1)(b) requires that a special medical purpose product for infants must have a ratio of linoleic acid to α-linolenic acid of no less than 5 to 1 and no more than 15 to 1.

Paragraph 2.9.1—34(1)(c) requires that a special medical purpose product for infants must contain no less than 90 mg/100 kJ of linoleic acid and no less than 12 mg/100 kJ of α-linolenic acid.

The Note to paragraph 2.9.1—34(1)(c) identifies and explains that it is recommended that a special medical purpose product for infants contain not more than 335 mg of linoleic acid. This is not a mandatory or binding maximum limit. This amount or Guidance Upper Level is provided as guidance only and a recommended upper level for this nutrient which poses no significant risks on the basis of current scientific knowledge. The level is a value derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the amount specified not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons.

Paragraph 2.9.1—34(1)(d) requires that a special medical purpose product for infants must have an arachidonic acid (20 to 4 n-6) content of equal to or more than docosahexaenoic acid (22 to 6 n-3) content.

Paragraph 2.9.1—34(1)(e) requires that a special medical purpose product for infants must contain no less than 0.5 mg of vitamin E per gram of polyunsaturated fatty acids.

Paragraph 2.9.1—34(1)(f) requires that any long chain polyunsaturated fatty acids that are present in a special medical purpose product for infants must have an eicosapentaenoic acid (20 to 5 n-3) content that is not more than the docosahexaenoic acid (22 to 6 n-3) content. The term ‘polyunsaturated fatty acid’ is defined in subsection 1.1.2—2(3) of the Code.

Paragraph 2.9.1—34(1)(g) lists requirements for certain fatty acids present in a special medical purpose product for infants. The paragraph provides that, if a fatty acid listed in Column 1 of the table to section S29—4 is present in a special medical purpose product for infants, that product must contain not more than the maximum (if any) amount of that fatty acid that is specified in Column 2 of that table.

Subsection 2.9.1—34(2) provides that a special medical purpose product for infants may only contain medium chain triglycerides that are either: a natural constituent of a milk-based ingredient of that product; or for a fat soluble vitamin that is specified in the table to section S29—5, a substance that was used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the special medical purpose product for infants. The phrase ‘used as a processing aid’ in relation to a food is defined in section 1.1.2—13 of the Code.

Subsection 2.9.1—34(3) provides that a special medical purpose product for infants must not have a phospholipid content of more than 72 mg/100 kJ.

Section 2.9.1—35: This provision provides a qualified permission for a special medical purpose product to contain a novel food. The section provides that, despite any other provision in the Code, a special medical purpose product for infants for retail sale may have, as an ingredient or a component, a novel food, but only if the presence of that novel food in that product is necessary to achieve that product’s intended medical purpose. The terms ‘component’ of a food and ‘novel food’ are defined in subsection 1.1.2—2(3) and section 1.1.2—8 of the Code respectively.

Section 2.9.1—36: This section provides that special medical purpose products for infants must contain certain nutritive substances.

Subsection 2.9.1—36(1) provides that a special medical purpose product for infants must contain each substance listed in Column 1 of the table to section S29—5 and in an amount (including any naturally-occurring amount) that is no less than the minimum amount specified in Column 2 of the table (paragraph 2.9.1—36(1)(a)); and no more than the maximum amount (if any) specified in Column 3 of the table (paragraph 2.9.1—36(1)(b)).

The Note to subsection 2.9.1—36(1) identifies and explains the operation of Column 4 of the table to section S29—5. This Note explains that it is recommended that a special medical purpose product for infants contain a substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in Column 4. This is not a mandatory or binding maximum limit. The amounts or Guidance Upper Levels are provided as guidance only and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the amounts specified in Column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of a special medical purpose product for infants or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

Subsection 2.9.1—36(2) provides that the ratio of calcium to phosphorus in a special medical purpose product for infants must be no less than 1 to 1 and no more than 2 to 1.

Section 2.9.1—37: This section provides that certain substances may be used as a nutritive substance in a special medical purpose product for infants. The phrase ‘used as a nutritive substance’ in relation to a food is defined in section 1.1.2—12 of the Code.

The section provides that a substance listed in Column 1 of the table to S29—7 may be used as a nutritive substance in a special medical purpose product for infants, provided that the amount of the substance in the product (including any naturally-occurring amount) is: no less than the minimum amount (if any) specified in Column 2 of the table; and no more than the maximum amount specified in Column 3 of the table.

Section 2.9.1—38: This section requires that any substance used in a special medical purpose product for infants in accordance with section 2.9.1—36 or 2.9.1—37 must be in the permitted form listed in either the table to section S29—23 (for vitamin, mineral or electrolytes) or the table to section S29—9 (in all other cases).

Section 2.9.1—39: This section permits the addition of L(+) lactic producing microorganisms to special medical purpose products for infants.

Section 2.9.1—40: This section restricts the addition of inulin-type fructans and galacto-oligosaccharides to special medical purpose products for infants. The terms ‘inulin-type fructans’ and ‘galacto-oligosaccharides’ are defined in subsection 1.1.2—2(3) of the Code.

The section lists the requirements that must be met if an inulin-type fructan or a galacto-oligosaccharide is added to a special medical purpose product for infants. The requirements are that the product must contain (taking into account both the naturally-occurring and added substances) no more than:

- if only inulin-type fructans are added—110 mg/100 kJ of inulin-type fructans; or
- if only galacto-oligosaccharides are added—290 mg/100 kJ of galacto-oligosaccharides; or
- if both inulin-type fructans and galacto-oligosaccharides are added:
  - no more than 110 mg/100 kJ of inulin-type fructans; and

- no more than 290 mg/100 kJ of combined inulin-type fructans and galacto-oligosaccharides.

Section 2.9.1—41: This section provides that a special medical purpose product for infants must not contain any of the following: detectable gluten; or more than 3.8 mg/100 kJ of free nucleotide-5′-monophosphates.

There are two Notes to this section.

Note 1 refers readers to section S19—4 that contains the maximum levels of contaminants in infant formula products.

Note 2 refers readers to Standard 1.3.1 and Schedule 15, which together permit the use of certain substances as food additives in infant formula products including a special medical purpose product for infants.

Section 2.9.1—42: This section provides an exception to certain compositional requirements imposed by the Code.

Subsection 2.9.1—42(1) provides that special medical purpose product for infants need not comply with a compositional requirement (as defined by subsection 2.9.1—42(2)) to the extent that a variation from that requirement: is needed to achieve the product's intended medical purpose; or would otherwise prevent the sale of the product.

The intent of subsection 2.9.1—42(1) is to allow special medical purpose products for infants to vary their specialised formulation based on the nutrient requirements of the specified medical disease, disorder or condition. This can include deviation from multiple composition parameters. An example is a special medical purpose product for infants formulated in accordance with an international regulation that has a lower prescribed substance level than that required by the Code. The existence of that lower substance level in line with the intentional regulation would not stop the sale of the food.

Subsection 2.9.1—42(2) defines 'a compositional requirement' for the purposes of subsection 2.9.1—42(1) as meaning a requirement imposed in relation to a special medical purpose product for infants by any of the following provisions of the Code:

- any of sections 2.9.1—32 to 2.9.1—41, but not section 2.9.1—35 (paragraph 2.9.1—42(2)(a));
- paragraph 1.1.1—10(6)(a) (this paragraph imposes a requirement that, unless expressly permitted by this Code, a food for sale must not have, as an ingredient or a component, a substance that was used as a food additive) (paragraph 2.9.1—42(2)(b));
- paragraph 1.1.1—10(6)(b) (this paragraph imposes a requirement that, unless expressly permitted by this Code, a food for sale must not have, as an ingredient or a component, a substance that was used as a nutritive substance) (paragraph 2.9.1—42(2)(c));
- paragraph 1.1.1—10(6)(c) (this paragraph imposes a requirement that, unless expressly permitted by this Code, a food for sale must not have, as an ingredient or a component, a substance that was used as a processing aid) (paragraph 2.9.1—42(2)(d)).

The term 'component' of a food is defined in subsection 1.1.2—2(3) of the Code. The phrases 'used as a food additive', 'used as a nutritive substance' and 'used as a processing aid' in relation to a food are defined in sections 1.1.2—11, 1.1.2—12 and 1.1.2—13 of the Code respectively.

Sections 2.9.1—43 to 2.9.1—55 set out the labelling and packaging requirements for special medical purpose products for infants.

Section 2.9.1—43: This section provides that a food may only be represented as a special medical purpose product for infants if it complies with Division 4 of Standard 2.9.1.

Section 2.9.1—44: This section requires that the label on a package of a special medical purpose product for infants must differentiate that product from other foods by the use of text, pictures and/or colours.

An example is provided: the text, pictures and/or colours used on a label on a package of a special medical purpose product for infants must differentiate that product from, among other things, infant formula, follow-on formula or a formulated supplementary food for young children.

Section 2.9.1—45: This section sets out the representations that the label on a package of a special medical purpose product for infants must not contain. The section provides that the label on a package of a special medical purpose product for infants must not contain any of the following:

- A picture of an infant (paragraph 2.9.1—45(a)).
- A picture or text that idealises the use of special medical purpose product for infants (paragraph 2.9.1—45(b)).
- The words ‘human milk oligosaccharide’, ‘human identical milk oligosaccharide’ or any word or words having the same or similar effect (paragraph 2.9.1—45(c)).
- The abbreviations ‘HMO’ or HiMO’ or any abbreviation having the same or similar effect (paragraph 2.9.1—45(d)).

Section 2.9.1—46: This section sets out a claim must not be made in relation to a special medical purpose product for infants**.**

Subsection 1.1.2—2(3) defines the term ‘claim’ to mean ‘an express or implied statement, representation, design or information in relation to a food or a property of food which is not mandatory in this Code’.

Subsections 2.9.1—46(1) and (2) provide the following claims are prohibited:

- A claim that refers to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition (paragraph 2.9.1—46(1)(a)).
- A claim that compares the special medical purpose product for infants to a good that is represented in any way to be for therapeutic use (subparagraph 2.9.1—46(1)(b)(i)).
- A claim that compares the special medical purpose product for infants to a good that is likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason (subparagraph 2.9.1—46(1)(b)(ii)).
- A nutrition content claim or health claim (subsection 2.9.1—46(2)). The term ‘health claim’ is defined in subsection 1.1.2—2(3) of the Code.

Subsection 2.9.1—46(3) provides exemptions to the prohibitions imposed by subsections 2.9.1—46(1) or (2). Subsection 2.9.1—46(3) provides that section 2.9.1—46 does not apply to: a claim that is expressly permitted by the Code; or a declaration that is required by an application Act.

Section 2.9.1—47: This section provides that a claim that a special medical purpose product for infants is lactose free may only be made if that special medical purpose product for infants contain no detectable lactose.

Section 2.9.1—48: This section sets out the general labelling and related requirements for special medical purpose product for infants for sale.

Subsection 2.9.1—48(1) provides that the requirements listed in section 2.9.1—48 apply to a food for sale that is a special medical purpose product for infants.

Subsection 2.9.1—48(2) requires the special medical purpose product for infants that is in a package to bear a label that complies with section 2.9.1—49 (see below). The phrase 'bear a label' is defined in subsection 1.1.2—2(3) of the Code.

Subsection 2.9.1—48(3) only applies to a special medical purpose product for infants for sale that is in an inner package. The term 'inner package' is defined in subsection 1.1.2—2(3) of the Code. Paragraph 2.9.1—48(3)(a) requires the inner package to bear a label that complies with section 2.9.1—54 (see below). Paragraph 2.9.1—48(3)(b) also requires that there is no other labelling requirement in the Code for any other packaging associated with that product.

Subsection 2.9.1—48(4) applies to a special medical purpose product for infants for sale that is in a transportation outer. 'Transportation outer' is defined in subsection 1.1.2—2(3) of the Code. Paragraph 2.9.1—48(4)(a) requires that the transportation outer or package containing that special medical purpose product for infants to bear a label that complies with section 2.9.1—55 (see below). Paragraph 2.9.1—48(4)(b) also requires that there is no other labelling requirement in the Code for any other packaging associated with that product.

Section 2.9.1—49: This section sets out the information that must be stated on the label required for a special medical purpose product for infants.

Subsection 2.9.1—49(1) requires the following information to be stated on the label.

- A name or description sufficient to indicate the true nature of the food, in accordance with section 1.2.2—2 (paragraph 2.9.1—49(1)(a)).
- Lot identification, in accordance with section 1.2.2—3 (paragraph 2.9.1—49(1)(b)).
- Information relating to foods produced using gene technology, in accordance with section 1.5.2—4, provided that the sale of that product is a sale to which Division 2 or Division 3 of Standard 1.2.1 applies (subparagraph 2.9.1—49(1)(c)(i)). The phrase 'food produced using gene technology is defined in subsection 1.1.2—2(3) of the Code.
- Information relating to irradiated food, in accordance with section 1.5.3—9, provided that the sale of that product is a sale to which Division 2 or Division 3 of Standard 1.2.1 applies (subparagraph 2.9.1—49(1)(c)(ii)).
- Any mandatory statements and declarations, in accordance with section 2.9.1—50 (paragraph 2.9.1—49(1)(d)).
- Information relating to ingredients, in accordance with section 2.9.1—51 (paragraph 2.9.1—49(1)(e)).
- Date marking information, in accordance with section 2.9.1—52 (paragraph 2.9.1—49(1)(f)).
- Directions for the preparation, use or storage of the food, if the food is of such a nature to require such directions for health or safety reasons (paragraph 2.9.1—49(1)(g))
- Nutrition information, in accordance with section 2.9.1—53 (paragraph 2.9.1—49(1)(h)).

Subsection 2.9.1—49(2) requires the label for a special medical purpose product for infants to comply with section 1.2.1—24 of the Code. Section 1.2.1—24 sets out general legibility requirements for food for sale.

Section 2.9.1—50: This section sets out the mandatory statements and declarations required for special medical purpose products for infants.

Paragraph 2.9.1—50(a) provides that the following statements are required for the purposes of paragraph 2.9.1—49(1)(d).

