13 June 2024
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Supporting document 1

Regulatory Intent

Approval report – Proposal P1028

Infant formula

Executive summary

Food Standards Australia New Zealand (FSANZ) has approved two draft variations to amend the provisions of the *Australia New Zealand Food Standards Code* (the Code) that set requirements for the sale, composition, labelling, and representation of infant formula products.

This document provides a summary of each amendment or regulatory measure made by the approved draft variations, its intent and rationale.

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Acronyms and abbreviations

Acronym/abbreviation	Full name
ARA	arachidonic acid
ALA	α-linolenic acid
AR	Approval Report
CFS	Call for submissions
Code	Australia New Zealand Food Standards Code
Codex	Codex Alimentarius Commission
Codex CXG 10-1979	Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children (Codex 1979)
Codex CXS 72-1981	Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex 1981)
Codex CXS 156-1987	Standard for Follow-up formula for Older Infants and Product for Young Children (Codex 1987)
CP	Consultation paper
DHA	Docosahexaenoic acid
ECCB	Exclusive Capturable Commercial Benefit
EC	European Commission
EC SCF	European Commission Scientific Committee on Food
EFSA	European Food Safety Authority
EPA	Eicosapentaenoic acid
ESPGHAN	European Society for Paediatric Gastroenterology, Hepatology and Nutrition
EU	European Union
FoF	Follow-on formula
FSANZ	Food Standards Australia New Zealand
FSF	Formulated supplementary food
FSFYC	Formulated supplementary foods for young children
FSMP	Food for special medical purposes
g	Gram
GMP	Good manufacturing practice
GOS	Galacto-oligosaccharides
GSFA	General Standard for Food Additives (Codex 1995)
GUL	Guidance upper level
IF	Infant formula
IFP	Infant formula products
IFPSDU	Infant formula products for special dietary use
ITF	Inulin-type fructans
JECFA	Joint WHO/FAO Expert Committee on Food Additives

kg	Kilogram
kJ	Kilojoule
L	Litre
LA	linoleic acid
LAM	Lactic acid-producing microorganisms
LSRO	Life Science Research Office
µg	Microgram
MCT	Medium chain triglycerides
mg	Milligram
ML	Maximum level
MPL	Maximum permitted level
NCF	Nitrogen conversion factor
NHMRC	National Health and Medical Research Council
NRV	Nutrient reference value
NIP	Nutrition information panel
NIS	Nutrition information statement
NS	Not specified
PKU	Phenylketonuria
PRSL	Potential renal solute load
PUFA	Polyunsaturated Fatty Acids
RE	Retinol equivalents
SD	Supporting document
SMPPi	Special medical purpose product for infants
TFA	Trans fatty acid
US	United States of America
WHO	World Health Organisation

Introduction

The Australia New Zealand Food Standards Code

The Australia New Zealand Food Standards Code (the Code) sets out food standards developed by Food Standards Australia New Zealand (FSANZ) to protect the health and safety of consumers. Each standard in the Code is a Commonwealth legislative instrument.

The Code has no operative effect by itself. Rather, the Code is implemented through New Zealand and Australian state and territory food laws. The Food Regulation Agreement between the states, territories and Commonwealth of Australia provides that the states and territories will adopt or incorporate the standards in the Code into state or territory food law. The Australian and New Zealand Governments have also entered into a Treaty by which New Zealand adopts the majority of food standards in the Code under New Zealand food law.

New Zealand and Australian state and territory food laws generally require food businesses to comply with all relevant requirements set by the Code. Failure to comply can be a criminal offence under the relevant food law.

A Commonwealth law, the Imported Food Control Act 1992, creates an offence of importing food into Australia if the importer knows, among other matters, that the food does not meet applicable standards, The latter include the standards that comprise the Code.

FSANZ does not have a role in relation to compliance with or enforcement of the Code as applied by the above laws. Instead this is the responsibility of government agencies responsible for the food laws that adopt and apply the Code as a part of those laws. This means that, in Australia, state and territory government agencies and in many cases local councils, are responsible for the application, interpretation and enforcement of the Code. The Australian Department of Agriculture, Fisheries and Forestry is responsible for enforcing the Code at the border. In New Zealand, enforcement is the responsibility of the New Zealand Ministry for Primary Industries.

Purpose of this document

The purpose of this document is to provide a summary of each regulatory measure or amendment contained in the approved draft variations, its intent and rationale.

It is important to note that requirements are spread horizontally across the Code. That means that this document is not inclusive of all considerations and requirements in the Code that may affect or apply to infant formula. For example, the draft variations approved as a result of P1028 do not detail the requirements for genetically modified foods in infant formula products. There is an express requirement in Standard 1.5.2 – Food produced using gene technology, that stipulates that all genetically modified foods must be assessed by FSANZ. Therefore, this requirement does not need to be prescribed again in Standard 2.9.1 as it already exists.

Notes about this document

Draft variations

FSANZ has approved two draft variations:

- the *Food Standards (Proposal P1028 – Infant Formula) Variation* (referred to in this Supporting Document as the 'primary variation') and
- the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation* (referred to in this Supporting Document as the 'consequential variation').

The primary variation amends:

- Standard 2.9.1 Infant formula products.

The consequential variation amends:

- Schedule 29—Special purpose foods
- Standard 1.1.2—Definitions used throughout the Code
- Standard 1.2.3—Information requirements – warning statements, advisory statements and declarations
- Standard 1.3.1—Food Additives
- Standard 1.5.1—Novel Foods
- Standard 2.9.2—Food for infants
- Standard 2.9.3—Formulated meal replacements and formulated supplementary foods
- Standard 2.9.5—Food for special medical purposes
- Schedule 8—Food additive names and code numbers (for statement of ingredients)
- Schedule 15—Substances that may be used as food additives
- Schedule 19—Maximum levels of contaminants and natural toxicants
- Schedule 25—Permitted novel foods.

The approved primary variation is at Attachment A to the Approval Report (AR) and the approved consequential variation is at Attachment B to the AR. Both variations will take effect on gazettal, with a five year transition period. The related explanatory statement is at Attachment C. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

The Code

References to the Code in this document are to the Code as in force without the amendments made by the two approved draft variations. These references provide for a comparison between the Code as it exists now and the Code as amended by the approved draft variations.

Nutritional composition decisions

A number of nutritional composition requirements in the Code will not be changed by the approved draft variations. If the table below does not state a reason for retention of nutritional composition requirement, the reason was that no issues were raised in the proposal with regard to that requirement and the requirement met all nutritional assessment criteria used in the Proposal’s risk assessment screen of all nutritional parameters.

References to the Call for Submissions

Entries in the table below include references to the first and second Call for Submissions where the rationale for a particular provision or amendment was explained. In these cases, unless otherwise stated below, the rationale or explanation in the relevant CFS remained unchanged or relevant at approval and after consideration of all submissions. Further details are provided in the approval report.

Formatting and numbering changes

Changes to formatting and numbering are not captured in the table below as a ‘change to the Code’ as these are considered to be administrative/editorial changes, not regulatory changes or decisions.

Document Navigation: Primary Variation

Primary Variation Section	*Primary Variation Standard Section Name*
Division 1 — Preliminary	
2.9.1—1	Name
2.9.1—2	Outline of Standard
2.9.1—3	Definitions
2.9.1—4	Interpretation
Division 2 — Compositional requirements for infant formula and follow on formula	
2.9.1—5	General requirements
2.9.1—6	Protein requirements
2.9.1—7	Fat requirements
2.9.1—8	Required nutritive substances
2.9.1—9	Optional nutritive substances
2.9.1—10	Required forms for nutritive substances
2.9.1—10A	Infant formula products—conditions on use of permitted nutritive substances
2.9.1—11	Addition of lactic acid producing microorganisms
2.9.1—12	Restriction on addition of inulin-type fructans and galacto-oligosaccharides
2.9.1—13	Restriction on levels of other substances
Division 3 — Labelling and packaging requirements for infant formula and follow-on formula	
2.9.1—14	Representations about food as infant formula or follow-on formula
2.9.1—15	Product differentiation
2.9.1—16	Prescribed names
2.9.1—17	Requirement for measuring scoop
2.9.1—18	Storage instructions
2.9.1—19	Requirement for the name of the food
2.9.1—20	Statement of protein source
2.9.1—21	Requirement for warning statements and directions
2.9.1—22	Print size
2.9.1—23	Optional format for the statement of ingredients – added vitamins and minerals
2.9.1—24	Declaration of nutrition information

2.9.1—55	Labelling requirements—special medical purpose product for infants in transportation outer

Document Navigation: Consequential Variation

Consequential Variation Section	*Consequential Variation Standard Section Name*
Schedule 29 — Special purpose foods	
S29—2	Infant formula products—calculation of energy content
S29—2A	Infant formula products—calculation of protein content
S29—2B	Infant formula products—calculation of vitamin A content
S29—3	Infant formula products—L-amino acids that must be present
S29—4	Infant formula products—limits on fatty acids
S29—5	Vitamins, minerals, electrolytes and other substances required in infant formula and special medical purpose product for infants
S29—6	Vitamins, minerals and electrolytes required in follow-on formula
S29—7	Optional nutritive substances in infant formula and special medical purpose product for infants
S29—8	Optional nutritive substances in follow-on formula
S29—9	Permitted forms of nutritive substances in infant formula products
S29—9A	Infant formula products—conditions on use of permitted nutritive substances
S29—10	Required format for a nutrition information statement
S29—10A	Example of a nutrition information statement including quantities expressed as sold
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
Standard 1.1.2—Definitions used throughout the Code	
1.1.2—2	Definitions—general
1.1.2—3	Definitions—particular foods
1.1.2—8	Definition of novel food

Standard 1.2.3—Information requirements - warning statements, advisory statements and declarations	
1.2.3—6	What a mandatory declaration must state
Standard 1.3.1—Food additives	
1.3.1—3	Carry-over of food additives
1.3.1—4	Maximum permitted levels of food additives in foods
Standard 1.5.1—Novel foods	
1.5.1—2	Definitions
1.5.1—3	Sale of novel foods
Standard 2.9.2—Food for infants	
2.9.2—4	Additional compositional requirements for cereal-based food for infants from the age of 6 months
2.9.2—5	Additional compositional requirements for cereal-based food for infants from the age of 4 months
2.9.2—6	Additional compositional requirements for non-cereal-based food for infants
Standard 2.9.3—Formulated meal replacements and formulated supplementary foods	
2.9.3—3	Compositional requirements for formulated meal replacements
Standard 2.9.5—Food for special medical purposes	
2.9.5—6	Permitted forms of particular substances
Schedule 8—Food additive names and code numbers (for statement of ingredients)	
S8—2	Food additive names and code numbers
Schedule 15—Substances that may be used as food additives	
S15—5	Table of permissions for food additives
Schedule 19—Maximum levels of contaminants and natural toxicants	
S19—4	Maximum level of metal contaminants
Schedule 25—Permitted novel foods	
S25—2	Sale of novel foods

Regulatory intent of requirements in the primary variation

The primary variation amends Standard 2.9.1—Infant formula products.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
Division 1 Preliminary			
2.9.1—1	**Name** This Standard is Australia New Zealand Food Standards Code – Standard 2.9.1 – Infant formula products.	To clearly prescribe the name and commencement of the Standard.	The Code is not changed.
2.9.1—2	**Outline of the Standard** The outline of the Standard has been changed to be comprised of four divisions: (1) Preliminary matters (2) Composition requirements for IF and FoF (3) Labelling and packaging for IF and FoF (4) Composition, labelling and restriction on sale requirements for SMPPi	The primary variation will insert new section 2.9.1—2 into the Standard. An aim of the new section is to state clearly the purpose of each Division and, in doing, more clearly delineate the requirements applicable to general IFP from those applicable to IFP having a special medical purpose.	The Code is changed. At present, Division 3 of the current Standard 2.9.1 sets requirements for various types of IFP for certain diseases, conditions and disorders. However, it does not differentiate low risk products that are safe for healthy infants to consume from those that are unsafe for healthy infants. New section 2.9.1—2 reflects the following changes made to the Standard by the primary variation: - Division 2 of the Standard will now contain the compositional requirements for IF and FoF - Division 3 of the Standard will now prescribe labelling requirements for IF and FoF - Division 4 of the Standard will now prescribe the requirements for SMPPi, thereby delinating these requirements from those that apply to IF and FoF - Division 6 (guidelines) of the current Standard will be removed. See AR, section 4.1 for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
2.9.1—3	**Definitions**	The primary variation will insert new section 2.9.1—3 and a related Note into the Standard. The Note sets out the definitions listed in Standards 1.1.2—2 and 1.1.2—3 for terms used in Standard 2.9.1.	The Code is changed. The consequential variation will change some of the definitions listed in Standards 1.1.2—2 and 1.1.2—3 to provide regulatory clarity and to ensure that products are accurately captured in the standard. It is not the purpose or role of a definition to set compositional requirements, parameters for the assessment of new substances, to ensure the Ministerial Policy Guideline is supported, or to promote breastfeeding. See Appendix 3, Section 2 of the AR and section 3.1.3 of the 2nd CFS (FSANZ 2023a) for information.
	Definitions Follow-on formula	***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. The new definition's purpose is to capture the products to be regulated as FoF by the Code.	The Code is changed. The definition is modified to ensure that products that are represented as a FoF are captured and regulated as FoF by the Code, particularly Standard 2.9.1. That is, they must meet the compositional, labelling and other requirements set by the Code for FoF. The amended definition does not require a product to actually be 'suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months' in order to be a FoF. Instead it only requires that the product be represented, offered for sale, held out to a consumer etc as such. As a FoF, that product will then be subject to compositional and other requirements set by the Code that will ensure, among other things, that it is 'suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months'. See Appendix 3, Section 2 of the AR and section 3.1.3 of the 2nd CFS (FSANZ 2023a) for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
	Definitions Infant formula	***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. The new definition's purpose is to capture the products to be regulated as infant formula by the Code.	The Code is changed. The definition is modified to ensure the products that represent themselves or are represented to consumers as a breast milk substitute for infants and as satisfying by itself the nutritional requirements of infants under the age of 6 months are captured and regulated as IF under Standard 2.9.1. The amended definition does not require a product to actually 'satisfy by itself the nutritional requirements of infants under the age of 4 to 6 months' in order to be an IF. Instead, it only requires that the product be represented, offered for sale, held out to a consumer etc as such. As an IF, that product will then be subject to compositional and other requirements set by the Code that will ensure, among other things, that it 'satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months'. The definition's relevant age range has been changed from 'under the age of 4 to 6 months' to 'under the age of 6 months'. This is consistent with the definition of older infant in Codex CXS 156-1987. See 1st CFS, section 3.1.2 (FSANZ 2022a), 2nd CFS, section 3.1 (FSANZ 2023a) and Appendix 3, Section 2 of the AR for information.
	Definitions Infant formula product	***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. The new definition's purpose is to capture the products to be regulated as IFP by the Code,	The Code is changed. The definition is modified to ensure the products that represent themselves or are represented to consumers as an IFP are captured and regulated under Standard 2.9.1. The amended definition does not require a product to actually be 'nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants' in order to be an IFP. Instead, it only requires that the product be represented, offered for sale, held out to a

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		including as a particular category of IFP (eg, IFm FoF, SMPPi) by Standard 2.9.1.	consumer etc as such. As an IFP, that product will then be subject to compositional and other requirements set by the Code that will ensure, among other things, that it is 'nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment' for the relevant infants. See Appendix 3, Section 2 of the AR and section 3.1.3 of the 2nd CFS (FSANZ 2023a) for information.
	Definitions Inner package	***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.	The Code is changed. A reference to the definition in Standard 1.1.2 of the term *inner package* has been included in new section 2.9.1—3. This is to account for that term's use in the revised Standard 2.9.1 in relation to labelling requirements for the inner package of SMPPi. See Appendix 3, Section 2 of the AR for information.
	Definitions Responsible institution	***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.	The Code is changed. A reference to the definition in Standard 1.1.2 of the term *responsible institution* has been included in new section 2.9.1—3. This is to account for that term's use in the revised Standard 2.9.1, particularly in relation to SMPPi restriction of sale requirements . Not all listed responsible institutions

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
			under the Code definition will be applicable to the supply of SMPPi. See AR, Section 4.3.6 and Appendix 3, Section 2 for information.
	Definitions Special medical purpose product for infants	***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. SMPPi are a subcategory of IFP. A SMPPi is an IFP that is specially formulated for the dietary management of infants who have medically determined nutrient recommendations due to a medically diagnosed condition. SMPPi constitute either	The Code is changed. A new definition of the term *special medical purpose product for infants* has been included in Standard 1.1.2 and in new section 2.9.1—3. The new definition reflects the introduction of SMPPi as a category of IFP and the removal of the IFPSDU category. The reason for the new definition and related regulatory changes is to regulate specialised or medical products formulated for use as sole source of nutrition for infants as IFP primarily by Standard 2.9.1, instead of Standard 2.9.5. See Section 4.1 and Appendix 3, Section 2 of the AR and 2nd CFS, section 3.2 (FSANZ 2023a) for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		the sole or principal source of nourishment, are used under medical supervision and are not suitable for general use. A product that meets each of the above criteria will be required o comply with the compositional, labelling and other requirements set by the Code for SMPPi. If a product is formulated with the purpose of providing the sole source of nutrition to an infant with a medical condition and meets the requirements prescribed in new Division 4, then it is a SMPPi. This means that a SMPPi may be both sole source of nutrition for infants and also a supplementary feed for age groups beyond 12 months of age. Therefore, a SMPPi could be formulated for 0–3 years, if it is represented as and its purpose is providing the sole source of nutrition to infants (birth – 12 months) and meets the requirements of Division 4. In addition, the SMPPi category does not include specialised medical products for infants that are not used as the sole or principal source of nutrition such as human milk fortifiers, modulatory formulas, food thickeners and medical infant foods or semi-solid foods. See AR, section 4.1.4 for information.	
	Definitions Medium chain triglycerides (removal)	Removal of definition for medium chain triglycerides. The removal of this definition does not affect the addition of MCT to SMPPi by virtue of the	The Code is changed. A definition of the term *medium chain triglycerides* has been removed from the Code. The definition was removed as the meaning of the term *medium chain triglycerides* is well understood and

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		permission for these products to vary their composition. FSANZ has provided further requirements for MCT at 2.9.1—7(2). See 2nd CFS, Table 8 (FSANZ 2023a) for information.	considered to be self-explanatory. Nor do other nutrient composition parameters have associated definitions. See Appendix 3, Section 2 of the AR and Section 3.4 of the 2nd CFS (FSANZ 2023a) for information.
	Definitions Pre-term formula (removal)	Removal of definition for pre-term formula.	The Code is changed. The definition for *pre-term formula* is removed from the Code. This is due to the repeal of the Code's specific requirements for IFPSDU products formulated for premature or low birthweight infants. This reflects assessment that the issue of infant feeding of pre-term and underweight infants is best addressed through guidance from medical professionals as opposed to through food legislation. This is consistent with the NHMRC Infant Feeding Guidelines and the Healthy Eating Guidelines for New Zealand Babies and Toddlers (NHMRC 2012; Ministry of Health 2021). See Appendix 3, Section 2 of the AR, Section 3.4 of the 2nd CFS (FSANZ 2023a) and Section 3.4.2 of the 1st CFS (FSANZ 2022a) for information.
	Definitions Protein substitute (removal)	Removal of definition for protein substitute.	The Code is changed. The definition for *protein substitute* is removed. This is due to the repeal of the Code's specific requirements for IFPSDU products that are based on a protein substitute. These products have been recategorised as SMPPi, which can deviate from the baseline composition of IF, where needed to achieve the medical purpose of the product. Therefore, SMPPi can still have protein substitutes such as L-amino acids, hydrolysate of one or more of the proteins

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
			on which infant formula product is normally based and/or a combination of these if required for the medical purpose. See Appendix 3, Section 2 of the AR, Section 3.3 of the 2nd CFS (FSANZ 2023a) and Section 3.3 of the 1st CFS (FSANZ 2022a).
	Definitions Soy-based formula (removal)	Removal of definition for soy-based formula.	The Code is changed. The definition for *soy-based formula* is removed from the Code. This is because the term is self-explanatory. See Appendix 3, Section 2 of the AR, Section 3.4 of the 2nd CFS (FSANZ 2023a) and Section 3.4.1 of the 1st CFS (FSANZ 2022a).
2.9.1—4	**Interpretation** 2.9.1—4(1)(a) and (b) – application of compositional requirements to powdered or concentrated forms and ready-to-drink forms	To clarify that, unless expressly stated, the compositional requirements in the Standard apply to a powdered and/or concentrated IFP that have been reconstituted with water according to directions and to a ready to drink IFP.	The Code is changed. New subsection 2.9.1—4(1) clarifies that compositional requirements apply to IFP (powdered, concentred or ready to drink) as sold, opposed to as reconstituted. The intent is to provide clarity for fluoride requirements and other labelling requirements.
	Interpretation 2.9.1—4(2)(a) – energy calculation	To require that energy must be calculated in accordance with section S29—2.	The Code is not changed.
	Interpretation 2.9.1—4(2)(b) – protein calculation	To require that protein content must be calculated in accordance with section S29—2A.	The Code is changed. Please see section S29—2A (below) for further details. The method of calculation for Potential Renal Solute Load (PRSL) has been removed from sections 2.9.1—4(2)(c) and S29—4 of the Code and is not prescribed in the primary or consequential variation. The PRSL is no longer prescribed on the basis that it is not aligned with international regulations. As maximum protein levels are

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
			already prescribed (see section 2.9.1—6) the PRSL is not needed. See 1st CFS, SD2, Section 3.2.2 (FSANZ 2022c) for information.
	Interpretation 2.9.1—4(2)(c) – vitamin A calculation	To require that vitamin A content must be calculated in accordance with section S29—2B.	The Code is changed. The calculation for vitamin A has been added to section 2.9.1—4 to clarify that only the retinol forms of vitamin A prescribed in Column 1 of Table of section S29—23 may be used in calculating vitamin A content. Further information is provided at section S29—2B. See CP2, Section 7.2.1 (FSANZ 2021b) and 1st CFS, SD2, Section 2.3.2 (FSANZ 2022c) for information.
Division 2	**Compositional requirements for infant formula and follow on formula**		
	Note	To note that subsection 1.5.1—3(2) provides that an IFP 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.	The Code is changed. The addition of the Note is to draw attention to other provisions and requirements in the Code that apply to IFP.
2.9.1—5	**General requirements** 2.9.1—5(1) - Energy requirements	To prescribe mandatory energy requirements for IF and FoF consisting of an energy minimum of 2510 kJ/L and maximum of 2930 kJ/L, reflective of current science.	The Code is changed. The energy minimum is higher and the maximum is lower because the range has been set to align with Codex CXS 72-1981 and incorporate conversion from kcal to kJ according to Code requirements. The revised range aligns with Codex CXS 156-1987. See 1st CFS, SD2, Section 2.1.2 (FSANZ 2022c) for information.
	General requirements	Subsection (2) requires that infant formula and follow-on formula must not contain added	The Code is changed.

Subsection	Name and description	Regulatory intent of the primary variation	Reason for the change (or no change)
	2.9.1—5(2) and (3) and (4) - Fructose and sucrose restrictions including for partially hydrolysed protein.	fructose and/or added sucrose (subject to subsections (3) and (4)). The intent of this subsection is to restrict the use of sucrose and fructose in IF and FoF as they are not present in human milk and their use in IF and FoF has associated safety concerns (ANZFA 2002a). Subsection (3) provides that IF and FoF manufactured from partially hydrolysed protein may contain added fructose and/or added sucrose if it is added to provide a source of carbohydrate and if the sum of fructose and/or sucrose in the formula does not exceed 20% of available carbohydrates. The intent of this subsection is to allow the use of added fructose and/or added sucrose in partially hydrolysed protein formulas where required. However, the subsection provides certain parameters (total amount and purpose of addition) that ensure they are not added at amounts that could pose risk to infant health. Sucrose and fructose can be added to formulas manufactured from protein hydrolysates internationally as they are used in order to mask the bitter taste of these formulae (EFSA 2014). Subsection (4) provides that subsection (2) does not apply to added fructose and/or added sucrose that is present in IF and FoF as a result of addition of inulin-type fructans and use of a substance as a processing aid. The intent of subsection (4) is to ensure the restriction on sucrose and fructose posed required by subsection 2.9.1—5(2) does not	The carbohydrate source is not specified in the Standard (i.e. as with protein). However limits on the type of carbohydrate have been included to reflect that certain carbohydrates cannot not make up essential composition for IFP. Limits on addition of sucrose and fructose are a new requirement and are internationally aligned with EU 2016/127 and Codex CXS 72-1981. See Section 4.8 of the AR for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		impose on other permissions in the Code, such as for inulin-type fructans and processing aids.	
	General requirements 2.9.1—5(5) and (6) - Fluoride requirements	Require the fluoride content of IF and FoF must not be more than 17 µg/100 kJ in powdered or concentrated forms and must not be more than 24 µg/100 kJ in 'ready-to-drink' forms. These requirements apply to IF and FoF as sold, not as reconstituted. The limits have been calculated with consideration to fluoride content in Australian and New Zealand water supplies.	The Code is changed. The Code previously prescribed statements for dental fluorosis if a powdered or concentrated IFP contained more than 17 µg of fluoride/100 kJ prior to reconstitution or more than 0.15 mg of fluoride/100 mL for a ready-to-drink formulas. The change to a mandatory compositional maximum better protects infant health and safety and aligns with international regulations. Because maximums have been prescribed, the requirement for labelling to indicate the potential risk of dental fluorosis is removed. See Appendix 3, Section 4 of the AR, CP2, Section 7.6, (FSANZ 2021b) and 2nd CFS, SD2, Section 7.2 (FSANZ 2023c) for information.
2.9.1—6	**Protein requirements** 2.9.1—6(1) – Protein sources	Prescribes mandatory requirements for the protein sources of IF and FoF. Permitted protein sources include cow milk protein, goat milk protein, sheep milk protein, soy protein isolate and partially hydrolysed protein of one or more of these specified proteins'. All other protein sources would require premarket assessment.	The Code is changed. Prescribing permitted protein sources increases regulatory clarity and aligns with EU 2016/127. As IF and FoF are formulated for a vulnerable population and are the most prescriptive food within the Code, it is warranted to prescribe permitted protein sources. In addition, FSANZ considered that not defining the protein sources for IF and FoF could pose risk to infant health. See Section 4.7 of the AR and Section 4.4 of the 2nd CFS, SD2 (FSANZ 2023c) for information.
	Protein requirements 2.9.1—6(2) and (3) – protein content for IF and FoF and PRSL removal	Prescribes mandatory requirements for protein levels in IF. Including a minimum of 0.43 g/100 kJ and a maximum of 0.72 g/100 kJ for milk-	The Code is changed. The requirements for protein levels in IF and FoF have been varied to account for calculation issues in converting

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		based IF and a minimum of 0.54 g/100 kJ and a maximum of 0.72 g/100 kJ for soy-based IF. Prescribes mandatory requirements for protein levels in FoF. Including a minimum of 0.38 g/100 kJ and a maximum of 0.72 g/100 kJ for milk-based IF and a minimum of 0.54 g/100 kJ and a maximum of 0.72 g/100 kJ for soy-based IF. The PRSL limit (8 mOsm/100 kJ) for FoF has been removed.	from kcal to kJ. The new ranges align with Codex and do not pose risk for infant health and safety. Introduction of protein levels for formula based on soy protein was based on international alignment adopting a NCF of 6.25. See Appendix 3, Section 4 of the AR and Section 4.2 of CP2 (FSANZ 2021b) for information. The requirement for PRSL is removed as it is not required from an infant health and safety perspective. The change aligns with international regulations and does not introduce risk to infant health and safety. See 1st CFS, SD2, section 3.2 (FSANZ 2022c) for information.
	Protein requirements 2.9.1—6(4) – Milk-based formula	Provides a definition of milk-based IF and FoF for the purposes of provisions setting protein content requirements for milk-based formulas. Milk-based IF and FoF means 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.	The Code is changed. The intent of the definitions is to clarify the application of provisions setting protein content requirements for milk-based formulas. See AR, Appendix 3, Section 4 for information.
	Protein requirements 2.9.1—6(5) –L-amino acid requirements	To set the requirements for prescribed minimum amounts of L-amino acids in IF and FoF in S29—3.	The Code is not changed. Protein quality is prescribed on the basis of minimum amino acids that must be present. L-amino acid levels are listed in S29—3. See AR, Appendix 3, Section 4 and CP2, Section 4.4 (FSANZ 2021b) for information.
	Protein requirements	States that the minimum levels specified in the table to section S29—3 for cysteine and methionine in IF and FoF do not apply if the	The Code is changed.