- A statement to the effect that the product must be used under medical supervision (paragraph 2.9.1—50(a)).
- A statement indicating, if applicable, any precautions and contraindications associated with consumption of the product (paragraph 2.9.1—50(b)).
- A statement indicating the medical purpose of the product, which may include a disease, disorder or medical condition for which the product has been formulated (paragraph 2.9.1—50(c)).
- A statement describing the properties or characteristics which make the product appropriate for the medical purpose indicated in paragraph 2.9.1—50(c) (paragraph 2.9.1—50(d)).
- if the product has been formulated for a specific age group—a statement to the effect that the product is intended for persons within the specified age group (paragraph 2.9.1—50(e)).
- A statement indicating whether or not the product is suitable for use as a sole source of nutrition (paragraph 2.9.1—50(f)).
- If the product is represented as being suitable for use as a sole source of nutrition, a statement to the effect that the product is not for parenteral use (subparagraph 2.9.1—50(g)(i)).
- If the product has been modified to vary from the compositional requirement of Division 4 such that the content of one or more nutrients falls short of the prescribed minimum, or exceeds the prescribed maximum (if applicable) (see section 2.9.1—42 above), then both the following statements are required for that product (in addition to the statement required by subparagraph 2.9.1—50(g)(i)):
  - a statement indicating the nutrient or nutrients which have been modified (sub-subparagraph 2.9.1—50(g)(ii)(A)); and
  - a statement indicating whether each modified nutrient has been increased, decreased, or eliminated from the product, as appropriate (sub-subparagraph 2.9.1—50(g)(ii)(B)

  The statements in sub-subparagraphs 2.9.1—50(g)(ii)(A) and (B) are not required to be on the label required for a special medical purpose product for infants if they are provided in other documentation about the product.
- The declarations required by section 1.2.3—4 (paragraph 2.9.1—50(h)). Section 1.2.3—4 relates to mandatory declarations of certain foods e.g. allergens.

Section 2.9.1—51: This section sets out the information relating to ingredients that must be stated on the label required for a special medical purpose product for infants in accordance with paragraph 2.9.1—49(1)(e). That information is:

- a statement of ingredients; or
- information that complies with Articles 18, 19 and 20 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers; or
- information that complies with 21 CFR § 101.4. That is, section 101.4 of Title 21 of the

United States Code of Federal Regulations.

Section 2.9.1—52: This section sets out the date marking information that must be stated on the label required for a special medical purpose product for infants in accordance with paragraph 2.9.1—49(1)(f).

Subsection 2.9.1—52(1) provides that the required date marking information is date marking information in accordance with Standard 1.2.5.

Subsection 2.9.1—52(2) provides that, for the purposes of subparagraph 1.2.5—5(2)(a)(ii), the words 'Expiry Date', or similar words, may be used on the label.

Section 2.9.1—53: This section sets out the nutrition information that must be stated on the label required for a special medical purpose product for infants in accordance with paragraph 2.9.1—49(1)(h).

Subsection 2.9.1—53(1) requires the following nutrition information about the product, expressed per given amount of the food:

- The minimum or average energy content (paragraph 2.9.1—53(1)(a)).
- The minimum amount or average quantity of: protein, fat and carbohydrate (subparagraph 2.9.1—53(1)(b)(i)).
- The minimum amount or average quantity of any vitamin, mineral or electrolyte that has been used as a nutritive substance in the food (subparagraph 2.9.1—53(1)(b)(ii)).
- A substance - other than a substance listed in paragraph 2.9.1—53(1)(b) - used as a nutritive substance in the special medical purpose product for infants and added to that product to achieve that product's intended medical purpose (paragraph 2.9.1—53(1)(c)).
- Information on sub-group nutrients of protein, fat and/or carbohydrate (subparagraph 2.9.1—53(1)(d)(i)).
- Osmolality and osmolarity (subparagraph 2.9.1—53(1)(d)(ii)).
- Acid-base balance (subparagraph 2.9.1—53(1)(d)(iii)).

The information referred to in subparagraphs 2.9.1—53(1)(d)(i) – (iii) is only required if declaration of that information is necessary for use of the special medical purpose product for infants for its intended medical purpose.

The terms 'average energy content' and 'average quantity' are defined in subsection 1.1.2—2(3) of the Code.

The phrase 'used as a nutritive substance' in relation to a food is defined in section 1.1.2—12 of the Code.

For clarity, subsection 2.9.1—53(2) provides that, a reference to 'the intended medical purpose' in subsection 2.9.1—53(1) is to the intended medical purpose as described in the statement required by paragraph 2.9.1—50(c) (see above).

Subsection 2.9.1—53(3) provides that the label that is required for a special medical purpose product for infants may state information relating to the source or sources of protein in that product. The provision of this information is optional.

Section 2.9.1—54: This section sets out the information that must be stated on the label on an inner package that contains a special medical purpose product for infants.

Subsection 2.9.1—54(1) requires the following information to be stated:

- A name or description sufficient to indicate the true nature of the food, in accordance with

section 1.2.2—2 (paragraph 2.9.1—54(1)(a)).
- Lot identification, in accordance with section 1.2.2—3 (paragraph 2.9.1—54(1)(b)).
- Any declaration that is required by section 1.2.3—4 (paragraph 2.9.1—54(1)(c)).
- Date marking information, in accordance with section 2.9.1—52 (paragraph 2.9.1—54(1)(d)).

Subsection 2.9.1—54(2) requires the label on an inner package that contains a special medical purpose product for infants to comply with section 1.2.1—24 of Standard 1.2.1. Section 1.2.1—24 sets out general legibility requirements for food for sale.

To avoid doubt, subsection 2.9.1—54(3) provides that section 2.9.1—54 continues to apply to the label on the inner package if a responsible institution subsequently supplies the inner package to a patient or resident of the responsible institution.

The terms ‘inner package’ and ‘responsible institution’ are defined in subsection 1.1.2—2(3) of the Code.

Section 2.9.1—55: This section sets out the labelling requirements for a special medical purpose product for infants contained in a transportation outer.

Subsection 2.9.1—55(1) provides that, if packages of a special medical purpose product for infants are contained in a transportation outer, the information in accordance with the provision indicated as specified in subsection 2.9.1—55(2) must be: contained in a label on the transportation outer; or contained in a label on a package of the food for sale, and clearly discernible through the transportation outer.

Subsection 2.9.1—55(2) specifies the following information for the purposes of subsection 2.9.1—55(1):

- A name or description sufficient to indicate the true nature of the food, in accordance with section 1.2.2—2 (paragraph 2.9.1—55(2)(a)).
- Lot identification, in accordance with section 1.2.2—3 (paragraph 2.9.1—55(2)(b)).
- The name and address of the supplier, in accordance with section 1.2.2—4 (paragraph 2.9.1—55(2)(c)). This information is not required to be contained in the label if it is provided in accompanying documentation. The term ‘supplier’ is defined in subsection 1.1.2—2(3) of the Code.

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1028 to revise and clarify standards relating to infant formula products comprising category definitions, composition, labelling and representation of products. The Authority has considered the Proposal in accordance with Division 2 of Part 3 and has approved two draft variations – the *Food Standards (Proposal P1028 – Infant Formula) Variation* and the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*.

This Explanatory Statement relates to the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation* (the approved draft variation).

Following consideration by the Food Ministers Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand,

Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority approved the draft variation to amend Schedule 29 and other Standards in the Code as a consequence of the Authority's approval of the amendments to Standard 2.9.1 of the Code in the *Food Standards (Proposal P1028 – Infant Formula) Variation*. The purpose of all of the approved amendments are to revise and clarify the Code as it relates to infant formula products comprising category definitions, composition, labelling and representation of products.

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1028 included two rounds of public comment following an assessment and the preparation of a draft variation and associated assessment summaries. The first call for submissions was issued on 4 April 2022 for an 11 week consultation period. The second call for submissions (including draft variations) was issued on 26 April 2023 for a 10-week consultation period.

The Authority also released a number of consultation papers prior to the issue of the first call for submissions, with each consultation paper focused on a key aspect of infant formula regulation.

A decision Regulation Impact Statement was prepared by the Authority and has been approved by The Office of Best Practice Regulation (Reference - OBPR 25089).

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

In this section, references to 'the variation' are references to the approved draft variation.

Clause 1 provides that the name of the variation is the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation.*

Clause 2 provides that the Code is amended by the Schedules to the variation.

Clause 3 provides that the variation will commence on the date of gazettal of the instrument.

Clause 4 provides a transitional arrangement.

Subclause 4(1) provides that the stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 does not apply to any of the amendments made by the variation.

Instead, subclauses 4(2) and (3) provide a transitional arrangement where during a five year transition period commencing on the date of gazettal of the *Food Standards (Proposal P1028 – Infant Formula) Variation*, an infant formula product may be sold if the product complies with either: the Code as in force without the amendments made by the variation and *Food Standards (Proposal P1028 – Infant Formula) Variation*; or the Code as amended by those two instruments.

Schedule 1 of the Variation

Schedule 1 of the variation amends Schedule 29 of the Code.

Item [1] of Schedule 1 repeals sections S29—2 to S29—10; and substitutes them with new sections S29—2 to S29—10.

New section S29—2: This section prescribes how the energy content of infant formula products must be calculated for the purposes of paragraph 2.9.1—4(2)(a).

Paragraph 2.9.1—4(2)(a) requires that, for the purposes of Standard 2.9.1, energy must be calculated in accordance with section S29—2.

New subsection S29—2(1) provides that the energy content of an infant formula product must be calculated using all of the following:

(a) the energy contributions of the following components only:

(i) fat; and
(ii) protein; and
(iii) carbohydrate; and

(b) the relevant energy factors set out in section S11—2.

The term ‘component’ of a food is defined in subsection 1.1.2—2(3) of the Code.

New subsection S29—2(2) provides that the energy content of an infant formula product must be expressed in kilojoules.

New section S29—2A: This section prescribes how the protein content of infant formula products must be calculated for the purposes of paragraph 2.9.1—4(2)(b).

Paragraph 2.9.1—4(2)(b) requires that, for the purposes of Standard 2.9.1, protein content must be calculated in accordance with section S29—2A.

New section S29—2A provides that the protein content of an infant formula product must be calculated by multiplying the nitrogen content of the product by a nitrogen to protein conversion factor of 6.25.

New section S29—2B: This section prescribes how the vitamin A content of infant formula and follow-on formula must be calculated for the purposes of paragraph 2.9.1—4(2)(c).

Paragraph 2.9.1—4(2)(c) requires that, for the purposes of Standard 2.9.1, vitamin A content must be calculated in accordance with section S29—2B.

New section S29—2B provides that the vitamin A content of infant formula products must be calculated using only the retinol forms of vitamin A prescribed in Column 1 of the table to S29—23 (see **item 2** below).

New section S29—3: This section prescribes the L-amino acids that must be present in: infant formula and follow-on formula for the purposes of subsection 2.9.1—6(5); and special medical purpose products for infants for the purposes of section 2.9.1—33.

Subsection 2.9.1—6(5) provides that the L-amino acids listed in the table to section S29—3 must be present in infant formula and follow-on formula at a level no less than the corresponding minimum level specified in that table.

Subsection 2.9.1—33(4) provides that the L-amino acids listed in the table to section S29—3 must be present in a special medical purpose product for infants at a level no less than the corresponding minimum level specified in that table.

However, subsections 2.9.1—33(5) and (6) provide certain exemptions from that requirement for cysteine, methionine, phenylalanine and tyrosine if specific conditions related to each of those L-amino acids are met.

Also, subsection 2.9.1—33(7) provides that despite subsections 2.9.1—33(4), (5) and (6), L-amino acids listed in the table to section S29—3 must only be added to a special medical purpose product for infants in an amount necessary to improve protein quality.

The table to section S29—3 lists the L-amino acids that must be present in infant formula products and special medical purpose products for infants; and their corresponding minimum amounts per 100 kJ of the respective products.

New section S29—4: This section prescribes the limits on fatty acids that may be present in: infant formula and follow-on formula for the purposes of paragraph 2.9.1—7(1)(g); and special medical purpose product for infants for the purposes of paragraph 2.9.1—34(1)(g).

Paragraph 2.9.1—7(1)(g) lists requirements for certain fatty acids present in infant formula and follow-on formula. The paragraph provides that, if a fatty acid listed in Column 1 of the table to section S29—4 is present in infant formula or follow-on formula, that formula must contain not more than the maximum amount (if any) specified in Column 2 of the table for that fatty acid.

Paragraph 2.9.1—34(1)(g) lists requirements for certain fatty acids present in special medical purpose product for infants. The paragraph provides that, if a fatty acid listed in Column 1 of the table to section S29—4 is present in special medical purpose product for infants, that product must contain not more than the maximum amount (if any) specified in Column 2 of the table for that fatty acid.

The table to new section S29—4 sets out the fatty acids that may be present in infant formula products; and their corresponding limits. The table has two Columns. Column 1 lists the fatty acids; and Column 2 sets out the maximum amount per 100 kJ for each fatty acid.

In summary:

- it is optional (i.e. not mandatory) for an infant formula product to contain a fatty acid listed in Column 1 of the table to section S29—4; and
- if an infant formula product contains a fatty acid listed in Column 1 of the table, the infant formula product must comply with the corresponding maximum limits for that

fatty acid which are set out in the table.

New section S29—5: This section prescribes the vitamins, minerals, electrolytes and other substances which infant formula and special medical purpose products for infants must contain for the purposes of subparagraph 2.9.1—7(2)(b)(i), subsection 2.9.1—8(1), paragraph 2.9.1—34(2)(b) and subsection 2.9.1—36(1).

Subparagraph 2.9.1—7(2)(b)(ii) states that (among other things) infant formula may only contain medium chain triglycerides that are, for a fat soluble vitamin that is specified in the table to section S29—5, a substance that was used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the infant formula. The phrase 'used as a processing aid' in relation to a food is defined in section 1.1.2—13 of the Code.

Subsection 2.9.1—8(1) prescribes the nutritive substances that infant formula must contain. This provision requires infant formula to contain each substance listed in Column 1 of the table to section S29—5 in an amount (including any naturally-occurring amount) that is:

- no less than the minimum amount specified in Column 2 of the table; and
- no more than the maximum amount (if any) specified in Column 3 of the table.

Paragraph 2.9.1—34(2)(b) states that a special medical purpose product for infants may only contain medium chain triglycerides that are, for a fat soluble vitamin that is specified in the table to section S29—5, a substance that was used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the product. The phrase 'used as a processing aid' in relation to a food is defined in section 1.1.2—13 of the Code.

Section 2.9.1—36 prescribes the nutritive substances that a special medical purpose product for infants must contain. Subsection 2.9.1—36(1) requires that, subject to subsection 2.9.1—36(2), a special medical purpose product for infants must contain each substance listed in Column 1 of the table to section S29—5 in an amount (including any naturally-occurring amount) that is:

- no less than the minimum amount specified in Column 2 of the table; and
- no more than the maximum amount (if any) specified in Column 3 of the table.

The table to new section S29—5 sets out the vitamins, minerals, electrolytes and other substances that infant formula and special medical purpose product for infants must contain; and their corresponding limits. The table has four Columns. Column 1 lists the vitamins, minerals, electrolytes, and other substances; and for each substance:

- Column 2 sets out the minimum amount per 100 kJ;
- Column 3 sets out *any* maximum amount per 100 kJ;
- Column 4 sets out *any* 'Guidance upper level per 100 kJ' (this term is explained in the Note to new section S29—5 below).

The Note to section S29—5 identifies and explains for readers the operation of Column 4 of the table to that section. This Note explains that it is recommended that infant formula and special medical purpose product for infants contain a substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in Column 4. This is not a mandatory or binding maximum limit. The amounts in Column 4 (Guidance Upper) Levels are provided as guidance only and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the

amounts specified in Column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and special medical purpose products for infants or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

The table to new section S29—5 also prescribes medium chain triglycerides that may be contained in infant formula and in special medical purpose product for infants for the purposes of subparagraph 2.9.1—7(2)(b)(ii) and paragraph 2.9.1—34(2)(b) (see above).

New section S29—6: This section prescribes the vitamins, minerals and electrolytes which follow-on formula must contain, and their corresponding limits, for the purposes of subparagraph 2.9.1—7(2)(b)(ii) and subsection 2.9.1—8(2).

Subparagraph 2.9.1—7(2)(b)(ii) states that follow-on formula may only contain medium chain triglycerides that are (among other things), for a fat soluble vitamin that is specified in the table to section S29—6, a substance that was used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the follow-on formula. The phrase “used as a processing aid” in relation to a food is defined in section 1.1.2—13 of the Code.

Subsection 2.9.1—8(2) requires follow-on formula to contain each substance listed in Column 1 of the table to section S29—6 in an amount (including any naturally-occurring amount) that is:

- no less than the minimum amount specified in Column 2 of the table; and
- no more than the maximum amount (if any) specified in Column 3 of the table.

The table to new section S29—6 sets out the vitamins, minerals and electrolytes that follow-on formula must contain; and their corresponding limits. The table has four Columns. Column 1 lists the vitamins, minerals and electrolytes; and for each substance:

- Column 2 sets out the minimum amount per 100 kJ;
- Column 3 sets out *any* maximum amount per 100 kJ;
- Column 4 sets out *any* ‘Guidance upper level per 100 kJ’.

The Note to section S29—6 identifies and explains for readers the operation of Column 4 of the table to that section. This Note explains that it is recommended that follow-on formula contain a substance listed in Column 1 of the table to section S29—6 in an amount that is not more than the amount (if any) specified for that substance in Column 4. This is not a mandatory or binding maximum limit. The amounts in Column 4 (Guidance Upper Levels) are provided as guidance only and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the amounts specified in Column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formula or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

The table to section S29—6 also prescribes medium chain triglycerides that may be contained in follow-on formula for the purposes of subparagraph 2.9.1—7(2)(b)(ii) (see above).

New section S29—7: This section prescribes the nutritive substances which infant formula may contain for the purposes of subsection 2.9.1—9(1) and which special medical purpose product for infants may contain for the purposes of section 2.9.1—37. That is, the addition of

these substances in infant formula and in special medical purpose product for infants is optional. The table to this section also sets out the corresponding limits for each substance.

Subsection 2.9.1—9(1) provides that a substance listed in Column 1 of the table to section S29—7 may be used as a nutritive substance in infant formula provided that the amount of the substance in the formula (including any naturally-occurring amount) complies with their corresponding limits in the table.

Section 2.9.1—37 provides that a substance listed in Column 1 of the table to section S29—7 may be used as a nutritive substance in a special medical purpose product for infants provided that the amount of the substance in the product (including any naturally-occurring amount) complies with their corresponding limits in the table.

The table to new section S29—7 sets out the substances that may be used as a nutritive substance in infant formula and special medical purpose product for infants; and the corresponding limits for each substance (this includes any naturally-occurring amount of the substance). The table has three Columns. Column 1 lists the nutritive substances; and for each substance:

- Column 2 sets out *any* minimum amount per 100 kJ;
- Column 3 sets out the maximum amount per 100 kJ

In summary:

- it is optional (i.e. not mandatory) for infant formula and special medical purpose product for infants to contain a nutritive substance listed in Column 1 of the table to section S29—7;
- if an infant formula or special medical purpose product for infants contains a nutritive substance listed in Column 1 of the table, the infant formula or special medical purpose product for infants must comply with corresponding minimum and / or maximum limits for that substance which are set out in the table;
- the amount of the nutritive substance in the infant formula or special medical purpose product for infants includes any naturally-occurring amount of the substance.

New section S29—8: this provision prescribes the nutritive substances which follow-on formula may contain for the purposes of subsection 2.9.1—9(2) i.e. the addition of these substances in follow-on formula is optional. The table to this section also sets out the corresponding limits for each substance.

Subsection 2.9.1—9(2) provides that a substance listed in Column 1 of the table to section S29—8 may be used as a nutritive substance in follow-on formula provided that the amount of the substance in the formula (including any naturally-occurring amount) complies with the corresponding limits in the table.

The Note to subsection 2.9.1—9(2) explains that, among other things, it is recommended that follow-on formula contain a substance listed in Column 1 of the table to section S29—8 in an amount that is not more than the amount (if any) specified for that substance in Column 4 of that table.

The table to new section S29—8 sets out the substances that may be used as a nutritive substance in follow-on formula; and the corresponding limits for each substance. The table has four Columns. Column 1 lists the nutritive substances; and for each substance:

- Column 2 sets out *any* minimum amount per 100 kJ;

- Column 3 sets out *any* maximum amount per 100 kJ;
- Column 4 sets out *any* 'Guidance upper level per 100 kJ' (this term is explained in the Note to section S29—8 below).

The Note to section S29—8 identifies and explains for readers the operation of Column 4 of the table to that section. This Note explains that it is recommended that follow-on formula contain a nutritive substance listed in Column 1 of the table to section S29—8 in an amount that is not more than the amount (if any) specified for that substance in Column 4. This is not a mandatory or binding maximum limit. The amounts in Column 4 (Guidance Upper Levels) are provided as guidance only and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. It is recommended that the amounts specified in Column 4 not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formula or due to technological reasons. Guidance Upper Levels are listed for substances where no maximum limit is set.

In summary:

- it is optional (i.e. not mandatory) for follow-on formula to contain a nutritive substance listed in Column 1 of the table to section S29—8;
- if a follow-on formula contains a nutritive substance listed in Column 1 of the table, the follow-on formula must comply with any corresponding minimum and / or maximum limits for that substance which are set out in the table;
- the amount of the nutritive substance in the follow-on formula includes any naturally-occurring amount of the substance.

New section S29—9: This section prescribes the permitted forms of nutritive substances in infant formula and follow-on formula for the purposes of paragraph 2.9.1—10(b) and in special medical purpose product for infants for the purposes of paragraph 2.9.1—38(b).

Paragraph 2.9.1—10(b) provides that a substance used in infant formula or follow-on formula in accordance with section 2.9.1—8 or 2.9.1—9 and which is not a vitamin, mineral or electrolyte, must be in the permitted form listed in the table to section S29—9.

Paragraph 2.9.1—38(b) provides that a substance used in special medical purpose product for infants in accordance with section 2.9.1—36 or 2.9.1—37 and, which is not a vitamin, mineral or electrolyte, must be in the permitted form listed in the table to section S29—9.

The table to new section S29—9 sets out the substances and their permitted forms for infant formula products. The table has two Columns. Column 1 lists the substances and Column 2 lists the corresponding permitted form or forms for each substance.

The Note to section S29—9 explains that new section S29—23 lists the permitted forms of vitamins, minerals and electrolytes in infant formula products (for the purposes of paragraphs 2.9.1—10(a) and 2.9.1—38(b)).

New section S29—9A: This section prescribes for the purposes of section 2.9.1—10A conditions of use for certain substances used as a nutritive substance in infant formula products. The phrase 'used as a nutritive substance' in relation to a food is defined in section 1.1.2—12 of the Code.

The section sets out a table headed ‘Conditions of use for permitted nutritive substances’. The table has three Columns listing the substance, the permitted form of the substance, and conditions of use for the permitted form of the substance respectively.

‘Lactoferrin’ is listed as a substance in Column 1.

‘Bovine lactoferrin’ is listed as permitted form of that substance in Column 2.

The following two conditions are listed in Column 3:

1. During the exclusive use period, *Lactoferrin* in the permitted form may only be sold under the brand Synlait for use as a nutritive substance in infant formula product.
2. For the purposes of condition 1 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1253 – Bovine Lactoferrin in Infant Formula Products) Variation* and ending 15 months after that date.

New section S29—10: This section prescribes the required format for a nutrition information statement required for infant formula and follow-on formula for the purposes of section 2.9.1—25 as follows.

Section 2.9.1—25 provides that the *statement of nutrition information* required by section 2.9.1—24 for infant formula and follow-on formula (the statement) must (among other things) be in the same format specified in the table to section S29—10, and state the nutrition information in the order specified in that table. Also, specific information contained in the statement must be in the format specified in the table to section S29—10.

The table to section S29—10 sets out the required format for the statement.

The table has two Columns. Column 1 lists the nutrients and/or subgroup nutrients for the purposes of requirements in section 2.9.1—24. Column 2 sets out the corresponding average quantity per 100 mL of prepared formula for each nutrient/subgroup nutrient.

The Note to section S29—10 explains that:

- Where an asterisk (*) is placed next to a nutrient or subgroup nutrient in the table, it refers the reader to the related explanation provided in this Note.

- Entries and amounts for the following only need to be included when stated in accordance with subsections 2.9.1—24(3), 2.9.1—24(4) and paragraph 2.9.1—25(6)(d):
  - whey;
  - casein;
  - docosahexaenoic acid (DHA);
  - eicosapentaenoic acid (EPA);
  - arachidonic acid (ARA).

- The heading ‘Other nutrients’ only need be included when required by subparagraph 2.9.1—25(2)(d)(ii) and paragraph 2.9.1—25(4)(a).

- The heading ‘Long chain polyunsaturated fatty acids’ need only be included when required by paragraph 2.9.1—25(6)(a).

- Entries and amounts for choline, inositol and L-carnitine are included under the

heading ‘Other nutrients’ when required by paragraph 2.9.1—25(4)(a), and under the heading ‘Additional’ when required by paragraph 2.9.1—25(4)(b).

New section S29—10A: sets out an example of a nutrition information statement, including quantities expressed as sold, for the purposes of subsection 2.9.1—25(7).

Subsection 2.9.1—24(1) provides that a statement of nutrition information is required for infant formula and follow-on formula. Subsections 2.9.1—24(2) to 8) prescribe what information that statement must or may contain or must not contain.

Subsection 2.9.1—24(7) provides that the statement of nutrition information may, in addition to stating each prescribed average quantity per 100 mL of prepared formula reconstituted according to directions, also state in another column that average quantity per 100 g of formula as sold in powdered form or 100 mL of formula as sold in liquid form.

Subsection 2.9.1—25(7) provides that that additional information must be in an additional column at the right hand side of Column 2 shown in the table to section S29—10A.

Subsection 2.9.1—25(8) provides that information included in that additional column must be in the form required by section 2.9.1—25.

7.2 Item [2] of Schedule 1 of the approved draft variation inserts new section S29—23 after existing section S29—22.

New section S29—23: This section prescribes the permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants, formulated meal replacements (vitamin K) and food for special medical purposes, for the purposes of the following provisions in the Code:

paragraph 2.9.1—10(a)	This provision requires that a substance used in infant formula or follow-on formula in accordance with section 2.9.1—8 or 2.9.1—9 and which is a vitamin, mineral or electrolyte, must be used or added in the permitted form listed in the table to section S29—23.
paragraph 2.9.1—38(a)	This provision requires that a substance used in a special medical purpose product for infants in accordance with section 2.9.1—36 or 2.9.1—37 and which is a vitamin, mineral or electrolyte, must be used or added in the permitted form listed in the table to new section S29—23.
section 2.9.2—4	This provision deals with additional compositional requirements for certain cereals for infants (from the age of 6 months) and permits such food to contain (among other things) added iron; as well as thiamin, niacin, vitamin B6, vitamin C, folate, magnesium; in forms permitted in the table to section S29—23.
section 2.9.2—5	This provision deals with additional compositional requirements for certain cereal-based food for infants from the age of 4 months and permits such food to contain added iron; and vitamin C to a maximum amount of 90 mg/100 g on a moisture

	free basis, both in forms permitted in the table to section S29—23.
section 2.9.2—6	This provision deals with additional compositional requirements for non-cereal-based food for infants and permits fruit-based food to contain vitamin C or folate or both in the permitted forms set out in the table to section S29—23.
subparagraph 2.9.3—3(2)(c)(iii)	This provision deals with compositional requirements for formulated meal replacements and permits vitamin K to be used as a nutritive substance in a formulated meal replacement if all of the following conditions are satisfied: the vitamin K is listed in Column 1 of the table to new section S29—13; the total of the naturally occurring and added vitamin K in a serving is not greater than the amount, if any, specified in relation to that vitamin in Column 2 of the table to section S29—13; and the vitamin K is in a permitted form specified in the table to section S29—23.
section 2.9.5—6	This provision deals with substances that may be added to food for special medical purposes; and permits (among other things) substances that are both listed in Column 1 of the table to section S29—23; and in a corresponding form listed in Column 2 of that table.

The table to section S29—23 sets out the relevant vitamins, minerals and electrolytes; and their permitted form(s), in infant formula products, food for infants, formulated meal replacements (vitamin K) and food for special medical purposes. The phrase ‘used as a nutritive substance’ in relation to a food is defined in section 1.1.2—12 of the Code.

Schedule 2 of the Variation

Schedule 2 of the variation amends Standards 1.1.2, 1.2.3, 1.3.1, 1.5.1, 2.9.2, 2.9.3, 2.9.5; and Schedules 8, 15, 19 and 25 of the Code.

Item [1] amends subsection 1.1.2—2(3) by inserting a definition of ‘inner package’ in relation to special medical purpose products for infants. The definition provides that ‘inner package’, in relation to a special medical purpose product for infants, means an individual package of the food that is:

(a) contained and sold within another package that is labelled in accordance with Division 4 of Standard 2.9.1; and
(b) not designed for individual sale, other than a sale by a responsible institution to a patient or resident of the responsible institution.

The term ‘responsible institution’ is defined in subsection 1.1.2—2(3) as a hospital, hospice, aged care facility, disability facility, prison, boarding school or similar institution that is responsible for the welfare of its patients or residents and provides food to them.

An example of an inner package is included at the end of the definition. The example is an individual sachet (or sachets) of a powdered food contained within a box that is fully labelled, being a box available for retail sale.

Item [2] amends subsection 1.1.2—2(3) by repealing the definition of 'medium chain triglycerides'

Item [2A] amends subsection 1.1.2—2(3) by repealing the definition of 'protein substitute'.