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	2.9.1—6(6) – Methionine and cysteine requirements	minimum amount of combined cysteine and methionine is not less than 15 mg per 100 kJ and the ratio of methionine to cysteine is less than 2 to 1. The intent of these requirements is to allow the combination of cysteine and methionine for calculation purposes as methionine can convert into cysteine. In addition, cysteine is typically found at lower levels in cow, goat and sheep milk in comparison to levels found in human milk. Combination of cysteine and methionine when the above requirements are met ensure that the concentrations and ratios of cysteine and methionine in human milk are reflected.	The ratio of methionine to cysteine along with minimum levels and allowance to add for calculation purposes has been changed to align with international regulations. These requirements have been introduced to ensure international consistency and protein quality. See AR, Appendix 3, Section 4, CP2, Section 4.5 (FSANZ 2021b) and 2nd CFS, SD2, Section 4.3 (FSANZ 2023c) for information.
	Protein requirements 2.9.1—6(7) – Phenylalanine and tyrosine requirements	States that the minimum levels specified in the table to section S29—3 for phenylalanine and tyrosine in IF and FoF do not apply if the minimum amount of combined phenylalanine and tyrosine is not less than 37 mg per 100 kJ and the ratio of tyrosine to phenylalanine is less than 2 to 1. Similar to the above, the intent of these requirement is to allow the combination of phenylalanine and tyrosine for calculation purposes and to reflect the levels in human milk.	The Code is changed. The ratio of tyrosine to phenylalanine along with minimum levels and allowance to add for calculation purposes aligns with international regulations. These requirements have been introduced to ensure international consistency and protein quality.
	Protein requirements 2.9.1—6(8) – single L-amino acid requirements	This subsection requires that despite subsections (5), (6) and (7), L-amino acids listed in the table to section S29—3 must only be added to IF or FoF in an amount necessary to improve protein quality.	The Code is not changed. L-amino acids must only be added to IF or FoF in an amount necessary to improve protein quality. This requirement ensures that the addition of unnecessary substances do not burden the infant digestive system.

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		The intent of this requirement is to ensure that L-amino acids are not added in excess and are only added at levels required for protein quality.	
2.9.1—7	**Fat requirements** 2.9.1—7(1) – fat content, including essential fatty acid composition and ratios	Prescribes compositional requirements for fats and fatty acids in IF and FoF.	The Code is changed. Most requirements for fats are now listed in new section 2.9.1—7 for clarity. The requirements are based on alignment with Codex CXS 72-1981 and FSANZ's assessment which showed that the changes would not introduce risk to infant health and safety. See AR, Appendix 3, Section 4 for information.
	2.9.1—7(1)(a)	Prescribes the minimum fat content as 1.1 g/100 kJ and the maximum fat content as 1.4 g/100 kJ.	The Code (1.05 g/100 kJ – 1.5 g/100 kJ) is changed. The minimum fat content has been increased and the maximum fat content decreased to align with Codex 72-1981, EU 2016/127 and fat content levels in human milk. See CP2, Section 5.1 (FSANZ 2021b) and 1st CFS, SD2, Table 2.1.1 (FSANZ 2022c) for information.
	2.9.1—7(1)(b)	Prescribes the LA to ALA ratio requirement of no less than 5 to 1 and no more than 15 to 1 is retained from the Code requirement.	The Code is not changed. The LA to ALA ratio aligns with Codex CXS 72-1981. See AR, Appendix 3, Section 4 and CP2, Section 5.3 (FSANZ 2021b) for information.
	2.9.1—7(1)(c)	Prescribes a minimum amount for LA of 90 mg/100 kJ (with a GUL of 335 mg/100 kJ) and a minimum amount for ALA of 12 mg/100 kJ.	The Code is changed. The LA and ALA levels have been changed from being expressed as % of total fatty acid to mg/100 kJ. The minimum level for LA is unchanged as it migrates risks surrounding the stability and palatability of IF and FoF. This minimum level also represents the best available option for

Subsection	Name and description	Regulatory intent of the primary variation	Reason for the change (or no change)
			alignment with Codex and mitigates risk of reformulation or trade implications. The LA maximum is changed. It has been decreased from 371 mg/100 kJ (equivalent to 26 % total fatty acids prescribed in the Code) to 335 mg/100 kJ and is now prescribed as a GUL. This is in alignment with Codex CXS 72-1981. The ALA minimum is changed. It has been increased to achieve alignment with Codex CXS 72-1981. The maximum amount of ALA is controlled by the maximum ratio of LA to ALA of The LA and ALA values are listed in section 2.9.1 instead of section S29. See AR, Appendix 3, Section 4 and CP2, Section 5.2 and 5.3 (FSANZ 2021b) for information.
	2.9.1—7(1)(d)	Permits the voluntary permission for DHA addition provided it does not exceed the ARA amount.	The Code is changed to insert the requirement that IF and FoF must have an ARA content of equal to or more than DHA content. See AR, Appendix 3, Section 4 and 2nd CFS, SD2 (FSANZ 2023c) for information.
	2.9.1—7(1)(e)	Requires IF and FoF contain no less than 0.5 mg of vitamin E per gram of polyunsaturated fatty acids.	The Code is not changed. The Vitamin E:PUFA ratio aligns with Codex CXS 72-1981. See CP2, Section 7.2.3 (FSANZ 2021b) for information.
	2.9.1—7(1)(f)	Requires any LCPUFA present to have an EPA content of no more than the DHA content.	The Code is not changed. The EPA:DHA ratio aligns with Codex CXS 72-1981. See CP2, section 5.4 (FSANZ 2021b) for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
	2.9.1—7(1)(g)	Requires that fatty acids (for example DHA) must comply with the requirements noted in the table to section S29—4.	The Code is changed only to reflect the changes to the numbering in the table to section S29.
	Fat requirements 2.9.1—7(2) – medium chain triglycerides	Requires that IF and FoF may only contain MCT 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 are a substance that was used as a processing aid in the preparation of a fat soluble vitamin specified in S29—5 or S29—6. The intent of this requirement is to clearly capture the MCTs that are naturally occurring in milk-based ingredients or are a part of a processing aid used in the preparation of a fat soluble vitamin. The intent is not to prohibit naturally occurring MCT in vegetable oils that are a part of processing aids used in the preparation of a fat soluble vitamin.	The Code is changed. The MCT definition has been removed from the Code (discussed above). The MCT requirements in new subsection 2.9.1—7(2) now require that MCT only contain predominantly the saturated fatty acids designated by 8 to 0 and 10 to 0 and clarify that MCT that are used as a part of a processing aid in the preparation of a fat soluble vitamin (specified in section S29—5 or S29—6) are permitted. The reason for these changes was to provide regulatory clarity. The restriction for MCT is retained as it is based on risk assessment conclusions, including that the presence of MCT in IF and FoF has no benefit to infant health and MCT are not normally present in human milk. See AR, Appendix 3, Section 4 and CP2, Section 5.6.1 (FSANZ 2021b) for information.
	Fat requirements 2.9.1—7(3) – phospholipid content	Requires that IF and FoF must not have a phospholipid content of more than 72 mg/100 kJ. This is intended to ensure phospholipids are not added to IF and FoF above levels naturally occurring in human milk.	The Code is changed. The new subsection is stated as and intended to operate as setting a restriction (limit). It is not, and is not intended to operate as a permission to add phospholipids (e.g. as a nutritive substance, noting the requirement in paragraph 1.1.1—10(6)(b) of the Code that there must be an 'express' permission). The limit for phospholipids applies to total phospholipid content, which is inclusive of phospholipids from lecithin as

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
			well as other sources (e.g. LC-PUFA, vegetable oils, milk fat). This approach aligns with Codex CXS 72-1981 and does not pose risk to infant health. See AR, Appendix 3, Section 4 and 6 and 2nd CFS, SD2, Section 4.6 (FSANZ 2023c) for information.
2.9.1—8	**Required nutritive substances** 2.9.1—8(1) and (2) IF and FoF minimum and maximum amounts for required nutritive substances.	Subsection 2.9.1—8(1) requires the mandatory addition to IF of nutritive substances that are listed in section S29—5. Subsection (2) requires the mandatory addition to FoF of nutritive substances that are listed in S29—6. The intent of this section is to separate required nutritive substances from those that may be voluntarily added to IF and FoF (2.9.1––9).	The Code is changed. New section 2.9.1—8, together with new section 2.9.1—9, replaces section 2.9.1—5 of the current Code. The reason for the separation of new section 2.9.1—8 (required nutritive substances) and new section 2.9.1—9 (optional nutritive substances) is because L-carnitine, inositol and choline are now required as mandatory additions to IF, however are still voluntary in FoF. Hence, the need for the two different new provisions. This provides regulatory clarity by separating the nutritive substances that are required in IF and FoF. Prescribed minimum and maximum amounts are listed in Schedule S29 (which is the same approach taken by the current Standard). The changes to these amounts are explained in the subsequent table. There is a Note to new subsection 2.9.1—8(1) that relates to GULs. This Note is discussed below in sections S29—5 and S29—6. See AR, Section 4.1 for information.
	Required nutritive substances 2.9.1—8(3) - calcium to phosphorus ratio	Prescribes that the ratio of calcium to phosphorus in IF and FoF must be no less than 1 to 1 and no more than 2 to 1.	The Code is changed. The ratio of calcium to phosphorus has been retained based on FSANZ's 2016 risk assessment that there is risk of hypocalcaemia in formula fed infants if no ratio was included. However the ratio has been amended to align

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
			with Codex CXS 72-1981. It was determined that alignment would not introduce risk to infant health and safety. See CP2, section 7.4.1 (FSANZ 2021b) for information.
	Required nutritive substances Zinc to copper ratio (removal)	The requirement for the ratio of zinc to copper in both IF and FoF has been removed from the Code.	The Code is changed. The zinc to copper ratio for IF and FoF is removed due to limited evidence as to a need to prescribe that ratio. FSANZ's assessment is that removing the ratio would have minimal impact on the micronutrient status of healthy term infants. See CP, SD1, section 7.3.3.8 (FSANZ 2016a); CP2, section 7.3.9 (FSANZ 2021b); 1st CFS, SD2, section 2.4.2 (FSANZ 2022c) and 2nd CFS, SD2, Table 6 (FSANZ 2023c) for information.
2.9.1—9	**Optional nutritive substances** 2.9.1—9 (1) and (2) IF and FoF minimum and maximum amounts for optional nutritive substances.	Subsection (1) requires the voluntary addition to IF of nutritive substances that are listed in S29—7. Subsection (2) requires the voluntary addition to FoF of nutritive substances that are listed in S29—8. The intent of this section is to separate voluntary nutritive substances from those that are mandatory in IF and FoF (2.9.1—9).	The Code is changed. New section 2.9.1—9, together with new section 2.9.1—8, replaces section 2.9.1—5 of the current Code. The reason for the separation of new section 2.9.1—8 (required nutritive substances) and new section 2.9.1—9 (optional nutritive substances) is because L-carnitine, inositol and choline are now required as mandatory additions to IF, however are still voluntary in FoF. Hence, the need for the two different new provisions. Prescribed minimums and maximum amounts are listed in Schedule S29 (which is the same approach taken by the current Standard). The changes to these amounts are explained in the subsequent table. See AR, Section 4.1 for information.
2.9.1—10	**Required forms for nutritive substances**	Requires that a substance used as a nutritive substance in IF or FoF must be added in the permitted form listed in section S29—23	The Code is changed.

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		(vitamins, minerals or electrolytes) or in section S29—9 (any other case).	The wording has been amended to reflect the changes in mandatory and voluntary permissions in IF and FoF. See sections S29—23 and S29—9 below for the rationale for the permitted forms.
2.9.1—10A	**Infant formula products—conditions on use of permitted nutritive substances**	Subsection (1) applies to a substance that is used as a nutritive substance in an IFP and has prescribed requirements in the table to section S29—9A. Subsection (2) notes the substance must comply with the conditions specified. These requirements relate to exclusive use periods, which can be granted through FSANZ Application procedures. This section is numbered as '10A' as it may be removed from the Code when the exclusive use period(s) have expired. Use of '10A' avoids the need for renumbering and cross-referencing amendments when the section is removed.	The Code is not changed These requirements and the relevant exclusive use period were set as a result of an application to FSANZ which underwent its own separate statutory assessment and process.
2.9.1—11	**Addition of lactic acid producing microorganisms**	Permits the addition of L(+) lactic acid producing microorganisms in IF and FoF. Similar to the existing permission the amendments to the Standard do not permit the addition of LAM as a nutritive substance or as a novel food. Restrictions on labelling and claims preclude any indication of probiotic or other stated function unless sought through the application process.	The Code is not changed. This permission is retained because of the following reasons: no safety concerns were identified, a long history of use, ubiquitous in products on the market, alignment with Codex and removal of the permission would result in large reformulation costs and disruption to the market. See AR Section 4.11 and 2nd CFS, Section 5 (FSANZ 2023a) for information.

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2.9.1—12	**Restriction on addition of inulin-type fructans and galacto-oligosaccharides**	Prescribes requirements for the addition of inulin-type fructans or galacto-oligosaccharides to IF or FoF. The intent of this section is to retain existing restrictions for adding ITF and GOS to IF or FoF, as stated in section 2.9.1—7 of the current Code. Further intent and rationale for this section can be found in Application A1155 (FSANZ 2019).	The Code is not changed. These substances are long-standing permissions in the current Code that came about through Proposal P306. The permissions are aligned Codex CXS 72-1981 and were not amended in P1028 as no concerns about safety were identified. Furthermore permissions for ITF and GOS have recently been approved to be included with permitted human identical milk oligosaccharides (A1251; FSANZ 2022f).
2.9.1—13	**Restriction on levels of other substances**	The section prohibits (a) detectable gluten and (b) amounts of more than 3.8 mg/100 kJ of free nucleotide-5′-monophosphates in IF and FoF. Notes to the section refers the fact that: Section S19—4 contains the maximum levels (ML) of contaminants in infant formula products; and Standard 1.3.1 and Schedule 15 permit the use of certain substances as food additives in infant formula products The Notes' intent is to highlight that Standards other than Standard 2.9.1 also impose restrictions on and provide permissions for substances in IF and FoF.	The Code is not changed for requirements relating to detectable gluten. The requirement for IF and FoF to be gluten free was not assessed in P1028 as no health and safety issues were identified with this requirement and it is aligned with Codex CXS 72-1981. The Code is changed for requirements relating to the maximum for nucleotide-5'-monophosphates. The name was amended to include the word 'free' to be consistent with international regulations. See 1st CFS, SD2, section 2.5.2 (FSANZ 2022c) for information.
Division 3	**Labelling and packaging requirements for infant formula and follow-on formula**		
Division 3	***Note***	The Note under the heading to Division 3 draws attention to the fact that Standard 1.2.7 prohibits a nutrition content claim or health claim being made about infant formula	The Code is changed. The reason for this note is to make clear that the existing prohibition for claims about infant formula products applies.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		products, including infant formula and follow-on formula.	
2.9.1—14	**Representations about food as infant formula or a follow-on formula**	To require that a food may only be represented as IF or FoF if that food complies with the Standard.	The Code is not changed. The requirement ensures that a food may only be represented as IF or FoF if that food complies with the requirements set by the Standard for IF and FoF respectively. The intent is to ensure products offered to or represented to caregivers as a IF or FoF are safe and appropriate for their infants.
2.9.1—15	**Product differentiation**	To require the label on a package of IF or FoF to be differentiated from other foods by the use of text, pictures and/or colour. One or more of the label elements may be used, although the use of all three label elements is considered more appropriate for ensuring IF or FoF are sufficiently differentiated from other foods.	The Code is changed. The intent of the requirement set by new section 2.9.1—15 is to minimise the risk of caregiver confusion between products and purchasing an inappropriate product. The requirement for IF and FoF to be differentiated from other foods, including from each other, is aligned with the labelling approach in Codex CXS 156-1987. An example has been added to provide further clarity regarding the other types of foods that may be similarly labelled and must be differentiated from IF or FoF, including that IF must be differentiated from FoF and vice versa. See AR, Appendix 3, section 7 and 2nd CFS, SD3, section 9.6 (FSANZ 2023d) for information.
2.9.1—16	**Prescribed names** 'Infant formula' and 'Follow-on formula' are prescribed names.	To ensure the prescribed name is used wherever the Code requires IF or FoF to be stated or used. The prescribed name is the name of food (see paragraph 1.2.2—2(1)(a)) and must be used on the label of a package of IF or FoF.	The Code is not changed. New section 2.9.1—16 retains the existing requirement in the Code. That requirement has been retained because IFP must be named in a consistent manner so that consumers can identify the appropriate product. Consumer evidence indicates the prescribed name is one of the three

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
			methods used by caregivers to differentiate between formula products. There is a long history of use of these prescribed names. See AR, Appendix 3, Section 7, CP, SD2, section 5.10 (FSANZ 2016c); 1st CFS, SD1, section 8.9 (FSANZ 2022b) and 1st CFS, SD3, section 6.4.5 (FSANZ 2022d) for information.
2.9.1—17	**Requirement for measuring scoop**	Subsection (1) requires a measuring scoop to be contained in packages of IF or FoF in a powdered form to enable the use of the formula in accordance with label directions. Subsection (2) states that this requirement does not apply to single serve sachets, or packages containing single serve sachets.	The Code is not changed. A measuring scoop is needed to ensure caregivers use the appropriate amount of powdered formula when preparing formula so that it meets the nutritional needs of their infants. The requirement for a measuring scoop in powdered products aligns with Codex CXS 72-1981, Codex CXS 156-1987 and EU 2016/127. Single serve sachets and packages containing single serve sachets contain pre-measured amounts of powder and therefore do not require a measuring scoop. See AR, Appendix 3, Section 7, CP, SD2, section 4.3 (FSANZ 2016c); CP1, section 5.4.3 (FSANZ 2021a) and 1st CFS, SD2, section 4.3 (FSANZ 2022c) for information.
2.9.1—18	**Storage instructions**	To require that the storage instructions for IF and FoF must cover the period after the package is opened.	The Code is not changed. This requirement provides caregivers with instructions for ensuring these products retain safety and quality characteristics through appropriate storage. The requirement aligns with Codex CXS 72-1981 for IF. See AR, Appendix 3, Section 7, CP, SD2, section 4.2 (FSANZ 2016c); CP1, section 5.4.2 (FSANZ 2021a) and 1st CFS, SD1, section 8.5 (FSANZ 2022b) for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
2.9.1—19	**Requirement for the name of the food**	To require the name of the food to be stated on the front of a package of IF or FoF. The specific location on the front of the package is not prescribed. The name of the food may also appear elsewhere on the package.	The Code is changed. Requiring the name of the food on the front of the package at least once is a new requirement. The intent is to ensure the name of the food (i.e. prescribed name) and co-located protein source statement (see below) are prominent on the label to clearly inform caregivers of the true nature of the food when making purchasing decisions. See AR, Appendix 3, Section 7, 1st CFS, SD1, section 8.14 (FSANZ 2022b) and 2nd CFS, SD3, section 4 (FSANZ 2023d) for information.
2.9.1—20	**Statement of protein source** 2.9.1—20(1) – specific animal or plant source(s)	To require the specific animal or plant source or sources of protein in IF or FoF to be included in the statement of the name of the food. The effect of this requirement is that the specific protein source together with the name of the food (prescribed name) must appear on the front of the package of IF or FoF (see section 2.9.1—19). Examples have been added to illustrate that the 'source' of the protein refers to the origin of the protein (e.g. cow milk) and not protein fractions (e.g. whey and casein). For example 'Infant formula based on cow milk'. The Note to this section signposts section 2.9.1—6 where the permitted sources of protein are listed.	The Code is changed. The effect of this provision, to require the source(s) of protein on the front of the package, aligns with Codex CXS 72-1981, Codex CXS 156-1987 and EU 2016/127 and will provide greater clarity for caregivers. Consumer evidence indicates caregivers lack understanding of protein fractions and look for the protein origin. Whey and casein are now only permitted as optional declarations in the NIS. Other protein sources that are not permitted and have been concentrated, refined or synthesised (e.g. hydrolysed) to a point of purification (e.g. α-lactalbumin), are considered nutritive substances and will require a pre-market approval. See AR, section 4.15; CP1, section 5.6.4 (FSANZ 2021a); 1st CFS, SD1, section 8.13 (FSANZ 2022b); 1st CFS, SD2, section 2.1.2 and 2nd CFS, SD3, issue A.12 in Table 4 (FSANZ 2023d) for information.
	Statement of protein source 2.9.1—20(2) – partially hydrolysed protein	To require the words 'partially hydrolysed' to appear immediately adjacent to the protein source required by subsection (1) if the IF or	The Code is changed. This requirement enables caregivers to identify if partially hydrolysed protein from the permitted protein sources is used in IF or FoF. The words 'partially hydrolysed' will be

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		FoF is derived solely or in part from a partially hydrolysed protein. The requirement is based on the use of partially hydrolysed protein from one or more of the permitted animal and plant protein sources listed in new section 2.9.1—6(1). If more than one partially hydrolysed protein source is used in an IF or FoF (for example cow milk and goat milk), the words 'partially hydrolysed' must be used immediately adjacent to each protein source. An Example has been added to illustrate how the words 'partially hydrolysed' may appear with the protein source stated and included in the statement of the name of the food. The wording of the protein source statement that includes the words 'partially hydrolysed' is not prescribed (although the name of the food is prescribed).	on the front of the package together with the protein source and the name of the food (section 2.9.1—19). The information will allow caregivers to compare the protein source or sources across products, thereby supporting informed choice. See AR, section 4.15; 1st CFS, SD3, section 5.2 (FSANZ 2022d) and 2nd CFS, SD3, section 8 (FSANZ 2023d) for information.
	Statement of protein source 2.9.1—20(3) – not using the word 'milk' as sole descriptor of protein source	To prohibit the statement of protein source from using the word 'milk' as the sole descriptor of the protein source. Examples have been added to illustrate that protein source statements such as 'Infant formula based on milk' or 'Infant formula sourced from milk' are not permitted. A Note has been added to direct the reader to the permission for the separate use of the word 'milk' elsewhere on the label and in addition to in a protein source statement (new sub-paragraph 2.9.1—28(1)(j)(i)).	The Code is changed. This new provision was included as the word 'milk' does not describe the protein source adequately for caregivers to make an informed choice. In addition, the word 'milk' does not reflect the permitted proteins cow milk, goat milk and sheep milk listed in subsection 2.9.1—6(1). See AR, section 4.15 for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
2.9.1—21	**Requirement for warning statements and directions** ***Warning statements*** 2.9.1—21(1)(a) **–** requirement for a warning statement to follow instructions exactly	To require the following warning statement on IF and FoF: • 'Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill.' The wording of the warning statement is prescribed, but its location is not prescribed. Other elements from the existing warning statements for powdered, concentrated and ready-to-drink formulas (i.e. to not change proportions of powder or concentrate and to not dilute or add anything to ready-to-drink formula) have been modified and have become required directions which now appear in new subsections 2.9.1—21(5)(e) and (f) (see under these specific subsections further below for information).	The Code is changed. The warning statement about following instructions exactly has been simplified to make it more accessible to caregivers. See CP1, section 5.5.2 (FSANZ 2021a); 1st CFS, SD1, section 8.7 (FSANZ 2022b) and 2nd CFS, SD3, section 2 (FSANZ 2023d) for information.
	Requirement for warning statements and directions ***Warning statements*** 2.9.1—21(1)(b) **–** requirement for a warning statement that breast milk is best for babies	To require the following warning statement on IF and FoF: • 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'. The wording of the warning statement is prescribed, but its location is not prescribed.	The Code is not changed. The statement aligns with the WHO Code principles and the corresponding Australian and New Zealand marketing agreements, Codex CXS 72-1981 and public health messages about the superiority of breastfeeding compared to formula feeding. See CP1, section 5.5.3 (FSANZ 2021a); 1st CFS, SD1, section 8.8 (FSANZ 2022b) and 2nd CFS, Table 8 (FSANZ 2023a) for information.
	Requirement for warning statements and directions	To require an age-related statement on IF indicating the IF may be used from birth. The wording of the statement is not prescribed.	The Code is changed. The words 'infant formula product' have been changed to 'infant formula' to identify the specific category of IFP to which the provision applies.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
	Required statements on use 2.9.1—21(2)(a) – age-related statement for IF	The required statement may indicate use for infants 'from birth', 'from 0 – 6 months', 'from 0 to 12 months' or similar.	The intent of the existing requirement in the Code has been retained. It is to enable caregivers to identify correctly the appropriate formula for their infants aged from birth. The provision is consistent with Codex CXS-72-1981 and EU 2016/127. See AR, section 4.16; CP1, sections 5.6.2 (FSANZ 2021a); 1st CFS, SD1, section 8.10 (FSANZ 2022b) and 2nd CFS, SD3, section 3 (FSANZ 2023d) for information.
	Requirement for warning statements and directions ***Required statements on use*** 2.9.1—21(2)(b) – age-related statement for FoF	To require an age-related statement on FoF indicating the follow-on formula should not be used for infants aged under the age of 6 months. The wording of the statement is not prescribed. The required statement may indicate use for infants 'from 6 months', 'from 6 – 12 months' or similar.	The Code is changed. The words 'infant formula product' have been changed to 'follow-on formula' to identify the specific category of IFP to which the provision applies. The intent of the existing requirement in the Code has been retained. It is to enable caregivers to identify correctly the appropriate formula for their infants aged from six months (consistent with Codex CXS 156-1987 standard and EU 2016/127) and to ensure FoF is not introduced before six months of age. See AR, section 4.16; 1st CFS, SD1, section 8.11 (FSANZ 2022b) and 2nd CFS, SD3, section 3 (FSANZ 2023d) for information.
	Requirement for warning statements and directions ***Required statements on use*** 2.9.1—21(2)(c) – age-related statement about offering food in addition to formula	To require an age-related statement on IF and FoF indicating it is recommended that infants from the age of 6 months should be offered foods in addition to the IFP. The wording and location of the statement is not prescribed.	The Code is changed. The reference to the provision exempting pre-term formula and the words 'infant formula product' have been removed. The provision now identifies that it applies to IF and FoF. The intent of the existing requirement in the Code has been retained. It is to support infant feeding guidance to introduce additional foods to an infant's diet. The timing of this introduction is subject to growth and developmental needs, as advised by health professionals and from the

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
			age of six months. The provision is consistent with Codex CXS 72-1981. See AR, section 4.16; CP1, sections 5.6.2 (FSANZ 2021a); 1st CFS, SD1, section 8.12 (FSANZ 2022b) and 2nd CFS, SD3, section 3 (FSANZ 2023d) for information.
	Requirement for warning statements and directions ***Location of required statements*** 2.9.1—21(3) & (4) – requirement for age-related statements to be on the front of the package	To require the age-related statements for IF and FoF required by paragraphs 2.9.1—21(2)(a) & (b) to appear on the front of the package. These age-related statements may appear more than once on the label.	The Code is changed. The new provision requires the specified age-related statements to appear on the front of the package of IF and FoF. The intent is to ensure age information is prominent for caregivers to identify an appropriate product for their infant. The requirement also provides regulatory certainty for industry and enforcement agencies. See AR, section 4.16 and 2nd CFS, SD3, section 3 (FSANZ 2023d) for information.
	Requirement for warning statements and directions ***Directions on preparation and use*** 2.9.1—21(5)(a) – bottle preparation	To require the direction on preparation of IF and FoF instructing that each bottle must be prepared individually. The direction must be in words and pictures; however the words and pictures are not prescribed. The location of the direction is not prescribed, but it should appear together with other required directions (except the direction required by subsection 2.9.1—21(8), which should appear separately).	The Code is changed. The existing directions in the Code on preparation and use have largely been maintained. However, the requirement now provides that the directions need to instruct that certain steps and actions ‘must’ be taken. The intent is to ensure the importance of following the specific direction is conveyed. The intent is also to ensure the correct ratio of powder to water is used so the formula provides the appropriate nutritional content for the infant. See AR, Appendix 3, section 7; CP, SD2, section 3.2 (FSANZ 2016c); CP1, section 5.3 (FSANZ 2021a); 1st CFS, SD1, sections 8.2 and 8.3 (FSANZ 2022b) and 2nd CFS, SD3, section 1 (FSANZ 2023d) for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
	Requirement for warning statements and directions ***Directions on preparation and use*** 2.9.1—21(5)(b) – storage of prepared formula prior to use.	To require the direction on preparation and use of IF and FoF instructing that if a bottle of prepared formula is to be stored prior to use, it must be refrigerated and used within 24 hours. The direction must be in words and pictures; however the words and pictures are not prescribed. The location of the direction is not prescribed, but it should appear together with other required directions (except the direction required by subsection 2.9.1—21(8), which should appear separately).	The Code is changed. The word 'prepared' has replaced the words 'made up' for consistency with other labelling requirements for IF and FoF. See AR, Appendix 3, section 7; CP, SD2, section 3.3 (FSANZ 2016c); CP1, sections 5.3 (FSANZ 2021a); 1st CFS, SD1, sections 8.2 and 8.3 (FSANZ 2022b) and 2nd CFS, SD3, section 1 (FSANZ 2023d) for information.
	Requirement for warning statements and directions ***Directions on preparation and use*** 2.9.1—21(5)(c) – water used to reconstitute formula.	To require the direction on preparation of IF and FoF instructing that previously boiled and cooled potable water must be used. The direction must be in words and pictures; however the words and pictures are not prescribed. The location of the direction is not prescribed, but it should appear together with other required directions (except the direction required by subsection 2.9.1—21(8), which should appear separately).	The Code is changed. The provision now requires the directions to include an instruction about the temperature of the water to be used to reconstitute formula. That is, that the previously boiled potable water must be 'cooled' before use. This change was made because evidence indicated warmer water may be a safety risk for stored IF and that caregivers may not always use cooled water. The requirement to instruct that the water must be 'cooled' is intended to ensure the importance of following this direction is understood. See AR, Appendix 3, section 7; CP, SD2, section 3.4 (FSANZ 2016c); CP1, sections 5.3 (FSANZ 2021a); 1st CFS, SD1, sections 8.2 and 8.3 (FSANZ 2022b) and 2nd CFS, SD3, section 1 (FSANZ 2023d) for information.
	Requirement for warning statements and directions	To require the direction on preparation of IF and FoF instructing that if a package contains a measuring scoop, only the enclosed scoop must be used.	The Code is changed. The direction has largely been maintained. However, as with the other above-mentioned directions, the word 'must'