Item [3] amends subsection 1.1.2—2(3) by repealing and replacing paragraph (c) of the definition of 'warning statement' . The new paragraph refers to 'subsection 2.9.1—21(1) (warning statements for infant formula product)'.

Item [4] amends subsection 1.1.2—3(2) by inserting a definition of 'special medical purpose product for infants'. The definition provides that 'special medical purpose product for infants' is a food that meets all of the following criteria.

- It is an infant formula product (as defined by subsection 1.1.2—3(2)).
- It is represented as being specially formulated for the dietary management of infants who have medically determined nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food).
- It is represented as being suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product.
- It is represented as being for the dietary management of a medically diagnosed disease, disorder or condition of an infant.
- It is intended to be used under medical supervision.
- It is not suitable for general use.

Item [5] amends subsection 1.1.2—3(2) by repealing the definition of 'follow-on formula' and substituting a new definition. The new definition provides that 'follow-on formula' is a food that meets all of the following criteria:

- It is an infant formula product (as defined by subsection 1.1.2—3(2)).
- It is represented as either a breast milk substitute or replacement for infant formula,
- It is represented as being suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.

Item [6] amends subsection 1.1.2—3(2) by repealing the definition of 'infant formula' and substituting a new definition. The new definition provides that 'infant formula' is a food that meets all of the following criteria:

- It is an infant formula product (as defined by subsection 1.1.2—3(2)).
- It is represented as being a breast milk substitute for infants.
- It is represented as satisfying by itself the nutritional requirements of infants under the age of 6 months.

Item [7] amends subsection 1.1.2—3(2) by repealing the definition of 'infant formula product' and substituting a new definition. The new definition provides that 'infant formula product' means a food that meets all of the following criteria.

- It is a product based on milk or other edible food constituents of animal or plant origin.

- It is represented as being 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.

Item [8] amends subsection 1.1.2—3(2) by repealing the definition of 'pre-term formula'.

Item [8A] repeals and replaces subsection 1.1.2—8(2), which relates to the definition of novel food. Section 1.1.2—8 defines 'novel food'. Current subsection 1.1.2—8(2) sets out what does not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of that section and definition. New subsection 1.1.2—8(2) restates the current subsection 1.1.2—8(2) with the following changes - the new subsection now also provides that, for the purposes of the definition of novel food in section 1.1.2—8, the presence and/or use of a food in a special medical purpose product for infants does not constitute a history of human consumption in Australia or New Zealand in relation to that food.

Item [9] repeals and replaces paragraph 1.2.3—6(4)(b).

Section 1.2.3—6 set out what a mandatory declaration must state. Subsection 1.2.3—6(4) sets out how a declaration in relation to a food for special medical purposes and certain types of infant formula products must be made. Current paragraph 1.2.3—6(4)(b) refers to an infant formula product that is:

- specifically formulated for premature or low birthweight infants;
- specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions;
- represented as lactose free formula or low lactose formula; or
- based on a protein substitute.

The new paragraph 1.2.3—6(4)(b) refers only to 'a special medical purpose product for infants' (as defined in subsection 1.1.2—3(2) (see item 4 above).

Item [10] repeals and replaces Note 2 to subsection 1.2.3—6(4).

Current Note 2 states that Division 4 of Standard 2.9.1 applies to infant formula products for special dietary use and sets out compositional and labelling requirements for such food.

The new Note 2 states that Division 4 of Standard 2.9.1 applies to a special medical purpose product for infants and sets out compositional and labelling requirements for such food.

Item [11] amends subsection 1.3.1—3(2) by inserting '(other than an infant formula product)' after 'any food' in that subsection. The change is to ensure that the carry-over of food additives noted in the subsection does not apply to infant formula products.

Item [12] repeals and replaces paragraph 1.3.1—4(6)(k) with new paragraphs 1.3.1—4(6)(k) and 1.3.1—4(6)(l). Paragraph 1.3.1—4(6)(k) remains unchanged and states that 'rosemary extract is calculated as the sum of carnosic acid and carnosol'. That paragraph is currently the last paragraph listed in subsection 1.3.1—4(6) and is being repealed and replaced for grammatical purposes i.e. to change the full stop at the end of the paragraph to a semi-colon as a new last paragraph is being added to this list. Paragraph 1.3.1—4(6)(l) is the new provision and provides that 'phosphoric acid and phosphates are calculated as phosphorus'.

Item [13] amends the Note to section 1.5.1—2. This Note sets out a copy of the definition of (among other things) novel food in subsection 1.1.2—2(3) of the Code. This item repeals and replaces subsection (2) of the definition of novel food as set out in that Note. This amendment is required as a result of the amendment made to the definition of novel food by item [8A] above.

Item [13A] repeals and replaces section 1.5.1—3, including the Note to that section.

The current section 1.5.1—3 permits a food for retail sale to consist of, or contain as an ingredient, any novel food listed in the table to section S25—2, provided that any conditions of use specified in that table for that novel food are complied with. The term 'novel food' is defined in section 1.1.2—8 of the Code.

The new section 1.5.1—3 comprises subsections 1.5.1—3(1) and (2) and a Note to subsection 1.5.1—3(1).

The new subsection 1.5.1—3(1) restates the current section 1.5.1—3 with one change. The change is that the subsection states that this subsection and the permission that this subsection provides do not apply to an infant formula product.

The Note to subsection 1.5.1—3(1) restates the current Note to section 1.5.1—3.

Also, a new provision is added - subsection 1.5.1—3(2), which sets out when an infant formula product for retail sale may consist of, or have as an ingredient or a component, a novel food. The subsection provides that this shall be permitted only when and if each of the following criteria is met.

- The novel food is listed in the table to section S25—2.
- The table to section S25—2 expressly permits the presence of that novel food in that infant formula product (i.e., the table contains an express permission).
- Any conditions of use specified for that novel food in the table to section S25—2 are complied with.

The term 'component' of a food is defined in subsection 1.1.2—2(3) of the Code.

Item [14] amends section 2.9.2—4 by omitting 'section S29—7' wherever occurring in section 2.9.2—4, and substituting with 'section S29—23'.

Item [15] amends section 2.9.2—5 by omitting 'section S29—7' wherever occurring in section 2.9.2—5, and substituting with 'section S29—23'.

Item [16] amends subsection 2.9.2—6(3) by omitting 'section S29—7' and substituting with 'section S29—23'.

Item [17] amends subparagraph 2.9.3—3(2)(c)(iii) by omitting 'section S29—7' and substituting with 'section S29—23'.

Item [18] amends paragraph 2.9.5—6(1)(b) by omitting 'section S29—7' and substituting with 'section S29—23'.

Item [19] amends the table to section S8—2 (food additive names—alphabetical listing) by inserting three new entries into that table. The three new entries are:

dl-Alpha-tocopherol	307c
Potassium hydroxide	525
Sodium hydroxide	524

Item [20] amends the table to section S8—2 (food additive names—numerical listing) by

inserting three new entries into that table. The three new entries are:

307c dl-Alpha-tocopherol

524 Sodium hydroxide

525 Potassium hydroxide

Item [21] amends the table to section S15—5 by:

- repealing the food classes 13.1 (Infant formula products), 13.1.1 (Soy-based infant formula), 13.1.2 (Liquid infant formula products), and 13.1.3 (Infant formula products for specific dietary use based on a protein substitute); and
- replacing these with new food classes 13.1 (Infant formula products) and 13.1.1 (Special medical purpose product for infants).

The result of this amendment is that the table of food additive permissions for infant formula products now only has two food classes (categories): ‘infant formula products’ as the higher class and which includes follow-on formula; and ‘special medical purpose product for infants’ as subclass of ‘infant formula products’.

The amended table also includes new food additive permissions, particularly for special medical purpose product for infants. Detailed condition statements have also been added for some food additives.

Item [22] inserts a new entry into the table to section S19—4 (Maximum levels of metal contaminants). The entry is:

Aluminium	Infant formula, follow-on formula and special medical purpose product for infants (other than special medical purpose product for infants formulated for pre-term infants)	0.5
	Soy-based infant formula products	1
	Special medical purpose product for infants formulated for pre-term infants	0.2

This amendment adds contaminant limits for aluminium to the contaminants schedule - Schedule 19 - with other metals. These limits were previously located in section 2.9.1—8 (see item 1 of the *Food Standards (Proposal P1028 – Infant Formula) Variation*). The new entry in the table to section S19—4 continues to set the maximum level for soy-based infant formula products at twice that of other products to take account of the higher natural levels in soy ingredients.

Item [23] repeals and replaces an entry in the table to section S19—4 (entry dealing with the food "infant formula products" and its associated maximum level for the table item dealing with ‘Lead’). The new entry is:

Infant formula products	0.01

The new entry reduced the permitted contaminant level for lead in infant formula products from 0.02 to 0.01 mg/kg for public health and safety reasons.

Item [24] amends the table to subsection S25—2 by repealing and replacing the permission and condition of use for four permitted novel foods derived from 'marine micro-algae Schizochytrium sp.' and 'marine micro-algae Ulkenia sp'.

The amendment changes the condition of use for:

- dried marine micro-algae (Schizochytrium sp.) rich in docosahexaenoic acid (DHA);
- oil derived from marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA); and
- oil derived from marine micro-algae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA).

Each of the above permitted novel foods will now have a condition of use that states expressly that the novel food 'may be added to infant formula products in accordance with Standard 2.9.1'.

The amendment also revises the condition of use for oil derived from marine micro-algae Schizochytrium sp. (American Type Culture Collection (ATCC) PTA-9695). The revised condition of use for this permitted novel food will now state 'Only permitted for use in infant formula products in accordance with Standard 2.9.1'. This revision makes clear that this novel food is permitted for use only in infant formula products.

This amendment is a consequence of the amendment made item 13A above to section 1.5.1—3 of the Code. The Code generally prohibits food for retail sale from being, or containing as an ingredient or component, a novel food unless the latter is expressly permitted by the Code. New subsection 1.5.1—3 will provide that an infant formula products for retail sale may consist of, or have as an ingredient or a component, a novel food *only* where each of the following criteria are met

- the novel food is listed in the table to section S25—2; and
- the presence of that novel food in the infant formula product is expressly permitted by that table; and
- any conditions of use specified in the corresponding row of that table are complied with

The requirement that the presence of the novel food in the infant formula product be expressly permitted by the table to section S25—2 required the above-mentioned amendments to that table.

Item [25] amends the table to subsection S25—2 by repealing and replacing the table item for the novel food 'Isomalto-oligosaccharide'.

The amendment changes the conditions of use for this permitted novel food by removing the condition prohibiting the addition of isomalto-oligosaccharide to infant formula products. The current conditions prohibiting the addition of isomalto-oligosaccharide to foods for infants and to formulated supplementary food for young children are retained.

This amendment is a consequence of the amendment made item 13A above to section 1.5.1—3 of the Code. The Code generally prohibits food for retail sale from being, or containing as an ingredient or component, a novel food unless the latter is expressly permitted by the Code. New subsection 1.5.1—3 will provide that an infant formula products for retail sale may consist of, or have as an ingredient or a component, a novel food *only* where each of the following criteria are met

- the novel food is listed in the table to section S25—2; and
- the presence of that novel food in the infant formula product is expressly permitted by that table; and

- any conditions of use specified in the corresponding row of that table are complied with

The requirement that the presence of the novel food in the infant formula product be expressly permitted by the table to section S25—2 required the above-mentioned amendment to that table. The table will not expressly permit the presence of isomalto-oligosaccharide in an infant formula product.

Item [26] amends the table to subsection S25—2 by repealing and replacing condition 2 of the conditions of use for the novel food ‘Rapeseed protein isolate’.

The amendment changes the conditions of use for this permitted novel food by removing the condition prohibiting the addition of rapeseed protein isolate to infant formula products. The current condition prohibiting the addition of rapeseed protein isolate to foods for infants is retained

This amendment is a consequence of the amendment made item 13A above to section 1.5.1—3 of the Code. The Code generally prohibits food for retail sale from being, or containing as an ingredient or component, a novel food unless the latter is expressly permitted by the Code. New subsection 1.5.1—3 will provide that an infant formula products for retail sale may consist of, or have as an ingredient or a component, a novel food *only* where each of the following criteria are met

- the novel food is listed in the table to section S25—2; and
- the presence of that novel food in the infant formula product is expressly permitted by that table; and
- any conditions of use specified in the corresponding row of that table are complied with

The requirement that the presence of the novel food in the infant formula product be expressly permitted by the table to section S25—2 required the above-mentioned amendment to that table. The table will not expressly permit the presence of rapeseed protein isolate in an infant formula product.

Item [27] amends the table to subsection S25—2 by repealing and replacing the table item dealing with the novel food ‘trehalose’.

The table to subsection S25—2 does not current impose a conditions of use for trehalose’ as a permitted novel food.

The amendment will impose a condition of use that permits trehalose to be added to infant formula products but only as a cryo-preservative for L(+) lactic acid producing microorganisms.

Attachment D - Primary draft variations to the Australia New Zealand Food Standards Code (call for submissions)

Food Standards (Proposal P1028 – Infant Formula) Variation

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1 Name

This instrument is the *Food Standards (Proposal P1028 – Infant Formula) Variation*.

2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The instrument commences on gazettal.

4 Effect of the variations made by this instrument

(1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.

(2) During the transition period, a food product may be sold if the product complies with one of the following:

(a) the Code as in force without the variations made by the instruments; or

(b) the Code as amended by the variations made by the instruments.

(3) For the purposes of this clause:

(a) the **instruments** means:

(i) this instrument; and

(ii) the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*;

(b) the **transition period** means the period commencing on the variation's date of commencement and ending 60 months after the date of commencement.

Schedule

Standard 2.9.1

[1] Sections 2.9.1—2 to 2.9.1—25

Repeal the sections, substitute:

2.9.1—2 Outline of Standard

(1) This Standard regulates various types of infant formula products.

(2) Division 1 deals with preliminary matters.

(3) Division 2 sets out compositional requirements for infant formula and follow-on formula.

(4) Division 3 sets out labelling and packaging requirements for infant formula and follow-on formula.

(5) Division 4 sets out compositional and labelling requirements for special medical purpose products for infants.

2.9.1—3 Definitions

Note In this Code (see sections 1.1.2—2 and 1.1.2—3):

follow-on formula means an infant formula product that is represented as:

(a) either a breast milk substitute or replacement for infant formula; and

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

infant formula means an infant formula product that is represented as:

(a) a breast milk substitute for infants; and

(b) satisfying by itself the nutritional requirements of infants under the age of 4 to 6 months.

infant formula product means a product based on milk or other edible food constituents of animal or plant origin which is represented as 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.

inner package, in relation to special medical purpose food for infants, means an individual package of the food that is:

(a) contained and sold within another package that is labelled in accordance with Division 4 of Standard 2.9.1; and

(b) not designed for individual sale, other than a sale by a *responsible institution to a patient or resident of the responsible institution.