Subsection	Name and description	Regulatory intent of the primary variation	Reason for the change (or no change)
	Directions on preparation and use 2.9.1—21(5)(d) – measuring scoop	The direction must be in words and pictures; however the words and pictures are not prescribed. The location of the direction is not prescribed, but it should appear together with other required directions (except the direction required by subsection 2.9.1—21(8), which should appear separately).	has replaced the word 'should' to convey the importance of following this direction. See AR, Appendix 3, section 7; CP, SD2, section 4.3 (FSANZ 2016c); CP1, section 5.4.3 (FSANZ 2021a); 1st CFS, SD1, sections 8.2 and 8.3 (FSANZ 2022b) and 2nd CFS, SD3, section 1 (FSANZ 2023d) for information.
	Requirement for warning statements and directions ***Directions on preparation and use*** 2.9.1—21(5)(e) & (f) – not to deviate from directions	To require the direction on preparation of IF and FoF instructing that: • 2.9.1—21(5)(e) for powdered or concentrated formula—do not change proportions of powder or concentrate or add other food except on medical advice. • 2.9.1—21(5)(f) for ready-to-drink formula—do not dilute of add other food except on medical advice. The direction must be in words and pictures; however the words and pictures are not prescribed. The location of each direction is not prescribed but should appear together with other required directions (except the direction required by subsection 2.9.1—21(8), which should appear separately).	The Code is changed. As noted in paragraph 2.9.1—21(1)(a) above for the existing warning statements to follow instructions exactly, the required information about not deviating from directions on the label for powdered, concentrated and ready-to-drink formulas has been replaced by two new directions on preparation. The new directions are specific to the product type (e.g. powdered, concentrated, or ready-to-drink formula). The changes were made based on consumer evidence suggesting • caregivers considered the preparation instructions were slightly more important than warning statements and paid more attention to them. • consumers noted the absence of an instruction to not add anything to powdered or concentrated IF/FoF from the preparation instructions. See AR, Appendix 3, section 7; CP1, section 5.5.2 (FSANZ 2021a), 1st CFS, SD1, section 8.3 (FSANZ 2022b) and 2nd CFS, SD3, section 2 (FSANZ 2023d) for information.
	Requirement for warning statements and directions	To require the direction on use of IF and FoF instructing that formula left in the bottle after a feed must be discarded within two hours.	The Code is changed. To minimise the public health and safety risk from bacterial contamination of formula, this requirement includes the

Subsection	Name and description	Regulatory intent of the primary variation	Reason for the change (or no change)
	Directions on preparation and use 2.9.1—21(5)(g) – discarding an unfinished feed	The direction must be in words and pictures; however the words and pictures are not prescribed. The location of the direction is not prescribed, but it should appear together with other required directions (except the direction required by subsection 2.9.1—21(8), which should appear separately).	words 'within 2 hours' as information about when to discard unfinished formula after a feed. This change provides greater clarity for caregivers and reflects best practice guidelines. See AR, Appendix 3, section 7; CP, SD2, section 3.5 (FSANZ 2016c); CP1, sections 5.3 and 5.4.3 (FSANZ 2021a); 1st CFS, SD1, sections 8.2 and 8.3 (FSANZ 2022b) and 2nd CFS, SD3, section 1 (FSANZ 2023d) for information.
	Requirement for warning statements and directions ***Directions on preparation and use*** 2.9.1—21(6) & (7) – certain directions do not apply to ready-to-drink formula or concentrated formula	To not apply the following directions for preparation and use to ready-to-drink formula: • bottle preparation (paragraph 2.9.1—21(5)(a)) • storage of prepared formula prior to use (paragraph 2.9.1—21)(5)(b)) • water used to reconstitute formula (paragraph 2.9.1—21(5)(c)). To not apply the following directions for preparation and use to concentrated formula and ready-to-drink formula: • relating to a measuring scoop (paragraph 2.9.1—21(5)(d)).	The Code is changed. These provisions have been added to clarify that certain directions are not applicable to ready-to-drink formula and concentrated formula. Ready-to-drink IFP can be used immediately and a measuring scoop is not necessary for either product type. See CP1, sections 5.3 and 5.4.3 (FSANZ 2021a) and 1st CFS, SD1, section 8.2 (FSANZ 2022b) for information.
	Requirement for warning statements and directions ***Directions on preparation and use*** 2.9.1—21(8) – declarations for product in powdered or concentrated form	To require the declaration of the proportion of powder or concentrate required to reconstitute powdered or concentrated IF and FoF. To require the declaration of the weight of one scoop for powdered IF and FoF. The format and location of the information is not prescribed.	The Code is changed. The intent of the existing Code has been maintained to ensure caregivers have adequate information to safely prepare formula. The required information is no longer permitted in the NIS. Its removal from the NIS simplifies the NIS. There is flexibility as to where the information may be declared elsewhere on the label (for example in close proximity to the feeding guide, which reflects current industry practice).

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
			See CP1, section 5.4.3 (FSANZ 2021a); 1st CFS, SD1, section 8.2 (FSANZ 2022b) and 2nd CFS, SD2, section 4.3 (FSANZ 2023c) for information.
2.9.1—22	**Print size**	To prescribe the minimum print size of warning statements required by subsection 2.9.1—21(1) on the basis of package size of IF or FoF. The size of type must be at least 3 mm if the package of IF or FoF has a net weight of more than 500 g. If the net weight is less than 500 g, the size of type must be at least 1.5 mm.	The Code is changed. The words 'infant formula product' have been replaced with 'infant formula or follow-on formula'. The intent of the existing requirement in the Code has been retained. A larger size of type enhances the noticeability and readability of important safety information for caregivers. See AR, Appendix 3, section 7; CP, SD2, section 5.1 (FSANZ 2016c); CP1, section 5.5.1 (FSANZ 2021a); 1st CFS, SD1, section 8.6 (FSANZ 2022b) and 2nd CFS, SD3, issue A.5 in Table 4 (FSANZ 2023d) for information.
2.9.1—23	**Optional format for the statement of ingredients – added vitamins and minerals**	To permit an optional format for declaring added vitamins and minerals in the statement of ingredients for IF and FoF. Vitamins and minerals added to IF or FoF need not be listed in descending order of ingoing weight provided they are listed in the statement of ingredients together under subheadings 'Vitamins' and 'Minerals', respectively. To not apply a permission to use class names 'vitamin' or 'mineral' (section 1.2.4—8) if the optional format for declaring added vitamins and minerals is used.	The Code is changed. This new permission is consistent with Codex specifications, provides clarity and flexibility for industry and may assist caregivers' understanding of these ingredients when listed under relevant subheadings. Given vitamins and minerals are subject to compositional limits, the order in which they are declared is of less value to caregivers. The class names 'vitamins' and 'minerals' will not apply because it would be redundant if vitamins and minerals are listed in a statement of ingredients using the optional format. See AR, Appendix 3, section 7; 1st CFS, SD3, section 2.1 (FSANZ 2022d) and 2nd CFS, SD3, Table 5 (FSANZ 2023d) for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
2.9.1—24	**Declaration of nutrition information** 2.9.1—24(1) & (2) – requirement for a statement	To require a statement of nutrition information (a NIS) for IF and FoF and specify that references to 'the statement' in section 2.9.1—24 means the required statement of nutrition information.	The Code is changed. The intent of the existing Code provision has been retained, however new subsections set and reflect requirements for a new NIS. References to product types (ready-to drink IFP and powdered or concentrated IFP) have been removed because they are redundant.
	Declaration of nutrition information 2.9.1—24(3) – information the statement must contain	The statement must contain certain nutrition information expressed in the relevant units of measurement that are specified. For nutrients that form part of the mandatory composition of IF and FoF, the following must be declared: • average energy content expressed in kilojoules per 100 mL of formula • average quantity of protein, fat and carbohydrate expressed in grams per 100 mL of formula, using the words 'protein', 'fat' and 'carbohydrate', respectively. Sub-group nutrients of these macronutrients cannot be declared unless they are expressly permitted (e.g. whey and casein) • average quantity of each vitamin or mineral expressed in micrograms or milligrams per 100 mL of formula (including any naturally-occurring amount) (the specific unit, i.e., micrograms or milligrams, required to be used for each specific vitamin and mineral is prescribed in the table to section S29—10 – see paragraph 2.9.1—25(2)(e) below) • for infant formula—the average quantity of choline, inositol and L-carnitine expressed	The Code is changed. The following amendments have been made to the existing Code requirements for labelling to state certain nutrition information: • The information is required to be expressed in per 100 mL of formula. • The term 'average amount' has been changed to 'average quantity' for consistency with the NIP for general foods. The term 'average quantity' is defined in the Code and is relied upon for the calculation methods to derive the average amount. See CP, SD3, section 2.6 (FSANZ 2016d) and 1st CFS, SD3, section 3.3 (FSANZ 2022d) for information. • The words 'protein', 'fat' and 'carbohydrate' have been added to clarify that only these macronutrients may be declared unless there is an express permission for voluntary subgroup nutrients of these macronutrients to be declared. • The reference to nutritive substances has now been grouped with ITF and GOS. None of these substances are essential to the composition of IF and FoF, however they may be added voluntarily. If added, they must be declared in the NIS. • There is a new compositional requirement for the mandatory addition of choline, inositol and L-carnitine

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		in milligrams per 100 mL of formula (including any naturally-occurring amount). The average quantity of the following substances expressed in micrograms, milligrams or grams per 100 mL of formula must also be declared if they are added voluntarily to IF and FoF: • any substance used as a nutritive substance (including any naturally-occurring amount). • inulin-type fructans. • galacto-oligosaccharides. • a combination of inulin-type fructans and galacto-oligosaccharides.	to IF. Therefore, there is a new declaration requirement for IF to include these nutrients in the NIS. See 2nd CFS, SD3, section 5 (FSANZ 2023d) for information.
	Declaration of nutrition information 2.9.1—24(4) – voluntary whey and casein declarations	To permit the voluntary declaration of the average quantity of whey or casein in grams per 100 mL of formula that is present in IF or FoF, in the NIS. The declaration must include any naturally-occurring amount.	The Code is changed. The intent of the new provision is to support informed choice by caregivers and health professionals. See AR, Appendix 3, Table 9 and 1st CFS, SD3, section 3.4 (FSANZ 2022d) for information.
	Declaration of nutrition information 2.9.1—24(5) – voluntary fatty acid declarations	To permit the voluntary declaration of the average quantity in milligrams per 100 mL of formula of each of the following substances that is present in IF or FoF, in the NIS: docosahexaenoic acid; eicosapentaenoic acid; and arachidonic acid. The declaration must include any naturally-occurring amount. If a manufacturer chooses to declare the above fatty acids, all three must be declared in the NIS.	The Code is changed. An express permission to declare these fatty acids is new. The intent is to support informed choice for caregivers and assist health professionals in a clinical setting where there may be a need to calculate total fatty acid content from the formula when it is combined with other supplementary products. The voluntary declaration of the permitted fatty acids is intended to provide flexibility for manufacturers. The condition that all three must be declared together is because a single fatty acid declaration may give the impression it has been specifically added as a point of

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
			difference to other IFP and may be perceived as a nutrition content claim. See AR, section 4.18 and Appendix 3, Table 9 and 1st CFS, SD3, section 3.4 (FSANZ 2022d) for information.
	Declaration of nutrition information 2.9.1—24(6) – mandatory expression of nutrition information per 100 mL of formula as reconstituted	To require that, if the IF or FoF is sold in a powdered or concentrated form, the quantities declared in the NIS in subsections 2.9.1—24(3), (4) or (5) must be expressed in per 100 mL of formula as reconstituted according to the directions on the package.	The Code is changed. The words 'infant formula product' have been replaced with 'infant formula or follow-on formula'. This requirement otherwise aligns with the existing requirement in the Code and provides for consistency in how the nutrition information is presented on the label for all types of formula, thereby assisting caregivers to easily compare products and make informed choices. See AR, Appendix 3, sections 4.17 and 7; 1st CFS, SD3, section 3.3 (FSANZ 2022d) and 2nd CFS, SD3, Table 5 (FSANZ 2023d) for information.
	Declaration of nutrition information 2.9.1—24(7) – optional expression of nutrition information per 100 mL or per 100 g of formula as sold.	To provide an express permission to optionally declare nutrition information in subsections 2.9.1—24(3), (4) or (5) in: • per 100 mL of the formula as sold (if the IF or FoF is sold in a concentrated form), or • per 100 g of the formula as sold (if the IF or FoF is sold in a powdered form). Only one of these optional base units of expression may be included in the NIS in addition to the requirement for per 100 mL.	The Code is changed. The new provision expressly permits nutrition information to be expressed in the NIS using base units for powdered or concentrated formula as it is sold. The permission enables IFP to be consistent with Codex CXS 72-1981 and CXS 156-1987 specifications and facilitate trade. The regulatory approach reflects the guideline NIS in new section S29—10 for IFP and aligns with EU 2016/127 in relation to the per 100 mL (as reconstituted) and optional base unit per 100 g (as sold). See AR, section 4.17 and Appendix 3, section 7; 1st CFS, SD3, section 3.3 (FSANZ 2022d) and 2nd CFS, SD3, Table 5 (FSANZ 2023d) for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
	Declaration of nutrition information 2.9.1—24(8) – only information expressly permitted can be in the NIS	To prohibit information, other than that expressly permitted in the Code, from being included in the NIS.	The Code is changed. This new provision clarifies that the NIS must not contain any other information unless that information is expressly permitted or required by the Code. Information that is not expressly permitted or required would constitute a prohibited representation (for example, a prohibited nutrition content claim). See AR, sections 4.17 and 4.18 and Appendix 3, section 7; CP, SD3, section 2.3 (FSANZ 2016d) and 1st CFS, SD3, section 3 (FSANZ 2022d) for information.
2.9.1—25	**Required form for the declaration of nutrition information** 2.9.1—25(1) & (2)(a) - general format of the NIS	To require the format of the NIS to be the same as the format given in the table to section S29—10, subject to any variations specified in section 2.9.1—25. Some variations apply in the case of voluntary additions to the NIS. See subsections 2.9.1—25(3), (4), (5) & (6) below.	The Code is changed. The prescribed format for the NIS is a new requirement to ensure the statement is presented in a consistent manner on labels. This approach is generally aligned with international regulations and is supported by consumer evidence which indicates a consistent approach can assist caregivers to make quicker product choices. See AR, sections 4.17 and 4.18 and Appendix 3, section 7; CP, SD3, section 2.3 (FSANZ 2016d); 1st CFS, SD3, section 3 (FSANZ 2022d) and 2nd CFS, SD3, sections 5 and 6 (FSANZ 2023d) for information.
	Required form for the declaration of nutrition information 2.9.1—25(2)(b) – order of nutrition information in the NIS	To require energy and nutrients to be listed in the statement in the order specified in the table to section S29—10.	The Code is changed. The overarching reasons relating to consistency for caregivers and international alignment are described above for subsection 2.1.9—25(1) and paragraph 2.9.1—25(2)(a). With the exception of certain subgroup nutrient and substance declarations that are now either permitted or required, the prescribed order listed in the NIS is mostly the

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
			same as it appears in the original Guideline NIS format in the table to subsection S29—10(3). See 1st CFS, SD3, section 3 (FSANZ 2022d) for information.
	Required form for the declaration of nutrition information 2.9.1—25(2)(c) – NIS title	To require the NIS to be titled 'Nutrition Information' in bold font.	The Code is changed. The overarching reasons relating to consistency for caregivers and international alignment are described above for subsection 2.1.9—25(1) and paragraph 2.9.1—25(2)(a). The new requirement is consistent with the original Guideline NIS format in the table to subsection S29—10(3).
	Required form for the declaration of nutrition information 2.9.1—25(2)(d) – subheadings	To require in the NIS: - the subheadings 'Vitamins', 'Minerals' and 'Additional' for IF and FoF - the subheading 'Other nutrients' for IF, under which choline, inositol and L-carnitine must be listed. - all subheadings to be printed in a size of type that is the same or larger than the nutrient names in the NIS. The format, other than the specific name and size of type of the subheading, is not prescribed.	The Code is changed. The overarching reasons relating to consistency for caregivers and international alignment are described above for subsection 2.1.9—25(1) and paragraph 2.9.1—25(2)(a). This new requirement is supported by consumer evidence that caregivers find subheadings helpful in making quicker product choices. Grouping of micronutrients and additional substances also assists caregiver understanding of the type of nutrient or substance and whether the nutrient or substance is required in the formulation or added optionally. The regulatory approach is similar to EU 2016/127 and US 21 CFS 107.10 requirements and to the approach applied to the NIP for general foods. Apart from the specific name and size of type requirement, there is flexibility for manufacturers to format subheadings that can assist caregivers ability to make quicker product comparisons (e.g. bolding, different type face, colour contrast).

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
			See 1st CFS, SD3, section 3.3 (FSANZ 2022d) and 2nd CFS, SD3, sections 5 and 6 and Table 5 (FSANZ 2023d) for information.
	Required form for the declaration of nutrition information 2.9.1—25(2)(e) – names and units of nutrients	To require nutrients and subgroup nutrients to be declared using the names and units of measurements specified in the table in section S29—10.	The Code is changed. The overarching reasons relating to consistency for caregivers and international alignment are described above for subsection 2.1.9—25(1) and paragraph 2.9.1—25(2)(a). This new requirement makes it clear how the nutrients and subgroup nutrients must be declared in the NIS and links to the required format in the table to section S29—10. This regulatory approach is similar to format requirements for the NIP for general foods. See 1st CFS, SD3, section 3.3 (FSANZ 2022d) for information.
	Required form for the declaration of nutrition information 2.9.1—25(2)(f) – permitted quantities expressed in NIS	To restrict how nutrition information may be expressed using only those base units and average quantity, listed in section 2.9.1—24 in the NIS.	The Code is changed. The restriction balances the need for consistency in how nutrition information is expressed for caregiver understanding and the need for consistency with Codex CXS 72-1981 and CXS 156-1987 to facilitate trade. See AR, section 4.17 for information.
	Required form for the declaration of nutrition information 2.9.1—25(3) – nutritive substances and inulin-type fructans, galacto-oligosaccharides	To require permitted nutritive substances, ITF and GOS (if added) to be listed under the subheading ‘Additional’ for IF and FoF and presented in the same format that is specified by the table to section S29—10 for the relevant substance. The order for listing under the ‘Additional’ heading must be as described in the table to section S29—10 (i.e. nutritional substances, ITF and GOS in that order).	The Code is changed. The overarching reasons relating to consistency for caregivers and international alignment are described above for subsection 2.1.9—25(1) and paragraph 2.9.1—25(2)(a). The new requirement now groups together nutritive substance, ITF and GOS to indicate these optional substances must be declared in the same manner. The requirement also links to the prescribed NIS format in section S29—10. The location of the declarations under the subheading ‘Additional’ will assist caregivers to identify

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			what has been added to IF and FoF and support an informed choice.
	Required form for the declaration of nutrition information 2.9.1—25(4) – choline, inositol, L-carnitine	To require the average quantity of choline, inositol and L-carnitine to be declared in the NIS for IF, under the subheading 'Other nutrients'. If added to FoF as a nutritive substance, the average quantity of these substances must be declared under the subheading 'Additional'. The average quantity of the above substances must be included in the NIS for IF and FoF in the same format that is specified by the table to section S29—10 for the relevant substance.	The Code is changed. The overarching reasons relating to consistency for caregivers and international alignment are described above for subsection 2.1.9—25(1) and paragraph 2.9.1—25(2)(a). A change in compositional requirements for IF means the nutrients choline, inositol and L-carnitine must be listed under the subheading 'Other nutrients' in the NIS, as they are no longer considered optional nutritive substances. These nutrients are still regulated as optional nutritive substances for FoF and (if added) they must be declared under the subheading 'Additional'. The prescribed locations for IF and FoF will provide consistency for caregivers and regulatory certainty for manufacturers and enforcement agencies. See 2nd CFS, SD3, section 5 and Table 5 (FSANZ 2023d) for information.
	Required form for the declaration of nutrition information 2.9.1—25(5) - whey and casein	To require the average quantity of whey and casein in the NIS in the same format that is specified for that substance by the table to section S29—10, if these sub-group nutrients are voluntarily declared. Whey and casein must be indented under the macronutrient protein.	The Code is changed. The overarching reasons relating to consistency for caregivers and international alignment are described above for subsection 2.1.9—25(1) and paragraph 2.9.1—25(2)(a). The location for declaration of whey and casein is prescribed and indicates to caregivers that these sub-group nutrients are inherent to the (animal protein-based) formulation. The new requirement links to the prescribed NIS in section S29—10. See AR, Appendix 3, section 7; CP, SD3, section 2.3 (FSANZ 2016d); 1st CFS, SD3, section 3.4 (FSANZ 2022d)

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
			and 2nd CFS, SD3, Table 5 (FSANZ 2023d) for information.
	Required form for the declaration of nutrition information 2.9.1—25(6) – fatty acids	To require the average quantity of docosahexaenoic acid, eicosapentaenoic acid and arachidonic acid in the NIS (if declared voluntarily), listed under the subheading 'Long chain polyunsaturated fatty acids' and in the same format and name that is specified for those substances by the table to section S29—10. The subheading 'Long chain polyunsaturated fatty acids' must be printed in a size of type that is the same or larger than the nutrient names in the NIS. The fatty acid acronyms specified in the table to section S29—10 may be used in addition to the required full names but cannot be used in isolation as nutrition information in the NIS.	The Code is changed. The overarching reasons relating to consistency for caregivers and international alignment are described above for subsection 2.1.9—25(1) and paragraph 2.9.1—25(2)(a). The requirement to indent docosahexaenoic acid, eicosapentaenoic acid and arachidonic acid under the subheading 'Long chain polyunsaturated fatty acids' is similar to the required format for 'polyunsaturated' in the NIP for general foods. The prescribed location indicates to caregivers that these fatty acids are inherent in the formulation. The requirements for the size of type of the subheading align with requirements for other mandated subheadings, to support consistency in formatting. Fatty acid acronyms may assist those caregivers more familiar with the acronyms than scientific names to identify the fatty acids in the NIS. The regulatory approach will also give manufacturers flexibility in how they wish to declare fatty acids if they choose to include them in the NIS. See AR, section 4.18 and Appendix 3, section 7; CP, SD3, section 2.3 (FSANZ 2016d); 1st CFS, SD3, section 3.4 (FSANZ 2022d) and 2nd CFS, SD3, Table 5 (FSANZ 2023d) for information.
	Required form for the declaration of nutrition information 2.9.1—25(7) & (8) –per 100 mL concentrated liquid	If included in the NIS, to require the quantity of nutrition information expressed as: • per 100 mL of concentrated liquid (as sold), or • per 100 g powder (as sold)	The Code is changed. This new requirement mandates the position of nutrition information expressed in the NIS using the voluntary base units of expression for powder or concentrate as sold, to

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	(as sold) and per 100 g powder (as sold)	to be declared in an additional column to the right hand side as shown in the Example in S29-10A and in the same form required by the section. The Note signposts the example NIS provided at section S29—10A.	ensure the statement is presented in a consistent manner on labels.
2.9.1—26	**How average quantity is to be calculated**	To prohibit the method in paragraph 1.1.1—6(3)(c) to be used to calculate the average quantity of a substance in IF or FoF.	The Code is changed. This new section prevents generally accepted data relevant to the food from being used to calculate the average quantity of a substance in IF or FoF. The method should not apply because of restrictions on the amounts of energy, nutrients, nutritive substances and other substances that can be present. See CP, SD3, section 2.6 (FSANZ 2016d); 1st CFS, SD3, section 3.3 (FSANZ 2022d); 2nd CFS, SD3, issue B.6 (FSANZ 2023d) for information.
2.9.1—27	**Requirements for use of stage numbers** 2.9.1—27(1) – permission to use stage numbers	To set out the numbers that may be used on the labels of IF (number '1') and FoF (number '2').	The Code is changed. This new provision provides manufacturers with an express permission in the Code to voluntarily declare stage numbers on IF and FoF labels. Consumer evidence indicates caregivers use the numbers to identify appropriate products for their infants. The provision is aligned with MAIF agreement guidance. See AR, section 4.20; 1st CFS, SD3, section 6.4 (FSANZ 2022d) and 2nd CFS, SD3, section 9 (FSANZ 2023d) for information.
	Requirements for use of stage numbers	To require the numbers, if they are used, to be on the front of the package immediately adjacent to the respective age-related	The Code is changed. The co-location of stage numbers with age-related statements on the front of the package will ensure

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	2.9.1—27(2) & (3) – if used, location of stage numbers	statements required by paragraphs 2.9.1—21(2)(a) and 2.9.1—21(2)(b). The numbers are also permitted to be elsewhere on the label.	important information relating to product differentiation is provided in the same field of view for caregivers. The new provision for stage numbers also permits them to be present elsewhere on the label to align with MAIF agreement guidance that permits a stage number to be on the back of the package. The use of numbers in more than one field of view will assist caregivers to make appropriate product choices. See AR, section 4.20; 1st CFS, SD3, section 6.4 (FSANZ 2022d) and 2nd CFS, SD3, section 9 (FSANZ 2023d) for information.
2.9.1—28	**Prohibited representations** 2.9.1—28(1)(a) & (b) – picture of infant, a picture that idealises IF or FoF	To prohibit a package of IF or FoF from containing: • a picture of an infant. • a picture that idealises the use of IF or FoF.	The Code is not changed. The prohibition supports the Australian and New Zealand governments' international commitments to the WHO International Code of Marketing of Breast-milk Substitutes and is consistent with the Ministerial Policy Guideline on the Regulation of Infant Formula Products. See 1st CFS, SD3, section 6.1 (FSANZ 2022d) and 2nd CFS, SD3, Table 5 (FSANZ 2023d) for information.
	Prohibited representations 2.9.1—28(1)(c) – proxy advertising on IF and FoF	To prohibit a package of IF from containing information about FoF, a SMPPi, a FSF or a FSFYC . To prohibit a package of FoF from containing information about IF, a SMPPi, a FSF or a FSFYC.	The Code is changed. This new provision prevents proxy advertising (i.e. a reference to similarly packaged and labelled product as indicated) on IF and FoF labels. The regulatory approach is similar to Codex CXS 156-1987. See AR, Appendix 3 section 7; 1st CFS, SD3, section 6.3 (FSANZ 2022d) and 2nd CFS, SD3, section 9.7 and Table 5 (FSANZ 2023d) for information.
	Prohibited representations	To prohibit a package of IF or FoF from containing the word 'humanised' or	The Code is not changed. The prohibition supports the Australian and New Zealand governments' international commitments to the WHO

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	2.9.1—28(1)(d) – the words 'humanised' or 'maternalised' or similar	'maternalised' or any word or words having the same or similar effect.	International Code of Marketing of Breast-milk Substitutes and is consistent with the Ministerial Policy Guideline on the Regulation of Infant Formula Products. See 1st CFS, SD3, section 6.1 (FSANZ 2022d) and 2nd CFS, SD3, Table 5 (FSANZ 2023d) for information.
	Prohibited representations 2.9.1—28(1)(e) & (f) – 'human milk oligosaccharide' terminology and 'HMO'/'HiMO' acronyms.	To prohibit a package of IF or FoF from containing: • 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.	The Code is not changed. The prohibitions support the Australian and New Zealand governments' international commitments to the WHO International Code of Marketing of Breast-milk Substitutes and are consistent with the Ministerial Policy Guideline on the Regulation of Infant Formula Products. The terminology and acronyms were prohibited on all IFP labels in 2011 through Application A1155 (FSANZ 2019). See AR, section 4.21.1, 1st CFS, SD3, section 6.1 (FSANZ 2022d) and 2nd CFS, SD3, Table 5 (FSANZ 2023d) for information.
	Prohibited representations 2.9.1—28(1)(g) & (h) – words claiming formula is suitable for all infants and information relating to the nutritional content of human milk.	To prohibit a package of IF or FoF from containing: • words claiming that the formula is suitable for all infants. • Information relating to the nutritional content of human milk.	The Code is not changed. The prohibitions support the Australian and New Zealand governments' international commitments to the WHO International Code of Marketing of Breast-milk Substitutes and are consistent with the Ministerial Policy Guideline on the Regulation of Infant Formula Products. See 1st CFS, SD3, section 6.1 (FSANZ 2022d) and 2nd CFS, SD3, Table 5 (FSANZ 2023d) for information.
	Prohibited representations 2.9.1—28(1)(i) – specified substances	To prohibit a package of IF or FoF from containing information relating to the presence of a substance listed in subsection 2.9.1—28(2) (see below) except for a reference to such a substance in a statement of ingredients, or in a declaration or statement expressly	The Code is changed. The specified substances are now listed in a separate subsection, otherwise the intent of the prohibition in section 2.9.1—24(1)(f) of the current Code is retained.

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		permitted or required by the Code (for example, where a nutrient or nutritive substance (if added) must be declared in the NIS).	This provision aligns with the Ministerial Policy Guideline on the Regulation of Infant Formula Products as it: • ensures information of the specified substances can only be provided when indicated, thus preventing information that may be considered a claim and • addresses the potential for caregivers to be misled by information about the listed substances elsewhere on the label. See 1st CFS, SD3, section 6 (FSANZ 2022d) and 2nd CFS, SD3, Table 5 (FSANZ 2023d) for information.
	Prohibited representations 2.9.1—28(1)(j) – information relating to ingredients	To prohibit a package of IF or FoF from containing information relating to ingredients except for use of the word 'milk' and to such information in a statement of ingredients or in a declaration or statement expressly permitted or required by the Code. The intent is to prohibit references to specific ingredients (other than where permitted), but not prohibit other types of representations about ingredients more generally such as 'organic ingredients' or 'sustainably sourced ingredients'.	The Code is changed. This new provision aligns with the policy guideline as it addresses the potential for caregivers to be misled from information about the listed substances elsewhere on the label. The word 'milk' can be used anywhere on the label to enable provenance-related statements such as 'made with New Zealand milk' to be used (noting 'milk' is not permitted to be used alone in the protein source statement – see subsection 2.9.1—20(3)). See AR section 4.19 and Appendix 3, section 7; CP, SD3, section 2.1 (FSANZ 2016d); 1st CFS, SD3, section 6.3 (FSANZ 2022d) and 2nd CFS, SD3, Table 5 (FSANZ 2023d) for information
	Prohibited representations 2.9.1—28(1)(k) - information relating to the animal or plant source	To prohibit a package of IF or FoF from containing information relating to the animal or plant source or sources of protein except for such information in a statement of ingredients or when required to be used in association with the name of the food (subsection 2.9.1—20(1)).	The Code is changed. This new provision aligns with the policy intent to prohibit nutrition content and health claims on IFPs and is consistent with Codex CXS 72-1981 and CXS 156-1987 (both (referencing CXG 23-1997), EU 2016/127. See 1st CFS, SD3, sections 6.1 and 6.3 (FSANZ 2022d) for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
	Prohibited representations 2.9.1—28(1)(l) – the words 'partially hydrolysed'	To prohibit a package of IF or FoF from containing the words 'partially hydrolysed' or any word or words having the same or similar effect, except in a statement of ingredients or when required to be used in association with the name of the food (subsection 2.9.1—20(2)).	The Code is changed. This new provision relates to the use of the words 'partially hydrolysed' that aligns with the prohibition for nutrition content claims and health claims on IFPs in the Ministerial Policy Guideline on the Regulation of Infant Formula Products See AR, Appendix 3, section 7; 1st CFS, SD3, sections 6.1 to 6.3 (FSANZ 2022d) and 2nd CFS, SD3, sections 4.14 and 8 and Table 5 (FSANZ 2023d) for information
	Prohibited representations 2.9.1—28(2) – listed substances for paragraph 2.9.1—28(1)(i)	This subsection lists the substances to which the prohibition imposed by paragraph 2.9.1—28(1)(i) applies. The listed substances are an ITF; a GOS; a nutrient; and a substance used as a nutritive substance. The Note indicates that inclusion of these substances in the NIS as required by subsection 2.9.1—24(2) in accordance with section 2.9.1—24 does not constitute a nutrition content claim.	The Code is changed. The new provision groups together mandatory nutrients and voluntary substances (ITF, GOS and nutritive substances) to indicate the prohibition in paragraph 2.9.1—28(1)(i) applies to all.
Note there is no section 2.9.1—29. This is due to editorial changes in the drafting process.			
Division 4	**Special medical purpose product for infants**		
Division 4	**Special medical purpose product for infants**	Amends the regulation of IFPSDU and the subcategories currently prescribed in Division 4 of the Code to a new Division and Category called SMPPi. This Division is intended to regulate products that are specifically formulated to meet the nutritional requirements of infants with a diagnosed disease, disorder or medical condition.	The Code is changed. IFPSDU are now categorised as SMPPi and compliment the new regulatory framework by prescribing clear, prescriptive requirements. The new category more clearly aligns with international regulations. See AR section 4.1, CP3, section 5.3 (FSANZ 2021d) and 1st CFS, section 2.4.3 (FSANZ 2022a) for information.

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		This clarifies the existing intent for a two tier framework and enables the composition of SMPPi to deviate from IF, if required, for a particular medical purpose. The regulation of SMPPi in Division 4 includes a definition, compositional requirements, mandatory labelling requirements, restriction on sale and food additive permissions. Where appropriate, the requirements have been modelled on the existing Standard 2.9.5 – Food for special medical purposes. See AR, section 4.1.4 for information.	The composition of SMPPi must mimic the baseline composition of IF, except where required to deviate for the product's special medical purpose. Therefore, the regulatory intent and the reasons for change or no change to the composition align with the reasons for IF outlined above in sections 2.9.1—5 to 2.9.1—13. See AR section 4.2 for information.
2.9.1—30	**Application of other standards**	Notes that unless the contrary intention appears, the Part 1.2 of Chapter 1 (labelling and other information requirements) and Division 3 of this Standard do not apply to SMPPi. The intent is that general labelling and other information, labelling or packaging requirements for IF and FoF do not apply to SMPPi. SMPPi have their own standalone information, labelling or packaging requirements prescribed in Division 4 of the primary variation.	The Code is changed. Labelling and packaging requirements specific to SMPPi are set out in Division 4 and outlined below.
2.9.1—31	**Restriction on the sale of SMPPi**	Subsection (1) requires that SMPPi must not be sold to a consumer other than from or by a medical practitioner, dietitian, medical practice, pharmacy, responsible institution or a majority seller of that SMPPi. The intent of this is to restrict the sale of SMPPi to responsible parties that can inform consumers of the product and provide medical advice if required. This requirement intends to	The Code is changed. The introduction of the restriction on sale is based on public health and safety. There are risks associated with the use of medical or specialised formulas by healthy infants. In addition, the restriction on sale replicates requirements for all other food for special medical purposes as per Standard 2.9.5. FSANZ considers that as SMPPi are medical purpose products for a vulnerable population, the same risk management strategies should be implemented. FSANZ is

Subsection	Name and description	Regulatory intent of the primary variation	Reason for the change (or no change)
		cease the sale of SMPPi in grocery stores or other unsupervised retail settings. Subsection (2) defines a majority seller and medical practitioner for the purposes of the restrictions. A responsible institution is defined in section 2.9.1—3, noting not all listed responsible institutions under the Code definition will be applicable to the supply of SMPPi. The intent of the definitions is to provide clarity.	unaware of evidence that suggest the current restriction in Standard 2.9.5 has a negative effect on the accessibility and availability of medical foods to the Australian and New Zealand population. In addition, given the requirement that SMPPi can deviate from the prescribed composition (section 2.9.1—42) FSANZ considers the restriction on sale balances this flexibility. The restriction on sale for SMPPi is based on risk management strategies that aim to provide caregivers with additional professional advice, discourage manufacturers from taking advantage of lesser compositional requirements for this category, more clearly differentiate general formula from specialised formula and minimise the inappropriate or misuse of specialised products. The reasoning is similarly applied to FSMP. See AR section 4.3, CP3, section 5.3 (FSANZ 2021d) and 2nd CFS, section 2.3 (FSANZ 2023a) for information.
2.9.1—32	**General compositional requirements**	Section 2.9.1—32 mimics the compositional requirements prescribed for IF in section 2.9.1—5. The intent of this section is that the composition of SMPPi should replicate the baseline composition of IF, as prescribed in Division 2 of the primary variation. Deviation from these compositional requirements should only occur under the requirements of section 2.9.1—42. The intent of this section is that the composition of SMPPi should replicate the baseline composition of IF, as prescribed in Division 2 of the primary variation. Deviation from these compositional requirements should only occur under the requirements of section 2.9.1—42.	The Code is changed. The intention that SMPPi nutrient composition reflects that of IF except where necessary to achieve the medical purpose is underpinned by the principles established for this category, consistent with the Policy Guideline and aligns with international regulations. See CP3, section 5.3 (FSANZ 2021d) and 2nd CFS, section 2.3 FSANZ 2023a) for information. In the Code IFPSDU products for specific dietary use based on a protein substitute have a different energy requirement than IF and FoF (2500 to 3150 kJ/L for IF and 2500 to 3550 kJ/L for FoF). This requirement is removed as SMPPi can vary energy requirement through the compositional variation at section 2.9.1—42. See AR section 4.2 for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
2.9.1—33	**Protein requirements**	Section 2.9.1—33 mimics the compositional protein requirements prescribed for IF in section 2.9.1—6. The intent of this section is that the composition of SMPPi should replicate the baseline composition of IF, as prescribed in Division 2 of the primary variation. Deviation from these compositional requirements should only occur under the requirements of section 2.9.1—42. The intent of this section is that the composition of SMPPi should replicate the baseline composition of IF, as prescribed in Division 2 of the primary variation. Deviation from these compositional requirements should only occur under the requirements of section 2.9.1—42.	The Code is changed. The protein requirements align with IF (see reasons at section 2.9.1—6 above). In the Code, products for specific dietary use based on a protein substitute required a protein range of 0.4 to 1.4 g/100 kJ. This requirement is removed as a result of the removal of the products for specific dietary use based on a protein substitute category. This range can still be achieved for amino acid, elemental or extensively hydrolysed formulas via the compositional variation at section 2.9.1—42. See AR section 4.2 for information.
2.9.1—34	**Fat requirements**	Section 2.9.1—34 mimics the compositional protein requirements prescribed for IF in section 2.9.1—7. The intent of this section is that the composition of SMPPi should replicate the baseline composition of IF, as prescribed in Division 2 of the primary variation. Deviation from these compositional requirements should only occur under the requirements of section 2.9.1—42. The intent of this section is that the composition of SMPPi should replicate the baseline composition of IF, as prescribed in Division 2 of the primary variation. Deviation from these compositional requirements should only occur under the requirements of section 2.9.1—42.	The Code is changed. The fat requirements align with IF (see reasons at 2.9.1—7 above). In the Code, products for specific dietary use based on a protein substitute have a required fat range of 0.93 to 1.5 g/100 kJ. This requirement is removed as a result of the removal of the products for specific dietary use based on a protein substitute category. The range can still be met via the compositional variation at section 2.9.1—42. See 1st CFS, SD4, section 2.4.2 (FSANZ 2022e) for information. Products for specific dietary use based on a protein substitute also allowed the addition of MCT. This permission is still possible as the intent has not changed. See AR section 4.2 for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
2.9.1—35	**Permitted novel foods**	Section 2.9.1—34 provides that SMPPi 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. This permission applies despite any other provisions in the Code, including paragraph 1.1.1—10(6)(f). The intent of this regulatory requirement is to ensure novel foods that are not expressly permitted in IFP may be added to SMPPi where medically required. That is, where the presence of that *particular* novel food in the product *is necessary* to achieve that product's intended medical purpose. A novel food may also be present in a SMPPI if and when another section of the Code – such as in Standard 1.5.1 and Schedule 25 - expressly permits that novel food's presence in that SMPPi.	The Code is changed. This provision ensures the importation of SMPPi will continue and despite differences in novel food permissions internationally. See AR section 4.2 for information.
2.9.1—36	**Required nutritive substances**	Section 2.9.1—36 mirrors the compositional protein requirements prescribed for IF in section 2.9.1—8. The intent of this section is that the composition of SMPPi should replicate the baseline composition of IF, as prescribed in Division 2 of the Standard. Deviation from these compositional requirements should only occur in accordance section 2.9.1—42.	The Code is changed. The required nutritive substances align with the requirements for IF (see reasons at section 2.9.1—8 above). In the Code, products for specific dietary use based on a protein substitute have a required chromium range of 0.35 to 2.0 µg/100 kJ and a molybdenum range of 0.36 to 3.0 µg/100kJ. These requirements are removed as a result of the removal of the products for specific dietary use based on a protein substitute category. The range can still be met via the compositional variation at section 2.9.1—42.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
			See 1st CFS, SD4, section 2.6.2 (FSANZ 2022e) for information. See AR section 4.2 for information.
2.9.1—37	**Optional nutritive substances**	Section 2.9.1—37 mirrors the compositional protein requirements prescribed for IF in section 2.9.1—9. The intent is as above.	The Code is changed. The optional nutritive substances align with the requirements for IF (see reasons at section 2.9.1—9 above). See AR section 4.2 for information.
2.9.1—38	**Required forms of nutritive substances**	Section 2.9.1—38 mirrors the compositional protein requirements prescribed for IF in section 2.9.1—10. The intent is as above.	The Code is changed. The required forms of nutritive substances align with the requirements for IF (see reasons at section 2.9.1—10 above). See AR section 4.2 for information.
2.9.1—39	**Addition of lactic acid producing microorganisms**	Section 2.9.1—39 mirrors the compositional protein requirements prescribed for IF in section 2.9.1—11. The intent is as above.	The Code is changed. The addition of LAM aligns with the requirements for IF (see reasons at section 2.9.1—11 above). See AR section 4.2 for information.
2.9.1—40	**Restriction on addition of inulin-type fructans and galacto-oligosaccharides**	Section 2.9.1—40 mirrors the compositional protein requirements prescribed for IF in section 2.9.1—12. The intent is as above.	The Code is changed. The restriction aligns with the requirements for IF (see reasons at section 2.9.1—12 above). See AR section 4.2 for information.
2.9.1—41	**Restriction on levels of other substances**	Section 2.9.1—41 mirrors the compositional protein requirements prescribed for IF in section 2.9.1—13. The intent is as above.	The Code is changed. The restriction on levels of other substances align with the requirements for IF (see reasons at 2.9.1—13 above). See AR section 4.2 for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
2.9.1—42	**Permitted variation from compositional requirements** 2.9.1—42(1)(a)	Paragraph (1)(a) prescribes that SMPPi need not comply with a compositional requirement to the extent that a variation from that requirement is necessary to achieve the product's intended medical purpose. The intent of this provision is to allow SMPPi to deviate from the compositional requirements (as described below) where required to achieve the product's intended medical purpose. For example, SMPPi formulated for PKU will have phenylalanine removed. This is because PKU is an inborn error of metabolism that results in decreased metabolism of the amino acid phenylalanine. Paragraph 2.9.1—42(1)(a) allows for this type of variation. The regulatory intent of this requirement is that SMPPi should only deviate to meet the needs of an infant with a disease, disorder or condition.	The Code is changed. The wording for this section is modelled on requirements currently in the Code for IFPSDU. FSANZ considers the responsibility of formulating and evaluating the efficacy and suitability of varied composition lies with the manufacturers of the SMPPi, medical specialists and experts and clinical nutrition guidelines. In addition, these products must be used under medical supervision. The Food Acts in Australia and New Zealand, require all food for sale in Australia and New Zealand be safe and suitable. The above ensures that any deviation made from the compositional requirements in sections 2.9.1—32 to 2.9.1—41 will not pose risk to the safety or health of infants with a disease, disorder or condition. See AR, section 4.2 for information.
	Permitted variation from compositional requirements 2.9.1—42(1)(b)	This provision prescribes that SMPPi need not comply with a compositional requirement to the extent that a variation from that requirement would otherwise prevent the sale of the product. The intent of the paragraph - which notes deviation may occur if it 'would otherwise prevent the sale of the product' - is to allow deviation from the Code's prescriptive compositional requirements where required to reflect the differences in international regulations. The majority of SMPPi are imported into the Australian and New Zealand market. Subjecting SMPPi to trade barriers could therefore discontinue the supply of these	The Code is changed. The reasoning is as above. See AR, section 4.2 for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		essential products to the Australian and New Zealand market and in turn place the health and safety of vulnerable infants who depend on these products as their sole source of nutrition at risk. An example of this is a SMPPi for cow's milk protein allergy that has been formulated in alignment with EU regulations and therefore has an iron minimum of 0.07 mg/100 kJ. This would be considered non-compliant with the iron minimum of 0.14 mg/100 kJ prescribed in section 2.9.1—36. The intent of paragraph 2.9.1—42(1)(b) is to avoid differences in international compositional requirements preventing importation. If this subsection did not exist, a large majority of SMPPi could be considered non-compliant with the Code.	
	Permitted variation from compositional requirements 2.9.1—42(2)(a)	Subsection (2) notes that for the purposes of subsection (1), a compositional requirement means a requirement imposed by any of the following any of sections: (a) any of sections 2.9.1—32 to 2.9.1—41, but not section 2.9.1—35. The intent of this section is to state clearly which compositional requirements can be varied or departed from in accordance with and to the extent permitted by subsection 2.9.1—42(1). Paragraph 2.9.1—42(2)(a) provides that these include the compositional requirements set by sections 2.9.1—32 to 2.9.1—41, but not section 2.9.1—35.	The Code is changed. The reasoning is as above. See AR, section 4.2 for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		The exclusion of section 2.9.1—35 from the list of relevant compositional requirements preserves that section's operation and restriction in relation to the presence of novel food in SMPPi. That is, a novel food may be present in SMPPi *only* if that presence is necessary to achieve the products medical purpose. A novel food may also be present in a SMPPI if and when another section of the Code – such as in Standard 1.5.1 and Schedule 25 - expressly permits that novel food's presence in that SMPPi.	
	Permitted variation from compositional requirements 2.9.1—42(2)(b)	Subsection (2) notes that for the purposes of subsection (1), a compositional requirement means a requirement imposed by: (b) paragraph 1.1.1—10(6)(a). Subsection 1.1.1—10 sets requirements relating to food for sale. Paragraph 1.1.1—10(6)(a) requires that unless expressly permitted by this Code, food for sale must not have as an ingredient or a component a substance that was used as a food additive. The intent of paragraph 2.9.1—42(2)(b) is to enable the compositional requirement imposed by paragraph 1.1.1—10(6)(a) to be varied or departed from in accordance with and to the extent permitted by subsection 2.9.1—42(1). That is, in those circumstances, a SMPPi may contain, as an ingredient or a component, a food additive that is not otherwise permitted by the Code for that product.	The Code is changed. The reasoning is as above. See AR, section 4.2 for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
	Permitted variation from compositional requirements 2.9.1—42(2)(c)	Subsection (2) notes that for the purposes of subsection (1), a compositional requirement means a requirement imposed by: (c) paragraph 1.1.1—10(6)(b). Subsection 1.1.1—10 sets requirements relating to food for sale. Paragraph 1.1.1—10(6)(b) requires that unless expressly permitted by this Code, food for sale must not have as an ingredient or a component a substance that was used as a nutritive substance. The intent of paragraph 2.9.1—42(2)(c) is to enable the compositional requirement imposed by paragraph 1.1.1—10(6)(b) to be varied or departed from in accordance with and to the extent permitted by subsection 2.9.1—42(1). That is, in those circumstances, a SMPPi may contain, as an ingredient or a component, a nutritive substance that is not otherwise permitted by the Code for that product.	The Code is changed. The reasoning is as above. See AR, section 4.2 for information.
	Permitted variation from compositional requirements 2.9.1—42(2)(d)	Subsection (2) notes that for the purposes of subsection (1), a compositional requirement means a requirement imposed by: (d) paragraph 1.1.1—10(6)(c). Section 1.1.1—10 sets requirements relating to food for sale. Paragraph 1.1.1—10(6)(c) requires that unless expressly permitted by the Code, food for sale must not have as an ingredient or a component a substance that was used as a processing aid. The intent of paragraph 2.9.1—42(2)(d) is to enable the compositional requirement imposed	The Code is changed. The reasoning is as above. See AR, section 4.2 for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		by paragraph 1.1.1—10(6)(c) to be varied or departed from in accordance with and to the extent permitted by subsection 2.9.1—42(1). That is, in those circumstances, a SMPPi may contain, as an ingredient or a component, a processing aid that is not otherwise permitted by the Code for that product.	
2.9.1—43	**Representations about food as a special medical purpose product for infants**	To require that a food may only be represented as SMPPi if that food complies with Division 4.	The Code is changed. SMPPi is not a prescribed name in the Code as this would prevent importation of necessary specialised products not manufactured in Australia and New Zealand. Therefore, this provision is needed to clarify that a product represented (e.g, offered for sale, held out to be, described to a consumer etc) as being a SMPPi must comply with the compositional and other requirements set out in Division 4 for SMPPi.
2.9.1—44	**Product differentiation**	To require the label on a package of SMPPi to be differentiated from other foods by the use of text, pictures and/or colour. The Example illustrates that the use of text, pictures and/or colours must differentiate SMPPi from, among other things, IF, FoF or FSFYC One or more of the label elements may be used, although the use of all three label elements is considered more appropriate for ensuring SMPPi is sufficiently differentiated from other foods.	The Code is changed. This new provision ensures SMPPi are differentiated from other foods, including IF, FoF and FSFYC, thereby enabling caregivers to identify products appropriate for their infants and make safe, informed choices. The regulatory approach for SMPPi was added at approval for consistency with the approach in section 2.9.1—15 for IF and FoF. See AR, section 7 of Appendix 3.
2.9.1—45	**Prohibited representations**	To specify representations that are prohibited on the label of a package of SMPPi. These representations are:	The Code is changed.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		• a picture of an infant • a picture or text that idealises the use of the SMPPi • 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.	Relevant EU regulations have been considered to ensure the provisions do not restrict trade or restrict appropriate clinical information from being included on the label. The existing prohibition of human milk oligosaccharide terminology and HMO/HiMO abbreviations has been retained as it supports the Ministerial Policy Guideline for the Regulation of Infant Formula Products. See AR, section 4.20 and Appendix 3, section 7; 1st CFS, SD3, section 6.1 (FSANZ 2022d) and 2nd CFS, SD3 section 12 (FSANZ 2023d) for information.
2.9.1—46	**Prohibited claims**	To prohibit claims in relation to a SMPPi that are: • therapeutic in nature, that is a reference to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or compare a product with a good that is represented in any way to be for/or likely be taken to be for therapeutic use. • a nutrition content claim (as defined in section 1.1.2—9) or a health claim (as defined in subsection 1.1.2—2(3)). The prohibition does not apply to claims that are expressly permitted by the Code or to a declaration that is required by an application Act. An 'application Act' is a Commonwealth, New Zealand, Australian State or Territory food law that applies the Code (see Note 1 in Division 4 of Standard 1.1.1). The prohibition does therefore not apply to the required nutrition information (see subsection 2.9.1—53(1)), mandatory statements and declarations (see subsection 2.9.1—52) and	The Code is changed. The new Standard 2.9.1 has been restructured to address requirements for SMPPi separately in Division 4. Paragraph 2.9.1—30(a) specifies that Part 1.2 of Chapter 1 (labelling and other information requirements) does not apply to a SMPPi unless the contrary intention appears. Therefore it is necessary to include a specific prohibition for claims in relation to SMPPi to clarify the existing policy for prohibited claims in Standard 1.2.7 for IFP applies to SMPPi.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		permission for protein source(s) information (see subsection 2.9.1—53(3)) for SMPPi.	
2.9.1—47	**Permitted lactose free claim**	To expressly permit a lactose free claim on the label of a package of SMPPi provided the food contains no detectable lactose.	The Code is changed. Due to a change in how lactose modified formulas are categorised, a lactose free claim can now only be made about a SMPPi. The condition that the food contains no detectable lactose is consistent with provisions for a lactose free claim across the Code for general foods and for FSMP (subsection 2.9.5—14(2)) and takes account of the Australian Consumer and Competition Commission and New Zealand Commerce Commission views that consumers are likely to consider 'free' means zero. See AR, section 4.4 and 2nd CFS, section 4.4 (FSANZ 2023a) for information.
2.9.1—48	**Labelling and related requirements**	To set out the generic and specific labelling requirements that apply to SMPPi: • if the food for sale is in a package it is required to bear a label that includes the mandatory labelling information set out in section 2.9.1—49 • if the food for sale is in an inner package it is required to bear a label that complies with section 2.9.1—54 • no other labelling requirement in the Code for any other packaging applies to inner packages • if the food for sale is in a transportation outer it is required to bear a label that complies with section 2.9.1—55	The Code is changed. This is a new requirement for SMPPi as a new category of IFP. Labelling provisions for FSMP in section 2.9.5—8 of the Code have been applied to SMPPi. These provisions require specific label information to support the safe and effective use of the specialised products with infants whose medical conditions make them more vulnerable than healthy infants. The provisions are intended to facilitate importation of SMPPi into Australia and New Zealand. See AR, Appendix 3, section 7, 1st CFS, section 8.2 (FSANZ 2022a); 1st CFS, SD4, section 3.2 (FSANZ 2022e) and 2nd CFS, SD3,Table 7 (FSANZ 2023d) for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		• no other labelling requirement in the Code for any other packaging applies to transportation outers.	
2.9.1—49	**Mandatory labelling information** 2.9.1—49(1) – required information	To require the following information on the label of a SMPPi: • name or description sufficient to indicate the true nature of the food (section 1.2.2—2) • lot identification (section 1.2.2—3) • gene technology (in accordance with section 1.5.2—4) if the sale of the product is for retail sale or the sale of the food is to a caterer • irradiation (in accordance with section 1.5.3—9) if the sale of the product is for retail sale or the sale of the food is to a caterer • mandatory statements and declarations (section 2.9.1—50) • ingredients (section 2.9.1—51) • date marking (section 2.9.1—52) • directions for preparation, use and storage if required for health or safety reasons (which now refer to 'preparation' as a requirement) • nutrition information (section 2.9.1—53).	The Code is changed. This is a new requirement for SMPPi as a new category of IFP. Mandatory labelling information for FSMP in subsection 2.9.5—9(1) has been applied to SMPPi with amendments. These ensure that SMPPi labels enable caregivers to identify products appropriate for their infants and make safe, informed choices. Information about food produced using gene technology has been added to clarify that existing labelling requirements will apply if genetically modified ingredients are used in SMPPi. This regulatory labelling approach is consistent with the approach for IF and FoF. See 1st CFS, SD4, section 3.2 (FSANZ 2022e) for information. Requirements for advisory statements, certain required statements and a warning statement (about royal jelly) are not relevant to SMPPi and have not been applied. See AR, section 4.22 for information.
	Mandatory labelling information 2.9.1—49(2) – legibility requirements	To require that the label of a SMPPi complies with general legibility requirements in section 1.2.4—24. These requirements are 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	The Code is changed. This is a new requirement for SMPPi as a new category of IFP. Labelling provisions for FSMP in subsection 2.9.5—9(3) have been applied to SMPPi with minor amendments. General legibility requirements have been applied for SMPPi as they are sufficiently broad to ensure a continued supply of imported product. See AR, Appendix 3, section 7 for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		language must not negate or contradict the information in English.	
2.9.1—50	**Mandatory statements and declarations – special medical purpose product for infants**	To require certain statements and declarations on the label of a SMPPi: • statement to the effect that the product must be used under medical supervision • statement indicating if applicable, any precautions and contraindications • statement indicating the medical purpose of the product • statement describing the properties or characteristics which make the product appropriate for the stated 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 • statement indicating 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, certain statements are required including that the product is not for parenteral use. Statements about the nutrient or nutrients that have been modified and if they have been increased, decreased or eliminated may be provided in other documentation about the food rather than on the label of the SMPPi product. The wording of these statements is not prescribed.	The Code is changed. Labelling provisions for FSMP in section 2.9.5—10 of the Code have been applied to SMPPi with minor amendments. References to requirements for very low energy foods for FSMP have been omitted because they are not relevant to SMPPi. Further, the requirement for a statement indicating the nutrient or nutrients which have been modified has been amended to enable it to be provided in other documentation about the food. The amendment was made because some SMPPi have significant compositional differences to achieve the product's intended purpose and it would be onerous and impractical to require a statement detailing all modifications on the label. Overall, section 2.9.1—50 requires specific label information to support the safe and effective use of the specialised products with infants whose medical conditions make them more vulnerable than healthy infants. These provisions are intended to support the importation into Australia and New Zealand. See AR, section 4.22 and Appendix 3, section 7; 1st CFS, section 8.2 (FSANZ 2022a); 1st CFS, SD4, section 3.2 (FSANZ 2022e) and 2nd CFS, SD3, Table 7 (FSANZ 2023d) for information.
2.9.1—51	**Information relating to ingredients – special**	To set out the information relating to ingredients that must be stated on the label of SMPPi. A manufacturer may comply with the	The Code is changed.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
	medical purpose product for infants	requirements for a statement of ingredients in the Code, or information that complies with EU 1169/2011 or US 21 CFR 101.4 for ingredient labelling.	Labelling provisions for FSMP in section 2.9.5—11 of the Code have been applied to SMPPi. The provisions enable imported products to be labelled in accordance with ingredient labelling requirements in EU or US to ensure their continued supply. See AR, Appendix 3, section 7, CP3, section 5.7.3 (FSANZ 2021d); 1st CFS, section 8.2 (FSANZ 2022a); 1st CFS, SD4, sections 3.2.1 and 3.2.4 (FSANZ 2022e) and 2nd CFS, SD3, Table 7 (FSANZ 2023d) for information.
2.9.1—52	**Date marking information – special medical purpose product for infants**	To require date marking information that complies with Standard 1.2.5. An exception is provided for the requirement imposed by subparagraph 1.2.5—5(2)(a)(ii) that the use-by date be expressed using the words 'Use By'. For a SMPPI, the latter may be replaced by 'Expiry Date' or similar words.	The Code is changed. Labelling provisions for FSMP in section 2.9.5—12 of the Code have been applied to SMPPi. The option of using an 'Expiry Date' or similar words, consistent with Codex CXS 146-1985 (and referencing CXS 1-1985), provides a flexible approach to ensure their continued supply, given the majority of SMPPi are imported from the EU. See CP3, section 5.7.4 (FSANZ 2021d); 1st CFS, section 8.2 (FSANZ 2022a); 1st CFS, SD4, section 3.2 (FSANZ 2022e) and 2nd CFS, SD3, Table 7 (FSANZ 2023d) for information.
2.9.1—53	**Nutrition information – special medical purpose product for infants** 2.9.1—53(1)(a) & (b) – nutrients and known nutritive substances	To set out the nutrition information that must be stated on the label of a SMPPi. The required information is: • the minimum or average energy content • 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 product.	The Code is changed. Nutrition information labelling provisions for FSMP in paragraphs 2.9.5—13(1)(a) and (b) have been applied to SMPPi to provide flexibility and ensure their continued supply, with some minor amendments: See AR, section 4.23 and Appendix 3, section 7; 1st CFS, SD4, section 3.2.2 (FSANZ 2022e) and 2nd CFS, SD3, section 4.2.2 (FSANZ 2023d) for information.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		The format of the nutrition information is not prescribed.	
	Nutrition information – special medical purpose product for infants 2.9.1—53(1)(c) & (d) – other nutritive substances, sub-group nutrients and additional nutrition information	To require nutrition information on the label of a SMPPi relating to any other substance that is used as a nutritive substance and is added to that product to achieve that product's intended medical purpose. To require any of the following nutrition information on the label of a SMPPi if the declaration of that information 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. The format of the nutrition information is not prescribed.	The Code is changed. Specific nutrition information labelling provisions have been added for consistency with Codex CXS 156-1987 and EU 206/128 to ensure the continued supply of imported SMPPi. See AR, section 4.23 and Appendix 3, section 7; 1st CFS, SD4, section 3.2.2 (FSANZ 2022e) and 2nd CFS, SD3, section 4.2.2 (FSANZ 2023d) for information.
	Nutrition information – special medical purpose product for infants 2.9.1—53(2) – reference to medical purpose	To clarify that 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).	The Code is changed. The purpose of the new provision is to ensure the nutrition information on the label is relevant to the intended medical purpose and not captured as a prohibited nutrition content claim. See AR, section 4.23 and Appendix 3, section 7; 1st CFS, SD4, section 3.2.2 (FSANZ 2022e) and 2nd CFS, SD3, section 4.2.2 (FSANZ 2023d) for information.
	Nutrition information – special medical purpose product for infants	To expressly permit information relating to the source or sources of protein in that product on the label of a SMPPi.	The Code is changed. The new provision allows for consistency with Codex and EU regulations to ensure the continued supply of SMPPi.