Example An example of an inner package is an individual sachet (or sachets) of a powdered food contained within a box that is fully labelled, being a box available for retail sale.

responsible institution means a hospital, hospice, aged care facility, disability facility, prison, boarding school or similar institution that is responsible for the welfare of its patients or residents and provides food to them.

special medical purpose product for infants means an infant formula product that is:

(d) represented as being:

(l) specially formulated for the dietary management of infants who have medically determined nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food); and

(v) suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product; and

(iii) for the dietary management of a medically diagnosed disease, disorder or condition of an infant; and

(e) intended to be used under medical supervision; and

(f) not suitable for general use.

soy-based formula means an infant formula product in which soy protein isolate is the sole source of protein.

2.9.1—4 Interpretation

Interpretation of compositional requirements

(1) Compositional requirements in this Standard apply to:

(a) a powdered or concentrated form of infant formula product that has been reconstituted with water according to directions; and

(b) an infant formula product in ‘ready to drink’ form.

Calculation of energy, and protein

(2) In this Standard:

(a) energy must be calculated in accordance with section S29—2; and

(b) protein content must be calculated in accordance with section S29—2A; and

(c) vitamin A content for infant formula and follow-on formula must be calculated in accordance with section S29—2B.

Division 2 Compositional requirements for infant formula and follow-on formula

2.9.1—5 General requirements

(1) Infant formula and follow-on formula must have an energy content of no less than 2510 kJ/L and no more than 2930 kJ/L.

(2) Subject to subsection (3), infant formula and follow-on formula must not contain added fructose and/or added sucrose.

(3) Infant formula manufactured from partially hydrolysed protein may contain added fructose and/or added sucrose, provided that:

(a) the fructose and/or sucrose is added to the formula to provide a source of carbohydrate; and

(b) the sum of the added fructose and/or sucrose in the formula does not exceed 20% of available carbohydrates in the formula.

(4) Infant formula and follow-on formula must not exceed a fluoride content of 17 µg/100kJ.

2.9.1—6 Protein requirements

(1) Infant formula and follow-on formula must be only derived from one or more of the following proteins:

(a) cow milk;

(b) goat milk;

(c) sheep milk;

(d) soy protein isolate;

(e) a partially hydrolysed protein of one or more of the above.

(2) Infant formula must have a protein content of:

(a) for a milk-based infant formula—no less than 0.43 g/100 kJ and no more than 0.72 g/100 kJ; and

(b) for all other infant formula—no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.

(3) Follow-on formula must have a protein content of:

(a) for a milk-based follow-on formula—no less than 0.38 g/100 kJ and no more than 0.72 g/100 kJ; and

(b) for all other follow-on formula—no less than 0.54 g/100 kJ and no more than 0.72 g/100 kJ.

(4) The L-amino acids listed in the table to section S29—3 must be present in infant formula and follow-on formula at a level no less than the corresponding minimum level specified in the table.

(5) Infant formula must have a ratio of methionine to cycteine of no more than 3 to 1.

(6) Despite subsection (4), L-amino acids listed in the table to section S29—3 must only be added to infant formula or follow-on formula in an amount necessary to improve protein quality.

2.9.1—7 Fat requirements

(1) Infant formula and follow-on formula must:

(a) have a fat content of no less than 1.1 g/100 kJ and no more than 1.4 g/100 kJ; and

(b) have a ratio of linoleic acid to α-linolenic acid of no less than 5 to 1 and no more than 15 to 1; and

(ba) have no less than:

(i) 90 mg/100kJ of linoleic acid; and

(ii) 12 mg/100kJ of α-linolenic acid; and

Note. It is recommended that infant formula and follow-on formula contain not more than 335 mg/100 kJ of linoleic acid. This amount is a Guidance Upper Level and a recommended upper level for this nutrient which poses no significant risks on the basis of current scientific knowledge. This Guidance Upper Level should not be exceeded unless a higher nutrient level cannot be avoided due to high or variable contents in constituents of infant formulas and follow-on formula or due to technological reasons.

(c) have an arachidonic acid (20:4) content of equal to or more than docosahexaenoic acid (22:6 n-3) content; and

(d) contain no less than 0.5 mg of vitamin E/g of polyunsaturated fatty acids; and

(e) for any long chain *polyunsaturated fatty acids that are present—have an eicosapentaenoic acid (20:5 n-3) content of no more than the docosahexaenoic acid (22:6 n-3) content; and

(f) for a fatty acid listed in Column 1 of the table to section S29—4 and present in the formula—contain not more than the maximum amount (if any) specified in Column 2 of the table for that fatty acid.

Note It is recommended that infant formula and follow-on formula contain a fatty acid listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in Column 3 of the table. An amount specified in Column 3 is a Guidance Upper Level and is a recommended upper level for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons.

(2) Infant formula and follow-on formula may only contain medium chain triglycerides that are:

(a) a natural constituent of a milk-based ingredient of that formula; or

(b) for a fat soluble vitamin that is specified in a following table—a substance that was *used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the formula:

(i) for infant formula—the table to section S29—5; and

(ii) for follow-on formula—the table to section S29—6.

(3) Infant formula and follow-on formula must not have a phospholipid content of more than 72 mg/100 kJ.

2.9.1—8 Required nutritive substances

(1) Infant formula must contain each substance listed in Column 1 of the table to section S29—5 in an amount that is:

(a) no less than the minimum amount specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note It is recommended that infant formula contain a substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in Column 4 of that table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons.

(2) Follow-on formula must contain each substance listed in Column 1 of the table to section S29—6 in an amount that is:

(a) no less than the minimum amount specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note It is recommended that follow-on formula contain a substance listed in Column 1 of the table to section S29—6 in an amount that is not more than the amount (if any) specified for that substance in Column 4 of that table. The amounts specified in Column 4 are Guidance Upper Levels, which are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. The Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons.

2.9.1—9 Optional nutritive substances

(1) A substance listed in Column 1 of the table to section S29—7 may be *used as a nutritive substance in infant formula, provided that the amount of the substance in the formula (including any naturally-occurring amount) is:

(a) no less than the minimum amount (if any) specified in Column 2 of the table; and

(b) no more than the maximum amount specified in Column 3 of the table.

(2) A substance listed in Column 1 of the table to section S29—8 may be *used as a nutritive substance in follow-on formula, provided that is the amount of the substance in the formula (including any naturally-occurring amount) is:

(a) no less than the minimum amount (if any) specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note It is recommended that follow-on formula contain a substance listed in Column 1 of the table to section S29—8 in an amount that is not more than the amount (if any) specified for that substance in Column 4 of that table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons.

2.9.1—10 Required forms for nutritive substances

A substance *used as a nutritive substance in infant formula or follow-on formula must be in the permitted form listed in:

(a) if a vitamin, mineral or electrolyte—the table to section S29—23; and

(b) in any other case— the table to section S29—9.

2.9.1—11 Addition of lactic acid producing microorganisms

L(+) lactic acid producing microorganisms may be added to infant formula and follow-on formula.

2.9.1—12 Restriction on addition of inulin-type fructans and galacto-oligosaccharides

(1) If an inulin-type fructan or a galacto-oligosaccharide is added to infant formula or follow-on formula, the product must contain (taking into account both the naturally-occurring and added substances) no more than:

(a) if only *inulin-type fructans are added—110 mg/100 kJ of inulin-type fructans; or

(b) if only *galacto-oligosaccharides are added—290 mg/100 kJ of galacto-oligosaccharides; or

(c) if both inulin-type fructans and galacto-oligosaccharides are added:

(i) no more than 110 mg/100 kJ of inulin-type fructans; and

(ii) no more than 290 mg/100 kJ of combined inulin-type fructans and galacto-oligosaccharides.

(2) Infant formula and follow-on formula to which an inulin-type fructan or a galacto-oligosaccharide is added must not contain lacto-N-neotetraose as an added substance.

2.9.1—13 Restriction on levels of other substances

Infant formula and follow-on formula must not contain:

(a) detectable gluten; or

(b) more than 3.8 mg/100 kJ of nucleotide-5′-monophosphates.

Note Section S19—4 contains the maximum level (ML) of lead contaminant in infant formula products.

2.9.1—14 Compositional requirements for infant formula represented as lactose free and low lactose

(1) If infant formula is represented as lactose free, it must contain no detectable lactose.

(2) If infant formula is represented as low lactose, it must contain no more than 0.3 g lactose/100 mL of the formula.

(3) A compositional requirement of this Standard, other than a requirement imposed by this section, applies to infant formula that is represented as lactose free formula or low lactose formula.

Division 3 Labelling and packaging requirements for infant formula and follow-on formula

2.9.1—15 Representations about food as infant formula or a follow-on formula

(1) A food may only be represented as infant formula or follow-on formula if it complies with this Standard.

(2) A food represented as infant formula or follow-on formula must not be also represented as another food.

Example A food represented as infant formula must not be also represented as, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children.

2.9.1—16 Prescribed names

(1) ‘Infant formula’ is the *prescribed name for infant formula.

(2) ‘Follow-on formula’ is the *prescribed name for follow-on formula.

Note Under the labelling provisions in Standard 1.2.1 and section 1.2.2—2, if a food has a prescribed name, that prescribed name must be used in the labelling of the food.

2.9.1—17 Requirement for measuring scoop

(1) A package of infant formula or follow-on formula in a powdered form must contain a scoop to enable the use of the formula in accordance with the directions contained in the label on the package.

(2) Subsection (1) does not apply to single serve sachets, or packages containing single serve sachets, of formula in a powdered form.

2.9.1—18 Storage instructions

For the labelling provisions, the storage instructions for infant formula and follow-on formula must cover the period after the package is opened.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—19 Requirement for the name of the food

For the labelling provisions, the name of the food must be stated on the front of a package of infant formula or follow-on formula.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—20 Statement of protein source

(1) For the labelling provisions, the specific animal or plant source or sources of protein in infant formula and follow-on formula must be included in the statement of the name of the food required by section 2.9.1—19.

Examples 'Infant Formula based on cows' milk'. 'Follow-on Formula based on goat's milk. 'Infant Formula based on 'soy protein'.

Note The labelling provisions are set out in Standard 1.2.1.

(2) If a label of infant formula represents that the formula is partially hydrolysed, the words 'partially hydrolysed' must be used immediately adjacent to the statement of protein source required by subsection (1).

Example 'Partially hydrolysed Infant Formula based on cows' milk'.

2.9.1—21 Labelling requirements for food represented as lactose free and low lactose formulas

(1) For the labelling provisions, if a label represents that an infant formula is lactose free or low lactose:

(a) for a formula represented as lactose free—the words 'lactose free' must be included in the statement of the name of the food required by section 2.9.1—19; and

Example 'Lactose free infant formula from cows milk'.

(b) for a formula represented as low lactose—the words 'low lactose' must be included in the statement of the name of the food required by section 2.9.1—19; and

Example 'Low lactose infant formula from cows milk'.

(c) the average quantity of lactose and galactose, expressed in grams, must be included in the statement required by section 2.9.1—25 and in the same format as specified in the table to section S29—10 for those substances.

Note The labelling provisions are set out in Standard 1.2.1.

(2) A labelling requirement of this Standard, other than a requirement imposed by subsection (1), applies to an infant formula that is represented as lactose free formula or low lactose formula.

2.9.1—22 Requirement for warning statements and directions

Warning statements

(1) For the labelling provisions, the following *warning statements are required for infant formula and follow-on formula:

(a) 'Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill.'; and

(b) a heading that states 'Important Notice' (or words to that effect), with under it the *warning statement—'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.'.

Note The labelling provisions are set out in Standard 1.2.1.

Required statements on use

(2) For the labelling provisions, the required statements for infant formula and follow--on formula are ones indicating that:

(a) for infant formula—the infant formula may be used from birth; and

(b) for follow-on formula—the follow-on formula should not be used for infants aged under the age of 6 months; and

(c) for infant formula and follow-on formula—it is recommended that infants from the age of 6 months should be offered foods in addition to the infant formula or follow-on formula.

Note The labelling provisions are set out in Standard 1.2.1.

Location of warning statements and required statements

(3) The statements required by paragraphs (2)(a) and (b) must appear on the front of the package of the product.

(4) Subsection (3) does not prevent a statement required by subsection (2) from appearing more than once on the label.

Directions on preparation and use

(5) For the labelling provisions, directions on preparation and use are required for infant formula and follow-on formula which instruct (in words and pictures) that:

(a) each bottle must be prepared individually; and

(b) if a bottle of prepared formula is to be stored prior to use, it must be refrigerated and used within 24 hours; and

(c) previously boiled and cooled potable water must be used; and

(d) if a package contains a measuring scoop—only the enclosed scoop must be used; and

(e) for powdered or concentrated formula—do not change proportions of the powder or concentrate or add other food except on medical advice; and

(f) for ready-to-drink formula—do not dilute or add other food except on medical advice; and

(g) formula left in the bottle after a feed must be discarded within 2 hours.

Note The labelling provisions are set out in Standard 1.2.1.

(6) Paragraphs (5)(a), (b) and (c) do not apply to ready-to-drink formula.

(7) Paragraph (5)(d) does not apply to concentrated formula and ready-to drink formula.

(8) For the labelling provisions, the following must be declared for a powdered or concentrated form of infant formula and follow-on formula:

(a) the proportion of powder or concentrate required to reconstitute the formula according to directions; and

(b) for a product in powdered form—the weight of one scoop.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—23 Print size

The statements required by subsection 2.9.1—22(1) must be in a *size of type of at least:

(a) if the package of infant formula or follow-on formula has a net weight of more than 500 g—3 mm;

(b) if the package of infant formula or follow-on formula has a net weight of 500 g or less—1.5 mm.

2.9.1—24 Optional format for the statement of ingredients – added vitamins and minerals

(1) Despite section 1.2.4—5, where a vitamin or mineral is added to infant formula or follow-on formula in accordance with section 2.9.1—8, the statement of ingredients not need list the added vitamin and mineral in descending order of ingoing weight, provided that the statement of ingredients also:

(a) lists all added vitamins together under the subheading ‘Vitamins’; and

(b) lists all added minerals together under the subheading ‘Minerals’.

Note See Standard 1.2.4 for other ingredient labelling requirements.

(2) Section 1.2.4—8 does not apply to a statement of ingredients referred to in subsection (1).