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
	2.9.1—53(3) – source(s) of protein	This information may appear anywhere on the label, including outside of the nutrition information.	
2.9.1—54	**Labelling requirement – special medical purpose product for infants in inner package**	To require specific information to be on the label of an inner package in relation to SMPPi (as now defined in subsection 1.1.2—2(3)). The information required is: • a name or description sufficient to indicate the true nature of the food (section 1.2.2—2) • lot identification (section 1.2.2—3) • any declaration that is required by section 1.2.3—4 • date marking information (section 2.9.1—52). The label must comply with legibility requirements in section 1.2.1—24. 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.	The Code is changed. Labelling provisions for FSMP in section 2.9.5—16 of the Code have been applied to SMPPi with one amendment. The label of a SMPPi must comply with general legibility requirements in section 1.2.1—24 rather than all of Division 6 in that Standard. This change has been made to facilitate the uninterrupted supply of imported products by not applying a more restrictive size of type to certain statements. These provisions require the specific label information to support the safe and effective use of the specialised products with infants whose medical conditions make them more vulnerable than healthy infants. The provisions are aligned with Codex, EU and US regulations to support importation into Australia and New Zealand. See AR, Appendix 3, section 7; 1st CFS, SD4, section 3.2 (FSANZ 2022e) and 2nd CFS, SD3, Table 7 (FSANZ 2023d) for information.
2.9.1—55	**Labelling requirement – special medical purpose product for infants in transportation outer**	To require specific information to be on the label of a transportation outer (as defined in subsection 1.1.2—2(3)) of a SMPPi or on the label of a package of a food for sale that is clearly discernible through a transportation outer of a SMPPi. The information required is: • a name or description sufficient to indicate the true nature of the food (section 1.2.2—2) • lot identification (section 1.2.2—3)	The Code is changed. Labelling provisions for FSMP in section 2.9.5—17 of the Code have been applied to SMPPi. These provisions require the specific label information to support the safe and effective use of the specialised products with infants whose medical conditions make them more vulnerable than healthy infants. The option to provide the name and address of the (Australian or New Zealand) supplier in accompanying documentation is consistent with FSMP and allows for a small volume of product that have shared international

Subsection	*Name and description*	*Regulatory intent of the primary variation*	*Reason for the change (or no change)*
		• the name and address of the supplier (unless it is provided in accompanying documentation) (section 1.2.2—4).	labels for multiple countries to continue to be imported into Australia and New Zealand. See AR, section 4.24 and Appendix 3, section 7; 1st CFS, SD4, section 3.2 (FSANZ 2022e) and 2nd CFS (FSANZ 2023a) for information.

Regulatory intent of requirements in the consequential variation

The consequential variation amends:

- Schedule 29—Special purpose foods
- Standard 1.1.2—Definitions used throughout the Code
- Standard 1.2.3—Information requirements – warning statements, advisory statements and declarations
- Standard 1.3.1—Food Additives
- Standard 1.5.1—Novel Foods
- Standard 2.9.2—Food for infants
- Standard 2.9.3—Formulated meal replacements and formulated supplementary foods
- Standard 2.9.5—Food for special medical purposes
- Schedule 8—Food additive names and code numbers (for statement of ingredients)
- Schedule 15—Substances that may be used as food additives
- Schedule 19—Maximum levels of contaminants and natural toxicants
- Schedule 25—Permitted novel foods.

The regulatory changes to each Standard and Schedule are listed in the order present in the consequential variation.

Subsection	***Name and description***	***Regulatory intent of the consequential variation***	***Reason for the change (or no change)***
Schedule 29—Special purpose foods			
S29—2	**Infant formula products—calculation of energy content**	Prescribes the requirement for paragraph 2.9.1—4(2)(a) that energy content of IFP must be calculated using the energy contributions of fat, protein and carbohydrate as listed in section S11—2. Requires energy content be expressed in kilojoules.	The Code is not changed. Requirements for energy are applied horizontally across the Code and were out of scope of the P1028 review. There was also no evidence that suggested these requirements needed to be updated.
S29—2A	**Infant formula products—**	Prescribes the requirement for paragraph 2.9.1—4(2)(b) that protein content of IFP must be calculated by multiplying the	The Code is changed. The specified NCF has been amended. A single NCF of 6.25 for all protein sources was concluded on the basis

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	calculation of protein content	nitrogen content of the product by a nitrogen to protein conversion factor of 6.25 for all protein sources.	that: it aligns with international regulations (EU 2016/127 and Codex CXS 156-1987); it is the scientifically valid NCF for whey-based IFP (which represents approximately 85% of the market); and it is valid to apply this NCF for soy-based protein as long as the minimum protein amount is increased to 0.54 g/100 kJ (see 2.9.1—6). See CP2, section 4.1 (FSANZ 2021b) for information.
S29—2B	**Infant formula products—calculation of vitamin A content**	Prescribes the requirement for paragraph 2.9.1—4(2)(c) that vitamin A content of IFP must be calculated using only the retinol forms of vitamin A prescribed in Column 1 of Table to section S29—23. This excludes β-carotene from the calculation.	The Code is changed. β-carotene is a permitted form of vitamin A in section S29—23 to allow for its inclusion as a colouring agent and anti-oxidant in foods. Many products are formulated to include β-carotene for these purposes. Given the uncertainty around β-carotene bioavailability in infants, it is not intended that β-carotene be added as a source of vitamin A and it is therefore not appropriate to include it in the calculation of vitamin A content. See CP2, section 7.2.1 (FSANZ 2021b) and 1st CFS, SD2, section 2.3.2 (FSANZ 2022c) for information.
S29—3	**Infant formula products—L-amino acids that must be present**	To specify the minimum amounts of cysteine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, tyrosine, valine. The minimum levels prescribed for the; cysteine & cysteine total; cysteine, cystine & methionine total; and phenylalanine & tyrosine total have been removed from Schedule S29. Required combinations and ratios have been added to section 2.9.1—6(5).	The specified amino acids are essential or semi-essential amino acids that the infant must obtain from the diet. The minimum amounts in the consequential variation were set according to the average concentration in mature human milk. See AR Appendix 3, section 4 and CP2, section 4.5 (FSANZ 2021b) for information.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		Cysteine: 9 mg/100 kJ.	The Code is changed. The cysteine minimum has been updated in alignment with Codex CXS 72-1981 and EU 2016/127.
		Histidine: 10 mg/100 kJ.	The Code is not changed. This amount was reviewed and changed in Application A1074 (FSANZ 2013).
		Isoleucine: 22 mg/100 kJ.	The Code (21 mg/100 kJ) is changed. The isoleucine minimum has been updated in alignment with Codex CXS 72-1981 and EU 2016/127.
		Leucine: 40 mg/100 kJ.	The Code (42 mg/100 kJ) is changed. The leucine minimum has been updated in alignment with Codex CXS 72-1981 and EU 2016/127.
		Lysine: 27 mg/100 kJ.	The Code (30 mg/100 kJ) is changed. The lysine minimum has been updated in alignment with Codex CXS 72-1981 and EU 2016/127.
		Methionine: 6 mg/100 kJ.	The Code is changed. The methionine minimum has been updated in alignment with Codex CXS 72-1981 and EU 2016/127.
		Phenylalanine: 19 mg/100 kJ.	The Code (17 mg/100 kJ) is changed. The phenylalanine minimum has been updated in alignment with Codex CXS 72-1981 and EU 2016/127.
		Threonine: 18 mg/100 kJ.	The Code (19 mg/100 kJ) is changed. The threonine minimum has been updated in alignment with Codex CXS 72-1981 and EU 2016/127.
		Tryptophan: 8 mg/100 kJ.	The Code (7 mg/100 kJ) is changed. The tryptophan minimum has been updated in alignment with Codex CXS 72-1981 and EU 2016/127.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		Tyrosine: 18 mg/100 kJ.	The Code is changed. The tyrosine minimum has been updated in alignment with Codex CXS 72-1981 and EU 2016/127.
		Valine: 22 mg/100 kJ.	The Code (25 mg/100 kJ) is changed. The valine minimum has been updated in alignment with Codex CXS 72-1981 and EU 2016/127.
S29—4	**Infant formula products—limits on fatty acids**	Prescribes limits on fatty acids that may be present in IFP, including: • DHA maximum of 12 mg/100 kJ • Total *trans* fatty acids maximum of not more than 4% of total fatty acids • Erucic acid maximum of not more than 1% of total fatty acids The intent of these permissions is to prescribe maximum levels and limits. The total trans fatty acids and erucic acid permissions are limits and act as restrictions. They are not consider as a permission to add (e.g. not used as a nutritive substance).	The Code is changed. See new section 2.9.1—7 for additional fat requirements for LA and ALA. The addition of DHA is a voluntary permission. A maximum has been set as excess DHA without equivalent ARA may introduce risk to infant health and safety. Total trans fatty acids and erucic are fatty acids that are endogenous components of IF ingredients and are not nutritionally relevant. Maximum amounts have been set as excess of these fatty acids may introduce risk to infant health and safety. See AR Appendix 3, section 4 and CP2, sections 5.4, 5.6.2 and 5.6.4 (FSANZ 2021b) for information.
S29—5	**Vitamins, minerals, electrolytes and other substances required in infant formula and special medical purpose product for infants**	Prescribes minimum and (where appropriate) maximum amounts of essential nutrients for IF and SMPPi. Where no maximum is set, GULs are listed in section S29—5, instead of a separate table in the Code. The regulatory intent for all essential nutrients is to set an appropriate range of each nutrient to meet an infant's nutritional needs.	The Code is changed. All minimums, maximums and GULs for required vitamins, minerals, electrolytes and other nutritive substances in IF and SMPPi are now listed in a single table in section S29—5 for regulatory clarity. Justification for the prescribed range (minimums, maximums and GULs) are listed below.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		Micronutrients and their associated range in the consequential variation are listed below.	GULs 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 these GULs not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of formulas; or due to technological reasons. The current Code provides guideline maximums in a standalone division. To align with international standards FSANZ has referred to GULs in Notes in Standard 2.9.1 and Schedule S29 in a manner similar to the approach taken by Codex regulations. See AR, Section 4.1 for information.
	S29—5: Vitamin A	Vitamin A: 0.14 – 43 µg RE/100 kJ.	The Code is not changed. The range of 0.14 – 43 µg RE/100 kJ aligns with Codex CXS 72-1981. The maximum in EU 2016/127 maximum is lower (27.2 µg RE/100 kJ). The maximum of 43 µg RE/100 kJ was retained based on no data indicating that the current maximum of 43 µg/100 kJ is associated with adverse health effects, the uncertainty around the basis for the EU 2016/127 amount and that the objective of this proposal is to align with Codex CXS 72-1981 where possible. See CP2, Appendix 1 (FSANZ 2021b) for information.
	S29—5: Vitamin D	Vitamin D: 0.24 – 63 µg/100 kJ.	The Code (0.25 – 0.63 µg/100 kJ) is changed. The minimum amount has been lowered in new section S29—5. This is to consistently apply a set conversion for kcal to kJ and align better with international standards.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			See 2nd CFS, SD2, section 3.1 (FSANZ 2023c) for information.
	S29—5: Vitamin C	Vitamin C: 1.7 – 17 (GUL) mg/100 kJ.	The Code (1.7 – 5.4 (GUL) mg/100 kJ) is changed. The GUL is increased to 17 mg/100 kJ which aligns with Codex CXS 72-1981 allows for vitamin C degradation over the product shelf life and ensures infants have adequate intakes. See CP2, Appendix 1 (FSANZ 2021b) for information.
	S29—5: Thiamin	Thiamin: 10 – 72 (GUL) µg/100 kJ.	The Code (10 – 48 (GUL) µg/100 kJ is changed. The GUL is increased to 72 mg/100 kJ to align with Codex CXS 72-1981 and the range in new section S29—5 meets the criteria set out in the 2016 nutrition risk assessment. See 1st CFS, SD2, section 2.2.2 (FSANZ 2022c) for information.
	S29—5: Riboflavin	Riboflavin: 14.3 – 120 (GUL) µg/100 kJ.	The Code (14 – 86 (GUL) µg/100 kJ) is changed. The minimum and GUL have been increased to better align with international regulations in the absence of any safety concerns being raised in relation to new section S29—5, including in relation to riboflavin. See 1st CFS, SD2, section 2.2.2 (FSANZ 2022c) for information.
	S29—5: Niacin	Niacin: 72 – 359 (GUL) µg/100 kJ.	The Code (130 – 480 (GUL) µg/100 kJ) is changed. 'Preformed' (CP2, section 7.2.4) is removed as the range in new section S29—5 reflects only added niacin (not niacin including that contributed from tryptophan). See CP2, section 7.2.4 (FSANZ 2021b) for information.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			The minimum is lowered to align with Codex CXS 72-1981 which is based on human milk concentrations of niacin and excludes the tryptophan contribution. See 2nd CFS, SD2, section 5.4 (FSANZ 2023c) for information. The GUL is lowered to align with Code CXS 72-1981 and also reflects added niacin only. See CP, SD1, Attachment A1.1, section 3.6.5 (FSANZ 2016b) for information.
	S29—5: Vitamin B_6	Vitamin B_6: 8 – 42 (GUL) µg/100 kJ.	The Code (9 – 36 µg/100 kJ) is changed. The minimum has been increased due to a calculation correction. In some cases, calculations in Codex CXS 72-1981 were calculated incorrectly. FSANZ has corrected this error and has adopted/recalculated the figures in line with Codex CXS 156-1987 and the International Standard Unit conversion factors and conventional rounding. There is no public health or safety issues associated with correcting the calculations for units of measure. See 2nd CFS, SD2, section 3.1 (FSANZ 2023c) for information. The amendments made by the consequential variation changed the maximum in the Code to a GUL to align with international standards and as no safety risk was identified in relation to such a change. See CP, SD1, Attachment A1.1, section 3.6.6 (FSANZ 2016b) for information.
	S29—5: Folic acid	Folic acid: 2.4 – 12 (GUL) µg/100 kJ.	The Code (2 – 8.0(GUL) µg/100 kJ as folate) is changed.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			The requirement in new section S29—5 is prescribed as folic acid (not folate) as the folate is listed as a permitted form in section S29—23 for regulatory clarity. See 1st CFS, SD2, section 2.3.2 (FSANZ 2022c) for information. The minimum in new section S29—5 has been amended to consistently apply a set conversion for kcal to kJ and align better with international standards. See 2nd CFS, SD2, section 3.1 (FSANZ 2023c) for information. The maximum (GUL) is increased in new section S29—5 to align with Codex CXS 72-1981 which is higher to account for stability over the shelf life of the products. See CP, SD1, Attachment A1.1, section 3.6.7 (FSANZ 2016b) for information.
	S29—5: Pantothenic acid	Pantothenic acid: 96 – 478 (GUL) µg/100 kJ.	The Code (70 – 360 (GUL) µg/100 kJ) is changed. The permitted range in new section S29—5 aligns with Codex CXS 72-1981. The range specified in the Codex CXS 72-1981 was found to meet nutritional safety requirements assessed in the 2016 nutrition assessment. See CP, SD1, Attachment A1.1, section 3.6.8 (FSANZ 2016b) for information.
	S29—5: Vitamin B_{12}	Vitamin B_{12}: 0.02 – 0.36 (GUL) µg/100 kJ.	The Code (0.025 – 0.17(GUL) µg/100 kJ) is changed. The permitted range in new section S29—5 aligns with Codex CXS 72-1981 and was found to meet nutritional safety requirements assessed in the 2016 nutrition assessment. The minimum in new section S29—5 is lower to allow for correct conversion from kcal to kJ. The GUL is increased to align with Codex CXS 72-1981,

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			which is unlikely to pose a risk to infant health as it has an established history of safe use and enables nutrient requirements to be met. See CP, SD1, Attachment A1.1, section 3.6.8 (FSANZ 2016b) and 2nd CFS, SD2, sections 5.2 and 3.1 (FSANZ 2023c) for information.
	S29—5: Biotin	Biotin: 0.24 – 2.4 (GUL) µg/100 kJ.	The Code (0.36 – 2.7 (GUL) µg/100 kJ is changed. The minimum in new section S29—5 aligns with EU 2016/127 and was determined to be appropriate as it aligns closely with human milk biotin concentrations and was unlikely to impact trade since products formulated for either EU 2016/127 or Codex CXS 72-1981 were accounted for within the range. The maximum (GUL) aligns with Codex CXS 72-1981 and was found to meet nutritional safety requirements assessed in the 2016 nutrition assessment and there was no evidence to support the EU 2016/127 maximum of 1.8 µg/100 kJ. See CP2, section 7.3.3 (2021b) and 1st CFS, SD2, section 2.2.2 (FSANZ 2022c) for information.
	S29—5: Vitamin E	Vitamin E: 0.14 mg – 1.2 (GUL) µg α-TE/100 kJ.	The Code (0.11 mg – 1.1 µg α-TE/100 kJ) is changed. The minimum is aligned with the EU 2016/127 to better meet the Australian and New Zealand NRV for Adequate Intake of vitamin E. See 2nd CFS, SD2, section 5.6 (FSANZ 2023c) for information. The amendments made by the consequential variation changed the maximum in the Code to a GUL to align with Codex CXS 72-1981 and as the GUL's maximum was found to meet nutritional safety requirements assessed in

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			the 2016 nutrition assessment. The maximum (GUL) has also been amended in new section S29—5 to allow for correct conversion from kcal to kJ. See CP, SD1, Attachment A1.1, section 3.6.3 (FSANZ 2016b) and 2nd CFS, SD2, section 3.1 (FSANZ 2023c) for information.
	S29—5: Vitamin K	Vitamin K: 0.24 – 6 (GUL) µg/100 kJ.	The Code (1 – 5.0 (GUL) µg/100 kJ) is changed. The minimum in new section S29—5 has been aligned with the EU 2016/127. Intakes based on the lower minimum specified by EU 2016/127 more closely aligns with the Australian and New Zealand NRV for Adequate Intake of vitamin K. The maximum (GUL) in new section S29—5 is also aligned with the EU 2016/127 and based on the conclusion of low risk of harm to infant health due to an excessive intake based on this amount. See CP2, SD1, section 5.1.4 (FSANZ 2021c) for information.
	S29—5: Calcium	Calcium: 12 – 35 (GUL) mg/100 kJ.	The Code (12 – 33 (GUL) /100 kJ) is changed. To achieve alignment with international standards and as no issues were identified in the nutritional safety assessment for this range. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—5: Phosphorus	Phosphorus: 6 – 24 (GUL) mg/100 kJ.	The Code (6 – 25 mg/100 kJ) is changed. The new amendments changed the maximum in the Code to a GUL to align with Codex CXS 72-1981. This is based on the 2016 Nutrition Assessment concluding the GUL was unlikely to pose risk to infant health as it has an

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			established history of safe use and enables nutrient requirements to be met. See CP, SD1, Attachment A1.1, section 4.7.2 (FSANZ 2016b) and CP2, section 7.4.1 (FSANZ 2021b) for information.
	S29—5: Magnesium	Magnesium: 1.2 – 3.6 (GUL) mg/100 kJ.	The Code (1.2 – 4.0 mg/100 kJ) is changed. The new amendments changed the maximum in the Code to a GUL to align with Codex CXS 72-1981. This is based on the 2016 Nutrition Assessment concluding the GUL was unlikely to pose risk to infant health as it has an established history of safe use and enables nutrient requirements to be met. See CP, SD1, Attachment A1.1, section 3.7 (FSANZ 2016b) for information.
	S29—5: Iron	Iron: 0.14 – 0.48 mg/100 kJ.	The Code (0.2 – 0.5 mg/100 kJ) is changed. The range for iron in new section S29—5 was amended to a minimum of 0.14 mg/100 kJ to improve alignment with the EU 2016/127 and Codex CXS 72-1981 when corrected in accordance with the International Standard Unit conversion factors and conventional rounding. Intakes based on the variation range in new section S29––5 are also more consistent with recommended intakes in the Australian and New Zealand NRVs. See 2nd CFS, SD2, section 5.7.3 (FSANZ 2023c) for information.
	S29—5: Iodine	Iodine: 2.4 – 14 (GUL) µg/100 kJ.	The Code (1.2 – 10 µg/100 kJ) is changed. The range was amended to align with Codex CXS 72-1981. The increased minimum provides adequate intakes of iodine when combined with iodine contained in potable

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			water and better meets international standards (EU 2016/127). The new amendments changed the maximum in the Code to a GUL to align with Codex CXS 72-1981. This is based on the 2016 Nutrition Assessment concluding the GUL was unlikely to pose risk to infant health as it has an established history of safe use and enables nutrient requirements to be met. FSANZ's assessment noted large variability in the iodine content of cow's milk which depends on season and hygienic and agricultural techniques. See CP, SD1, Attachment A1.1, section 3.7.6 (FSANZ 2016b) and 2nd CFS, SD2, section 5.8.3 (FSANZ 2023c) for information.
	S29—5: Copper	Copper: 8 – 29 (GUL) µg/100 kJ.	The Code (14 – 43 µg/100 kJ) is changed. The range was amended to align with Codex CXS 72-1981. FSANZ's assessment noted that the higher minimum in EU 2016/127 was based on a higher reported copper levels in human milk in that population and that copper deficiency is rare in humans except for pre-term infants. The new amendments changed the maximum in the Code to a GUL to align with Codex CXS 72-1981. This is based on the 2016 Nutrition Assessment concluding the GUL was unlikely to pose risk to infant health. See CP, SD1, Attachment A1.1, section 3.7.7 (FSANZ 2016b); CP2, section 7.3.5 (FSANZ 2021b) and 1st CFS, SD2, section 2.2.2 (FSANZ 2022c) for information.
	S29—5: Zinc	Zinc: 0.12 – 0.36 (GUL) mg/100 kJ.	The Code (0.12 – 0.43 mg/100 kJ) is changed.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			The range was amended to align with Codex CXS 72-1981. The maximum presents no evidence of risk to infant health as the upper level is overly conservative and accommodates the higher concentration of zinc in soy-based formula. The new amendments changed the maximum in the Code to a GUL to align with Codex CXS 72-1981. This is based on the 2016 Nutrition Assessment concluding the GUL was unlikely to pose risk to infant health as no safety risk was identified if the change was adopted. See CP, SD1, Attachment A1.1, section 3.7.5 (FSANZ 2016b) and CP2, section 7.3.9 (FSANZ 2021b) for information.
	S29—5: Manganese	Manganese: 0.24 – 24. 0 (GUL) µg/100 kJ.	The Code (0.24 – 24 µg/100kJ) is changed. While the minimum and maximum levels are unchanged, the maximum in the Code has been changed to a GUL to align with international standards and because no safety risk was identified if the change was adopted. See CP, SD1, Attachment A1.1, section 3.7.8 (FSANZ 2016b) and CP2, section 7.3 (FSANZ 2021b) for information. The Code provided a guideline maximum of 7.2 µg/100kJ for IFPSDU. This has been removed as SMPPi can deviate from the IF baseline composition to address the product's special medical purpose. The manganese guideline maximum for metabolic, immunological, renal, hepatic and malabsorptive conditions was established due to concerns that some infants with liver disease may not be able to excrete usual levels of manganese. The guideline maximum was established to guide manufacturers to prepare formula for

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			such infants with a much lower manganese content (ANZFA 1999). As this guideline maximum was used as guidance to manufacturers and was not legally binding, FSANZ considers its regulatory intent to be the same as Division 4 for SMPPi. Products for metabolic, immunological, renal, hepatic and malabsorptive conditions are still expected to be specially formulated for the products special medical purpose and have composition that reflects this. See 1st CFS, SD4, section 2.3.2 (FSANZ 2022e) for information.
	S29—5: Selenium	Selenium: 0.48 – 2.2 (GUL) µg/100 kJ.	The Code (0.25 – 1.19 µg/100 kJ) is changed. The amendments change the maximum in the Code to a GUL to align with Codex CXS 72-1981 and because no safety risk was identified if the change was adopted. FSANZ's assessment noted that human milk concentrations equivalent to 2.2 µg/100 kJ were not associated with adverse effects. See CP, SD1, Attachment A1.1, section 3.7.9 (FSANZ 2016b); CP2, section 7.3.11 (FSANZ 2021b) and 1st CFS, SD2, section 2.3.2 (FSANZ 2022c) for information.
	S29—5: Chloride	Chloride: 12 – 38 mg/100 kJ.	The Code (12 – 35 mg/100 kJ) is changed. The maximum has been increased to align with Codex CXS 72-1981 and because no safety risk was identified if the change was adopted. See CP, SD1, Attachment A1.1, section 3.7 (FSANZ 2016b) and CP2, section 7.3 (FSANZ 2021b) for information.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	S29—5: Sodium	Sodium: 4.8 – 14 mg/100kJ.	The Code (5 – 15 mg/100 kJ) is changed. The range has changed to align with Codex CXS 72-1981. FSANZ noted it is within the range of human milk concentrations, was appropriate to meet adequate intake, did not exceed the upper limit and no safety risk was identified if the change was adopted. See CP, SD1, Attachment A1.1, section 3.7 (FSANZ 2016b) and CP2, section 7.3 (FSANZ 2021b) for information.
	S29—5: Potassium	Potassium: 14 – 43 mg/100 kJ.	The Code (20 – 50 mg/100 kJ) is changed. The range has changed to align with Codex CXS 72-1981 and because no safety risk was identified if the change was adopted. See CP, SD1, Attachment A1.1, section 3.7.1 (FSANZ 2016b) and CP2, section 7.3 (FSANZ 2021b) for information.
	S29—5: Choline	Choline: 1.7 – 12 (GUL) mg/100 kJ.	The Code (1.7 – 7.1 mg/100 kJ) is changed. New section 2.9.1—8prescribes choline as an essential substance, as opposed to the voluntary permission in the current Code in order to align with international standards. The FSANZ assessment noted that choline has been classed as an essential nutrient in the NRVs since 2006. The minimum reflects the human milk concentration of choline and not the additional potentially bioactive forms not permitted. The maximum is changed to a GUL and increased to align with Codex CXS 72-1981 and because no safety risk was identified if the change was adopted. Due to the