2.9.1—25 Declaration of nutrition information

Statement of nutrition information

(1) For the labelling provisions, a statement of the following nutrition information is required for infant formula and follow-on formula:

(a) the *unit quantity of the food expressed in per 100 mL; and

(b) the *average energy content expressed in kilojoules; and

(c) the *average quantity of protein, fat and *carbohydrate expressed in grams and as 'protein', 'fat' and 'carbohydrate', respectively; and

(d) the average quantity of each vitamin or mineral expressed in micrograms or milligrams (including any naturally-occurring amount); and

(e) for infant formula—the average quantity of choline, inositol and L-carnitine expressed in milligrams (including any naturally-occurring amount);

(f) if added, the average quantity of the following, expressed in micrograms or milligrams:

(i) any substance *used as a nutritive substance (including any naturally-occurring amount); or

(ii) inulin-type fructans; or

(iii) galacto-oligosaccharides; or

(iv) a combination of *inulin-type fructans and galacto-oligosaccharides.

Note The labelling provisions are set out in Standard 1.2.1.

(2) If one of the following substances is present in the infant formula or follow-on formula, the statement required by subsection (1) may include the average quantity of that substance (including any naturally-occurring amount), expressed in milligrams or grams:

(a) docosahexaenoic acid; and

(b) eicosapentaenoic acid; and

(c) arachidonic acid; and

(d) whey; and

(e) casein.

(3) If the infant formula and follow-on formula is in a powdered or concentrated form, the information mentioned in subsections (1) and (2) must be expressed in terms of the product as reconstituted according to the directions on the package.

(4) Unless expressly provided elsewhere in this Code, the statement required by this section must not contain any other information.

2.9.1—26 Required form for the declaration of nutrition information

(1) A reference to 'the table' in this section is a reference to the table to section S29—10.

(2) The statement required by section 2.9.1—25 must:

(a) be in the same format as specified in the table; and

(b) state the nutrition information in the order specified in the table; and

(c) be titled 'Nutrition Information'; and

(d) have the following subheadings printed in a size of type that is the same or larger than the nutrient names in the statement:

(i) for infant formula and follow-on formula—'Vitamins', 'Minerals' and 'Additional'; and

(ii) for infant formula only—'Other nutrients';

(e) state nutrients and subgroup nutrients using the names and units of measurement specified in that table for that nutrient and subgroup; and

(f) not include a *unit quantity other than per 100 mL.

(3) If the statement includes the average quantity of a permitted nutritive substance, an inulin-type fructan or a galacto-oligosaccharide, that average quantity must be included in the statement:

(a) under the subheading 'Additional'; and

(b) in the same format as specified in the table for that substance.

(4) If the statement includes the average quantity of choline, inositol or L-carnitine, that average quantity must be included in the statement:

(a) for infant formula—under the subheading 'Other Nutrients'; and

(b) for follow-on formula—under the subheading 'Additional'; and

(c) in the same format as specified in the table for that substance.

(5) If the statement includes the average quantity of a substance listed in subsection 2.9.1—25(2), that average quantity must be included in the statement in the same format as specified in the table for that substance.

2.9.1—27 How average quantity is to be calculated

Despite section 1.1.1—6, the method in paragraph 1.1.1—6(3)(c) must not be used to calculate the average quantity of a substance in infant formula or follow-on formula.

2.9.1—28 Requirements for use of stage numbers

(1) The following numbers may be used on the label on a package of infant formula or follow-on formula to identify for consumers that product is infant formula or follow-on formula:

(a) if the product is infant formula—the number '1'; and

(b) if the product is follow-on formula—the number '2'.

(2) A number used in accordance with subsection (1) must appear:

(a) on the front of the package of the product; and

(b) immediately adjacent to:

(i) for infant formula—the statement required by paragraph 2.9.1—22(2)(a); and

(ii) for follow-on formula—the statement required by paragraph 2.9.1—22(2)(b).

2.9.1—29 Prohibited representations

(1) The label on a package of infant formula or follow-on formula must not contain:

(a) a picture of an infant; or

(b) a picture that idealises the use of infant formula or a follow-on formula; or

(c) information relating to another product; or

Example The label on a package of infant formula must not refer to, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children.

(d) the word 'humanised' or 'maternalised' or any word or words having the same or similar effect; or

(e) the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect; or

(f) the abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect; or

(g) words claiming that the formula is suitable for all infants; or

(h) information relating to the nutritional content of human milk; or

(i) information relating to the presence of a substance listed in subsection (3), except for a reference in:

(i) a statement of ingredients; or

(ii) a declaration or statement expressly permitted or required by this Code; or

(j) information relating to ingredients, except for a reference in:

(i) a statement of ingredients; or

(ii) a declaration or statement expressly permitted or required by this Code; or

(k) information relating to the animal or plant source or sources of protein in the infant formula or follow-on formula, except:

(i) in a statement of ingredients; or

(ii) where required by subsection 2.9.1—20(1); or

(l) the words 'partially hydrolysed' or any word or words having the same or similar effect, except:

(i) in a statement of ingredients; or

(ii) where required by subsection 2.9.1—20(2); or

(m) the words 'lactose free' or 'low lactose', except for a declaration or statement required by section 2.9.1—21; and

(n) a number used to identify for consumers that the product is infant formula or follow-on formula, except where required by section 2.9.1—28.

Note *S*tandard 1.2.7 prescribes requirements for making health claims and nutrition content claims, including in relation to infant formula products. Section 1.2.7—4 provides that a nutrition content claim or *health claim must not be made about an infant formula product. Section 1.2.7—8 provides that a claim – including a claim about an infant formula product - must not be therapeutic in nature.

(2) For the purposes of subsection (1), 'information' includes a reference by means of a name, a number, a picture, an image, a word or words.

(3) For the purposes of paragraph (1)(i), the following substances are listed:

(a) an inulin-type fructan; and

(b) a galacto-oligosaccharide; and

(c) a nutrient; and

(d) a substance *used as a nutritive substance'.

Note Section 2.9.1—25 expressly requires or permits these substances to be declared or stated in the declaration of nutrition information required by that section.

Division 4 Special medical purpose products for infants

2.9.1—30 Application of other Standards

The following provisions do not apply to special medical purpose product for infants:

(a) paragraphs 1.1.1—10(6)(b) (foods used as nutritive substances) and 1.1.1—10(6)(f) (novel foods); and

(b) unless the contrary intention appears:

(i) Part 1.2 of Chapter 1 (labelling and other information requirements); and

(ii) Division 3 of this Standard.

2.9.1—31 Restriction on the sale of special medical purpose products for infants

(1) A special medical purpose product for infants must not be sold to a consumer, other than from or by:

(a) a medical practitioner or dietitian; or

(b) a medical practice, pharmacy or responsible institution; or

(c) a majority seller of that special medical purpose product for infants.

(2) In this section:

medical practitioner means a person registered or licensed as a medical practitioner under legislation in Australia or New Zealand, as the case requires, for the registration or licensing of medical practitioners.

majority seller means, in relation to a special medical purpose product for infants, a person who:

(a) during any 24 month period, sold that special medical purpose product for infants to any of the following:

(i) a medical practitioner;

(ii) a dietitian;

(iii) a medical practice;

(iv) a pharmacy;

(v) a responsible institution; and

(b) the sales mentioned in paragraph (a) represent more than one half of the total amount of that special medical purpose product for infants sold by the person during that 24 month period.

2.9.1—32 Compositional requirements for special medical purpose products for infants

(1) A special medical purpose product for infants must contain each substance listed in Column 1 of the table to section S29—5 in an amount that is:

(a) no less than the minimum amount specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

Note It is recommended that a special medical purpose product for infants contain a substance listed in Column 1 of the table to section S29—5 in an amount that is not more than the amount (if any) specified for that substance in Column 4 of that table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of special medical purpose products for infants or due to technological reasons.

(2) However, the food is not required to comply with subsection (1) to the extent that a variation from a maximum or minimum amount:

(a) is required for a particular medical purpose; or

(b) would otherwise prevent the sale of the food.

2.9.1—33 Representations about food as a special medical purpose product for infants

A food may only be represented as a special medical purpose product for infants if it complies with this Division.

2.9.1—35 Prohibited representations

The label on a package of a special medical purpose product for infants must not contain:

(a) a picture of an infant; or

(b) the word ‘humanised’ or ‘maternalised’ or any word or words having the same or similar effect; or

(c) the words ‘human milk oligosaccharide’, ‘human milk identical oligosaccharide’ or any word or words having the same or similar effect; or

(d) the abbreviations ‘HMO’ or HiMO’ or any abbreviation having the same or similar effect; or

(e) information relating to another food.

Note *S*tandard 1.2.7 prescribes requirements for making health claims and nutrition content claims, including in relation to infant formula products, including a special medical purpose product for infants. Section 1.2.7—4 provides that a nutrition content claim or *health claim must not be made about an infant formula product. Section 1.2.7—8 provides that a claim – including a claim about a special medical purpose product for infants - must not be therapeutic in nature.

2.9.1—36 Labelling and related requirements

(1) This section applies to a food for sale that is a special medical purpose product for infants.

(2) If the food for sale is in a package, it is required to *bear a label that complies with section 2.9.1—37.

(3) If the food for sale is in an *inner package:

(a) the inner package is required to *bear a label that complies with section 2.9.1—42; and

(b) there is no labelling requirement under this Code for any other packaging associated with the food for sale.

(4) If the food for sale is in a *transportation outer:

(a) the transportation outer or package containing the food for sale is required to *bear a label that complies with section 2.9.1—43; and

(b) there is no labelling requirement under this Code for any other packaging associated with the food for sale.

2.9.1—37 Mandatory labelling information

(1) The label that is required for a special medical purpose product for infants must state the following information in accordance with the provision indicated:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2);

(b) lot identification (see section 1.2.2—3);

(c) if the sale of the food for sale is one to which Division 2 or Division 3 of Standard 1.2.1 applies:

(i) information relating to *foods produced using gene technology (see section 1.5.2—4); and

(ii) information relating to irradiated food (see section 1.5.3—9);

(d) any required advisory statements, *warning statements, other statements, and declarations (see section 2.9.1—38);

(e) information relating to ingredients (see section 2.9.1—39);

(f) date marking information (see section 2.9.1—40);

(g) directions for the use or the storage of the food, if the food is of such a nature to require such directions for health or safety reasons;

(h) nutrition information (see section 2.9.1—41).

(2) The label must comply with Division 6 of Standard 1.2.1.

2.9.1—38 Mandatory statements and declarations— special medical purpose products for infants

(1) For paragraph 2.9.1—37(1)(d), the following statements are required:

(a) a statement to the effect that the food must be used under medical supervision;

(b) a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food;

(c) a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated;

(d) a statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated in paragraph (c);

(e) if the food has been formulated for a specific age group—a statement to the effect that the food is intended for persons within the specified age group;

(f) a statement indicating whether or not the food is suitable for use as a sole source of nutrition;

(g) if the food is represented as being suitable for use as a sole source of nutrition:

(i) a statement to the effect that the food is not for parenteral use; and

(ii) if the food has been modified to vary from the compositional requirements of section 2.9.1—32 such that the content of one or more nutrients falls short of the prescribed minimum, or exceeds the prescribed maximum (if applicable):

(A) a statement indicating the nutrient or nutrients which have been modified; and

(B) unless provided in other documentation about the food—a statement indicating whether each modified nutrient has been increased, decreased, or eliminated from the food, as appropriate.

(2) For paragraph 2.9.1—37(1)(d), the required advisory statements and declarations are any that are required by:

(a) items 1, 4, 6 or 9 of the table to section S9—2; or

(b) subsection 1.2.3—2(2); or

(c) section 1.2.3—4.

(3) For paragraph 2.9.1—37(1)(d), the *warning statement referred to in section 1.2.3—3, if applicable, is required.

2.9.1—39 Information relating to ingredients—special medical purpose products for infants

For paragraph 2.9.1—37(1)(e), the information relating to ingredients is:

(a) a statement of ingredients; or

(b) information that complies with Articles 18, 19 and 20 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers; or

(c) information that complies with 21 CFR § 101.4.

2.9.1—40 Date marking information—special medical purpose products for infants

(1) For paragraph 2.9.1—37(1)(f), the required date marking information is date marking information in accordance with Standard 1.2.5.

(2) Despite subsection (1), for subparagraph 1.2.5—5(2)(a)(ii), the words ‘Expiry Date’, or similar words, may be used on the label.

2.9.1—41 Nutrition information—special medical purpose products for infants

(1) For paragraph 2.9.1—37(1)(h), the nutrition information required for a special medical purpose product for infants is the following, expressed per given amount of the food:

(a) the minimum or *average energy content; and

(b) the minimum amount or *average quantity of:

(i) protein, fat and carbohydrate; and

(ii) any vitamin, mineral or electrolyte that has been *used as a nutritive substance in the food; and

(c) any other substance:

(i) *used as a nutritive substance in that product; and

(ii) added to that product to achieve that product's intended medical purpose as described in the statement required by paragraph 2.9.1—38(1)(c).

(2) The label that is required for a special medical purpose product for infants may state information relating to the source or sources of protein in that product.

2.9.1—42 Labelling requirement—special medical purpose products for infants in inner package

(1) The label on an *inner package that contains a special medical purpose product for infants must state the following information in accordance with the provision indicated:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2);

(b) lot identification (see section 1.2.2—3);

(c) any declaration that is required by section 1.2.3—4;

(d) date marking information (see section 2.9.1—40).

(2) The label must comply with Division 6 of Standard 1.2.1.

(3) To avoid doubt, this section continues to apply to the label on the *inner package if a *responsible institution subsequently supplies the inner package to a patient or resident of the responsible institution.

2.9.1—43 Labelling requirement— a special medical purpose product for infants in transportation outer

(1) If packages of a special medical purpose product for infants are contained in a transportation outer, the information specified in subsection (2) must be:

(a) contained in a label on the transportation outer; or

(b) contained in a label on a package of the food for sale, and clearly discernible through the transportation outer.

(2) For subsection (1), the information is:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2); and

(b) lot identification (see section 1.2.2—3); and

(c) unless it is provided in accompanying documentation—the name and address of the *supplier (see section 1.2.2—4).

———————————

Attachment E - Consequential draft variations to the Australia New Zealand Food Standards Code (call for submissions)

Food Standards (Proposal P1028 – Infant Formula Products – Consequential Amendments) Variation

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1 Name

This instrument is the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*.

2 Variation to standards in the *Australia New Zealand Food Standards Code*

(1) The Schedules to this instrument vary Standards in the *Australia New Zealand Food Standards Code*.

(2) Each Standard that is specified in a Schedule to this instrument is amended as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

3 Commencement

This instrument commences immediately after the commencement of the *Food Standards (Proposal P1028 – Infant Formula) Variation.*

4 Effect of the variations made by this instrument

(1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.

(2) During the transition period, a food product may be sold if the product complies with one of the following:

(a) the Code as in force without the variations made by the instruments; or

(b) the Code as amended by the variations made by the instruments.

(3) For the purposes of this clause:

(a) the **instruments** means:

(i) this instrument; and

(ii) the *Food Standards (Proposal P1028 – Infant Formula) Variation*;

(b) the **transition period** means the period commencing on this instrument's date of commencement and ending 60 months after the date of commencement.

Schedule 1

Schedule 29—Special purpose foods

[1] Sections S29—2 to S29—10

Repeal the sections, substitute:

S29—2 Infant formula products—calculation of energy content

(1) For paragraph 2.9.1—4(2)(a), the energy content of infant formula product must be calculated using:

(a) the energy contributions of the following *components only:

(i) fat; and

(ii) protein; and

(iii) carbohydrate; and

(b) the relevant energy factors set out in section S11—2.

(2) The energy content of infant formula product must be expressed in kilojoules.

S29—2A Infant formula products—calculation of protein content

For paragraph 2.9.1—4(2)(b), the protein content of infant formula product must be calculated by multiplying the nitrogen content of the product by a nitrogen-to-protein conversion factor of 6.25.

S29—2B Infant formula products—calculation of vitamin A content in infant formula and follow-on formula

For paragraph 2.9.1—4(2)(c), the vitamin A content of infant formula and follow-on formula must be calculated using only the retinol forms of vitamin A prescribed in column 1 of Table S29—23.

S29—3 Infant formula products—L-amino acids that must be present in infant formula and follow-on formula

For subsection 2.9.1—6(4), the table is:

L-amino acids that must be present in infant formula and follow-on formula

L-amino acid	*Minimum amount per 100 kJ*
Cysteine	9 mg
Histidine	10 mg
Isoleucine	22 mg
Leucine	40 mg
Lysine	27 mg
Methionine	6 mg
Phenylalanine	19 mg
Threonine	18 mg
Tryptophan	8 mg
Tyrosine	18 mg
Valine	22 mg

S29—4 Infant formula products—limits on fatty acids that may be present in infant formula and follow-on formula

For paragraph 2.9.1—7(1)(f), the table is:

Limits on fatty acids that may be present in infant formula and follow-on formula

Column 1	*Column 2*	*Column 3*
Substance	*Maximum amount per 100 kJ*	*Guidance upper level per 100 kJ (see Note)*
Docosahexaenoic acid		7 mg

Long chain omega 6 series fatty acids (C> = 20)	Not more than 2% of the total fatty acids
Long chain omega 3 series fatty acids (C> = 20)	Not more than 1% of the total fatty acids
Total *trans* fatty acids	Not more than 4% of the total fatty acids
Erucic acid (22:1)	Not more than 1% of the total fatty acids

Note It is recommended that infant formula and follow-on formula contain a fatty acid listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in Column 3 of the table. An amount specified in Column 3 is a Guidance Upper Level and is a recommended upper level for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons.

S29—5 Vitamins, minerals, electrolytes and other substances required in infant formula and special medical purpose products for infants

For subsection 2.9.1—8(1) and section 2.9.1—32, the table is:

Vitamins, minerals, electrolytes and nutritive substances required in infant formula and special medical purpose products for infants

Column 1	***Column 2***	***Column 3***	***Column 4***
Substance	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*	*Guidance upper level per 100 kJ (see Note)*
Vitamins			
Vitamin A	14 µg RE	43 µg RE	
Vitamin D	0.24 µg	0.63 µg	
Vitamin C	1.7 mg		17 mg
Thiamin	10 µg		72 µg
Riboflavin	14.3 µg		120 µg
Niacin	70 µg		359 µg
Vitamin B_6	8 µg		42 µg
Folic acid	2.4 µg		12 µg
Pantothenic acid	96 µg		478 µg
Vitamin B_{12}	0.02 µg		0.36 µg
Biotin	0.24 µg		2.4 µg
Vitamin E	0.14 mg α-TE		1.2 mg α-TE
Vitamin K	0.24 µg		6 µg
Minerals			
Calcium	12 mg		35 mg
Phosphorus	6 mg		24 mg
Magnesium	1.2 mg		3.6 mg
Iron	0.14 mg	0.48 mg	
Iodine	2.4 µg		14 µg
Copper	8 µg		29 µg
Zinc	0.12 mg		0.36 mg

Manganese	0.24 µg		24 µg
Selenium	0.48 µg		2.2 µg
Electrolytes			
Chloride	12 mg	38 mg	
Sodium	4.8 mg	14 mg	
Potassium	14 mg	43 mg	
Other essential substances			
Choline	1.7 mg		12 mg
L-carnitine	0.30 mg		0.80 mg
Myo-inositol	1.0 mg		10 mg

Note It is recommended that infant formula and a special medical purpose product for infants contain a substance listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in Column 4 of the table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or special medical purpose products for infants; or due to technological reasons.

S29—6 Vitamins, minerals and electrolytes required in follow-on formula

For subsection 2.9.1—8(2), the table is:

Vitamins, minerals and electrolytes required in follow-on formula

Column 1	***Column 2***	***Column 3***	***Column 4***
Vitamin, mineral or electrolyte	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*	*Guidance upper level per 100 kJ (see Note)*
Vitamins			
Vitamin A	14 µg RE	43 µg RE	
Vitamin D	0.24 µg	0.63 µg	
Vitamin C	1.7 mg		17 mg
Thiamin	10 µg		72 µg
Riboflavin	14.3 µg		120 µg
Niacin	70 µg		359 µg
Vitamin B_6	8 µg		42 µg
Folic acid (not including naturally occurring folate)	2.4 µg		12 µg
Pantothenic acid	96 µg		478 µg
Vitamin B_{12}	0.02 µg		0.36 µg
Biotin	0.24 µg		2.4 µg
Vitamin E	0.14 mg α-TE		1.2 mg α-TE
Vitamin K	0.24 µg		6 µg
Minerals			
Calcium	12 mg		43 mg
Phosphorus	6 mg		24 mg
Magnesium	1.2 mg		3.6 mg
Iron	0.24 mg	0.48 mg	
Iodine	2.4 µg		14 µg

Copper	8 µg		29 µg
Zinc	0.12 mg		0.36 mg
Manganese	0.24 µg		24 µg
Selenium	0.48 µg		2.2 µg
Electrolytes			
Chloride	12 mg	38 mg	
Sodium	4.8 mg	14 mg	
Potassium	14 mg	43 mg	

Note It is recommended that follow-on formula contain a substance listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in column 4 of the table. The amounts specified are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. The Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow on formula or due to technological reasons.

S29—7 Optional nutritive substances in infant formula

For subsection 2.9.1—9(1), the table is set out below.

Optional nutritive substances in infant formula

Column 1	***Column 2***	***Column 3***
Substance	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*
2′-fucosyllactose permitted for use by Standard 1.5.2		96 mg
A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2		96 mg which contains not more than 24 mg of lacto-N-neotetraose
Adenosine-5′-monophosphate		0.36 mg
Cytidine-5′-monophosphate		0.60 mg
Guanosine-5′-monophosphate		0.40 mg
Inosine-5′-monophosphate		0.24 mg
Lactoferrin		40 mg
Lutein	1.5 µg	5.0 µg
Taurine		2.9 mg
Uridine-5′-monophosphate		0.42 mg

S29—8 Optional nutritive substances in follow-on formula

For subsection 2.9.1—9(2), the table is set out below.

Optional nutritive substances in follow-on formula

Column 1	***Column 2***	***Column 3***	***Column 4***
Substance	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*	*Guidance upper level per 100 kJ (see Note)*
2′-fucosyllactose permitted for use by Standard 1.5.2		96 mg	

A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2		96 mg which contains not more than 24 mg of lacto-N-neotetraose	
Adenosine-5′-monophosphate		0.36 mg	
L-carnitine	0.30 mg		
Choline			12 mg
Cytidine-5′-monophosphate		0.60 mg	
Guanosine-5′-monophosphate		0.40 mg	
Inosine-5′-monophosphate		0.24 mg	
Lactoferrin		40 mg	
Lutein	1.5 µg	5.0 µg	
Myo-inositol			9.5 mg
Taurine		2.9 mg	
Uridine-5′-monophosphate		0.42 mg	

Note It is recommended that follow-on formula contain a substance listed in Column 1 of the table in an amount that is not more than the amount (if any) specified for that substance in Column 4 of the table. The amounts specified in Column 4 are Guidance Upper Levels and are recommended upper levels for nutrients which pose no significant risks on the basis of current scientific knowledge. The Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-on formula or due to technological reasons.

S29—9 Permitted forms of nutritive substances in infant formula and follow-on formula

For paragraph 2.9.1—10(b), the table is set out below.

Infant formula products—substances permitted for use as nutritive substances

Substance	***Permitted forms***
2′-fucosyllactose permitted for use by Standard 1.5.2	2′-fucosyllactose
A combination of: 2′-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2	2′-fucosyllactose and lacto-N-neotetraose
Adenosine-5′-monophosphate	Adenosine-5′-monophosphate
L-carnitine	L-carnitine L-carnitine hydrochloride L-carnitine tartrate
Choline	Choline chloride Choline bitartrate Choline Choline citrate Choline hydrogen tartrate
Cytidine-5′-monophosphate	Cytidine-5′-monophosphate
Guanosine-5′-monophosphate	Guanosine-5′-monophosphate Guanosine-5′-monophosphate sodium salt
Inosine-5′-monophosphate	Inosine-5′-monophosphate

	Inosine-5′-monophosphate sodium salt
Lactoferrin	Bovine lactoferrin
Lutein	Lutein from *Tagetes erecta L.*
Myo-inositol	Inositol
Taurine	Taurine
Uridine-5′-monophosphate	Uridine-5′-monophosphate sodium salt

Note Section S29—23 lists the permitted forms of vitamins, minerals and electrolytes in infant formula products.

S29—10 Required format for a nutrition information statement

The table to this section is:

NUTRITION INFORMATION	
	Average quantity per 100 mL prepared formula
Energy	kJ
Protein	g
— Whey*	g
— Casein*	g
Fat	g
— Long chain polyunsaturated fatty acids*	
— Docosahexaenoic acid*	mg
— Eicosapentaenoic acid*	mg
— Arachidonic acid**	mg
Carbohydrate	
— Lactose*	g
— Galactose*	g
Vitamins	
Vitamin A	µg
Vitamin B_6	µg
Vitamin B_{12}	µg
Vitamin C	mg
Vitamin D	µg
Vitamin E	µg
Vitamin K	µg
Biotin	µg
Niacin	mg
Folate	µg
Pantothenic acid	µg
Riboflavin	µg
Thiamin	µg
Minerals	
Calcium	mg
Copper	µg

Iodine	µg
Iron	mg
Magnesium	mg
Manganese	µg
Phosphorus	mg
Selenium	µg
Zinc	mg
Chloride	mg
Potassium	mg
Sodium	mg
Other nutrients*	
Choline*	mg
Inositol*	mg
L-carnitine*	mg
Additional	
(insert any other substance used as a nutritive substance; or inulin-type fructans and / or galacto-oligosaccharides, to be declared)	g, mg, µg

Note: *See the following.

Entries and amounts for the following only need be included when stated in accordance with subsection 2.9.1—25(2): whey; casein; long chain polyunsaturated fatty acids; docosahexaenoic acid; eicosapentaenoic acid; arachidonic acid.

Entries and amounts for lactose and galactose only need be included when stated in accordance with paragraph 2.9.1—21(1)(c).

The heading 'Other nutrients' only need be included when required by subparagraph 2.9.1—26(2)(d)(ii).

Entries and amounts for choline, inositol, L-carnitine are included under the heading 'Other nutrients' when required by paragraph 2.9.1—26(4)(a) and under the heading 'Additional' when required by paragraph 2.9.1—26(4)(b).

[2] After section S29—22

Insert

S29—23 Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants, formulated meal replacements (vitamin K) and food for special medical purposes

For sections 2.9.1—10(a), 2.9.2—4, 2.9.2—5, 2.9.2—6, 2.9.3—3(2)(c)(iii) and 2.9.5—6, the table is:

Permitted forms of vitamins, minerals and electrolytes in infant formula products, etc

Vitamin, mineral or electrolyte	***Permitted forms***
Vitamin A	
Retinol forms	vitamin A (retinol)
	vitamin A acetate (retinyl acetate)
	vitamin A palmitate (retinyl palmitate)
	retinyl propionate
Provitamin A forms	beta-carotene
Vitamin C	L-ascorbic acid
	L-ascorbyl palmitate

	calcium ascorbate
	potassium ascorbate
	sodium ascorbate
Vitamin D	vitamin D_2 (ergocalciferol)
	vitamin D_3 (cholecalciferol)
	vitamin D (cholecalciferol-cholesterol)
Thiamin	thiamin hydrochloride
	thiamin mononitrate
Riboflavin	riboflavin
	riboflavin-5′-phosphate, sodium
Niacin	niacinamide (nicotinamide)
Vitamin B_6	pyridoxine hydrochloride
	pyridoxine-5′-phosphate
Folic acid	Folate (excluding naturally occurring folate)
Pantothenic acid	calcium pantothenate
	dexpanthenol
	D-panthenol
	calcium D-pantothenate
	sodium D-pantothenate
Vitamin B_{12}	cyanocobalamin
	hydroxocobalamin
Biotin	d-biotin
Vitamin E	dl-α-tocopherol
	d-α-tocopherol concentrate
	tocopherols concentrate, mixed
	d-α-tocopheryl acetate
	dl-α-tocopheryl acetate
	d-α-tocopheryl acid succinate
	dl-α-tocopheryl succinate
Vitamin K	Vitamin K_1 as phylloquinone (phytonadione)
Calcium	calcium carbonate
	calcium chloride
	calcium citrate
	calcium gluconate
	calcium glycerophosphate
	calcium hydroxide
	calcium lactate
	calcium oxide
	calcium phosphate, dibasic
	calcium phosphate, monobasic
	calcium phosphate, tribasic
	calcium sulphate

Chloride	calcium chloride
	magnesium chloride
	potassium chloride
	sodium chloride
Chromium	chromium sulphate
Copper	copper gluconate
	cupric sulphate
	cupric citrate
	cupric carbonate
Iodine	potassium iodate
	potassium iodide
	sodium iodide
Iron	ferric ammonium citrate
	ferric pyrophosphate
	ferrous citrate
	ferrous fumarate
	ferrous gluconate
	ferrous lactate
	ferrous succinate
	ferrous sulphate
	ferric citrate
	ferrous bisglycinate
	ferrous sulphate
Magnesium	magnesium carbonate
	magnesium chloride
	magnesium gluconate
	magnesium oxide
	magnesium phosphate, dibasic
	magnesium phosphate, tribasic
	magnesium sulphate
	magnesium hydroxide carbonate
	magnesium hydroxide
	magnesium salts of citric acid
Manganese	manganese chloride
	manganese gluconate
	manganese sulphate
	manganese carbonate
	manganese citrate
Molybdenum	sodium molybdate VI
Phosphorus	calcium glycerophosphate
	calcium phosphate, dibasic
	calcium phosphate, monobasic
	calcium phosphate, tribasic

	magnesium phosphate, dibasic
	potassium phosphate, dibasic
	potassium phosphate, monobasic
	potassium phosphate, tribasic
	sodium phosphate, dibasic
	sodium phosphate, monobasic
	sodium phosphate, tribasic
Potassium	potassium bicarbonate
	potassium carbonate
	potassium chloride
	potassium citrate
	potassium glycerophosphate
	potassium gluconate
	potassium hydroxide
	potassium phosphate, dibasic
	potassium phosphate, monobasic
	potassium phosphate, tribasic
	potassium L-lactate
Selenium	seleno methionine
	sodium selenate
	sodium selenite
Sodium	sodium bicarbonate
	sodium carbonate
	sodium chloride
	sodium chloride iodised
	sodium citrate
	sodium gluconate
	sodium hydroxide
	sodium iodide
	sodium lactate
	sodium phosphate, dibasic
	sodium phosphate, monobasic
	sodium phosphate, tribasic
	sodium sulphate
	sodium tartrate
Zinc	zinc acetate
	zinc chloride
	zinc gluconate
	zinc oxide
	zinc sulphate
	zinc lactate
	zinc citrate (zinc citrate dehydrate or zinc citrate trihydrate)

Schedule 2

Standard 1.1.2—Definitions used throughout the Code

[1] Subsection 1.1.2—2(3)

Insert:

inner package, in relation to special medical purpose products for infants, means an individual package of the food that is:

(a) contained and sold within another package that is labelled in accordance with Division 4 of Standard 2.9.1; and

(b) not designed for individual sale, other than a sale by a *responsible institution to a patient or resident of the responsible institution.