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			absence of an upper limit the use of a GUL is more appropriate and maintains consistency with Codex CXS 72-1981. See CP, SD1, Attachment A1.1, section 3.8.1 (FSANZ 2016b); CP2, section 8.1 (FSANZ 2021b) and 2nd CFS, SD2, Table 7 (FSANZ 2023c) for information.
	S29—5: L-Carnitine	L-Carnitine: 0.30 – 0.80 (GUL) mg/100 kJ.	The Code (0.21 – 0.8 mg/100 kJ) is changed. New section 2.9.1—8 prescribes L-carnitine as an essential substance, as opposed to a voluntary permission in the current Code because L-carnitine is considered as conditionally essential for infants mainly because they may lack the developmental maturity for endogenous synthesis. The minimum is increased to align with Codex CXS 72-1981. The maximum is changed to a GUL to account for the natural variability of L-carnitine content in differing milks, to provide flexibility for manufacturers and to avoid trade barriers. The GUL reflects the upper levels present in human milk. FSANZ's Nutrition Assessment 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, new sections 2.9.1—8 and S29—5 will specify L-carnitine as a mandatory substance in infant formula with a range of 0.3–0.8 (GUL) mg/100 kJ.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			See CP, SD1, section 9.2 (FSANZ 2016a); CP2, section 8.2 (FSANZ 2021b) and 1st CFS, SD2, section 2.5.2 (FSANZ 2022c) for information.
	S29—5: Myo-inositol	Myo-inositol: 1.0 – 10 (GUL) mg/100 kJ.	The Code (1.0 – 9.5 mg/100 kJ) is changed. New sections 2.9.1—8 and S29—5 prescribe myo-inositol as an essential substance, as opposed to the voluntary permission currently in the Code. The reason for this change is that inositol is considered to be conditionally essential for infants mainly because they may lack the developmental maturity for endogenous synthesis. The evidence identified its presence in human milk, low serum concentrations and physiological or biochemical outcomes suggesting inadequacy in infants fed un-supplemented formulas. The maximum is changed to a GUL to align with Codex CXS 72-1981 and because this is unlikely to pose a risk to infant health. The GUL is increased due to a calculation correction. In some cases, calculations in Codex CXS 72-1981 were calculated incorrectly. FSANZ corrected this error and has adopted/recalculated the figures in line with Codex CXS 156-1987 and the International Standard Unit conversion factors and conventional rounding. There is no public health or safety issues associated with correcting the calculations for units of measure. See 2nd CFS, SD3, section 3.1 (FSANZ 2023d) for information. The minimum aligns with Codex CXS 72-1981 and aligns closely to EU 2016/127. The minimum accounts for the variance in human milk concentrations any myo-inositol that is synthesised endogenously.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			See CP, SD1, section 9.3 (FSANZ 2016a); CP2, section 8.3 (FSANZ 2021b); CP2, SD1, section 9.3 (FSANZ 2021c) and 1st CFS, SD2, section 2.5.2 (FSANZ 2022c) for information.
S29—6	**Vitamins, minerals, and electrolytes required in follow-on formula**	Prescribes minimum and (where appropriate) maximum amounts of essential nutrients for FoF. Where no maximum is set, GULs are listed in section S29—6, instead of a separate table in the Code. The regulatory intent for all essential nutrients is to set an appropriate range of each nutrient to meet an infant's (6 to 12 months) nutritional needs. Micronutrients and range in the consequential variation are listed below. The nutrient composition for FoF should only deviate from IF when there is substantiated science to support the differences in needs between the age groups.	The Code is changed. All minimums, maximums and GULs for FoF are now listed in a single table in section S29—6 for regulatory clarity. Justification for the prescribed range (minimums, maximums and GULs) are listed below. Where the composition aligns with that of IF please see the rationale provided above in relation to section S29—5. GULs 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 GULs should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of formulas; or due to technological reasons. The Code prescribes guideline maximums in a standalone division. To align with international standards FSANZ has referred to the GULs in Notes in Standard 2.9.1 and Schedule 29.
	S29—6: Vitamin A	Vitamin A: 0.14 – 43 µg RE/100 kJ.	The Code range (0.14 – 43 µg RE/100 kJ) is not changed. The range aligns with the composition for IF. Codex CXS 156-1987 applies a higher minimum however this is not reflective of the Australian and New Zealand population and does not account for additional intake from complementary foods.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Vitamin D	Vitamin D: 0.24 – 72 µg/100 kJ.	The Code range (0.25 – 0.63 µg/100 kJ) is changed. The minimum has been revised and aligns with the composition for IF. The maximum has been increased. To comply with both EU regulations and the Code would require a smaller vitamin D range (0.48–0.63 µg/100 kJ) thus making meeting technological requirements difficult. Based on evidence from EFSA and the fact that the addition of vitamin D is not permitted in infant foods in Australia and New Zealand, the increased maximum is unlikely to result in exceeding safe levels. See AR, section 4.9 for information.
	S29—6: Vitamin C	Vitamin C: 1.7 – 17 (GUL) mg/100 kJ.	The Code (1.7 – 5.4 (GUL) mg/100 kJ) is changed. The range aligns with the composition for IF. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) and 2nd CFS, SD2, Table 5 (FSANZ 2023c) for information.
	S29—6: Thiamin	Thiamin: 10 – 7 2(GUL) µg/100 kJ.	The Code (10 – 48 (GUL) µg/100 kJ) is changed. The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Riboflavin	Riboflavin: 14.3 – 120 (GUL) µg/100 kJ.	The Code (14 – 86 (GUL) µg/100 kJ) is changed. The range aligns with the composition for IF. The GUL is consistent with Codex CXS 156-1987.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Niacin	Niacin: 72 – 359 (GUL) µg/100 kJ.	The Code (130 – 480 (GUL) µg/100 kJ of preformed niacin) is changed. The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Vitamin B_6	Vitamin B_6: 8 – 42 (GUL) µg/100 kJ.	The Code (9 – 36 µg/100 kJ) is changed. The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Folic acid	Folic acid: 2.4 – 12 (GUL) µg/100 kJ.	The Code (2 – 8.0 (GUL) µg/100 kJ as folate) is changed. The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Pantothenic acid	Pantothenic acid: 96 – 478 (GUL) µg/100 kJ.	The Code (70 – 360 (GUL) µg/100 kJ) is changed. The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Vitamin B_{12}	Vitamin B_{12}: 0.02 – 0.36 (GUL) µg/100 kJ.	The Code (0.025 – 0.17 (GUL) µg/100 kJ) is changed.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987.
	S29—6: Biotin	Biotin: 0.24 – 2.4 (GUL) µg/100 kJ.	The Code (0.36 – 2.7 (GUL) µg/100 kJ) is changed. The range aligns with the composition for IF. In addition, the proposed minimum and maximum were determined to be unlikely to pose a risk to infant health, including older infants 6 – 12 months. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Vitamin E	Vitamin E (0.14 mg – 1.2 (GUL) mg/100 kJ.	The Code (0.11 – 1.1 mg α-TE/100 kJ) is changed. The range aligns with the composition for IF.
	S29—6: Vitamin K	Vitamin K: 0.24 – 6 (GUL) µg/100 kJ.	The Code (1 – 5.0 (GUL) µg/100 kJ) is changed. The range aligns with the composition for IF.
	S29—6: Calcium	Calcium: 12 – 43 (GUL) mg/100 kJ.	The Code (12 – 33 (GUL) /100 kJ) is changed. The maximum deviates from the maximum for IF. The range is consistent with Codex CXS 156-1987 and acknowledges the increase in calcium requirements, reduced intakes of FoF and that calcium intakes are often limited in the diets of this age group. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) and 2nd CFS, SD2, Table 9 (FSANZ 2023c) for information.
	S29—6: Phosphorus	Phosphorus: 6 – 24 (GUL) mg/100 kJ.	The Code (6 – 25 mg/100 kJ) is changed. The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Magnesium	Magnesium: 1.2 – 3.6 (GUL) mg/100 kJ.	The Code (1.2 – 4.0 mg/100 kJ) is changed. The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987.
	S29—6: Iron	Iron: 0.24 – 0.48 mg/100 kJ.	The Code (0.2 – 0.5 mg/100 kJ) is changed. The minimum deviates from the minimum for IF, however is retains the requirements in the Code. The range is consistent with Codex CXS 156-1987. See 1st CFS, SD2, Section 3.2.2 (FSANZ 2022c) for information. 2nd CFS, SD2, Section 5.7.3 (FSANZ 2023c) notes the range of 0.24 – 0.48 mg/100 kj is corrected figures from the originally proposed 0.2 – 0.5 mg/100 kJ.
	S29—6: Iodine	Iodine: 2.4 – 14 (GUL) µg/100 kJ.	The Code (1.2 – 10 µg/100 kJ) is changed. The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987. See 2nd CFS, SD2, section 5.8.1 (FSANZ 2023c) for information.
	S29—6: Copper	Copper: 8 – 29 (GUL) µg/100 kJ.	The Code (14 – 43 µg/100 kJ) is changed. The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Zinc	Zinc: 0.12 – 0.36 (GUL) mg/100 kJ.	The Code (0.12 – 0.43 mg/100 kJ) is changed.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Manganese	Manganese: 0.24 – 24.0 (GUL) µg/100 kJ.	The Code (0.24 – 24 µg/100 kJ) is changed. The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Selenium	Selenium: 0.48 – 2.2 (GUL) µg/100 kJ.	The Code (0.25 – 1.19 µg/100 kJ) is changed. The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Chloride	Chloride: 12 – 38 mg/100 kJ.	The Code (12 – 35 mg/100 kJ) is changed. The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Sodium	Sodium: 4.8 – 14 mg/100 kJ.	The Code (5 – 15 mg/100 kJ) is changed. The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
	S29—6: Potassium	Potassium: 14 – 43 mg/100 kJ.	The Code (20 – 50 mg/100 kJ) is changed.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			The range aligns with the composition for IF. The range is also consistent with Codex CXS 156-1987. See 1st CFS, SD2, section 3.3.2 (FSANZ 2022c) for information.
S29—7	**Optional nutritive substances in infant formula and special medical purpose product for infants**	Prescribe minimum and maximum amounts (where appropriate) of optional nutritive substances for IF and SMPPi. Nutritive substances that are captured in the table to section S29—7 are not considered as an essential part of the composition in IF for varying reasons. Some substances such as taurine and nucleotides have held voluntary permissions in IF for over 20 years, consistent with international standards. While other substances have been permitted more recently via FSANZ's application process. The regulatory intent for all optional nutrients is to set a range that provides an appropriate amount of the substance that aids normal growth and development of infants and does not have any associate safety risks. All substances prescribed in section S29—7 are present in human milk or are an equivalent form (e.g. bovine lactoferrin is considered to provide nutritional equivalence when compared to human lactoferrin). Nutritive substances and the associated permitted range in the consequential variation are listed below.	The Code is changed. Justification for the prescribed range (minimums and maximums) are listed below. Some nutritive substances (choline, L-carnitine and myo-inositol) were optional but have now been made mandatory in IF.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	S29—7: 2′-fucosyllactose	2′-fucosyllactose permitted for use by Standard 1.5.2: NS – 96 mg/100 kJ.	The Code (NS – 96 mg/100 kJ) is not changed. As these requirements have already been assessed and consulted through a statutory process (A1155; FSANZ 2019) FSANZ did not reassess within P1028. See 1st CFS, SD2, section 2.5.2 (FSANZ 2022c) for information.
	S29—7: 3′-sialyllactose sodium salt	3′-sialyllactose sodium salt permitted for use by Standard 1.5.2: NS – 8 mg/100 kJ.	The Code (NS – 8 mg/100 kJ) is not changed. As these requirements have already been assessed and consulted through a statutory process (A1265; FSANZ 2023f) FSANZ did not reassess within P1028.
	S29—7: 6′-sialyllactose sodium salt	6′-sialyllactose sodium salt permitted for use by Standard 1.5.2: NS – 16 mg/100 kJ.	The Code (NS – 16 mg/100 kJ) is not changed. As these requirements have already been assessed and consulted through a statutory process (A1265; FSANZ 2023f) FSANZ did not reassess within P1028.
	S29—7: 2′-fucosyllactose and difucosyllactose	A combination of 2′-fucosyllactose and difucosyllactose, permitted for use by Standard 1.5.2: NS – 96 mg/100 kJ.	The Code (NS – 96 mg/100 kJ) is not changed. As these requirements have already been assessed and consulted through a statutory process (A1265; FSANZ 2023f) FSANZ did not reassess within P1028.
	S29—7: 2′-fucosyllactose and lacto-N-neotetraose	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: NS – 96 mg/100 kJ which contains not more than 24 mg of lacto-N-neotetraose.	The Code (NS – 96 mg/100 kJ which contains not more than 24 mg of lacto-N-neotetraose) is not changed. As these requirements have already been assessed and consulted through a statutory process (A1155; FSANZ 2019) FSANZ did not reassess within P1028. See 1st CFS, SD2, section 2.5.2 (FSANZ 2022c) for information.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	S29—7: Adenosine-5′-monophosphate	Adenosine-5′-monophosphate: NS – 0.36 mg/100 kJ.	The Code (0.14 – 0.38 mg/100 kJ) is changed. Adenosine-5′-monophosphate is retained as optional for consistency with EU 2016/127 and Codex CXS 72-1981 and due to no known safety concerns associated with the consumption of nucleotides. The minimum is removed to align with EU 2016/127, US and Canadian regulations and the recommendations of the LSRO (Raiten et al. 1998), EC SCF (EC SCF 2003) and ESPGHAN (Koletzko et al. 2005). See 1st CFS, SD2, section 2.5.2 (FSANZ 2022c) and 2nd CFS, SD2, Table 7 (FSANZ 2023c) for information. The maximum has been lowered based on the conclusions of EFSA (2014) and to align with EU 2016/127. See 2nd CFS, SD2, Table 7 (FSANZ 2023c) for information.
	S29—7: Cytidine-5′-monophosphate	Cytidine-5′-monophosphate: NS – 0.60 mg/100 kJ.	The Code (0.22 –0.6 mg/100 kJ) is changed. Cytidine-5′-monophosphate is retained as optional for consistency with EU 2016/127 and Codex CXS 72-1981 and due to no known safety concerns associated with the consumption of nucleotides. The minimum is removed to align with EU 2016/127, US and Canadian regulations and the recommendations of the LSRO (Raiten et al. 1998), EC SCF (EC SCF 2003) and ESPGHAN (Koletzko et al. 2005). See 1st CFS, SD2, section 2.5.2 (FSANZ 2022c) and 2nd CFS, SD2, Table 7 (FSANZ 2023c) for information.
	S29—7: Guanosine-5′-monophosphate	Guanosine-5′-monophosphate: NS – 0.40 mg/100 kJ.	The Code (0.04 – 0.12 mg/100 kJ) is changed. Adenosine-5′-monophosphate is retained as optional for

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			consistency with EU 2016/127 and Codex CXS 72-1981 and due to no known safety concerns associated with the consumption of nucleotides. The minimum is removed to align with EU 2016/127, US and Canadian regulations and the recommendations of the LSRO (Raiten et al. 1998), EC SCF (EC SCF 2003) and ESPGHAN (Koletzko et al. 2005). See 1st CFS, SD2, section 2.5.2 (FSANZ 2022c) and 2nd CFS, SD2, Table 7 (FSANZ 2023c) for information. The maximum is increased in recognition of the levels found naturally in goat milk-based formula and for alignment with the upper end of averages found in human milk. FSANZ notes goat milk is commonly used in IFP in Australia and New Zealand. See 2nd CFS, SD2, Table 7 (FSANZ 2023c) for information.
	S29—7: Inosine-5′-monophosphate	Inosine-5′-monophosphate: NS – 0.24 mg/100 kJ.	The Code (0.08 – 0.24 mg/100 kJ) is changed. Inosine-5′-monophosphate is retained as optional for consistency with EU 2016/127 and Codex CXS 72-1981 and due to no known safety concerns associated with the consumption of nucleotides. The minimum is removed to align with EU 2016/127, US and Canadian regulations and the recommendations of the LSRO (Raiten et al. 1998), EC SCF (EC SCF 2003) and ESPGHAN (Koletzko et al. 2005). See 1st CFS, SD2, section 2.5.2 (FSANZ 2022c) and 2nd CFS, SD2, Table 7 (FSANZ 2023c) for information.
	S29—7: Lactoferrin	Lactoferrin: NS – 40 mg/100 kJ.	The Code (NS – 40 mg/100 kJ) is not changed.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			As these requirements have already been assessed and consulted through a statutory process (A1253; FSANZ 2023e) FSANZ did not reassess within P1028.
	S29—7: lacto-N-tetraose	lacto-N-tetraose permitted for use by Standard 1.5.2: NS – 32 mg/100 kJ.	The Code (NS – 32 mg/100 kJ) is not changed. As these requirements have already been assessed and consulted through a statutory process (A1265; FSANZ 2023f) FSANZ did not reassess within P1028.
	S29—7: Lutein	Lutein: 1.5 – 5.0 µg/100 kJ.	The Code (1.5 – 5.0 µg/100 kJ) is not changed. As these requirements have already been assessed and consulted through a statutory process (A594; FSANZ 2008) FSANZ did not reassess within P1028. See 2nd CFS, SD2, Table 7 (FSANZ 2023c) for information.
	S29—7: Taurine	Taurine: NS – 2.9 mg/100 kJ.	The Code (0.8 – 3 mg/100 kJ) is changed. The minimum is removed and the maximum is corrected to align with Codex CXS 72-1981 and EU 2016/127. The assessment found no evidence of adverse effects and a history of safe use. See 1st CFS, SD2, section 2.5.2 (FSANZ 2022c) and 2nd CFS, SD2, section 7.1 (FSANZ 2023c) for information.
	S29—7: Uridine-5′-monophosphate	Uridine-5′-monophosphate: NS – 0.42 mg/100 kJ.	The Code (0.13 – 0.42 mg/100 kJ) is changed. Uridine-5′-monophosphate is retained as optional for consistency with EU 2016/127 and Codex CXS 72-1981 and due to no known safety concerns associated with the consumption of nucleotides. The minimum is removed to align with EU 2016/127, US and Canadian regulations and the recommendations of

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			the LSRO (Raiten et al. 1998), EC SCF (EC SCF 2003) and ESPGHAN (Koletzko et al. 2005). See 1st CFS, SD2, section 2.5.2 (FSANZ 2022c) and 2nd CFS, SD2, Table 7 (FSANZ 2023c) for information.
S29—8	**Optional nutritive substances in follow-on formula**	To set minimum and maximum amounts (where appropriate) of optional nutritive substances for FoF. Nutritive substances that are captured in the table to section S29—8 are not considered as an essential part of the composition in FoF for varying reasons. Some substances such as taurine and nucleotides have held voluntary permissions in FoF for over 20 years, consistent with international standards. While other substances have been permitted more recently via FSANZ's application process. The regulatory intent for all optional nutrients is to set a range that provides an appropriate amount of the substance that aids normal growth and development of infants and does not have any associate safety risks. All substances prescribed in section S29—8 are present in human milk or are an equivalent form (e.g. bovine lactoferrin is considered to provide nutritional equivalence when compared to human lactoferrin). Nutritive substances and the associated permitted range in the consequential variation are listed below.	The Code is changed. Justification for the prescribed range (minimums and maximums) is listed below. Where the composition aligns with that of IF, see rationale provided above for section S29—7.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	S29—8: 2′-fucosyllactose	2′-fucosyllactose permitted for use by Standard 1.5.2: NS – 96 mg/100 kJ.	The Code (NS – 96 mg/100 kJ) is not changed. The permission aligns with that for IF.
	S29—8: 3′-sialyllactose sodium salt	3′-sialyllactose sodium salt permitted for use by Standard 1.5.2: NS – 8 mg/100 kJ.	The Code (NS – 8 mg/100 kJ) is not changed. The permission aligns with that for IF.
	S29—8: 6′-sialyllactose sodium salt	6′-sialyllactose sodium salt permitted for use by Standard 1.5.2: NS – 16 mg/100 kJ.	The Code (NS – 16 mg/100 kJ) is not changed. The permission aligns with that for IF.
	S29—8: 2′-fucosyllactose and difucosyllactose	A combination of 2′-fucosyllactose and difucosyllactose, permitted for use by Standard 1.5.2: NS – 96 mg/100 kJ.	The Code (NS – 96 mg/100 kJ) is not changed. The permission aligns with that for IF.
	S29—8: 2′-fucosyllactose and lacto-N-neotetraose	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: NS – 96 mg/100 kJ which contains not more than 24 mg of lacto-N-neotetraose.	The Code (NS – 96 mg/100 kJ which contains not more than 24 mg of lacto-N-neotetraose) is not changed. The permission aligns with that for IF.
	S29—8: Adenosine-5′-monophosphate	Adenosine-5′-monophosphate: NS – 0.36 mg/100 kJ.	The Code (0.14 – 0.38 mg/100 kJ) is changed. The permission aligns with that for IF. See 2nd CFS, SD2, Table 10 (FSANZ 2023c) for information.
	S29—8: L-carnitine	L-carnitine: 0.30 – NS mg/100 kJ.	The Code (0.21 – 0.8 mg/100 kJ) is changed. L-carnitine is retained as optional as there is a lack of evidence to suggest the voluntary permission is not of benefit to infants and due to the addition of other complementary food sources and endogenous synthesis in older infants.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			Consistent with Codex CXS 72-1981 no maximum is specified. See 1st CFS, SD2, section 3.5.2 (FSANZ 2022c) and 2nd CFS, SD2, Table 10 (FSANZ 2023c) for information.
	S29—8: Choline	Choline: NS – 12 (GUL) mg/100 kJ.	The Code (0.17 – 7.1 mg/100 kJ) is changed. Choline is retained as optional as it can be synthesised endogenously and provided by other foods in the complementary diet of older infant. Voluntary permission is consistent with Codex CXS 156-1987. The range is consistent with IF and Codex CXS 72-1981. See 1st CFS, SD2, section 3.5.2 (FSANZ 2022c) and 2nd CFS, SD2, Table 10 (FSANZ 2023c) for information.
	S29—8: Cytidine-5′-monophosphate	Cytidine-5′-monophosphate: NS – 0.60 mg/100 kJ.	The Code (0.22 – 0.6 mg/100 kJ) is changed. The permission aligns with that for IF.
	S29—8: Guanosine-5′-monophosphate	Guanosine-5′-monophosphate: NS – 0.40 mg/100 kJ.	The Code (0.04 – 0.12 mg/100 kJ) is changed. The permission aligns with that for IF.
	S29—8: Inosine-5′-monophosphate	Inosine-5′-monophosphate: NS – 0.24 mg/100 kJ.	The Code (0.08 – 0.24 mg/100 kJ) is changed. The permission aligns with that for IF.
	S29—8: Lactoferrin	Lactoferrin: NS – 40 mg/100 kJ.	The Code (NS – 40 mg/100 kJ) is not changed. The permission aligns with that for IF.
	S29—8: lacto-N-tetraose	lacto-N-tetraose permitted for use by Standard 1.5.2: NS – 32 mg/100 kJ.	The Code (NS – 32 mg/100 kJ) is not changed. The permission aligns with that for IF.
	S29—8: Lutein	Lutein: 1.5 – 5.0 µg/100 kJ.	The Code (1.5 – 5.0 µg/100 kJ) is not changed.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			As these requirements have already been assessed and consulted through a statutory process (A594; FSANZ 2008) FSANZ did not reassess within P1028. See 2nd CFS, SD2, Table 10 (FSANZ 2023c) for information.
	S29—8: Myo-inositol	Myo-inositol: NS – 10 mg (GUL)/100 kJ.	The Code (1 – 9.5 mg/100 kJ) is changed. Myo-inositol is retained as optional and the minimum is removed as it can be synthesised endogenously and provided by other foods in the complementary diet of older infant. Voluntary permission is consistent with Codex CXS 156-1987. The range aligns with that for IF. See 1st CFS, SD2, section 3.5.2 (FSANZ 2022c) and 2nd CFS, SD2, Table 10 (FSANZ 2023c) for information.
	S29—8: Taurine	Taurine: NS – 2.9 mg/100 kJ.	The Code (0.8 – 3 mg/100 kJ) is changed. Taurine is retained as optional, with no minimum and with a corrected maximum of 2.9 mg/100 kJ due to no evidence of adverse effects, a history of safe use and based on alignment with Codex CXS 156-1987 and EU 2016/127. See 2nd CFS, SD2, section 7.1 (FSANZ 2023c) for information.
	S29—8: Uridine-5′-monophosphate	Uridine-5′-monophosphate: NS – 0.42 mg/100 kJ.	The Code (0.13 – 0.42 mg/100 kJ) is changed. The permission aligns with that for IF.
S29—9	**Permitted forms of nutritive substances**	Prescribes the permitted forms for nutritive substances intended for use as a nutritive substance when added to IFP.	The Code is changed. Codex CXS 72-1981 and Codex CXS 156-1987 use the Advisory Lists of Nutrient Compounds for Use in Foods