Example An example of an inner package is an individual sachet (or sachets) of a powdered food contained within a box that is fully labelled, being a box available for retail sale.

[2A] Subsection 1.1.2—2(3) (definition of *medium chain triglycerides*)

Repeal the definition.

[2] Subsection 1.1.2—2(3) (definition of *protein substitute*)

Repeal the definition.

[3] Subsection 1.1.2—2(3) (paragraph (c) of the definition of *warning statement*)

Repeal the paragraph, substitute:

(c) subsection 2.9.1—22(1) (warning statements for infant formula product);

[4] Subsection 1.1.2—3(2) (definitions—particular foods)

Insert:

special medical purpose product for infants means an infant formula product that is:

(a) represented as being:

(i) specially formulated for the dietary management of infants who have medically determined nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food); and

(ii) suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product; and

(iii) for the dietary management of a medically diagnosed disease, disorder or condition of an infant; and

(b) intended to be used under medical supervision; and

(c) not suitable for general use.

[5] Subsection 1.1.2—3(2) (definition of *follow-on formula*)

Repeal the definition, substitute:

follow-on formula means an infant formula product that is represented as:

(a) either a breast milk substitute or replacement for infant formula; and

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

[6] Subsection 1.1.2—3(2) (definition of *infant formula*)

Repeal the definition, substitute:

infant formula means an infant formula product that is represented as:

(a) a breast milk substitute for infants; and

(b) satisfying by itself the nutritional requirements of infants under the age of 4 to 6 months.

[7] Subsection 1.1.2—3(2) (definition of *infant formula product*)

Repeal the definition, substitute:

infant formula product means a product based on milk or other edible food constituents of animal or plant origin which is represented as 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.

[8] Subsection 1.1.2—3(2) (definition of *pre-term formula*)

Repeal the definition.

Standard 1.2.3—Information requirements – warning statements, advisory statements and declarations

[9] Paragraph 1.2.3—6(4)(b)

Repeal the paragraph, substitute

(b) a special medical purpose product for infants.

[10] Note 2 to subsection 1.2.3—6(4)

Repeal the note, substitute:

Note 2 Division 4 of Standard 2.9.1 applies to special medical purpose products for infants and sets out compositional and labelling requirements for such food.

Standard 1.3.1—Food Additives

[11] Subsection 1.3.1—3(2)

After 'any food', insert '(other than an infant formula product)'

[12] Paragraph 1.3.1—4(6)(k)

Repeal the paragraph, substitute:

(k) rosemary extract is calculated as the sum of carnosic acid and carnosol;

(l) phosphoric acid and phosphates are calculated as phosphorus.

Standard 1.5.1—Novel Foods

[13] Section 1.5.1—3

Omit the section, substitute:

1.5.1—3 Sale of novel foods

(1) Despite paragraphs 1.1.1—10(5)(b) and (6)(f), a food offered for retail sale (other than an infant formula product) may consist of, or have as an ingredient, a *novel food if:

(a) the novel food is listed in the table to section S25—2; and

(b) any conditions of use specified in the corresponding row of that table are complied with.

Note Novel foods are added to the table to section S25—2 by variations to the Code. When added for the first time, the conditions may include some that apply to the novel food only during the first 15 months after gazettal of the variation. Conditions may also deal with matters such as the following:

- the need for preparation or cooking instructions, warning statements or other advice;
- the need to meet specific requirements of composition or purity;
- the class of food within which the food must be sold;
- during the first 15 months after gazettal, the brand under which the food may be sold.

(2) An infant formula product food for retail sale may consist of, or have as an ingredient or a component, a novel food only if:

(a) the novel food is listed in the table to section S25—2; and

(b) the presence of that novel food in the infant formula product is expressly permitted by that table; and

(c) any conditions of use specified in the corresponding row of that table are complied with.

Standard 2.9.2—Food for infants

[14] Section 2.9.2—4

Omit ‘section S29—7’ (wherever occurring), substitute ‘section S29—23’.

[15] Section 2.9.2—5

Omit ‘section S29—7’ (wherever occurring), substitute ‘section S29—23’.

[16] Subsection 2.9.2—6(3)

Omit ‘section S29—7’, substitute ‘section S29—23’.

Standard 2.9.3—Formulated meal replacements and formulated supplementary foods

[17] Subparagraph 2.9.3—3(2)(c)(iii)

Omit ‘section S29—7’, substitute ‘section S29—23’.

Standard 2.9.5—Food for special medical purposes

[18] Paragraph 2.9.5—6(1)(b)

Omit ‘section S29—7’, substitute ‘section S29—23’.

Schedule 8—Food additive names and code numbers (for statement of ingredients)

[19] The table to section S8—2 (food additive names—alphabetical listing)

Insert:

Potassium hydroxide	525
Sodium hydroxide	524

[20] The table to section S8—2 (food additive names—numerical listing)

Insert in numerical order:

524	Sodium hydroxide
525	Potassium hydroxide

Schedule 15—Substances that may be used as food additives

[21] The table to section S15—5 (food classes 13.1, 13.1.1, 13.1.2 and 13.1.3)

Repeal food classes, substitute:

13.1	***Infant formula products***		
270	Lactic acid	GMP	
300	Ascorbic acid	50 mg/L	See Note 1, below.
301	Sodium ascorbate	50 mg/L	See Note 1, below.

302	Calcium ascorbate	50 mg/L	See Note 1, below.
304	Ascorbyl palmitate	50 mg/L	See Note 1, below.
304	Ascorbyl palmitate	10 mg/L	
307b	Tocopherols concentrate, mixed	10 mg/L	
307b	Tocopherols concentrate, mixed	30 mg/L	See Note 1, below
308	Gamma-tocopherol	10 mg/L	
309	Delta-tocopherol	10 mg/L	
322	Lecithin	5 000 mg/L	
330	Citric acid	GMP	
331	Sodium citrates	GMP	
332	Potassium citrates	GMP	
338	Phosphoric acid	450 mg/L	Not for follow-on formula
339	Sodium phosphates	450 mg/L	Not for follow-on formula
340	Potassium phosphates	450 mg/L	Not for follow-on formula
407	Carrageenan	300 mg/L	Only in a liquid product
410	Locust bean (carob bean) gum	1 000 mg/L	
412	Guar gum	1 000 mg/L	Only in a liquid product that contains hydrolysed protein
440	Pectins	10 000 mg/L	See Note 1, below
471	Mono- and diglycerides of fatty acids	4 000 mg/L	
472c	Citric and fatty acid esters of glycerol	7 500 mg/L	Only in a powdered product
		9 000 mg/L	Only in a liquid product
500	Sodium carbonates	2 000 mg/L	
501	Potassium carbonates	2 000 mg/L	
524	Sodium hydroxide	2 000 mg/L	
525	Potassium hydroxide	2 000 mg/L	
526	Calcium hydroxide	2 000 mg/L	
551	Silicon dioxide (amorphous)	10 mg/L	May only be added as part of a nutrient preparation
1412	Distarch phosphate	5 000 mg/L	See Note 2, below.
1413	Phosphated distarch phosphate	5 000 mg/L	See Note 3, below.
1414	Acetylated distarch phosphate	5 000 mg/L	See Note 4, below.
1422	Acetylated distarch adipate	5 000 mg/L	See Note 5, below.
1440	Hydroxypropyl starch	5 000 mg/L	See Note 6, below.

Note 1. For additives 300, 301, 302, 304, 307b, 440—the additive may only be used in follow-on formula products.

Note 2. Additive 1412 may only be used in:

(c) soy based infant formula product (other than follow-on formula) either singly or in combination with one or more of additives 1413, 1414 and 1440; and

(d) soy based follow-on formula either singly or in combination with one or more of additives 1413, 1414 and 1422.

Note 3. Additive 1413 may only be used in:

(c) soy based infant formula product (other than follow-on formula) either singly or in combination with one or more of additives 1412, 1414 and 1440; and

(d) soy based follow-on formula either singly or in combination with one or more of additives 1412, 1414 and 1422.

Note 4. Additive 1414 may only be used in:

(c) soy based infant formula product (other than follow-on formula) either singly or in combination with one or more of additives 1412, 1413, and 1440; and

(d) soy based follow-on formula either singly or in combination with one or more of additives 1412, 1413, and 1422.

Note 5. Additive 1422 may only be used in soy based follow-on formula, either singly or in combination with one or more of additives 1412, 1413 and 1414.

Note 6. Additive 1440 may only be used in soy based infant formula product (other than follow-on formula), either singly or in combination with one or more of additives 1412, 1413, and 1414.

13.1.1	**Special medical purpose products for infants**		
170	Calcium carbonates	GMP	
304	Ascorbyl palmitate	100	
333	Calcium citrate	GMP	
338	Phosphoric acid	450 mg/L	For pH adjustment only
339	Sodium phosphates	450 mg/L	
340	Potassium phosphates	450 mg/L	
341	Calcium phosphates	450 mg/L	
401	Sodium alginate	1 000 mg/L	Only in a product specifically formulated for both the dietary management of metabolic disorders of infants aged 4 months and above and general tube-feeding of infants aged 4 months and above.
407	Carrageenan	1 000 mg/L	Only in a liquid product that contain hydrolysed proteins and/or amino acids
410	Locust bean (carob bean) gum	5 000 mg/L	Only in a product specifically formulated for reduction of gastro-oesophageal reflux
412	Guar gum	10 000 mg/L	See Note 1, below.
415	Xanthan gum	1 000 mg/L	Only in a powdered hydrolysed protein and/or amino acid based product

		1 200 mg/L	Only in a product that is: based on amino acids or peptides; and formulated for infants with gastrointestinal tract problems, protein mal-adsorption or inborn errors of metabolism
440	Pectins	2 000 mg/L	Only in a liquid product that contain hydrolysed protein
		5 000 mg/L	Only in a product formulated for infants with gastro-intestinal disorders
471	Mono- and diglycerides of fatty acids	5 000 mg/L	Only in product formulated for diets devoid of proteins
473	Sucrose esters of fatty acids	120 mg/L	Only in products that contain hydrolysed proteins, peptides and amino acids
1412	Distarch phosphate	25 000 mg/L	See Notes 2 and 7, below.
1413	Phosphated distarch phosphate	25 000 mg/L	See Notes 3 and 7, below.
1414	Acetylated distarch phosphate	25 000 mg/L	See Notes 4 and 7, below.
1422	Acetylated distarch adipate	25 000 mg/L	See Notes 5 and 7, below
1440	Hydroxypropyl starch	25 000 mg/L	Sees Note 6 and 7, below.
1450	Starch sodium octenylsuccinate	20 000 mg/L	See Note 7, below

Note 1. Additive 412 may only be used in a product that contains one or more of the following: hydrolysed proteins; peptides; amino acids.

Note 2. Additive 1412 may only be used in:

(c) a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1413, 1414 and 1440; and

(d) a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1413, 1414 and 1422.

Note 3. Additive 1413 may only be used in:

(c) a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1412, 1414 and 1440; and

(d) a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1412, 1414 and 1422.

Note 4. Additive 1414 may only be used in:

(c) a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1412, 1413 and 1440; and

(d) a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1412, 1413 and 1422.

Note 5. Additive 1422 may only be used in a product formulated for infants aged 6 to 12 months either singly or in combination with one or more of additives 1412, 1413 and 1414.

Note 6. Additive 1440 may only be used in a product (other than a product formulated for infants aged 6 to 12 months) either singly or in combination with one or more of additives 1412, 1413, and 1414.

Note 7. Additives 1412, 1413, 1414, 1422, 1440 and 1450 may only be used in a product that contains hydrolysed proteins, amino acids or both.

Schedule 19—Maximum levels of contaminants and natural toxicants

[22] The table to section S19—4 (Maximum levels of metal contaminants)

Insert:

Aluminium	Infant formula and follow-on formula	0.5
	Special medical purpose products for infants formulated for pre-term infants	0.2

[23] The table to section S19—4 (items dealing with 'Lead')

Insert:

	Infant formula products	0.01

Schedule 25—Permitted novel foods

[24] Subsection S25—2 (table item dealing with "Oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695)"

Repeal item, substitute:

Oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695)	1.	May only be added to infant formula products.

[25] Subsection S25—2 (table item dealing with "Isomalto-oligosaccharide")

Repeal item, substitute:

Isomalto-oligosaccharide	3.	Must not be added to: (c) food for infants; and (d) formulated supplementary food for young children.

[26] Subsection S25—2 (table item dealing with "Rapeseed protein isolate", column headed "*Conditions of use*", condition 2)

Repeal the condition, substitute:

	4.	Must not be added to food for infants.

[27] Subsection S25—2 (table item dealing with "Trehalose")

Repeal item, substitute:

Trehalose	1.	May be added to infant formula products only as a cryo-preservative for L(+) lactic acid producing microorganisms.