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	in infant formula products		for Special Dietary Uses Intended for Infants and Young Children (Codex CXG 10-1979) to identify permitted forms. Therefore, for permitted forms, consistency with the Codex CXS 72-1981 and Codex CXS 156-1987 is referred to in this table as consistency with Codex CXG 10-1979.
	S29—9: 2′-fucosyllactose	Permitted forms of 2′-fucosyllactose permitted for use by Standard 1.5.2: • 2′-fucosyllactose	The Code is not changed. As these requirements have already been assessed and consulted through a statutory process (A1155; FSANZ 2019) FSANZ did not reassess within P1028. See 1st CFS, SD2, section 2.5.2 (FSANZ 2022c) for information.
	S29—9: 3′-sialyllactose sodium salt	Permitted forms of 3′-sialyllactose sodium salt permitted for use by Standard 1.5.2: • 3′-sialyllactose sodium salt	The Code is not changed. As these requirements have already been assessed and consulted through a statutory process (A1265; FSANZ 2023f) FSANZ did not reassess within P1028.
	S29—9: 6'-sialyllactose sodium salt	Permitted forms of 6'-sialyllactose sodium salt permitted for use by Standard 1.5.2: • 6'-sialyllactose sodium salt	The Code is not changed. As these requirements have already been assessed and consulted through a statutory process (A1265; FSANZ 2023f) FSANZ did not reassess within P1028.
	S29—9: 2'-fucosyllactose and difucosyllactose	Permitted forms of A combination of 2′-fucosyllactose and difucosyllactose, permitted for use by Standard 1.5.2: • 2'-fucosyllactose and difucosyllactose	The Code is not changed. As these requirements have already been assessed and consulted through a statutory process (A1265; FSANZ 2023f) FSANZ did not reassess within P1028.
	S29—9: 2′-fucosyllactose and lacto-N-neotetraose	Permitted forms of A combination of: 2′-fucosyllactose permitted for use by Standard	The Code is not changed.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2: • 2′-fucosyllactose and lacto-N-neotetraose	As these requirements have already been assessed and consulted through a statutory process (A1155; FSANZ 2019) FSANZ did not reassess within P1028. See 1st CFS, SD2, section 2.5.2 (FSANZ 2022c) for information.
	S29—9: Adenosine-5′-monophosphate	Permitted forms of Adenosine-5′-monophosphate: • Adenosine-5′- monophosphate	The Code is not changed. The permitted forms are internationally aligned. See CP2, section 8.4 (FSANZ 2021b) for information.
	S29—9: L-carnitine	Permitted forms of L-carnitine: • L-carnitine • L-carnitine hydrochloride • L-carnitine tartrate	The Code is changed. L-carnitine remains a permitted form. L-carnitine hydrochloride and L-carnitine tartrate have been added as permitted forms. The permitted forms have no associated safety issues, as shown by inclusion in Codex CXS 72-1981 and by FSANZ's assessment of Application A1102- L-carnitine in Food. L-carnitine tartrate also has technological benefits such as being less hygroscopic. See CP2, section 8.2 (FSANZ 2021b) for information.
	S29—9: Choline	Permitted forms of Choline: • Choline chloride • Choline bitartrate • Choline • Choline citrate • Choline hydrogen tartrate	The Code is changed. Choline chloride and Choline bitartrate remain permitted forms. Choline, Choline citrate and Choline hydrogen tartrate have been added as permitted forms as they have a history of safe use in IFP, the bioavailability is comparable to other current permitted forms and choline hydrogen tartrate is an alternative name for choline bitartrate. The revised permissions align with Codex CXG 10-1979 and EU 2016/127. See CP2, section 8.1 (FSANZ 2021b) for information.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	S29—9: Cytidine-5′-monophosphate	Permitted forms of Cytidine-5′-monophosphate: • Cytidine-5′-monophosphate	The Code is not changed. The permitted forms are internationally aligned. See CP2, section 8.4 (FSANZ 2021b) for information.
	S29—9: Guanosine-5′-monophosphate	Permitted forms of Guanosine-5′-monophosphate: • Guanosine-5′-monophosphate • Guanosine-5′-monophosphate sodium salt	The Code is not changed. The permitted forms are internationally aligned. See CP2, section 8.4 (FSANZ 2021b) for information.
	S29—9: Inosine-5′-monophosphate	Permitted forms of Inosine-5′-monophosphate: • Inosine-5′-monophosphate • Inosine-5′-monophosphate sodium salt	The Code is not changed. The permitted forms are internationally aligned. See CP2, section 8.4 (FSANZ 2021b) for information.
	S29—9: Lactoferrin	Permitted forms of Lactoferrin: • Bovine lactoferrin	The Code is not changed. As these requirements have already been assessed and consulted through a statutory process (A1253; FSANZ 2023e) FSANZ did not reassess within P1028.
	S29—9: lacto-N-tetraose	Permitted forms of lacto-N-tetraose permitted for use by Standard 1.5.2: • lacto-N-tetraose	The Code is not changed. As these requirements have already been assessed and consulted through a statutory process (A1265; FSANZ 2019) FSANZ did not reassess within P1028.
	S29—9: Lutein	Permitted forms of Lutein: • Lutein from *Tagetes erecta L*.	The Code is not changed. As these requirements have already been assessed and consulted through a statutory process (A594; FSANZ 2008) FSANZ did not reassess within P1028.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			See 1st CFS, SD2, section 2.5.2 (FSANZ 2022c) and 2nd CFS, SD2, Tables 7 and 10 (FSANZ 2023c) for information.
	S29—9: Inositol	Permitted forms of Inositol: • Myo-Inositol	The Code is changed. The permitted form has been revised from inositol to myo-inositol to provide clarity and align with Codex CXS 72-1981 and EU 2016/127. See CP2, section 8.3 (FSANZ 2021b) for information.
	S29—9: Taurine	Permitted forms of Taurine: • Taurine	The Code is not changed. The original permission is retained.
	S29—9: Uridine-5′-monophosphate	Permitted forms of Uridine-5′-monophosphate: • Uridine-5′-monophosphate sodium salt	The Code is not changed. The permitted forms are internationally aligned. See CP2, section 8.4 (FSANZ 2021b) for information.
S29—9A	**Infant formula products—conditions on use of permitted nutritive substances**	Lactoferrin, in the permitted form of Bovine lactoferrin, may only be sold under the brand name Synlait during the exclusive use period which commenced on gazettal of Application A1253 – Bovine Lactoferrin in Infant Formula Products (21 April 2023) and ends 15 months after that date.	The Code is not changed. As these requirements have already been assessed and consulted through a statutory process (A1253; FSANZ 2023e) FSANZ did not reassess within P1028.
S29—10	**Required format for a nutrition information statement**	Prescribes the required format for a NIS for the purpose of IF and FoF in Standard 2.9.1. Section 2.9.1—25 provides that the *statement of nutrition information* required by section 2.9.1—24 for IF and FoF must be, subject to variations specified in section 2.9.1—25, in the same format specified in the	The Code is changed. The provision prescribes the format of the NIS to enable caregivers to compare products more easily. See AR, sections 4.17 and 4.18, Appendix 3, section 7; 1st CFS, SD3, section 3 (FSANZ 2022d) and 2nd CFS, SD3, sections 5 and 6 (FSANZ 2023d) for information.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		table (including headings, names and units) and state the nutrition information in the order specified in the table. *Units of measurement* • Vitamin E must be declared using milligrams. • Niacin must be declared using micrograms. *Names of certain vitamins* • The full names and number notations are required for niacin, pantothenic acid, riboflavin and thiamin. The Note refers to permitted variations to the table as specified in sections 2.9.1—24 and 2.9.1—25.	The units of measurement for Vitamin E and Niacin have changed from those indicated in the current Guideline format to reflect current industry practice, enable easier compliance with compositional requirements and greater consistency. Numbered notations were added to the names of the specified B vitamins to help caregivers who are more familiar with the number notations to identify them more readily. See AR, section 4.18 and Appendix 3, section 7 for information.
S29—10A	**Example of a nutrition information statement including quantities expressed as sold**	To provide an example of a NIS if the option of expressing quantity of food per 100 g powder or per 100 mL liquid concentrate is used.	The Code is changed. The provision provides an example of a NIS to illustrate the application of subsection 2.9.1—25(7). See AR, section 4.17 for information.
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**	Prescribes the permitted forms for vitamins, minerals and electrolytes intended for use as nutrients when added to IFP.	The Code is changed. Codex CXS 72-1981 and Codex CXS 156-1987 use the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (Codex CXG 10-1979) to identify permitted forms. Therefore, for permitted forms, consistency with the Codex CXS 72-1981 and Code CXS 156-1987 is referred to in this table as consistency with Codex CXG 10-1979.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			Submissions to the 2012 Consultation paper generally supported aligning the permitted forms of nutrients in Standard 2.9.1 with Codex CXG 10-1979 on the basis that these forms have been evaluated by Codex for nutritional adequacy and safety in IFP. Submitters did not support the removal of any currently permitted nutrient forms from Standard 2.9.1. See CP2, section 7.5 (FSANZ 2021b) for information. Except for niacin, vitamin A, pantothenic acid, copper, iron, magnesium, potassium and zinc there was general support to align permitted forms with Codex. See CP2, Table 7.17 (FSANZ 2021b) for information.
	S29—23: Vitamin A	Permitted forms of vitamin A: • *Retinol forms:* vitamin A (retinol), vitamin A acetate (retinyl acetate), vitamin A palmitate (retinyl palmitate), retinyl propionate • *Provitamin A forms*: beta-carotene	The Code is not changed. Due to a lack of safety concern and based on alignment with international regulations. See CP, SD1, sections 7.2.1 and 8.1.1 (FSANZ 2016a); CP2, section 7.2.1 (FSANZ 2021b) and 1st CFS, SD2, section 2.3.2 (FSANZ 2022c) for information.
	S29—23: Vitamin C	Permitted forms of vitamin C: • L-ascorbic acid • L-ascorbyl palmitate • calcium ascorbate • potassium ascorbate • sodium ascorbate	The Code is not changed. Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IF and align with Codex CXG 10-1979. See CP, SD1, section 8 (FSANZ 2016a) for information.
	S29—23: Vitamin D	Permitted forms of vitamin D: • vitamin D_2 (ergocalciferol) • vitamin D_3 (cholecalciferol) • vitamin D (cholecalciferol-cholesterol)	The Code is not changed. Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IF and align with Codex CXG 10-1979.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	S29—23: Thiamin	Permitted forms of thiamin: • thiamin hydrochloride • thiamin mononitrate	The Code is not changed Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IF and align with Codex CXG 10-1979. See CP, SD1, section 8 (FSANZ 2016a) for information.
	S29—23: Riboflavin	Permitted forms of riboflavin: • riboflavin • riboflavin-5′-phosphate, sodium	The Code is not changed. Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IF and align with Codex CXG 10-1979. See CP, SD1, section 8 (FSANZ 2016a) for information.
	S29—23: Niacin	Permitted forms of niacin: • niacinamide (nicotinamide)	The Code is not changed. Niacinamide (nicotinamide) has been evaluated by Codex for nutritional adequacy and safety in IF and align with Codex CXG 10-1979. Nicotinic acid is a permitted form in Codex CGX 10-1979, however FSANZ considered its permission was not required as nicotinamide has a lower risk of toxicity and serves the same biological function. See CP, SD1, sections 8 and 8.1.4 (FSANZ 2016a) and 1st CFS, SD2, section 4.1.2 (FSANZ 2022c) for information.
	S29—23: Vitamin B_6	Permitted forms of vitamin B_6: • pyridoxine hydrochloride • pyridoxine-5′-phosphate	The Code is not changed. Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IFP and align with Codex CXG 10-1979. See CP, SD1, section 8 (FSANZ 2016a) for information.
	S29—23: Folate	Permitted forms of folate:	The Code is not changed.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		• Folic acid	See CP2, section 7.2.2 (FSANZ 2021b).
	S29—23: Pantothenic acid	Permitted forms of pantothenic acid: • calcium pantothenate • dexpanthenol • D-panthenol • calcium D-pantothenate • sodium D-pantothenate	The Code is changed. Calcium pantothenate and dexpanthenol remain permitted forms. D-panthenol, calcium D-pantothenate and sodium D-pantothenate have been added as permitted forms. These are all permitted forms in Codex CXG 10-1979 and is consistent with EU 2016/127. Codex CXG 10-1979 also lists DL-panthenol as a permitted form. The physiological activity of the DL form of panthenol is half of the D-isomer. DL-panthenol was not included as a permitted form due to its decreased activity. See CP, SD1, section 8.1.3 (FSANZ 2016a) and 1st CFS, SD2, section 4.1.2 (FSANZ 2022c) for information.
	S29—23: Vitamin B_{12}	Permitted forms of vitamin B_{12}: • cyanocobalamin • hydroxocobalamin	The Code is not changed. Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IFP and align with Codex CXG 10-1979. See CP, SD1, section 8 (FSANZ 2016a) for information.
	S29—23: Biotin	Permitted forms of biotin: • d-biotin	The Code is not changed. Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IFP and align with Codex CXG 10-1979. See CP, SD1, section 8 (FSANZ 2016a) for information.
	S29—23: Vitamin E	Permitted forms of vitamin E: • dl-α-tocopherol • d-α-tocopherol concentrate	The Code is not changed. FSANZ did not consider additional permitted forms of vitamin E were required for IFP.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		• tocopherols concentrate, mixed • d-α-tocopheryl acetate • dl-α-tocopheryl acetate • d-α-tocopheryl acid succinate • dl-α-tocopheryl succinate	
	S29—23: Vitamin K	Permitted forms of vitamin K: • Vitamin K_1 as phylloquinone (phytonadione)	The Code is not changed. FSANZ did not consider additional permitted forms of vitamin K were required for IFP.
	S29—23: Calcium	Permitted forms of 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	The Code is not changed. Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IFP and align with Codex CXG 10-1979. See CP, SD1, section 8 (FSANZ 2016a) for information.
	S29—23: Chloride	Permitted forms of chloride: • calcium chloride • magnesium chloride • potassium chloride • sodium chloride	The Code is not changed. FSANZ did not consider additional permitted forms of chloride were required for IFP.
	S29—23: Chromium	Permitted forms of chromium: • chromium sulphate	The Code is not changed. While the express permission for chromium has been removed from IFP, the permitted form prescribed in

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			Schedule 29 is retained. This is on the basis that the table to section S29—23 prescribes forms for products other than IFP, such as food for infants and FSMP.
	S29—23: Copper	Permitted forms of copper: • copper gluconate • cupric sulphate • cupric citrate • cupric carbonate	The Code is changed. Copper gluconate, cupric sulphate and cupric citrate remain permitted forms. Cupric carbonate is added as a permitted form. Codex CXG 10-1979 lists cupric carbonate as an additional form of copper. Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IFP and align with Codex CXG 10-1979, including cupric carbonate. See CP, SD1, section 8 (FSANZ 2016a) and CP2, Table 7.17 (FSANZ 2021b) for information.
	S29—23: Iodine	Permitted forms of iodine: • potassium iodate • potassium iodide • sodium iodide	The Code is not changed. Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IFP and align with Codex CXG 10-1979. See CP, SD1, section 8 (FSANZ 2016a) for information.
	S29—23: Iron	Permitted forms of iron: • ferric ammonium citrate • ferric citrate • ferric pyrophosphate • ferrous bisglycinate • ferrous citrate • ferrous fumarate • ferrous gluconate • ferrous lactate • ferrous succinate	This Code is changed. Ferric citrate and ferrous bisglycinate have been added as permitted forms. These permitted forms align with Codex CXG 10-1979. They have been evaluated by Codex for nutritional adequacy and safety in IFP. See CP, SD1, sections 8 and 8.2.5 (FSANZ 2016a); CP2, Table 7.17 (FSANZ 2021b) and 1st CFS, SD2, Table 4.1.1 (FSANZ 2022c) for information.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		• ferrous sulphate	
	S29—23: Magnesium	Permitted forms of 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	The Code is changed. Magnesium hydroxide carbonate, magnesium hydroxide and magnesium salts of citric have been added as permitted forms. The permitted forms align with Codex CXG 10-1979. They have been evaluated by Codex for nutritional adequacy and safety in IFP. See CP, SD1, sections 8 and 8.2.2 (FSANZ 2016a); CP2, Table 7.17 (FSANZ 2021b) and 1st CFS, SD2, Table 4.1.1 (FSANZ 2022c) for information.
	S29—23: Manganese	Permitted forms of manganese: • manganese carbonate • manganese chloride • manganese citrate • manganese gluconate • manganese sulphate	This Code is not changed. Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IFP and align with Codex CXG 10-1979. See CP, SD1, section 8 (FSANZ 2016a) for information.
	S29—23: Molybdenum	Permitted forms of molybdenum: • sodium molybdate VI	The Code is not changed. While the express permission for molybdenum has been removed from IFP the permitted form prescribed in Schedule 29 is retained. This is on the basis that the Table to section S29—23 prescribes forms for products other than IFP, such as food for infants and FSMP. See CP, SD1, section 8 (FSANZ 2016a) for information.
	S29—23: Phosphorus	Permitted forms of phosphorus: • calcium glycerophosphate • calcium phosphate, dibasic • calcium phosphate, monobasic	The Code is not changed.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		• calcium phosphate, tribasic • magnesium phosphate, dibasic • potassium phosphate, dibasic • potassium phosphate, monobasic • potassium phosphate, tribasic • sodium phosphate, dibasic • sodium phosphate, monobasic • sodium phosphate, tribasic	Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IFP and align with Codex CXG 10-1979. See CP, SD1, section 8 (FSANZ 2016a) for information.
	S29—23: Potassium	Permitted forms of 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	The Code is changed. Potassium L-lactate has been added as a permitted form. The permitted form aligns with Codex CXG 10-1979 and has been evaluated by Codex for nutritional adequacy and safety in IFP. Potassium glycerophosphate is an existing permitted form in the Code. However, in Codex CXG 10-1979 this permission is limited to IFP for special medical purposes. No comments were received for submitters and the permission was retained. See CP, SD1, sections 8 and 8.2.3 (FSANZ 2016a) and CP2, Table 7.17 (FSANZ 2021b) for information.
	S29—23: Selenium	Permitted forms of selenium: • seleno methionine • sodium selenate • sodium selenite	The Code is not changed. Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IFP and align with Codex CXG 10-1979. See CP, SD1, section 8 (FSANZ 2016a) for information.
	S29—23: Sodium	Permitted forms of sodium: • sodium bicarbonate • sodium carbonate • sodium chloride	The Code is not changed. Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IFP and align with Codex CXG 10-1979.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		• 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	See CP, SD1, section 8 (FSANZ 2016a) for information.
	S29—23: Zinc	Permitted forms of zinc: • zinc acetate • zinc chloride • zinc citrate (zinc citrate dehydrate or zinc citrate trihydrate) • zinc gluconate • zinc lactate • zinc oxide • zinc sulphate	The Code is changed. Zinc citrate (zinc citrate dehydrate or zinc citrate trihydrate) and zinc lactate have been added as permitted forms. Permitted forms have been evaluated by Codex for nutritional adequacy and safety in IFP and align with Codex CXG 10-1979. See CP, SD1, section 8 (FSANZ 2016a) for information.
Standard 1.1.2—Definitions used throughout the Code			
1.1.2—2(3)	**Definitions - general**	Inserts the following updated definitions into Standard 1.1.2: • Inner package • Warning statement. Removes the following updated definitions from Standard 1.1.2: • Medium chain triglycerides • Protein substitute • Pre-term formula.	The Code is changed. Amended definitions that were revised, repealed or inserted to Standard 2.9.1 are consistently applied throughout the Code.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		These are consequential amendments to definitions as noted in Division 1 of the primary variation table (above). These amendments ensure changes made to the primary variation extend across the Code.	
1.1.2—3(2)	**Definitions - particular foods**	Inserts updated definitions for SMPPi, FoF, IF and IFP into Standard 1.1.2 under the particular foods subsection. These are consequential amendments to definitions as noted in Division 1 of the primary variation table (above). These amendments ensure changes made to the primary variation extend across the Code.	The Code is changed. Amended definitions that were revised, repealed or inserted to Standard 2.9.1 are consistently applied throughout the Code.
1.1.2—8(2)	**Definition of novel food**	Inserts the updated definition for novel foods into Standard 1.1.2. The new novel food definition is discussed in detail in the table entry below relating to Standard 1.5.1.	The Code is changed. Amended definitions that were revised, repealed or inserted to Standard 2.9.1 are consistently applied throughout the Code.
Standard 1.2.3—Information requirements – warning statements, advisory statements and declarations			
1.2.3—6	**What a mandatory declaration must state** 1.2.3—6(4)(b) – declarations about SMPPi	To refer to the new name of infant formula products specifically formulated for special medical purposes.	The Code is changed. The provision reflects the new name for the products – SMPPi.
	What a mandatory declaration must state	The Note states that Division 4 of Standard 2.9.1 applies to SMPPi and sets out	The Code is changed.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	1.2.3—6(4) Note 2	compositional and labelling requirements for such food.	The Note reflects the new name for the products – SMPPi.
Standard 1.3.1—Food additives			
1.3.1—3(2)	**Carry-over of food additives**	Excludes infant formula products from the carry-over of food additives. The intent is that: Carry-over (from raw materials and ingredients to the final food) is not permitted when there is no specific permission for the food additive in the IFP. Carry-over (from raw materials and ingredients to the final food) is permitted when there is a specific permission for the food additive in the IFP.	The Code is changed. The consequential variation does not allow carry-over of food additives for IFP. This is consistent with both Codex standards and EU Regulations. The reason for the change is to minimise food additive use and ensure the safety of IFP, which provide the sole source of nutrition to infants who are a vulnerable population.
1.3.1—4(6)(k)	**Maximum permitted levels of food additives in foods**	Prescribes that rosemary extract is calculated as the sum of carnosic acid and carnosol and that phosphoric acid and phosphates are calculated as phosphorus.	The Code is changed. This ensures phosphates are calculated as phosphorus which is consistent with Codex.
Standard 1.5.1—Novel foods			
1.5.1—2(2)	**Definition of novel food**	(1) In this Code: ***novel food*** means a non-traditional food that requires an assessment of the public health and safety considerations having regard to: (a) the potential for adverse effects in humans; or (b) the composition or structure of the food; or	The Code is changed (only subsection (2)). New subsection 1.5.1—2(2) provides that use of a food in or as FSMP and/or SMPPi does not constitute a 'history of safe consumption', meaning that food may still constitute a novel food and, as such, require pre-market assessment for use in foods other than FSMP and SMPPi.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		(c) the process by which the food has been prepared; or (d) the source from which it is derived; or (e) patterns and levels of consumption of the food; or (f) any other relevant matters. ***Note*** Possible categories of novel foods are described in guidelines issued by FSANZ. Categories of novel foods may include, but are not limited to, the following: • plants or animals and their components; • plant or animal extracts; • herbs, including extracts; • dietary macro-components; • single chemical entities; • microorganisms, including probiotics; • foods produced from new sources, or by a process not previously applied to food. ***non-traditional food*** means: (a) a food that does not have a history of human consumption in Australia or New Zealand; or (b) a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or (c) any other substance, where that substance, or the source from which it is derived, does not have a history of	

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		human consumption as a food in Australia or New Zealand. (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. The intent of the changes to the definition are to clarify that the use of a substance in a SMPPi does not constitute 'a history of human consumption' i.e. the substance may still meet the definition of a novel food as defined by subsections 1.1.2—8(1) and (2) and subsection 1.5.1—2(1).	
1.5.1—3	**Sale of novel foods**	Section 1.5.1—3 permits a food for retail sale may consist of, or have as an ingredient, a novel food if the requirements set out in that section are met. That section's requirements which set out when an IFP may consist of, or have as an ingredient, a novel food have been changed. New subsection (2) states that:	The Code is changed. This change is to emphasise that IFP have specific pre-market assessment requirements that go beyond the requirements for general foods. See 2nd CFS, section 4.1.3 (FSANZ 2023a) for information.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		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			
2.9.2—4	**Additional compositional requirements for cereal-based food for infants from the age of 6 months**	This is a consequential amendment required to reflect the amendments made to Schedule 29 by the consequential variation. The current reference to 'section S29—7' is changed to 'section S29—23'.	The Code is changed. The consequential variation amends clause numbering, to ensure the correct (renumbered) section is specified.
2.9.2—5	**Additional compositional requirements for cereal-based food for infants from the age of 4 months**	This is a consequential amendment required to reflect the amendments made to Schedule 29 by the consequential variation. The current reference to 'section S29—7' is changed to 'section S29—23'.	The Code is changed. The consequential variation amends clause numbering, to ensure the correct (renumbered) section is specified.
2.9.2—6(3)	**Additional compositional requirements for non-cereal-based food for infants**	This is a consequential amendment required to reflect the amendments made to Schedule 29 by the consequential variation. The current reference to 'section S29—7' is changed to 'section S29—23'.	The Code is changed. The consequential variation amends clause numbering, to ensure the correct (renumbered) section is specified.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
Standard 2.9.3—Formulated meal replacements and formulated supplementary foods			
2.9.3—3(2)(c)(iii)	**Compositional requirements for formulated meal replacements**	This is a consequential amendment required to reflect the amendments made to Schedule 29 by the consequential variation. The current reference to 'section S29—7' is changed to 'section S29—23'.	The Code is changed. The consequential variation amends clause numbering, to ensure the correct (renumbered) section is specified.
Standard 2.9.5—Food for special medical purposes			
2.9.5—6(1)(b)	**Permitted forms of particular substances**	This is a consequential amendment required to reflect the amendments made to Schedule 29 by the consequential variation. The current reference to 'section S29—7' is changed to 'section S29—23'.	The Code is changed. The consequential variation amends clause numbering, to ensure the correct (renumbered) section is specified.
Schedule 8—Food additive names and code numbers (for statement of ingredients)			
S8—2	**Food additive names and code numbers (for statement of ingredients)**	Inserts the following entries into the table for food additive names – *alphabetical listing* as newly permitted food additives: dl-Alpha-tocopherol 307c Potassium hydroxide 525 Sodium hydroxide 524	The Code is changed. The consequential variation reflects amendments made to Schedule 15.
	Food additive names and code numbers (for statement of ingredients)	Inserts the following entries into the table for Food additive names – *numerical listing* as newly permitted food additives: 307c dl-Alpha-tocopherol 524 Sodium hydroxide 525 Potassium hydroxide	The Code is changed. The consequential variation reflects amendments made to Schedule 15.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
Schedule 15—Substances that may be used as food additives			
S15—5	**Table of permissions for food additives**	Replace the current entries for food classes 13.1 – Infant formula products and subclasses, 13.1.1, 13.1.2 and 13.1.3.	The Code is changed. The consequential variation updates food additive permissions based on safety, technological justification and alignment with international regulations. As noted in subsection 1.3.1—3(2) carry-over permissions have been removed for IFP.
	Food class 13.1 – Infant formula products		
	S15—5: Lactic acid	Permits lactic acid (270) at GMP in IFP.	The Code is not changed. The permission remains consistent with Codex CXS 72-1981,GSFA and EU Regulations.
	S15—5: Ascorbic acid	Permits ascorbic acid (300) at an MPL of 50 mg/L in FoF only.	The Code is changed. The amendment is consistent with Codex CXS 156-1987. See 2nd CFS, SD1, section 3.3.1 (FSANZ 2023b) for information.
	S15—5: Sodium ascorbate	Permits sodium ascorbate (301) at an MPL of 50 mg/L in FoF only.	The Code is changed. The amendment is consistent with Codex CXS 156-1987. See 2nd CFS, SD1, section 3.3.1 (FSANZ 2023b) for information.
	S15—5: Sodium ascorbate	Permits sodium ascorbate (301) at an MPL of 75 mg/L in IFP. May only be added to polyunsaturated fatty acid preparations.	The Code is changed. Permission is added to nutrient preparations of polyunsaturated fatty acids. The change is consistent with EU Regulations and Codex CXG 10-1979.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			See AR, section 4.13 for information.
	S15—5: Calcium ascorbate	Permits calcium ascorbate (302) at an MPL of 50 mg/L in FoF only.	The Code is changed. The amendment is consistent with Codex CXS 156-1987. See 2nd CFS, SD1, section 3.3.1 (FSANZ 2023b) for information.
	S15—5: Ascorbyl palmitate	Permits ascorbyl palmitate (304) at an MPL of 10 mg/L in IFP.	The Code is not changed. The permission remains consistent with Codex CXS 72-1981, GSFA and EU Regulations.
	S15—5: Ascorbyl palmitate	Permits ascorbyl palmitate (304) at an MPL of 50 mg/L in FoF only.	The Code (10 mg/L) is changed. The amendment is consistent with Codex CXS 156-1987. See 2nd CFS, SD1, section 3.3.2 (FSANZ 2023b) for information.
	S15—5: Tocopherols concentrate	Permits tocopherols concentrate, mixed (307b) at an MPL of 10 mg/L in IFP.	The Code is not changed. The permission remains consistent with Codex CXS 72-1981, GSFA and EU Regulations.
	S15—5: Tocopherols concentrate	Permits tocopherols concentrate, mixed (307b) at an MPL 30 mg/L in FoF only.	The Code (MPL 10 mg/L) is changed. The amendment is consistent with Codex CXS 156-1987. See 2nd CFS, SD1, section 3.3.2 (FSANZ 2023b) for information.
	S15—5: dl-Alpha-tocopherol	Permits dl-Alpha-tocopherol (307c) at an MPL of 10 mg/L in IFP.	The Code is changed. Risk assessment conducted and confirmed safe and suitable for IFP. The change is consistent with EU Regulations. See AR, section 4.13.1 for information.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	S15—5: dl-Alpha-tocopherol	Permits dl-Alpha-tocopherol (307c) at an MPL of 30 mg/L in FoF only.	The Code is changed. Risk assessment conducted and confirmed safe and suitable for IFP. The change is consistent with Codex CXS 156-1987. See AR, section 4.13.1 for information.
	S15—5: Gamma-tocopherol	Permits gamma-tocopherol (308) at an MPL of 10 mg/L in IFP.	The Code is changed. The amendment is consistent with EU Regulations. See 2nd CFS, SD1, section 3.3.2 (FSANZ 2023b) for information.
	S15—5: Delta-tocopherol	Permits delta-tocopherol (309) at an MPL of 10 mg/L in IFP.	The Code is changed. The amendment is consistent with EU Regulations. See 2nd CFS, SD1, section 3.3.2 (FSANZ 2023b) for information.
	S15—5: Lecithin	Permits lecithin (322) at an MPL of 5,000 mg/L in IFP.	The Code is not changed. The permission remains consistent with Codex CXS 72-1981 and GSFA.
	S15—5: Citric acid	Permits citric acid (330) at GMP in IFP.	The Code is not changed. The permission remains consistent with Codex CXS 72-1981, GSFA and EU Regulations.
	S15—5: Sodium citrates	Permits sodium citrates (331) at GMP in IFP.	The Code is not changed. The permission remains consistent with Codex CXS 72-1981 and EU Regulations.
	S15—5: Potassium citrates	Permits potassium citrates (332) at GMP in IFP.	The Code is not changed.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			The permission remains consistent with Codex CXS 72-1981 and EU Regulations.
	S15—5: Calcium citrates	Permits calcium citrates (333) at an MPL of 0.1 mg/L in IFP, as calcium and may only be added as part of a nutrient preparation.	The Code is changed. Permission is added only to nutrient preparations. The change is consistent with EU Regulations. See AR, section 4.13.2 for information.
	S15—5: Phosphoric acid	Permits phosphoric acid (338) at an MPL of 450 mg/L in IFP.	The Code is changed. The change is consistent with Codex CXS 72-1981 and EU Regulations. The permission applies to both IF and FoF. See AR, section 4.13.6 for information.
	S15—5: Sodium phosphates	Permits sodium phosphates (339) at an MPL of 450 mg/L in IFP.	The Code is changed. The change is consistent with Codex CXS 72-1981 and EU Regulations. The permission applies to both IF and FoF. See AR, section 4.13.6 for information.
	S15—5: Potassium phosphates	Permits potassium phosphates (340) at an MPL of 450 mg/L in IFP.	The Code is changed. The change is consistent with Codex CXS 72-1981 and EU Regulations. The permission applies to both IF and FoF. See AR, section 4.13.6 for information.
	S15—5: Carrageenan	Permits carrageenan (407) at an MPL of 300 mg/L, only in a liquid product.	The Code is not changed. The permission remains consistent with Codex CXS 72-1981 and GSFA.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	S15—5: Locust bean (carob bean) gum	Permits locust bean (carob bean) gum (410) at an MPL of 1,000 mg/L in IFP.	The Code is not changed. The permission remains consistent with Codex CXS 72-1981 and GSFA.
	S15—5: Guar gum	Permits guar gum (412) at an MPL of 1,000 mg/L in IFP, only in a liquid product that contains hydrolysed protein.	The Code is changed. The change relates to the addition of a condition statement. This change is consistent with Codex CXS 72-1981 and GSFA and EU Regulations. See 2nd CFS, SD1, section 3.3.7 (FSANZ 2023b) for information.
	S15—5: Gum arabic (acacia)	Permits gum arabic (acacia) (414) at an MPL of 10 mg/L in IFP, may only be added as part of a nutrient preparation.	The Code is changed. Permission is added only to nutrient preparations. This change is consistent with EU Regulations and Codex CXG 10-1979 and GSFA. See AR, section 4.13 for information.
	S15—5: Pectins	Permits pectins (440) at an MPL of 10,000 mg/L in FoF only.	The Code is changed. The amendment is consistent with Codex CXS 156-1987. See 2nd CFS, SD1, section 3.3.9 (FSANZ 2023b) for information, noting the error: MPL stated as 1,000 mg/L when meant to be 10,000 mg/L as per the draft variation)
	S15—5: Mono- and diglycerides of fatty acids	Permits mono- and diglycerides of fatty acids (471) at an MPL of 4,000 mg/L in IFP.	The Code is not changed. The permission remains consistent with Codex CXS 72-1981 and GSFA and EU Regulations.
	S15—5: Citric and fatty acid esters of glycerol	Permits citric and fatty acid esters of glycerol (472c) at an MPL of 7,500 mg/L in IFP, only in a powdered product.	The Code is changed. The amendment is consistent with Codex CXS 72-1981 and GSFA and EU Regulations.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	S15—5: Citric and fatty acid esters of glycerol	Permits citric and fatty acid esters of glycerol (472c) at an MPL of 9,000 mg/L in IFP, only in a liquid product.	The Code is changed. The amendment is consistent with Codex CXS 72-1981 and GSFA and EU Regulations.
	S15—5: Sodium carbonates	Permits sodium carbonates (500) at an MPL of 2,000 mg/L in IFP.	The Code is changed. The amendment is consistent with Codex CXS 72-1981 and GSFA. See CP1, section 2.4.2 (FSANZ 2021a) and 1st CFS, SD1, section 3.5.1 (FSANZ 2022b) for information. FSANZ notes that it did not add condition statements relating to complying with various maximum limits of salts in other sections of the Code with the food additive permissions as per Codex and EU Regulations since they must be complied with regardless. This note applies to other acidity regulators below, INS 501, 524, 525 and 526.
	S15—5: Potassium carbonates	Permits potassium carbonates (501) at an MPL of 2,000 mg/L in IFP.	The Code is changed. The amendment is consistent with Codex CXS 72-1981 and GSFA. See CP1, section 2.4.2 (FSANZ 2021a) and 1st CFS, SD1, section 3.5.1 (FSANZ 2022b) for information.
	S15—5: Sodium hydroxide	Permits sodium hydroxide (524) at an MPL of 2,000 mg/L in IFP.	The Code is changed. The amendment is consistent with Codex CXS 72-1981 and GSFA. See CP1, section 2.4.2 (FSANZ 2021a) and 1st CFS, SD1, section 3.5.1 (FSANZ 2022b) for information.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	S15—5: Potassium hydroxide	Permits potassium hydroxide (525) at an MPL of 2,000 mg/L in IFP.	The Code is changed. The amendment is consistent with Codex CXS 72-1981 and GSFA. See CP1, section 2.4.2 (FSANZ 2021a) and 1st CFS, SD1, section 3.5.1 (FSANZ 2022b) for information.
	S15—5: Calcium hydroxide	Permits calcium hydroxide (526) at an MPL of 2,000 mg/L in IFP.	The Code (GMP) is changed. The amendment is consistent with Codex CXS 72-1981 and GSFA. See CP1, section 2.4.2 (FSANZ 2021a) and 1st CFS, SD1, section 3.5.1 (FSANZ 2022b) for information.
	S15—5: Silicon dioxide (amorphous)	Permits silicon dioxide (amorphous) (551) at an MPL of 10 mg/L in IFP, may only be added as part of a nutrient preparation.	The Code is changed. Permission is added only to nutrient preparations. This change is consistent with EU Regulations, Codex CXG 10-1979 and GSFA. See 2nd CFS, SD1, section 3.3.14 (FSANZ 2023b) for information.
	S15—5: Distarch phosphate	Permits distarch phosphate (1412) at an MPL of 5,000 mg/L, with two conditions: • Soy based IFP (other than FoF) singly or in combination with 1413, 1414 and 1440. • Soy based FoF singly or in combination with 1413, 1414 and 1422.	The Code is changed. The MPL for distarch phosphate in infant formula products is required to be added in accordance with two condition statements. This is consistent with Codex CXS 72-1981 and GSFA. Requirements for use in SMPPi are captured separately below.
	S15—5: Phosphated distarch phosphate	Permits phosphated distarch phosphate (1413) at an MPL of 5,000 mg/L, with two conditions:	The Code is changed. The MPL for phosphated distarch phosphate in infant formula products is required to be added in accordance

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		• Soy based IFP (other than FoF) singly or in combination with 1412, 1414 and 1440. • Soy based FoF singly or in combination with 1412, 1414 and 1422.	with two condition statements. This is consistent with Codex CXS 72-1981 and GSFA. Requirements for use in SMPPi are captured separately below.
	S15—5: Acetylated distarch phosphate	Permits acetylated distarch phosphate (1414) at an MPL of 5,000 mg/L, with two conditions: • Soy based IFP (other than FoF) singly or in combination with 1412, 1413 and 1440. • Soy based FoF singly or in combination with 1412, 1413 and 1422.	The Code is changed. The MPL for acetylated distarch phosphate in infant formula products is required to be added in accordance with two condition statements. This is consistent with Codex CXS 72-1981 and GSFA. Requirements for use in SMPPi are captured separately below.
	S15—5: Acetylated distarch adipate	Permits acetylated distarch adipate (1422) at an MPL of 5,000 mg/L, with the condition statement: • Soy based FoF singly or in combination with 1412, 1413 and 1414.	The Code is changed. The condition statement has harmonised with Codex CXS 156-1987. See 2nd CFS, SD1, section 3.3.12 (FSANZ 2023b) for information.
	S15—5: Hydroxypropyl starch	Permits hydroxypropyl starch (1440) at an MPL of 5,000 mg/L, with the condition statement: • Soy based IFP (other than FoF) singly or in combination with 1412, 1413 and 1414.	The Code is changed. The MPL for hydroxypropyl starch in soy based IFP (other than FoF) has been lowered from 25,000 to 5,000 mg/L. The MPL is also required to be added in accordance with the condition statements This is consistent with Codex CXS 72-1981 and GSFA.
	S15—5: Starch sodium octenylsuccinate	Permits starch sodium octenylsuccinate (1450) at an MPL of 100 mg/L in IFP, may only be added as part of a nutrient preparation.	The Code is changed. The permission is added only to nutrient preparations. The change is consistent with Codex CXG 10-1979 and EU Regulations. See AR, section 4.13 for information.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	S15—5: Starch sodium octenylsuccinate	Permits starch sodium octenylsuccinate (1450) at an MPL of 1,000 mg/L in IFP, may only be added to polyunsaturated fatty acid preparations.	The Code is changed. The permission is added only to polyunsaturated fatty acid preparations. The change is consistent with EU Regulations. See AR, section 4.13 for information.
	Food class 13.1.1 – Special medical purpose products for infants		
	S15—5: Calcium carbonates	Permits calcium carbonates (170) at GMP in SMPPi.	The Code is changed. The consequential variation inserts a new SMPPi category. This permission is consistent with EU Regulations.
	S15—5: Ascorbyl palmitate	Permits ascorbyl palmitate (304) at an MPL of 100 mg/L in SMPPi.	The Code is changed. The consequential variation inserts a new SMPPi category. This permission is consistent with EU Regulations.
	S15—5: Calcium citrates	Permits calcium citrates (333) at GMP in SMPPi.	The Code is changed. The consequential variation inserts a new SMPPi category. This permission is consistent with EU Regulations. See AR, section 4.13.2 for information.
	S15—5: Phosphoric acid	Permits phosphoric acid (338) at an MPL of 450 mg/L in SMPPi, for pH adjustment only.	The Code is changed. The consequential variation inserts a new SMPPi category. This permission is consistent with EU Regulations, where phosphoric acid has the technological purpose as an acidity regulator to reduce the pH of the solution during manufacturing. See 2nd CFS, SD1, section 3.3.4 (FSANZ 2023b) for information.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	S15—5: Sodium phosphates	Permits sodium phosphates (339) at an MPL of 450 mg/L in SMPPi.	The Code is changed. The consequential variation inserts a new SMPPi category. This permission is consistent with EU Regulations. See 2nd CFS, SD1, section 3.3.4 (FSANZ 2023b) for information.
	S15—5: Potassium phosphates	Permits potassium phosphates (340) at an MPL of 450 mg/L in SMPPi.	The Code is changed. The consequential variation inserts a new SMPPi category. This change is consistent with EU Regulations. See 2nd CFS, SD1, section 3.3.4 (FSANZ 2023b) for information.
	S15—5: Calcium phosphates	Permits calcium phosphates (341) at an MPL of 450 mg/L in SMPPi.	The Code is changed. The consequential variation inserts a new SMPPi category. This permission is consistent with EU Regulations. See 2nd CFS, SD1, section 3.3.4 (FSANZ 2023b) for information.
	S15—5: Sodium alginate	Permits sodium alginate (401) at an MPL of 1,000 mg/L in SMPPi, 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.	The Code is changed. The consequential variation inserts a new SMPPi category. This permission is consistent with EU Regulations. See 2nd CFS, SD1, section 3.3.5 (FSANZ 2023b) for information.
	S15—5: Carrageenan	Permits carrageenan (407) at an MPL of 1,000 mg/L in SMPPi, only in a liquid product	The Code is changed.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		that contain hydrolysed proteins and/or amino acids.	The consequential variation inserts a new SMPPi category. A new condition statement is included to be consistent with Codex CXS 72-1981 and GSFA.
	S15—5: Locust bean (carob bean) gum	Permits locust bean (carob bean) gum (410) at an MPL of 5,000 mg/L in SMPPi, only in a product specifically formulated for reduction of gastro-oesophageal reflux.	The Code is changed. The consequential variation inserts a new SMPPi category. This permission is consistent with EU Regulations. The MPL was halved from 10,000 mg/L in the EU to 5,000 mg/L as that was a maximum use level required from information provided from industry. See 2nd CFS, SD1, section 3.3.6 (FSANZ 2023b) for information.
	S15—5: Guar gum	Permits guar gum (412) at an MPL of 10,000 mg/L in SMPPi, may only be used in a product that contains one or more of hydrolysed proteins, peptides and amino acids.	The Code is changed. The consequential variation inserts a new SMPPi category. This permission is consistent with EU Regulations. See 2nd CFS, SD1, section 3.3.7 (FSANZ 2023b) for information.
	S15—5: Xanthan gum	Permits xanthan gum (415) at an MPL of 1,200 mg/L in SMPPi, only in a product that is based on hydrolysed protein, amino acids or peptides.	The Code is changed. The consequential variation inserts a new SMPPi category. This permission is consistent with EU Regulations. The EFSA opinion concluded that it is safe for the proposed purpose at an MPL of 1,200 mg/L, as an update of the earlier JECFA assessment of safety at 1,000 mg/L. It was agreed it was therefore appropriate to only have one condition statement, not two as had been proposed in the 2nd CFS, SD1 (FSANZ 2023b). See AR, section 4.13.3 for information.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
	S15—5: Pectins	Permits pectins (440) at an MPL of 2,000 mg/L in SMPPi, only in a liquid product that contain hydrolysed protein.	The Code is changed. The consequential variation inserts a new SMPPi category. This permission is consistent with Codex CXS 72-1981. See 2nd CFS, SD1, section 3.3.9 (FSANZ 2023b) for information.
	S15—5: Pectins	Permits pectins (440) at an MPL of 5,000 mg/L in SMPPi, only in a product formulated for infants with gastro-intestinal disorders.	The Code is changed. The consequential variation inserts a new SMPPi category. This permission is consistent with EU Regulations. The MPL was halved from 10,000 mg/L in the EU to 5,000 mg/L. This is due to an EFSA 2021 opinion that use levels up to 5,000 mg/L were appropriate. See 2nd CFS, SD1, section 3.3.9 (FSANZ 2023b) for information.
	S15—5: Mono- and diglycerides of fatty acids	Permits mono- and diglycerides of fatty acids (471) at an MPL of 5,000 mg/L in SMPPi, only in product formulated for diets devoid of proteins.	The Code is changed. The consequential variation inserts a new SMPPi category. A condition statement has been added. This change is consistent with EU Regulations.
	S15—5: Diacyltartaric and fatty acid esters of glycerol	Permits diacyltartaric and fatty acid esters of glycerol (472e) at an MPL of 400 mg/L in SMPPi.	The Code is changed. The Code prescribes diacyltartaric and fatty acid esters at an MPL of 400 mg/L in IFPSDU based on a protein substitute. The consequential variation varies the permission to apply the MPL to the SMPPi category. The permission for diacyltartaric and fatty acid esters is not prescribed in Codex CXS 72-1981 or EU Regulations. The use of this food additive has been retained due to use date in Australian and New Zealand SMPPi products.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			See AR, section 4.13.4 for information.
	S15—5: Distarch phosphate	Permits distarch phosphate (1412) at an MPL of 25,000 mg/L in SMPPi, with three conditions: • IFP (other than FoF) singly or in combination with 1413, 1414 and1440. • FoF singly or in combination with 1413, 1414 and 1422. • May only be used in a product that contains hydrolysed proteins, amino acids or both.	The Code is changed. The consequential variation inserts a new SMPPi category. The condition statement for IFP has not been amended as it is consistent with Codex CXS 72-1981 and GSFA. The condition statement for FoF has been amended to be consistent with Codex CXS 156-1987. The condition statement for products that contains hydrolysed proteins, amino acids or both is consistent with Codex CXS 72-1981, CXS 156-1987 and GSFA.
	S15—5: Phosphated distarch phosphate	Permits phosphated distarch phosphate (1413) at an MPL of 25,000 mg/L in SMPPi, with three conditions: • IFP (other than FoF) singly or in combination with 1412, 1414 and1440. • FoF singly or in combination with 1412, 1414 and 1422. • May only be used in a product that contains hydrolysed proteins, amino acids or both.	The Code is changed. The consequential variation inserts a new SMPPi category. The condition statement for IFP is not changed from the Code. This is consistent with Codex CXS 72-1981 and GSFA. The condition statement for FoF has been amended to be consistent with the Codex CXS 156-1987. The condition statement for products that contains hydrolysed proteins, amino acids or both is consistent with Codex CXS 72-1981, CXS 156-1987 and GSFA.
	S15—5: Acetylated distarch phosphate	Permits acetylated distarch phosphate (1414) at an MPL of 25,000 mg/L in SMPPi, with three conditions: • IFP (other than FoF) singly or in combination with 1412, 1413 and1440.	The Code is changed. The consequential variation inserts a new SMPPi category. The condition statement for IFP is not changed from the Code. This is consistent with Codex CXS 72-1981 and

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		• FoF singly or in combination with 1412, 1413 and 1422. • May only be used in a product that contains hydrolysed proteins, amino acids or both.	GSFA. The condition statement for FoF has been written to be consistent with Codex CXS 156-1987 standard. The condition statement for products that contains hydrolysed proteins, amino acids or both is consistent with Codex CXS 72-1981, Codex CXS 156-1987 and GSFA.
	S15—5: Acetylated distarch adipate	Permits acetylated distarch adipate (1422) at an MPL of 25,000 mg/L in SMPPi, with two conditions: • FoF singly or in combination with 1412, 1413 and 1414. • May only be used in a product that contains hydrolysed proteins, amino acids or both.	The Code is changed. The consequential variation inserts a new SMPPi category. The condition statements are amended to be consistent with Codex CXS 156-1987. See 2nd CFS, SD1, section 3.3.12 (FSANZ 2023b) for information.
	S15—5: Hydroxypropyl starch	Permits hydroxypropyl starch (1440) at an MPL of 25,000 mg/L in SMPPi, with two conditions: • IFP (other than FoF) singly or in combination with 1412, 1413 and 1414. • May only be used in a product that contains hydrolysed proteins, amino acids or both.	The Code is changed. The consequential variation inserts a new SMPPi category. The IFP condition is not changed from the Code. This is consistent with Codex CXS 72-1981 and GSFA. The condition statement for products that contains hydrolysed proteins, amino acids or both is also consistent with Codex CXS 72-1981 and GSFA.
	S15—5: Starch sodium octenylsuccinate	Permits starch sodium octenylsuccinate (1450) at an MPL of 20,000 mg/L in SMPPi, may only be used in a product that contains hydrolysed proteins, amino acids or both.	The Code is changed. The consequential variation inserts a new SMPPi category. The permission and condition statement are consistent with Codex CXS 72-1981 and GSFA. The MPL is also consistent with EU Regulations.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			See 2nd CFS, SD1, section 3.3.13 (FSANZ 2023b) for information.
Schedule 19—Maximum levels of contaminants and natural toxicants			
S19—4	**Maximum level of metal contaminants**	Prescribes maximum levels of metal contaminants within the table to section S19—4.	The Code is changed. MLs have been amended on the following basis: • contaminants that present a significant risk to public health and safety • foods that significantly contribute to the dietary exposure of the contaminant • ensure that levels are as low as reasonably achievable (ALARA) • consistency with Codex levels, where possible. However, harmonisation with Codex is secondary to measures put in place to protect the public health and safety of Australians and New Zealanders. The outcome of the assessment in relation to contaminants in IFP for this proposal related only to the MLs for lead and aluminium.
	S19—4: Lead	Prescribes an ML of 0.01 mg/kg for lead in IFP.	The Code is changed. The ML for lead was lowered from 0.02 mg/kg to 0.01 mg/kg. Reducing the lead contamination ML by half may lead to potentially improved health outcomes for formula fed infants. See CP1, section 3.3.5 (FSANZ 2021a) for information.
	S19—4: Aluminium	Prescribes the following MLs for aluminium: • mg/kg for soy-based infant formula products.	The Code is changed. The aluminium MLs have been moved from Standard 2.9.1 into Schedule 19.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		• 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). • 0.2 mg/kg for special medical purpose product for infants formulated for pre-term infants.	The units have been changed from mg/100 mL to mg/kg to be consistent with how ML units are expressed within section S19—4. The ML for aluminium in soy-based IFP has been left at 1.0 mg/kg. This is because some soy-based IFP manufacturers may not be able to consistently meet a lower ML. To ensure certainty and not produce an unintended gap the aluminium MLs were amended so that the aluminium ML for IF, FoF and SMPPi (excluding those formulated for pre-term infants) is 0.5 mg/kg. The ML for the new category of SMPPi formulated for pre-term infants is 0.2 mg/kg, consistent with the current category of pre-term formula. See AR, section 4.14.2 for information.
Schedule 25—Permitted novel foods			
S25—2	**Sale of novel foods**	Prescribes permitted novel foods for section 1.5.1—3 and their associated conditions for use.	The Code is changed. The condition statement paired with other associated changes to the novel food definition and sale of novel foods clearly requires that novel foods are only allowed in IFP if expressly permitted in Schedule 25. Further, the addition must be made in accordance with any corresponding condition statement. Previous condition statements in Schedule 25 were inconsistent; some permitted the use of a novel food in IFP whereas some restricted the use of a novel food, creating confusion. Amending the Code to only include express permissions in this way creates consistency and clarity.

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
			The variations to this table (outlined below) are to indicate clearly which novel foods are permitted for use in IFP and which are not. See 2nd CFS, section 4.2 (FSANZ 2023a) for information.
	S25—2: Dried marine micro-algae (Schizochytrium sp.) rich in docosahexaenoic acid (DHA)	Permits the addition of dried marine micro-algae (Schizochytrium sp.) rich in DHA as a novel food in to IFP in accordance with Standard 2.9.1. The condition statement has been amended to note that this novel food may be permitted in IFP in accordance with permissions within Standard 2.9.1.	The Code is change. This permission statement now notes that this novel food may be added to IFP in accordance with Standard 2.9.1. This novel food can also be added to other general foods consistent with the permission granted through Application A428 (ANZFA 2002b). As these requirements have already been assessed and consulted through a statutory process, FSANZ did not reassess within P1028. See 2nd CFS, section 4.1.3 (FSANZ 2023a) for information.
	S25—2: Oil derived from marine micro-algae Schizochytrium sp. (American Type Culture Collection (ATCC) PTA-9695)	Only permits the addition of oil derived from marine micro-algae Schizochytrium sp. (American Type Culture Collection (ATCC) PTA-9695) as a novel food in to IFP in accordance with Standard 2.9.1. This novel food is not permitted in other general food.	The Code is change. This permission statement now notes that this novel food may only be added to IFP and not other foods. This is consistent with the permission granted through Application A1124 (FSANZ 2017). As these requirements have already been assessed and consulted through a statutory process FSANZ did not reassess within P1028.
	S25—2: Oil derived from marine micro-algae (Schizochytrium sp.) rich in docosahexaenoic acid (DHA)	Permits the addition of oil derived from marine micro-algae (Schizochytrium sp.) rich in DHA as a novel food in to IFP in accordance with Standard 2.9.1. The condition statement has been amended to note that this novel food may be permitted	The Code is change. This permission statement now notes that this novel food may be added to IFP in accordance with Standard 2.9.1. This novel food can also be added to other general foods consistent with the permission granted through Application A428 (ANZFA 2002b). As these requirements

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		in IFP in accordance with permissions within Standard 2.9.1.	have already been assessed and consulted through a statutory process FSANZ did not reassess within P1028.
	S25—2: Oil derived from marine micro-algae (Ulkenia sp.) rich in docosahexaenoic acid (DHA)	Permits the addition of Oil derived from marine micro-algae (Ulkenia sp.) rich in DHA as a novel food in to IFP in accordance with Standard 2.9.1. The condition statement has been amended to note that this novel food may be permitted in IFP in accordance with permissions within Standard 2.9.1.	The Code is change. This permission statement now notes that this novel food may be added to IFP in accordance with Standard 2.9.1. This novel food can also be added to other general foods consistent with the permission granted through Application A522 (FSANZ 2005). As these requirements have already been assessed and consulted through a statutory process FSANZ did not reassess within P1028.
	S25—2: Isomalto-oligosaccharide	Restricts the addition of isomalto-oligosaccharide from food for infants and FSFYC. As there is no express permission for IFP, this novel food cannot be added to IFP. This is not a change to the permission and the regulatory intent remains the same. The intent of this change is to remove any reference to IFP from the previous wording, providing regulatory clarity and consistency with other items in the table.	The Code is changed. Previously this permission stated that this substance 'must not be added to infant formula products'. This wording was a restriction of use in IFP, which did not align with the new requirement in subsection 1.5.3—3(2) to have an express permission in the Code for the use of any novel food in IFP. While the regulatory intent is the same, the rationale for this change is to have consistent wording in the table. See 2nd CFS, section 4.1.3 (FSANZ 2023a) for information.
	S25—2: Rapeseed protein isolate	Restricts the use of rapeseed protein isolate from food for infants. As there is no express permission for IFP, this novel food cannot be added to IFP. This is not a change to the permission and the regulatory intent remains the same. The intent of this change is to remove any reference to IFP from the previous wording,	The Code is changed. Previously this permission stated in subsection 2(a) that this substance 'must not be added to infant formula products'. This wording was a restriction of this substance's use in IFP, which no longer aligns with the new requirement in subsection 1.5.3—3(2) to have an express permission in the Code for the use of a novel food in IFP. While the

Subsection	*Name and description*	*Regulatory intent of the consequential variation*	*Reason for the change (or no change)*
		providing regulatory clarity and consistency with other items in the table.	regulatory intent is the same, the rationale for this change is to have consistent wording in the table and to align with the subsection 1.5.3—3(2) above which inserts express permissions in IFP only. See 2nd CFS, section 4.1.3 (FSANZ 2023a) for information.
	S25—2: Trehalose	Permits the addition of trehalose to IFP only as a cryo-preservative for L(+) lactic acid producing microorganisms. This is a change to the existing permission via a new condition statement which expressly permits it in IFP but only for use as a cryo-preservative for LAM.	The Code is changed. The rationale for this change is that the use of trehalose as a cryo-preservative in IFP does not pose a safety risk for infants for the following reasons: • The substance has been approved in multiple jurisdictions and in the Code for use in all foods, including IF products, since 2003. • As a cryo-preservative for LAM, the potential exposure to infants is very low and unlikely to pose a health risk. • FSANZ is unaware of any evidence that the substance used at levels needed for cryo-preservation of added LAM is associated with adverse health outcomes for infants. The permission for trehalose in Schedule 25 has been amended to explicitly state the permission for use is only for a cryo-preservative purpose for LAMP in IFP (and not as a carbohydrate source). See 2nd CFS, section 4.3.5 (FSANZ 2023a). for information.

References

ANZFA (1999) Preliminary Inquiry Report. Proposal P93 – Review of Infant Formula. Australia New Zealand Food Authority, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/P93%20-%20Prelim%20IR%20ATTACH%204.zip

ANZFA (2002a) Supplementary Final Assessment (Inquiry – S.24) Report. Proposal P93 – Review of Infant Formula. Australia New Zealand Food Authority, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/proposals/proposalp93reviewofinfantformula/p93finalassessreport1397

ANZFA (2002b) A428 – Marine microalgae as a novel food. Australia New Zealand Food Authority, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/applications/applicationa428marinemicroalgaeasanovelfood/index

Codex (1979). Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children. CXG 10-1979. Codex Alimentarius Commission, Rome. Available online at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B10-1979%252FCXG_010e_2015.pdf

Codex (1981). Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants. Codex CXS 72-1981. Codex Alimentarius Commission, Rome. Available online at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B72-1981%252FCXS_072e.pdf

Codex (1985a) General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses. Codex CXS 146-1985. Codex Alimentarius Commission, Rome. Available online at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B146-1985%252FCXS_146e.pdf

Codex (1985b) General Standard for the Labelling of Prepackaged Foods. Codex CXS 1-1985. Codex Alimentarius Commission, Rome. Available online at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B1-1985%252FCXS_001e.pdf

Codex (1987) Standard for Follow-up formula for Older Infants and Product for Young Children. Codex CXS 156-1987. Codex Alimentarius Commission, Rome. Available online at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B156-1987%252FCXS_156e.pdf

Codex (1995) General Standard for Food Additives. Codex CXS 192-1995. Codex Alimentarius Commission, Rome. Available online at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B192-1995%252FCXS_192e.pdf

EC SCF (2003) Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae. European Commission Health and Consumer Protection Directorate- General, Brussels. Available online at: https://food.ec.europa.eu/document/download/e933a10d-080b-4692-a543-2c267897f046_en?filename=sci-com_scf_out199_en.pdf

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

European Commission (2016) Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding. *Official*

Journal of the European Union, 59:1-29. Available online at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2016.025.01.0001.01.ENG

FSANZ (2005) A522 – DHA-rich micro-algal oil from *Ulkenia sp.* as a novel food. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/applications/applicationa522dhari2348

FSANZ (2008) A594 – Lutein as a nutritive substance in infant formula. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/applications/applicationa594lutei3490

FSANZ (2013) A1074 – Minimum L-histidine in Infant Formula Products. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/applications/applicationa1074mini5583

FSANZ (2016a) Consultation Paper - Proposal P1028. Supporting Document 1 – Definitions and Nutrient Composition. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/P1028-Consult-SD1.pdf

FSANZ (2016b) SD1 Attachment A1.1 – Nutrition Assessment. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/P1028-Consult-SD1-Attach-A1.pdf

FSANZ (2016c) Consultation Paper - Proposal P1028. Supporting Document 2 – Safety and Food Technology. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/P1028-Consult-SD2-SafetyTechnology.pdf

FSANZ (2016d) Consultation paper – Proposal P1028. Supporting Document 3 – Provision of information. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/P1028-ConsultSD3-Information.pdf

FSANZ (2017) A1124 – Alternative DHA Algal Oil in Infant Formula. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/applications/A1124DHAAlgalOilinInfantFormula

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

FSANZ (2021a) Consultation Paper 1 – Safety and Food Technology. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/CP1%20P1028%20(added%20reference).pdf

FSANZ (2021b) Consultation Paper 2 – Nutrient Composition. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/applications/Documents/CP2%20P1028.pdf

FSANZ (2021c) Consultation Paper 2 - Proposal P1028. Supporting Document 1 – Nutrition Assessment. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/SD1%20Nutrition%20risk%20assessment.pdf

FSANZ (2021d) Consultation Paper 3 - Proposal P1028. Regulatory Framework and definitions. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/P1028%20Reg%20framework%20Consultation%20paper%200322.pdf

FSANZ (2022a) Call for Submissions – Proposal P1028. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/P1028%20CFS.pdf

FSANZ (2022b) 1st Call for Submissions - Proposal P1028. Supporting Document 1 – Safety and Food Technology. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/SD1%20-%20Safety%20and%20Food%20Technology.pdf

FSANZ (2022c) 1st Call for Submissions - Proposal P1028. Supporting Document 2 – Nutrient Composition for Infant Formula Products. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/SD2%20-%20Nutrient%20Composition.pdf

FSANZ (2022d) 1st Call for Submissions - Proposal P1028. Supporting Document 3 – Provision of Information. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/SD3%20-%20Provision%20of%20information.pdf

FSANZ (2022e) 1st Call for Submissions - Proposal P1028. Supporting Document 4 – Special Medical Purpose Products for Infants. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/SD4%20-%20Special%20Medical%20Purpose%20Products%20for%20infants.pdf

FSANZ (2022f) A1251 – 2'-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/applications/A1251-2-ca-b9-FL-combined-with-galacto-oligosaccharides-and-inulin-type-fructans-in-infant-formula-products

FSANZ (2023a) 2nd Call for Submissions – Proposal P1028. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/2nd%20Call%20for%20Submissions%20-%20Proposal%20P1028.pdf

FSANZ (2023b) 2nd Call for Submissions - Proposal P1028. Supporting Document 1 – Food Technology for Infant Formula Products. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/Supporting%20Document%201%20-%20Food%20technology.pdf

FSANZ (2023c) 2nd Call for Submissions - Proposal P1028. Supporting Document 2 – Nutrient Composition for Infant Formula Products. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/SiteAssets/Pages/P1028/Supporting%20Document%202%20-%20Nutrient%20composition.pdf

FSANZ (2023d) 2nd Call for Submissions - Proposal P1028. Supporting Document 3 – Labelling for Infant Formula Products. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/Supporting%20Document%203%20-%20Labelling.pdf

FSANZ (2023e) A1253 – Bovine lactoferrin in infant formula products. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/applications/A1253-Bovine-lactoferrin-in-infant-formula-products

FSANZ (2023f) A1265 - 2'-FL DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt for use as nutritive substances in infant formula products. FSANZ, Canberra. Available online at: https://www.foodstandards.gov.au/food-standards-code/applications/A1265-2-27-FL-DFL-2c-LNT-2c-6-27-SL-sodium-salt-and-3-27-SL-sodium-salt-for-use-as-nutritive-substances-in-infant-formula-products

Koletzko B, Baker S, Cleghorn G, Neto UF, Gopalan S, Hernell O, Hock QS, Jirapinyo P, Lonnerdal B, Pencharz P, Pzyrembel H, Ramirez-Mayans J, Shamir R, Turck D, Yamashiro Y, Zong-Yi D (2005). Global standard for the composition of infant formula: recommendations of an ESPGHAN coordinated international expert group. *Journal of Pediatric Gastroenterology Nutrition*, 41(5):584-99, doi:10.1097/01.mpg.0000187817.38836.42.

Ministry of Health (2021) Healthy Eating Guidelines for New Zealand Babies and Toddlers (0 - 2 Years old). Ministry of Health, Wellington. Available online at: https://www.health.govt.nz/publication/healthy-eating-guidelines-new-zealand-babies-and-toddlers-0-2-years-old

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

Raiten DJ, Talbot JM, Waters JH (1998) LSRO Report: Assessment of Nutrient Requirements For Infant Formulas. *The Journal of Nutrition*, 128(S11):2059S-2293S, doi:10.1093/jn/128.suppl_11.2059S.

US Code of Federal Regulations (2024a). Part 107.10 Nutrient information: Labeling, in Part 107 Infant formula. Chapter 1 Food and Drug Administration, Subchapter B Food for Human Consumption, Department of Health and Human Services https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-107

US Code of Federal Regulations (2024b) Part 101.4 Food; designation of ingredients: in Part 101 Food Labeling. Chapter 1 Food and Drug Administration, Subchapter B Food for Human Consumption, Department of Health and Human Services https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101/subpart-A/section-101.4